



*International Society for
Quality of Life Research*

ISOQOL 2004 Symposium



Stating the Art:
Advancing Outcomes Research
Methodology and
Clinical Applications

June 27-29, 2004
Boston Park Plaza Hotel
Boston, MA, USA

Chairs: William Lenderking, PhD and Dennis Revicki, PhD

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Schedule-At-A-Glance

Sunday, June 27, 2004

1:00 - 4:30 pm INVITED WORKSHOPS - Additional fees and registration are required.

1. **Q-TWiST Methodology** - *Rich Gelber and Bernard Cole* - Cabot Room
2. **Applications of Item Response Theory Modeling for Improving Health Outcomes Measurement** - *Bryce Reeve and Chih-Hung Chang* - Whittier Room
3. **Utility and Value Measurement - An Update** - *Les Lenert* - Thoreau Room
4. **Introduction to Bayesian Data Analysis for Outcomes Researchers** - *Dennis Fryback* - Back Bay Room
5. **Strategies for Multiple Endpoints in Longitudinal Studies of Quality of Life** - *Diane Fairclough* - Franklin Room
6. **Beyond the QALY: Using Conjoint Analysis to Quantify Health-Outcome Preferences** - *Reed Johnson and Andrew Lloyd* - Stuart Room
7. **Theoretical Models of Quality of Life** - *Bruce Rapkin and Carolyn Schwartz* - Beacon Hill Room
8. **Quality of Life Assessment with Computerized Text Analysis** - *James Pennebaker and Ivan Barofsky* - Lexington Room

6:00 - 7:00 pm OPENING RECEPTION - Georgian Room

Monday, June 28, 2004

9:00 am -

10:00 pm POSTERS ON DISPLAY - Plaza Ballroom

9:00 -

10:30 am Plenary Session I - Imperial Ballroom
State-of-the-Art of HRQOL Assessment
Invited Speakers: *Marcia Testa and Robert Kaplan*

10:30 -

10:45 am BREAK - Plaza Ballroom

10:45 am -

12:45 pm CONCURRENT SESSIONS

SESSION 1: **Modern Measurement Theory and Applications** - Imperial Ballroom
Chair: *Kathleen Wyrwich*

SESSION 2: **Cognitive Sciences and Health Outcomes Assessment** - Stanbro Room
Chair: *Andrew Lloyd*

12:45 -

2:00 pm LUNCH ON YOUR OWN

2:00 -

4:00 pm CONCURRENT SESSIONS

SESSION 3: **Advanced Statistical Analysis I** - Imperial Ballroom
Chair: *Joseph Cappelleri*

SESSION 4: **Qualitative Research Methods** - Stanbro Room
Chair: *Ivan Barofsky*

4:00 -

5:00 pm MEET THE AUTHOR POSTER SESSION AND RECEPTION - Plaza Ballroom

6:00 pm DINE-AROUND - Park Plaza Lobby
(Sign-up required by 12:00 noon, June 28)

Tuesday, June 29, 2004

8:30 -

10:00 am Plenary II
Outcomes Research Applied - Imperial Ballroom
Invited Speakers: *Gordon Guyatt, David Osoba and Robert J. Meyer*

10:00 -

10:15 am BREAK - Plaza Ballroom

10:15 am -

12:15 pm CONCURRENT SESSIONS

SESSION 5: **Advanced Statistical Analysis II** - Imperial Ballroom
Chair: *Diane Fairclough*

SESSION 6: **Theoretical Models for HRQL Research** - Stanbro Room
Chair: *Donald Patrick*

12:15 -

1:30 pm LUNCH ON YOUR OWN AND CONTINUED POSTER VIEWING

1:30 -

3:30 pm CONCURRENT SESSIONS

SESSION 7: **Experience Sampling and Daily Process Analysis** - Stanbro Room
Chair: *William Lenderking*

SESSION 8: **State of the Art Utilities/DCE/Q-TWiST** - Imperial Ballroom
Chair: *Dennis Revicki*

3:30 -

5:00 pm **Plenary Session III: Looking to the Future of Outcomes Research** - Imperial Ballroom
Invited Speaker: *Peter Fayers*
Discussants: *Chairs of Paper Sessions 1-8*
Chairs: *William Lenderking and Dennis Revicki*

ISOQOL 2004 Symposium Committee and Leadership

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Dennis Revicki, PhD, USA

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M. Haim Erder, PhD, USA
Peter Fayers, PhD, United Kingdom
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Welcome

Dear Friends and Colleagues:

We are delighted to welcome you to Boston, Massachusetts and to the first mid-year International Society for Quality of Life Research sponsored meeting. Our streamlined agenda focuses on advanced conceptual, measurement and statistical methodology. We have three interesting plenary sessions, 18 invited presentations, 26 oral presentations, and over 80 posters oriented around eight topics related to state-of-the-art methods for measuring, analyzing, and understanding health outcomes and quality-of-life data. These themes are organized in two tracks: one primarily statistical, the other conceptual, clinical, and applied. At any given time throughout the meeting, there will only be two sessions at most (one from each track) to choose from, so those who wish to stay in one track can do so for the whole meeting. But feel free to jump across tracks too if that is where your interests take you!

ISOQOL is committed to advancing the methods, measurement and applications of health outcomes in clinical trials, population-based studies, and in clinical practice applications. This conference was specifically designed to introduce advanced and state-of-the-art methods to health outcomes researchers, students, and clinicians from academia, industry and the greater health outcomes research community. We hope that you will enjoy the stimulating presentations and discussions, and take away new ideas from the conference. We also encourage you to take the time to view the posters and discuss the research presented.

While you are in Boston, we hope that you will find some time to explore the city's wonderful historical and other attractions, and many restaurants and entertainment activities.

We hope that you enjoy the conference.

William Lenderking, PhD

Co-Chair

Symposium Organizing Committee

Dennis Revicki, PhD

Co-Chair

Symposium Organizing Committee

About ISOQOL

ISOQOL Mission

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
- Educational Outreach
- International Conferences
- Collaborative Support for HRQOL Initiatives

ISOQOL Special Interest Groups

Special Interest Groups have been established to facilitate communications between researchers with specific interests, ranging from methodology (e.g. clinical applications; cross-cultural research and translation methods), to applications of QoL in particular populations (e.g. oncology and HIV/AIDS). For more information and to join a Special Interest Group, visit our website at www.isoqol.org.

ISOQOL Committees

ISOQOL members are encouraged to serve on the following Society committees and subcommittees: Membership; Communications - Newsletter, Website; Finances and Budget Planning — Fundraising and Grantwriting; Education - Scholarship and Training, Policy Guidelines, Conferences and Workshops and Scientific Program Committee.

General Information

Conference Venue

All workshops, plenary, invited and poster sessions will take place at the Boston Park Plaza Hotel, 64 Arlington Street, Boston, MA 02116. The telephone number is 617-426-2000 and the fax number is 617-426-5545.

Registration

Registration fees include participation in the symposium, certificate of attendance, Welcome Reception on Sunday, June 27 and refreshments/coffee breaks on Monday and Tuesday, June 28 - 29.

Poster Session and Reception

Each poster is assigned a specific number which can be found just before the abstract title in this program. Each poster station will be numbered--please mount your poster on the correct poster station. All authors are requested to be at their poster during the Poster Session and Reception on Monday, June 28, 4:00pm - 5:00pm. The posters will be on display Monday, June 28, 9:00am - 10:00pm and on Tuesday, June 29, 8:30am - 1:30pm.

Opening Reception

Start the meeting by visiting old friends and meeting new colleagues at the Opening Reception on Sunday, June 27, 6:00pm - 7:00pm in the Georgian Room. The reception is included in the Symposium registration fee.

Dinner Dine-Around

Continue the wonderful discussions stimulated by the meeting over dinner! These will be informal, yet lively, opportunities to eat well with your colleagues who wish to have more discussion around certain topics. This is a chance for you to continue with attendees of a session you went to or are planning to attend, or to hear about a topic from a session that you couldn't attend.

There will be 8 groups meeting in the Park Plaza lobby on Monday, June 28 at 6:00 pm. Each group will be loosely organized around a specific area of interest and might include invited speakers if available - Modern Measurement and Theory, Cognitive Sciences, 2 groups of Advanced Statistical Analysis, Qualitative Research Methods, Theoretical Models, Experience Sampling, and State of the Art Utilities.

To register for this event, sign your name on the Topic Area Reservation Sheet at the Registration Desk. Remember, there are a limited number of seats and this is a first-come, first-served list. Sign up early to ensure your seat. Groups will meet in the lobby (signs will be posted to identify each topic area group) and proceed to the restaurant together. There are several different restaurants that have been selected and they are all within walking distance of the hotel. Each person will be responsible for their own dinner expenses.

ISOQOL 2004 Symposium

Program Schedule

Sunday, June 27, 2004

1:00 - 4:30

Workshops

1. Q-TWiST Methodology

Cabot

Richard Gelber, PhD and Bernard Cole, PhD

Patients and physicians need information regarding the quality-of-life effects of therapeutic options before making treatment decisions. This is especially true in cancer where cytotoxic therapy may initially reduce quality of life due to toxicity before the benefits of delayed disease progression and delayed death are realized. Quality-adjusted survival analysis has been useful for evaluating therapies with respect to the trade-off between clinical benefit and adverse effects of toxicity. This workshop will provide an introductory review of the Q-TWiST technique for estimating quality-adjusted survival in clinical trials. We will cover the basic methodology along with extensions for including covariates, conducting meta-analysis, and incorporating quality-of-life data into a Q-TWiST evaluation. Examples from early and advanced-stage cancer will be shown. We will also illustrate software tools for Q-TWiST with emphasis on SAS macros for generating numerical estimates and graphical display.

2. Applications of Item Response Theory Modeling for Improving Health Outcomes Measurement

Whittier

Bryce Reeve, PhD and Chih-Hung Chang, PhD

There is a great need in health outcomes research to develop instruments that accurately measure a person's health status with minimal response burden. This need for psychometrically sound and clinically meaningful measures calls for better analytical tools beyond the methods available from traditional measurement theory. Applications of item response theory (IRT) modeling have increased considerably because of its utility for instrument development and evaluation, assessment of measurement equivalence, instrument linking, and computerized adaptive testing. IRT models the relationship, in probabilistic terms, between a person's response to a survey question and their standing on a health construct such as fatigue or depression. This introductory workshop will discuss the basics of IRT models and applications of these models to improve health outcomes measurement. Illustrations will be used throughout the presentation that focus on measuring key health-related quality of life domains in cancer populations.

3. Utility and Value Measurement – An Update

Thoreau

Leslie Lenert, MD

This course will take an evidence-based approach to the topic of health-related quality of life. The course will cover both basic and advanced topics focusing on how researchers can develop the most valid protocols. Topics covered will include comparison of different valuation methods (standard gamble, time trade off, person trade off, etc.) approaches for describing health and disease, and methods for administration of protocols.

4. Introduction to Bayesian Data Analysis for Outcomes Researchers

Back Bay

Dennis Fryback, PhD

Bayesian methods for data analysis in outcomes research are now feasible given Markov Chain Monte Carlo (MCMC) computational methods and available, fast-improving, software (WinBUGS). This workshop will introduce the basic principles of Bayesian data analysis, provide a conceptual introduction to MCMC, and a quick overview of WinBUGS. Example analyses will be discussed to demonstrate the Bayesian approach and software. Though this is mostly an applied and not theoretical workshop, the material is directed to persons with good foundation in, and experience with, conventional statistical methods and mathematical notation.

5. Strategies for Multiple Endpoints in Longitudinal Studies of Quality of Life

Franklin

Diane Fairclough, DrPH

Multiplicity of potential endpoints arises in longitudinal studies of HRQoL from the multiple domains used to assess HRQoL and the repeated measures that occur in a longitudinal study. Testing a large number of hypotheses creates problems in the interpretation of the results and inflates the Type I error rate. However, over control of the Type I error rate has the potential to severely decrease the power of the study to detect meaningful differences (Type II errors). In this workshop, we will start by examining the advantages and disadvantages of a range of strategies including 1) limiting confirmatory tests, 2) summary measures/statistics across time, 3) creation of indices from the component subscales, and 4) multiple comparisons procedures. Next, we will split into small working groups with the task of developing a strategy for a hypothetical trial. Finally, the proposals will be presented to the entire group and discussed.

6. Beyond the QALY: Using Conjoint Analysis to Quantify Health-Outcome Preferences

Stuart

F. Reed Johnson, PhD and Andrew Lloyd, DPhil

Conjoint analysis (CA) is increasingly being used by outcomes researchers and health economists as a method for obtaining patients', physicians', and other decision makers' stated preferences. These preference estimates are used to value treatment outcomes and processes in preference, utility or monetary terms. CA estimates provide more information about preferences than conventional QALY weights or QoL scores. They thus can be used to answer a number of questions about how various treatment and outcome factors contribute to patient satisfaction and guide physicians' therapy decisions. The objective of this workshop is to introduce participants to the uses of CA measures for informing drug-development decision making. Participants will learn how to derive, interpret, and use CA preference measures. Participants will first evaluate and critique the design and administration of a survey instrument. We will then demonstrate estimation using appropriate statistical techniques and widely available statistical packages, assess the quality of the resulting estimates, and evaluate the information obtained. Participants will then complete a series of exercises to translate coefficient estimates into relative utility weights, rates of substitution, and value to patient. The workshop will conclude by discussing how each of these measures can be used to inform decision making.

7. Theoretical Models of Quality of Life

Beacon Hill

Bruce Rapkin, PhD, and Carolyn Schwartz, ScD

Health-related quality of life is most often treated as a practical matter in studies of disease course and treatment outcomes. Thus, quality of life measures have generally been developed to capture a face-valid impression of an individual's status. Despite considerable attention to the psychometric properties of quality of life (QOL) measures, there is actually very little discussion of QOL as a theoretical construct. What are we measuring when we assess self-reported QOL? What are the relationships among different dimensions and facets of QOL? How is QOL related to personal, social, situational and cultural variables? How is QOL related to constructs of adaptation and adjustment? Is it possible to develop models to better understand and predict changes in QOL? How can development of QOL theory contribute to our understanding of QOL as a health outcome? In this workshop, we will examine our current state of understanding regarding these questions. We will look at several recent attempts to develop theoretical models of QOL. In particular, we will present our own recent work on the nature of QOL appraisal processes. Assessment of QOL appraisal provides a richer, more dynamic way of understanding how individuals think about and rate their health and well-being. At the same time, appraisal assessment opens the door to new problems and complexities in QOL research. Through this workshop, we hope to broaden perspectives on the role of theory in studies of health-related QOL, introduce new assessment tools and new types of data that may be of use in advancing theory, and envision the research agenda for further theoretical development in our field.

8. Quality of Life Assessment with Computerized Text Analysis

Lexington

James Pennebaker, PhD and Ivan Barofsky, PhD

This workshop demonstrates how computerized text analysis can inform quality of life assessments. It provides an overview over existing quantitative text analysis approaches and gives participants the opportunity to apply one of these methods to quality of life data. Participants are encouraged to bring laptop computers, although demonstration computers will be available. Computerized text analysis can be used on any electronic samples of natural language

that contain at least 60-100 words. Samples can be transcriptions of conversations such as interviews or doctor-patient communications. Responses to open-ended survey questions are also appropriate. Computerized text analytic procedures aim to quantify how people talk (i.e., linguistic style) and what people talk about (i.e., content). By analyzing examples of quality of life data, we will show how these techniques can provide clues about the way that a respondent views their quality of life, offering an alternative to judgment-based methods (e.g., content analysis). This information can be used to compare groups of respondents or follow changes in a respondent's quality of life over time. The workshop will cover issues involved in applying text analysis, from data preparation to the implications of comparing groups who do not even share the same language.

6:00 - 7:00 pm
Opening Reception

Georgian

Monday, June 28, 2004

9:00 - 10:30 am

Plenary Session I: State-of-the-Art of HRQOL Assessment

Chairs: William Lenderking, PhD and Dennis Revicki, PhD

Imperial Ballroom

Measuring Quality of Life for Policy Analysis: Past, Present and Future

Robert M. Kaplan, PhD

Bridging the Gaps Between Conceptualization, Application and Practice: Optimizing the Analysis of Patient-Reported Outcomes in Clinical and Health Research

Marcia Testa, MPH, MPhil, PhD

Discussants: Albert Wu, MPH, MD and Ivan Barofsky, PhD

9:00 am - 10:00 pm

Posters On Display

Plaza Ballroom

10:30 - 10:45 am

Break

Plaza Ballroom

10:45 am - 12:45 pm

Concurrent Paper Sessions

Session 1: Modern Measurement Theory and Applications

Chair: Kathleen Wyrwich, PhD

Imperial Ballroom

Item Banking and Computerized Adaptive Testing in Health Outcomes Assessment

Chih-Hung Chang, PhD

Choosing Among Item Response Theory Models

Ronald K. Hambleton, PhD

Comparing Standard Psychometric and Rasch Approaches using the CES-D

L. Douglas Ried, PhD

Using Item Response Theory to Improve the Measurement of Physical Function: A Study in Rheumatoid Arthritis

Marie Martin, PhD

Multidimensional Computerized Adaptive Testing of the EORTC QLQ-C30: Basic Developments and Evaluations

Mogens Groenvold, MD

Evaluation of a Computer Adaptive Test for Depression

Otto Walter, MD

Session 2: Cognitive Sciences and Health Outcomes Assessment

Chair: Andrew Lloyd, DPhil

Stanbro

Measuring Health Related Quality of Life: Does Prospect Theory Help?

Eve Wittenberg, PhD

How Relations Between Self-Regulatory Orientations and Strategic Actions Influence the Quality of Life as it Unfolds: A Theory of Regulatory Fit

Antonio L. Freitas, PhD

Cognitive Factors in Mental Health Outcome Measurement

Martha Shumway, PhD

Developing a Symptoms Diary - The Contribution of CASM Techniques

Elaine McColl, MSc

Patient-Reported Instrument to Assess the Functional Status of Patients with Bipolar Disorder

Sheri Fehnel, PhD

12:45 - 2:00 pm

Lunch on your own

2:00 - 4:00 pm

Concurrent Paper Sessions

Session 3: Advanced Statistical Analysis I

Chair: Joseph Cappelleri, PhD

Imperial Ballroom

Applications of GEE for Handling Missing Data in Longitudinal Studies

Joseph W. Hogan, PhD

Missing Data in HRQL Studies with Dropout Associated with Morbidity and Mortality

Diane Fairclough, DrPH

The Use of Bootstrap Methods for Analysing Health-Related Quality of Life Outcomes (Particularly the SF-36)

Stephen Walters, PhD

Longitudinal Changes in Perceived Energy Before and After Lung Transplantation: Comparing Results of Complete Case, Cross-Sectional, and Multi-Level Analysis

Karin Vermeulen, MSc

A Unified Framework for Scoring and Missing Data Estimation for the SF-36, SF-12, and SF-8

Renee Saris-Baglana, PhD

Quality of Life (QOL) Results of a Randomized Study of Intravenous (IV) Paclitaxel and Cisplatin Vs. IV Paclitaxel, Intraperitoneal (IP) Cisplatin and IP Paclitaxel in Optimal State III Epithelial Ovarian Cancer (OC): A Gynecologic Oncology Group Trial

Lari Wenzel, PhD

Session 4: Qualitative Research Methods

Chair: Ivan Barofsky, PhD

Stanbro

What Our Words Say About Us: Use of Computerized Text Analysis in Research and Practice

James Pennebaker, PhD

Automated Systems that Analyze Text and Discourse: AutoTutor, Coh-Metrix, and QUAID

Arthur C. Graesser, PhD

Evaluation of the SEIQOL-DW as a Measure of QOL Using Qualitative Analysis

Hanne Bruhn, MA

A Quality of Life Scale for Children with Cerebral Palsy: Quality of Life from the Perspective of Families

Elizabeth Waters, DPhil

A Mixed Method Approach to Qualitatively Examining Latinas' Perspective of Gynecological Health and Cervical Cancer Survivorship

Juliet McMullin, PhD

4:00 - 5:00 pm

Poster Session and Reception

Plaza Ballroom

6:00 pm

Special Evening Social Event - Local Dine-Around

Hotel Lobby

Tuesday, June 29, 2004

8:30 - 10:00 am

Plenary Session II: Outcomes Research Applied

Chair: David Osoba, MD

Imperial Ballroom

Clinical Research Challenges in HRQOL Assessment

David Osoba, MD

Interpreting the Results of Quality of Life Measures in Clinical Trials: The Clinicians Perspective

Gordon Guyatt, MD

Regulatory Considerations for Outcomes Research

Robert J. Meyer, MD

10:00 - 10:15 am

Break

Plaza Ballroom

10:15 am - 12:15 pm

Concurrent Paper Sessions

Session 5: Advanced Statistical Analysis II

Chair: Diane Fairclough, DrPH

Imperial Ballroom

Sensitivity Analysis for Longitudinal Clinical Trials

Herbert Thijs, PhD

Bayesian Analysis of Health Status and Quality of Life Data

Dennis Fryback, PhD

Quality of Life Trajectories Among Massachusetts Adults with Substance Use Disorder

Kevin Smith, MA

Rasch-Informed Categorizations of Transition Rating Scales

Kathleen Wyrwich, PhD

Mixed Effects Modeling of the Relationship of Cytokines and Symptom Severity in Patients During First 30 Days of Autologous BMT

Xin Shelley Wang, MD

Session 6: Theoretical Models for HRQL Research

Chair: Donald Patrick, PhD

Stanbro

Title: TBA

Julia Fox-Rushby, PhD

Toward an Integrative Psychological Theory of Quality of Life

Joseph Sirgy, PhD

Testing the Wilson and Cleary HRQOL Conceptual Model in Persons Living with AIDS Using Structural Equation Modeling

Karen Sousa, PhD

The Effect of Materialism on Emotional Well-Being and Life Satisfaction: An Application of Multiple Discrepancies Theory

James Shaw, PharmD

Has the Measurable Driven Out the Important? Individualized Quality of Life

Lena Ring, PhD

Relationship of Individual Quality of Life with Psychological and Subjective Well-Being

Stefan Höfer, PhD

12:15 - 1:30 pm

Lunch on your own and Poster Viewing

1:30 - 3:30 pm

Concurrent Paper Sessions

Session 7: Experience Sampling and Daily Process Analysis

Chair: William Lenderking, PhD

Stanbro

Exploring Patient Outcomes as Daily Processes: The Promise and the Challenge

Howard Tennen, PhD

Daily Measurement Detects an Earlier Onset Antidepressant Effect

William Lenderking, PhD

Does Better Data from Electronic Patient Reported Outcomes (EPRO) Methodology Actually Improve Clinical Research? Results from a Randomized Trial Comparing Paper and EPRO Diaries

Stephen Raymond, PhD

Feasibility of Using Handheld Computers for Real-Time Assessment of Fatigue in Cancer Patients

Karen Basen-Engquist, PhD

Emotions, Stress and Health in Everyday Life

Alex Zautra, PhD

Session 8: State of the Art Utilities/DCE/Q-TWiST

Chair: Dennis Revicki, PhD

Imperial Ballroom

Comparing and Contrasting Utilities and Willingness to Pay

David Feeny, PhD

Bridges and Barriers: Willingness to Pay, Willingness to Wait, and Health-State Utility Measures

F. Reed Johnson, PhD

Q-Twist: Do's and Dont's

Richard Gelber, PhD

Atrasentan Increases Quality Adjusted Time to Progression in Men with Hormone-Refractory Prostrate Cancer Metastasized to Bone

Parvez Mulani, PhD

Time Trade-Off Valuations of EQ-5D Health States: Are the US and UK Different?

Jeffrey Johnson, PhD

3:30 - 5:00 pm

Plenary Session III: Looking to the Future of Outcomes Research

Imperial Ballroom

Chairs: William Lenderking, PhD and Dennis Revicki, PhD

Future Directions for HRQOL: The Hope and Achievement

Presenter: Peter Fayers, PhD

Discussants: Chairs of Paper Sessions 1-8

Plenary Session Descriptions

Plenary Session I: State-of-the-Art of HRQOL Assessment

Measuring Quality of Life for Policy Analysis: Past, Present and Future

Robert M. Kaplan, PhD, Department of Family and Preventive Medicine, UCSD, La Jolla, CA

The purpose of health care is to extend life expectancy and to improve quality of life. Until the late 1960s, quality of life was rarely discussed or measured. Over the last few decades the growth in quality of life studies has been nearly exponential. Several approaches to quality of life assessment were developed to supply data for comprehensive health policy models. This presentation traces the development of generic approaches to quality of life measurement and reviews applications of the methods in policy analysis. Problems with the models and related measurement approaches will be reviewed and directions for future research will be offered.

Bridging the Gaps Between Conceptualization, Application and Practice: Optimizing the Analysis of Patient-Reported Outcomes in Clinical and Health Research

Marcia Testa, MPH, MPhil, PhD, Senior Lecturer, Harvard School of Public Health, Boston, MA

The emergence of evidence-based methods for medical and public health research has led to an increasing emphasis on the roles of evaluation and inferential statistics to determine the effectiveness of new medical interventions and public health programs. While there has been an exponential rise in research involving measurement and assessment of quality of life and patient-reported outcomes, including the development of thousands of disease-specific instruments, advances in analytical methods dealing with their application to medical and health care evaluation has not been as widely developed. There is great need for such development since the standard statistical tests used in clinical and health research typically ignore measurement error, invoke time-invariance assumptions, assume normality and seldom deal with the required statistical methods for overall hypothesis testing of multiple endpoints. While newer approaches to assessment, such as item banking and computer adaptive testing, promise to aid in the standardization and efficiency of measurement and assessment, these methods will not solve the problems of evaluation, statistical analysis and inference faced by researchers. Unless some major critical analytical issues are addressed, applications of the advances in measurement and assessment to research and practice will be limited. The purpose of this session is to provide guidance for using the scales and indices of quality of life and other patient-reported outcomes in the evaluation of medical interventions and public health programs. Examples will be given to highlight potential areas of ongoing and future research. The specific focus of this presentation will be on procedures for handling multiple outcomes to answer the question “Is this treatment or program beneficial to the patient or participant?” A review of several methods will be given including, alpha adjustment, latent regression models, restricted hypothesis testing and overall statistical tests to address this issue.

Plenary Session II: Outcomes Research Applied

Clinical Research Challenges in HRQOL Assessment

David Osoba, MD, Consultant, West Vancouver, BC, Canada

What are meaningful changes in HRQOL scores? How should meaningful changes be presented in terms that resonate with the needs of various users? Is there a role for sensitivity analyses? How can HRQOL assessment be more widely taught and implemented? These items will be discussed.

Interpreting the Results of Quality of Life Measures in Clinical Trials: The Clinicians Perspective

Gordon Guyatt, MD, Department of Clinical Epidemiology, Biostatistics and Medicine, McMaster University Health Sciences Center, Hamilton, ON, Canada

Interpretation problems for clinicians looking at the results of clinical trials are not restricted to quality of life. For instance, large cardiology trials report absolute reductions in combined endpoints such as death and myocardial infarction. Clinicians seem willing to ignore the relative frequency of deaths versus infarcts, and large infarcts versus small. As long as they are convinced events are serious, the number prevented makes results interpretable. This provides a lesson to the optimal approach to making quality of life data interpretable to clinicians. First, establish the minimal important difference. Second, report mean differences (ideally in change, and in relation to the MID). Third, choose a threshold (ideally a threshold of change, and ideally the MID) and determine the proportion

of patients in both groups who meet this threshold. Finally, use these data to determine the proportion of patients who have achieved important benefit from treatment, and the associated number needed to treat (NNT).

Regulatory Considerations for Outcomes Research

Robert J. Meyer, MD, United States FDA, Rockville, MD

In the regulatory context of new drug approvals, “outcomes” research may have a number of meanings. Typically, the FDA does not have much experience with “outcomes” assessments as a part of the primary evidence of effectiveness, but this is not always the case. This talk will first seek to clarify the terminology from the regulatory perspective and then to reflect on the use of patient-reported outcomes and other types of outcomes research from the FDA perspective. Past examples will be shared as well as some thoughts on future directions.

Plenary Session III: Looking to the Future of Outcomes Research

Future Directions for HRQOL: The Hope and Achievement

Peter Fayers, PhD

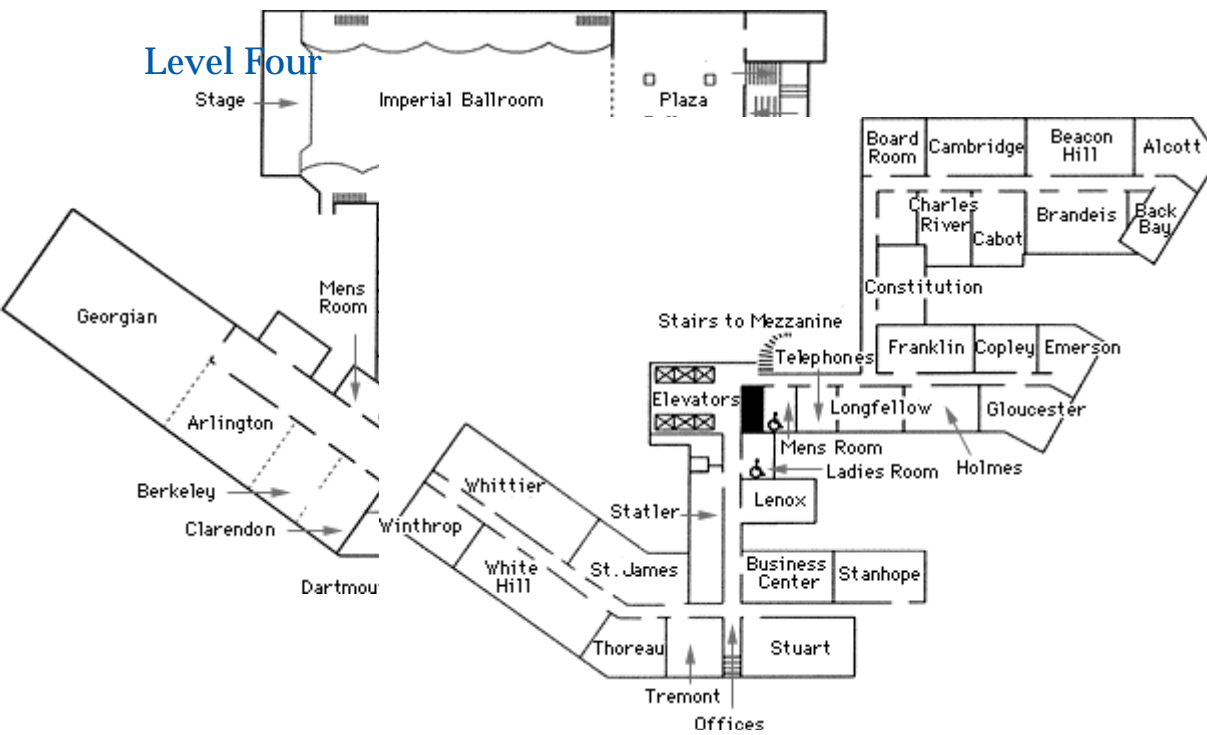
Boston Park Plaza Hotel & Towers Map

Mezzanine Level (Meeting Registration Area)



Basement Level

Level Four





11th Annual ISOQOL Conference
October 16-19, 2004

Hong Kong
<http://www.isoqol.org>

Harmonizing International Health-Related
Quality of Life (HRQOL) Research

A Meeting of Minds ~ A Blending of Cultures
A Quest for Quality ~ A Unique Experience

Conference Venue
The Hong Kong Academy of Medicine
Hong Kong Special Administrative Region
People's Republic of China



Co-organized by the Hospital Authority of Hong Kong
<http://www.ha.org.hk>

