Assessing Clinical Significance for Quality of Life Measures in Oncology Research: State-of-the-Science

April 5 – 6, 2002

Mayo Clinic
Siebens Medical Education Building
Rochester, Minnesota

Abstract Submission Deadline:
December 15, 2001
www.mayo.edu/cme/QOLmeeting
General Information

MEETING DESCRIPTION

What does a change in a quality of life score mean?
This meeting is an opportunity for clinicians and researchers to participate in a state-of-the-science investigation into the methods and challenges of assessing quality of life (QOL). The central issue is how to identify when a score change on a quality of life instrument is significant enough to patients and clinicians to direct a change in health care. On October 6-7, 2000, a meeting of 30 international QOL experts was held at Mayo Clinic in Rochester, Minnesota, to discuss issues surrounding assessing clinical significance of QOL measures. The meeting produced six manuscripts summarizing the state-of-the-science for assessing clinical significance of QOL measurement. The six manuscripts dealt with the following topics:

1. Methods used-to-date to assess clinical significance
2. Group versus individual comparisons
3. Single-item versus multi-item scales
4. Patient versus clinician versus population perspective
5. Assessing changes over time
6. Incorporating/communicating clinical significance into industry/clinical practice

The purpose of this meeting is to disseminate the results of the manuscript series and to broaden the input and feedback from the scientific community on this important topic.

MEETING DATE AND LOCATION

“Assessing Clinical Significance for QOL Measures in Oncology Research: State-of-the-Science” will be held April 5-6, 2002, on the Mayo Clinic Campus, Rochester, Minnesota. Meeting headquarters will be located in the Siebens Medical Education Building, on the corner of Second Avenue and First Street SW. Meeting facilities are easily accessible by skyway and pedestrian subway, which connect Mayo Clinic to shops, theaters, restaurants, and hotels.

FINAL CALL FOR ABSTRACTS

This mailing serves as a final call for interested individuals and organizations to submit abstracts for contributed paper/poster presentation. Online abstract submission is available at www.mayo.edu/cme/QOLmeeting. The abstracts must reinforce the key concept of clinical significance. Final abstract submission deadline is December 15, 2001.
COURSE CO-DIRECTORS

Jeff Sloan, PhD
Mayo Clinic
Cancer Center Quality of Life Research
Phone: 507-284-9985
FAX: 507-266-2477
E-mail: jsloan@mayo.edu
Rochester, MN

Marlene Frost, RN, PhD
Mayo Clinic
Women’s Cancer Program
Phone: 507-266-6945
FAX: 507-266-2478
E-mail: frost.marlene@mayo.edu
Rochester, MN

KEYNOTE SPEAKER

Patricia Ganz, MD
Professor of Health Services and Medicine
UCLA School of Public Health
Department of Health Services
Los Angeles, CA

MANUSCRIPT SERIES WRITING TEAM

Neil Aaronson, PhD
Cancer Institute
Amsterdam,
The Netherlands

Ivan Barofsky, PhD
Johns Hopkins University
School of Medicine
Baltimore, MD

Rick Berzon, PhD
Boehringer Ingelheim
Pharmaceuticals
Killingworth, CT

Amy Bonomi, MPH
MacColl Institute for Healthcare Innovation
Seattle, WA
Monika Bullinger, PhD
University of Hamburg
Hamburg, Germany

Joseph Cappelleri, PhD
Pfizer, Inc.
Groton, CT

David Cella, PhD
Core & Evanston Northwestern Healthcare
Evanston, IL

Diane Fairclough, DrPH
AMC Cancer Research Center
Denver, CO

Carol Estwing Ferrans, RN, PhD
University of Illinois at Chicago
Chicago, IL

Larry Gorkin, PhD
Pfizer, Inc.
New York, NY

Gordon Guyatt, MD
McMaster University Health Sciences Centre
Hamilton, Ontario, Canada

Ron Hays, PhD
UCLA Division of General Internal Medicine & Health Services Research
Los Angeles, CA

Patrick Marquis, PhD
MAPI Values
Lyon, France

Carol Moinpour, PhD
Southwest Oncology Group
Statistical Center MP
Seattle, WA

Timothy Moynihan, MD
Mayo Clinic
Rochester, MN

Geoff Norman, PhD
McMaster University
Hamilton, Ontario, Canada
David Osoba, MD  
QOL Consulting  
West Vancouver,  
British Columbia, Canada

Donald Patrick, PhD  
University of Washington  
Seattle, WA

Dennis Revicki, PhD  
MEDTAP International Inc.  
Bethesda, MD

Teresa Rummans, MD  
Mayo Clinic  
Rochester, MN

Charles Scott, PhD  
American College of Radiology  
Philadelphia, PA

Mirjam Sprangers, PhD  
Academic Medical Center, Univ. of Amsterdam  
Amsterdam, The Netherlands

Tara Symonds, PhD  
Pfizer, Inc.  
Sandwich Kent, United Kingdom

Claudette Varricchio, RN, PhD  
National Cancer Institute  
Bethesda, MD

Gilbert Wong, MD  
Mayo Clinic  
Rochester, MN

Albert Wu, MD  
Johns Hopkins University  
Baltimore, MD

Kathleen Wyrwich, PhD  
Saint Louis University  
St. Louis, MO
Program Schedule

FRIDAY, APRIL 5, 2002

7:30 - 8:45 a.m. REGISTRATION/CONTINENTAL BREAKFAST/EXHIBITS

8:45 - 9:00 a.m. Opening Remarks
Jeff Sloan, PhD

9:00 - 9:15 a.m. Greetings from the Mayo Clinic Cancer Center

9:15 - 9:30 a.m. Format Commentary
Jeff Sloan, PhD

MANUSCRIPT SERIES PLENARY SESSION I
Paper #1: Methods Used-to-Date for Clinical Significance

9:30 - 9:50 a.m. Paper Synopsis
Gordon Guyatt, MD, et. al.

9:50 - 10:30 a.m. Open Q & A Discussion
Clinician, Industry, and Regulatory Panel

10:30 - 11:00 a.m. REFRESHMENT BREAK/EXHIBITS

MANUSCRIPT SERIES PLENARY SESSION II
Paper #2: Group Versus Individual Clinical Significance Differences

11:00 - 11:20 a.m. Paper Synopsis
David Cella, PhD, et. al.

11:20 a.m. - 12:00 p.m. Open Q & A Discussion
Clinician, Industry, and Regulatory Panel

12:00 - 1:30 p.m. LUNCHEON

MANUSCRIPT SERIES PLENARY SESSION III
Paper #3: Single Item Versus Summated Scale Scores

1:30 - 1:50 p.m. Paper Synopsis
Jeff Sloan, PhD, et. al.

1:50 - 2:30 p.m. Open Q & A Discussion
Clinician, Industry, and Regulatory Panel

2:30 - 3:00 p.m. REFRESHMENT BREAK/EXHIBITS

3:00 - 5:00 p.m. POSTER SESSION

5:00 - 6:00 p.m. Optional Tour of Mayo Clinic

7:00 p.m. DINNER AT MAYO FOUNDATION HOUSE
SATURDAY, APRIL 6, 2002

8:00 - 8:30 a.m.   CONTINENTAL BREAKFAST/EXHIBITS

MANUSCRIPT SERIES PLENARY SESSION IV
Paper #4: Patient, Clinician and Population Perspectives on Determining the Clinical Significance of Health-Related Quality of Life Scores

8:30 - 8:50 a.m.   Paper Synopsis
   Marlene Frost, RN, PhD, et. al.

8:50 - 9:30 a.m.   Open Q & A Discussion
   Clinician, Industry, and Regulatory Panel

MANUSCRIPT SERIES PLENARY SESSION V
Paper #5: Assessing Meaningful Changes Over Time in Quality of Life

9:30 - 9:50 a.m.   Paper Synopsis
   Mirjam Sprangers, PhD, et. al.

9:50 - 10:30 a.m.   Open Q & A Discussion
   Clinician, Industry, and Regulatory Panel

10:30 - 11:00 a.m.   REFRESHMENT BREAK/EXHIBITS

MANUSCRIPT SERIES PLENARY SESSION VI
Paper #6: Incorporating Clinical Significance into Clinical Practice/Industry

11:00 - 11:20 a.m.   Paper Synopsis
   Tara Symonds, PhD, et. al.

11:20 a.m. - 12:00 p.m.   Open Q & A Discussion
   Clinician, Industry, and Regulatory Panel

12:00 - 1:30 p.m.   LUNCHEON

1:30 - 2:30 p.m.   Contributed Papers

2:30 - 3:30 p.m.   Keynote Address:
   Response to the Papers and Future Research
   Patricia Ganz, MD

3:40 - 4:00 p.m.   Networking Opportunity With Writing Teams

4:00 - 5:00 p.m.   Writing Teams – Executive Session

7:00 p.m.   DINNER/BARN DANCE
LEARNING OBJECTIVES

At the conclusion of this meeting, participants should be able to:

• Identify literature regarding assessing the significance of score changes on QOL measures
• Interpret the methods used-to-date for determining clinical significance of QOL scores
• Define a prior change in QOL scores as being clinically significant
• Communicate results of QOL assessments to patients
• Present results of QOL clinical research to peers and regulatory agencies
• Assess changes in patient QOL over time
• Select the appropriate measurement endpoint for clinical application and research
• Explain the issues of missing data and patient compliance with QOL assessment
• Minimize patient burden with respect to QOL assessment

INTENDED AUDIENCE

This meeting is intended for clinicians and researchers who have an interest in assessing quality of life.

CREDIT

Mayo Foundation is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Mayo Foundation designates this educational activity for a maximum of 11.25 hours in category 1 credit towards the AMA Physician’s Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Nurses, social workers, psychologists and other health care professionals will be provided a certificate of attendance for requesting credits in accordance with state nursing boards, specialty societies, or other professional associations.
TRAVEL ARRANGEMENTS

Rochester, Minnesota, is a friendly city that greets thousands of visitors from around the world each year. The city is serviced by a modern international airport with multiple flights daily from Chicago and Minneapolis via American or Northwest Airlines. Access to and from the airport is provided by taxi cab and shuttle service. The airport is located approximately 10 driving miles from the Mayo Clinic campus.

For participants arriving via the Minneapolis/St. Paul International Airport, there is ground shuttle service to/from Rochester available through Rochester Direct. For reservations and further information, call 507-280-9270.

American Airlines is the official carrier for this Mayo meeting. Reduced airfares are available for participants by calling American Airlines at 800-433-1790/817-267-2222. Reference this meeting as Index#S9988, Authorization#0442AE. You may contact the designated travel agency, Corporate Travel, for additional assistance with airfare or ground transportation arrangements by calling 800-526-4540/507-282-9121.

LODGING ACCOMMODATIONS

Blocks of guestrooms have been reserved at special group rates at each of the following downtown Rochester hotels. To ensure accommodations and the discounted rate, please make your reservations by March 15, 2002, and identify yourself as a participant in the Mayo Clinic Quality of Life Meeting.

<table>
<thead>
<tr>
<th>Hotel</th>
<th>Address</th>
<th>Phone Numbers</th>
<th>Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hilton Garden Inn</td>
<td>225 South Broadway</td>
<td>800-445-8667/507-285-1234</td>
<td>$69 single/double</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kahler Grand Hotel</td>
<td>20 Second Avenue SW</td>
<td>800-533-1655/507-282-2581</td>
<td>$72 single/DOUBLE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kahler Inn and Suites</td>
<td>9 Third Avenue NW</td>
<td>800-533-1655/507-289-8646</td>
<td>$65 single/DOUBLE (standard)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$85 single/DOUBLE (suite)</td>
</tr>
<tr>
<td>Radisson Plaza Hotel</td>
<td>150 South Broadway</td>
<td>800-333-3333/507-281-8000</td>
<td>$79 single/DOUBLE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kahler Inn and Suites</td>
<td>9 Third Avenue NW</td>
<td>800-533-1655/507-289-8646</td>
<td>$65 single/DOUBLE (standard)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$85 single/DOUBLE (suite)</td>
</tr>
<tr>
<td>Rochester Marriott Hotel</td>
<td>101 First Avenue SW</td>
<td>877-623-7775/507-280-6000</td>
<td>$129 single/DOUBLE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holiday Inn City Centre</td>
<td>220 South Broadway</td>
<td>800-241-1597/507-252-8200</td>
<td>$72 single/DOUBLE</td>
</tr>
</tbody>
</table>

The hotels listed above are connected by skyway and pedestrian subway to conference facilities, downtown shops, restaurants, and theaters. For additional accommodation options, you may also wish to visit the Rochester Convention and Visitors Bureau website at www.rochestercvb.org.
PARKING

Parking is available in hotel, city, and Mayo patient/visitor ramps. The cost for parking is not included in the registration fee. A map indicating the location of downtown parking facilities will be mailed with the registrant confirmation letter.

REGISTRATION

To register, complete the attached registration form and return by mail or FAX with the appropriate registration fee. The registration fee includes tuition, meeting syllabus, continental breakfasts, refreshment breaks, and specified luncheons and dinners. Although it is not Mayo School of Continuing Medical Education policy to limit the number of registrants for a meeting, conference room facilities may necessitate closing of enrollment; therefore, early registration is strongly advised. A letter of confirmation will be sent upon receipt of payment and completed registration form. Meeting check-in will be conducted from 7:30 - 8:45 a.m. Friday, April 5, 2002, in the Siebens Medical Education Building, Mayo Clinic Campus.

SOCIAL PROGRAMS

Dinner at Mayo Foundation House
Friday, April 5, 2002 (7:00 p.m.)
This semi-formal dinner will be held in one of Rochester’s historical landmarks, an English manor house which once served as the residence of Dr. William J. and Mrs. Hattie May Mayo. This event welcomes meeting participants to the Mayo Clinic and offers attendees an opportunity to network with existing and new colleagues. Cost is $25 per person. Pre-registration is requested.

Dinner/Barn Dance
Saturday, April 6, 2002 (6:30 p.m.)
This rustic evening of down-home Minnesota charm, BBQ and socializing includes a “barn dance” with traditional folk music provided by Bovee and Heil. Participants are encouraged to wear country attire. Pre-registration is requested.

CANCELLATION

Your registration fee, less a $50 administrative fee, will be refunded when written notification is received by the Mayo School of Continuing Medical Education before March 23, 2002 (fax#: 507-284-0532). No refunds will be made after March 23, 2002.
Assessing Clinical Significance for Quality of Life Measures in Oncology Research: State-of-the-Science

April 5-6, 2002 • Rochester, Minnesota

To register, complete and return this registration form by mail or fax. The registration fee includes tuition, meeting syllabus, continental breakfasts, refreshment breaks, and specified luncheons and dinner. Pre-registration is required. A letter of confirmation will be sent upon receipt of payment and completed registration form. Enrollment is limited; early registration is encouraged.

Mail form and payment to:
Mayo School of Continuing Medical Education
200 First Street SW
Rochester, MN 55905

Telephone: 800-323-2688
FAX: 507-284-0532
Website: www.mayo.edu
E-mail: cme@mayo.edu

(Please print or type all information. You may duplicate this form for multiple registrations.)

Name ____________________________________________________________ Degree ______________________
First Name M.I. Last Name
Institution ______________________ Medical Specialty ______________________
Contact Address ______________________________________________________
City _____________________ State/PV __________ ZIP/PC __________ Country ___________
Phone (_________) ____________ FAX __________________________
E-mail Address ______________________________________________________

☐ Check box if you have special accommodation/dietary needs. If so, please indicate your needs here: __________________

Social Events

I plan to attend the…

Dinner at Mayo Foundation House on Friday, April 5 ($25/person): ☐ Yes ☐ No
Dinner/Barn Dance on Saturday, April 6 (complimentary): ☐ Yes ☐ No

Payment

Registration Fees:
Physician Fee: $250 $________________
Non-Physician Fee: $200 $________________
Fee for Friday Dinner: $25 $________________
Total Payment Enclosed: $________________

Payment Method:
☐ Check Enclosed (make checks payable to Mayo Foundation)
☐ Credit Card: ☐ Visa ☐ MasterCard ☐ Discover

Card Number _____________________________ Expiration Date _____________
Signature _____________________________ Date _____________

Check box if you have special accommodation/dietary needs. If so, please indicate your needs here: __________________

Social Events

I plan to attend the…

Dinner at Mayo Foundation House on Friday, April 5 ($25/person): ☐ Yes ☐ No
Dinner/Barn Dance on Saturday, April 6 (complimentary): ☐ Yes ☐ No

Payment

Registration Fees:
Physician Fee: $250 $________________
Non-Physician Fee: $200 $________________
Fee for Friday Dinner: $25 $________________
Total Payment Enclosed: $________________

Payment Method:
☐ Check Enclosed (make checks payable to Mayo Foundation)
☐ Credit Card: ☐ Visa ☐ MasterCard ☐ Discover

Card Number _____________________________ Expiration Date _____________
Signature _____________________________ Date _____________