Quality of Life

The Quality of Life (QOL) working group was established in September 1999 as a research program of NCCTG. This is an exciting opportunity and provides external validation that the work done to date within NCCTG in QOL research is of high scientific caliber and clinical relevance to cancer patients. Now that the organizational structure is in place, we intend to move forward with an expanded and coordinated effort to improve the QOL of cancer patients by identifying specific resources dedicated to QOL considerations within the NCCTG.

Our committee has incorporated members from The University of Manitoba and Mayo Scottsdale as well as personnel from Mayo Rochester. Members include statisticians, patient advocates, nursing, psychosocial researchers, nicotine researchers, and chaplains. This committee meets monthly by teleconference. A monthly Quality of Life Initiatives Luncheon has also been created where QOL researchers can present their proposals and members of the committee can discuss them.

QOL research in NCCTG is more than simply including questionnaires in oncology clinical trials. Our primary goal is to assess only relevant QOL endpoints that have tangible outcomes for cancer patients and clinical practice. Research has been organized into a systematic and programmatic approach following three themes:

1). Assessing QOL endpoints efficiently within treatment trials;
2). Designing trials targeted specifically to QOL endpoints;
3). Developing new QOL methodology.

Currently, there are many studies in NCCTG with a QOL component. We have 30 studies open at present with QOL components, 17 closed studies 11studies in development and 9 completed protocols. We continue to develop the QOL web site http://ncctg.mayoedu/ncctg/qol/index.html, adding more instruments, references and information as a quick reference site. Members are encouraged to visit the site for updates on particular studies or to gather resource information on QOL measures, papers, and activities.

The most notable activity over the past six months has to do with our work on furthering the science of determining the clinical significance of QOL assessments. The first Consensus Meeting on Assessing Clinical Significance for Oncology QOL occurred in October 2000. This 'think tank' consisted of meetings between 30 experts in QOL and resulted in the preparation of a series of 6 papers on clinical significance in QOL research. The April, May and June 2002 issues of the Mayo Clinic Proceedings published the series of seven manuscripts detailing the state of the science in this vital research topic. The papers coincide with a second Clinical Significance for Oncology QOL meeting, held at Mayo Clinic, Rochester, MN, April 5-6, 2002. This work identifies NCCTG as a contributor to the state of the science in assessing oncology patient QOL, efficiently and effectively, consistent with our programmatic themes.

Several other papers have been published or have been accepted for publication in the past six months. Papers highlighting methodology on quality-adjusted life years (QALY) analysis (A new graphic for quality adjusted life years (Q-Twist) survival analysis: The Q0TWIST plot; in press) and a re-analysis of the NCCTG lung cancer clinical trial 892052 have been published (Journal of Clinical Oncology 52:371-381). The development of the new stratification factor (the GBU index) for use in clinical trials involving advanced cancer patients appeared in JCO recently (Journal of Clinical Oncology 19:3539-3546). A methodology paper for the analysis of hot flash studies also appeared in JCO (Journal of Clinical Oncology 19:4280-4290). The study that identified differences between genders in terms of the amount of toxicity patients being treated for colorectal cancer with 5FU-based chemotherapy is in press at JCO and will have appeared by the time of the NCCTG meeting. A paper on the smoking habits of patients on NCCTG lung cancer clinical trials is in press at the Journal of Pain and Symptom Management (Smoking behavior change of 226...
patients with newly diagnosed stage IIIA/IIIB non-small cell lung cancer; in press).

The Mayo/University of Manitoba Summer Institute proved to be very successful producing two proposals that will be submitted to NCI and NCIC. The Summer Institute allowed for a process whereby a researcher could spend a month of dedicated time in the development of a clinical research protocol. The proposals are "Sleep Disturbance in Women with Breast Cancer" and "Nursing Role in Transitional Cancer Care". Both these studies are planned ultimately for NCCTG. A second summer institute is being planned for June 24-July 17, 2002, at Mayo Clinic, Rochester, MN. A similarly structured Winter Institute a collaborative effort of Mayo Rochester and Mayo Scottsdale under the direction of Dr. Michele Halyard has been approved and is in the process of reviewing the protocols submitted to their March deadline.

The spirituality research working group two protocol proposals that may be brought through NCCTG: The "Spiritual Well-Being and Overall Quality of Life in Women with Ovarian Cancer and Their Spouse/Partners" and "Spiritual Distress at the End of Life Concept".

Protocols on music therapy, massage therapy, and acupuncture therapy are continuing to be developed. Patient advocates have put forth a study on "Support Group for Clinical Trial Patients" this intervention process would measure the type of support group patients and families and have while going through NCCTG clinical trials.

Our primary role of facilitating QOL assessment where appropriate within other NCCTG tumor group clinical trials has expanded. A simple, single-page collection of numerical analogue QOL items has been constructed and implemented in a number of NCCTG clinical trials. Within the colorectal tumor group, N9741, N9841, N9941, N9942 have included these simple QOL assessments. In lung cancer, further work has been done in protocols N0021, N0022, N0027. In neuro-oncology, a separate protocol, "QOL in Patients with Newly-Diagnosed Gliomas," has been incorporated into 3 recent NCCTG cancer treatment trials (98-72-51, 98-72-52, N0074) in high-grade gliomas in order to gain preliminary information about the incidence and severity of fatigue, somnolence, and depression in this population, as well as to assess all aspects of their QOL. To date, baseline QOL data has been collected for more than 125 patients enrolled in these trials, and QOL data recorded at follow-up evaluations has been received for more than half of them. Data collection continues while data cleanup is performed in preparation for final analysis.

The first QOL-driven protocol has been approved in the past six months. Dr. Tom Pisansky received approval for protocol N0052 as a special NCCTG clinical trial. The protocol N0052 tracks QOL of patients undergoing brachytherapy. A second QOL protocol for prostate cancer patients is in the review process at NCI. NCCTG N0054, ________, will assess the relative long-term QOL of patients receiving the three most common primary treatments for prostate cancer.

The QOL research program is still growing and evolving from a now solid foundation. Members are encouraged to share feedback on the studies that follow this summary and the research efforts initiated. Please contact Dr. Jeff Sloan, 507-284-9985 or email at jsloan@mayo.edu for questions, input or feedback on the QOL research program.
# Program Status Reports for QUALITY OF LIFE - April 2002

<table>
<thead>
<tr>
<th>Open Studies</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>N0052 A Trial of Neoadjuvant Androgen Suppression and Dose Escalation-Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent-Prostate Adenocarcinoma Following External Beam Radiotherapy</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Protocol Concepts</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>N0054 A Comparative Study of Quality of Life Following Radiotherapeutic-Management of Localized Prostate Cancer</td>
<td>3</td>
</tr>
</tbody>
</table>
A Trial of Neoadjuvant Androgen Suppression and Dose Escalation Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Adenocarcinoma Following External Beam Radiotherapy

- **TREATMENT**
  1) To determine the nature, intensity & time course of health-related QOL changes associated with prostate brachytherapy for this patient population
  2) To determine the morbidity associated with prostate brachytherapy at two different dose levels for this patient population after EBRT
  3) To determine the overall survival, disease-free survival, disease-specific survival, clinical patterns of tumor recurrence, time to biochemical failure, & post-brachytherapy dosimetric coverage

- **TRANSLATIONAL**
  1) To determine whether concurrent over-representation of 8q24 & loss of 8p12 are independently associated with disease outcome and if deletion of the PTEN gene has a similar association independent of chromosome 8 alterations in this patient group.

**Study Chairs:**
Thomas M. Pisansky M.D.  Jeffrey S. Brindle M.D.

**Data Monitor:**
Butch K. Kvittem

**Statistician:**
Susan M. Geyer Ph.D.

**Nurse Resource:**
Wilma H. Knutson R.N.

**Status:**
02/15/2002  Activated

**Projected Number of Patients:**
83

**Stratification Factors:**
None

**Schema:**
Register
  Health-Related Quality of Life
  Total androgen suppression
  Prostate Brachytherapy
  Health-Related Quality of Life

**Treating Schedule:**

Total androgen supression: Administered 16 weeks before prostate brachytherapy. Choice between Zoladex, Lupron & Casodex or Eulexin at MD discretion.

Prostate Brachytherapy: 2 different dose levels used in sequential fashion. First group receive either 125-iodine: 120 Gy minimum targer dose OR 103-palladium: 100 Gy minimum target dose. If well tolerated, second group receive 125-iodine: 140 Gy minimum target dose or 103-palladium: 120 Gy minimum target dose.
Accrual: This study just opened for accrual February 15, 2002. No patients have been accrued at the time of this report.
A Comparative Study of Quality of Life Following Radiotherapeutic Management of Localized Prostate Cancer

**Purpose of Study:**

1) To determine the nature, intensity & time course of health-related quality of life changes associated with EBRT, prostate brachytherapy, or their combined use in this patient population.

2) To compare health-related quality of life indices & changes over time between the treatments.

3) To determine the morbidity associated with EBRT, prostate brachytherapy, or their combination for this study group.

4) To determine the overall survival, disease-free survival, disease-specific survival, clinical patterns of tumor recurrence and time to biochemical failure in this patient population.

**Translational Research**

1) To determine whether concurrent over-representation of 8q24 & loss of 8p12 are independently associated with disease outcome.

2) To determine if deletion of the PTEN gene has a similar association independent of chromosome 8 alterations in this patient group.

**Schema:**

Registration
- EBRT
  - Health-Related Quality of Life Assessment
- Brachytherapy
  - Health-Related Quality of Life Assessment
- EBRT + Brachytherapy
  - Health-Related Quality of Life Assessment