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Response

We read with great interest the remarks of Drs. Roland Skeel (*1*) and Patricia Ganz on quality of life measurement in clinical trials. We are heartened by the considerable agreement emerging in the literature with respect to the following major issues addressed in our review (*2*):

(*a*) supplementation of the physician's report with the patient's report of quality of life;

(*b*) development of a component-based view of quality of life, with components measured separately (as opposed to a more global construct) and modules tailored to different protocols (e.g., treatment-specific symptoms); and

(*c*) consideration of the quality control issues that affect successful implementation in a clinical trial setting.

While emphasizing the mutual agreement about these broad issues, we would like to address three minor clarifications in response to points raised by Drs. Skeel and Ganz.

First, use of separate or companion protocols for quality of life assessment in Southwest Oncology Group trials is an administrative device currently mandated by the National Cancer Institute. It primarily serves as a mechanism for distinguishing credits for cancer control research from those for therapeutic research. We have no reason to believe that this approach will "limit clinician involvement in implementation of the research and the data collection process," a concern noted by Dr. Ganz. To the contrary, Drs. Ian Thompson and Stephen Smalley, investigators for two Southwest Oncology Group therapeutic trials, have contributed to all aspects of the design of these companion protocols—for example, development of treatment-specific items for the questionnaire, discussions regarding expected effects on different components of quality of life over time, and identification of meaningful times for assessment.

An earlier experience with quality of life assessment as an add-on end point in a breast cancer therapeutic trial resulted in poor data collection compliance. We believe this was due to group inexperience with collection of patient-based quality of life data and with insufficient quality control procedures. Physician interest and a substantial investment in data manager training are key variables in successful quality of life assessment in a cooperative group study.

Second, given sufficient physician involvement, we would be interested in assessing quality of life in phase II trials. Limited resources and greater physician interest in such assessment for phase III trials led to our decision to begin with comparative trials. We agree with Dr. Skeel that studying quality of life in patients on a combined-modality regimen for head and neck cancer at the phase II level could yield informative data on trade-offs relating to treatment response and toxicity prior to the design of the phase III trial.

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Third, we also agree with Dr. Skeel (*1*) that a modular approach is best suited to the varying nature of clinical trial protocols. We do, however, think that we have selected existing instruments appropriate for measuring physical functioning, emotional functioning, social functioning, general symptoms, and global quality of life in a number of different protocols. Only the treatment-specific items change with the protocol, and even these items can be used across trials that examine the same disease site (e.g., the two current prostate cancer trials).

We recognize the imperfect nature of existing measures of quality of life, including those we selected, and the vigorous research activity that is generating new instruments [e.g., the developmental work on a core instrument by the European Oncology Group on Research and Treatment of Cancer (*3*)]. Consequently, we have elected annual re-evaluation of the questionnaires constituting our Quality of Life Questionnaire. These reviews will allow us to judge the appropriateness of the measures for different patient groups. In this vein, we are exploring the possibility of translating our Quality of Life Questionnaire into Spanish so we do not eliminate from our data base patients who speak Spanish but not English. Communication with other investigators involved in measuring quality of life in clinical trials or multi-institution research settings can facilitate this process of continual examination of the appropriateness of selected questionnaires.

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(*3*) Aaronson NK, Bullinger M, Ahmedzai S: A modular approach to quality-of-life assessment in cancer clinical trials. Recent Results Cancer Res 111:231-249, 1988

Response

We agree with Dr. Patricia Ganz that there is a need to expedite the incorporation of quality of life assessments in clinical trials in the United States and that the National Cancer Institute (NCI) should lead the way in the facilitation of this goal. A national meeting on the development of quality of life assessments and incorporation in clinical trials would be an excellent first step. Following this conference, as Dr. Ganz suggested, it will be necessary to establish an ongoing working group of physicians, social scientists, and other professionals with a research interest in this problem, who would meet with NCI representatives periodically to monitor the progress of quality of life assessments and their contribution to our understanding of the benefits and burdens of cancer and its therapy.

Equally important will be acknowledgement by the NCI of the importance of quality of life assessments in clinical trials and recognition that research on measurement approaches in this developing field must be supported. This type of research and its application in additional end points in clinical trials cannot be accomplished without additional cost to the individual institutions, the cooperative groups, and the NCI.

Quality of life assessments and, in particular, research on these assessments are not within the traditional scope of expertise in the NCI's Cancer Therapy Evaluation Program or of its support. For this reason, they have not been a priority for expenditure of effort or funds within the cooperative groups. If this difficulty is to be remedied, there must be a policy decision in the NCI that this research is an important part of cancer therapy evaluation. The recent involvement of NCI's Division of Cancer Prevention and Control with the cooperative groups provides an additional opportunity to redress this situation. Quality of life assessments related to cancer treatment interventions in the cooperative groups seem to fall well within the scope of the research interests of the Division of Cancer Prevention and Control. As this research progresses, a second level of intervention—physical and psychological measures to improve quality of life—can be introduced.

Factors that constitute the domain of quality of life assessments are of vital importance to the patient. The degree to which support for quality of life research and end points for clinical trials is forthcoming from the scientific community and the NCI will be a major determinant of the rate at which our understanding in this essential field will advance.

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