

Consider the following hypothetical involving study drug and active control drug, where the study drug has the property of having immediate toxicity, and the control drug has the property of delayed (but severe) toxicity. Adverse events that influence the patient's quality of life materialize shortly after administering the study drug, but in the case of the control drug, have a delayed effect (23). Hence, in this hypothetical, administering the HRQoL form shortly after chemotherapy will show poor outcome for the study drug, but will show favorable outcome for the active control drug. This favorable outcome for the control drug is an artifact, and can result in false conclusions in the study.

V. HRQoL INSTRUMENTS IN ONCOLOGY

a. Introduction

The following concerns HRQoL instruments from clinical trials on colorectal cancer, melanoma, non-small cell lung cancer (NSCLC), and breast cancer. The lessons from these trials may be applicable to HRQoL for drugs used for treating a variety of other diseases, including other cancers, chronic immune disorders, and chronic infections.

Data from HRQoL instruments are often used as endpoints in oncology clinical trials. Buchanan et al. (24) identified about 20 different instruments for measuring HRQoL for cancer patients enrolled in clinical trials. Wilson et al. (25) compared the discriminatory abilities, and the degrees of overlap in questions, of these questionnaires. HRQoL instruments for various chronic disorders, including cancer, include:

- **SF-36[®]** (RAND 36-Item Health Survey (SF-36));
- **EORTC** (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire);
- **FACT** (Functional Assessment of Cancer Treatment);
- **FLIC** (Functional Living Index: Cancer), also known as the Manitoba Functional Living Cancer Questionnaire;
- **GWB** (Rand General Well-Being Scale);
- **SQLI** (Spitzer Quality of Life Index); and
- **V-RQOL** (Voice-Related Quality of Life), for use in clinical trials on laryngeal cancer (26).

²³ EORTC Quality of Life Group. *Guidelines for Assessing Quality of Life in EORTC Clinical Trials*. Brussels, Belgium: EORTC; 2002 [32 pages].

²⁴ Buchanan DR, O'Mara AM, Kelaghan JW, Minasian LM. Quality-of-life assessment in the symptom management trials of the National Cancer Institute-supported Community Clinical Oncology Program. *J Clin Oncol*. 2005;23:591-598.

²⁵ Wilson RW, Hutson LM, Vanstry D. Comparison of 2 quality-of-life questionnaires in women treated for breast cancer: the RAND 36-Item Health Survey and the Functional Living Index-Cancer. *Phys Ther*. 2005;85:851-860.

²⁶ Fung K, Lyden TH, Lee J, et al. Voice and swallowing outcomes of an organ-preservation trial for advanced laryngeal cancer. *Int J Radiat Oncol Biol Phys*. 2005;63:1395-1399.