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NCIC-CTG Position on the Inclusion of Utility Measures in Clinical Trials: Summary of report from the joint WGEA/QOLC Task Force on Utilities Assessment

1.0 Background

The Quality of Life Committee (QOLC) and the Working Group on Economic Analysis (WGEA), two committees of the National Cancer Institute of Canada Clinical Trials Group (NCIC-CTG), considered whether the NCIC-CTG should incorporate utility assessments into their cancer clinical trials.

At a joint meeting of a Task Force3 made up of representatives of both groups in June 2001 the elements of this report and recommendations were agreed to.

2.0 Should the NCIC-CTG incorporate utility assessment into selected trials?

It was considered important for the NCIC-CTG to begin to incorporate utility assessments into selected trials for the following reasons:

1. Cancer is an appropriate disease in which to apply these methods: there may be small differences in survival (or surrogate measures of survival such as disease-free interval, response rate, etc), making measures of morbidity, such as HRQOL, more important.
2. Utility measures are important for decision makers as they provide a means by which comparisons can be made between different treatment interventions across a variety of malignant and non-malignant diseases, a factor that is also important for decision makers in Canada.
3. The NCIC-CTG is in a position to become a leader in this area, as it has been in the area of measurement of HRQOL within cancer clinical trials.

In summary, the Task Force agreed unanimously that the NCIC-CTG should introduce utility assessment into selected clinical trials. The science in the area is growing and the NCIC-CTG is well positioned to make a valuable contribution to the development of the science. As well, it is an area of research where Canadian-specific data is essential for decision making relevant to the Canadian situation. The NCIC-CTG can, and should, take a lead in collecting this data. Further, it is in a position to become a leader in the area for relatively little extra cost.

For NCIC-CTG to include utility measures in some of its trials requires that patients either be interviewed or administered a questionnaire to determine their valuation of health states arising in the context of a particular trial. This can be complex, time consuming and invasive of the patient's comfort and time. Hence, it is unlikely that NCIC-CTG would seek to gather utilities in all trials.

Guidelines for selecting those trials that should incorporate utility assessment include the following:

- health-related quality of life is the predominant outcome or a very important outcome of interest;

- it is important to have a common unit of outcome that combines the effects of morbidity and mortality;

3.0 Which methods of measuring utilities should be used?

Utilities can be measured by either direct or indirect methods.[1] The most appropriate utility measure should be determined on a trial-by-trial basis. Generally, an indirect utility assessment (e.g., HUI[2] or EQ-5D[3]) is the most appropriate. In certain instances direct utility assessment outside the trial maybe appropriate.

4.0 Recommendations

1. NCIC-CTG should continue its international leadership role in clinical trials research methodology by becoming a leader in furthering the science of integrating utility assessments into clinical trials.

2. Trials with an economic component should incorporate a utility assessment unless a convincing argument is presented against this.

3. Trials with the potential of a post hoc economic component should be identified and the possibility of a including a utility assessment should be considered.

4. Trials where HRQOL is considered an important outcome should consider including a utility assessment measure. This can be achieved with a low burden indirect measure.

5. The most appropriate utility measure should be determined on a trial-by-trial basis. Generally, an indirect utility assessment (e.g., HUI or EQ-5D) is the most appropriate. In certain instances direct utility assessment outside the trial maybe appropriate. Rarely, direct measurement within a trial may be necessary.

6. In some cases it may be possible to derive a utility measure from a quality of life instrument. For example, the SF-6D is a utility measure derived from the SF-36 health status questionnaire.[45] The advantage to this approach is that one questionnaire can be used to measure HRQOL as well as utilities and thus minimize respondent burden. However, there is concern that the utilities derived do not align with other widely used utility measures, particularly at the lower end of the scale. This is particularly important in many cancer clinical trials where the SF-6D may underestimate the benefits in HRQOL for those patients at the lower end of the scale.[6]

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[1] See for more details:"Feeny DH, Torrance GW. Incorporating utility-based quality of life assessment measures in clinical trials. Two examples. Medical Care. 1989;27(3)supppl:S190-S204.

[2] Drummond MK, O'Brien B, Stoddart GL, Torrance GW. Methods for the Economic Evaluation of Health Care Programmes 2nd edition. Oxford University Press; 1997:168-169.
For more information visit website www.fhs.mcmaster.ca/hug.

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[3] Drummond MK, O'Brien B, Stoddart GL, Torrance GW. Methods for the Economic Evaluation of Health Care Programmes 2nd edition. Oxford University Press; 1997:163-164. For more information and scoring system visit website www.eurogol.org

[4] Brazier J, Usherwood T, Harper R, Tomas K. Deriving a preference-based single index from the UK SF-36 Health Survey. J Clin Epidemiol 1998;51:1115-28.

[5] Brazier J, Robers J, Deverill M. The estimation of a preference-based measure of health from the SF-26. J Health Economics 2002;21:271-292.

[6] Longworth L, Bryan S. An empiral comparison of EQ-5D and SF-6D in liver transplant patients. Health Econ 2003;12:1061-67.