Japan Clinical Oncology Group

Policy No. 30
Title: QOL Assessment
Scope of Coverage:
Study group, QOL study coordinator, Protocol Review Committee (PRC) and Data Center

---

QOL Assessment

1. Current Situation and History

1.1. Current Situation in QOL Assessment

As stated in the large monograph recently published by NCI (Cancer Outcomes Research: The Arenas of Application, J Natl Cancer Inst Monogr. 2004,(33)), the significance of outcome evaluation from the patient's point of view is widely recognized and various instruments exist in assessing Health-related Quality of Life (HRQOL). However, since HRQOL is inadequately measured, the results of the analysis have limited impact. On the other hand, the collection rate of QOL questionnaire in recent clinical trials in Japan is >90% and the differences in QOL between treatment arms have become to be detected.

1.2. QOL Ad hoc Committee and Policy Development

In the QOL assessments conducted at JCOG in the past, despite significant burden to the researchers and the Data Center, there were almost no useful assessments in terms of the collection rate, reliability, usefulness of the data and methodology. Given this fact, implementation of full-scale QOL assessment study (JCOG9803) was planned and conducted, but a decision was made that QOL assessment was not feasible under the system at that time, when almost half of the planned accrual was done. However, there was increasing demand from researchers in various specialties to use QOL as a secondary endpoint in JCOG studies. Therefore, a QOL Ad hoc Committee, which included the investigators of each organ group at JCOG, was established to determine future directions for QOL assessment at JCOG. The QOL Ad hoc Committee held three meetings to discuss the definition of QOL assessments in JCOG and requirements for conducting QOL assessments.

2. Objectives

The objectives of this policy are to define QOL assessment in JCOG and establish guidelines for implementation of QOL assessments.

3. Definition of a QOL Assessment

In JCOG, a QOL assessment is defined as follows: If any of the followings are not applicable, the QOL assessment is outside of the scope of this policy.

3.1. The Questionnaire to be used

Use a questionnaire with a patient self-reporting format. Whenever possible, use a questionnaire that has been validated. (An assessment where a primary physician/CRC interviews patients and completes the form is not designated as a QOL assessment.)

3.2. Collection Method for Questionnaires

Questionnaires must be returned directly to the QOL Study Coordinator without the questionnaires being seen by the primary physicians. This is the only collection method permitted.

Note: So-called patient reported outcomes, such as assessment of symptoms, are included in the QOL assessment mentioned above.

4. Handling of QOL Assessments

Handling of QOL assessment in JCOG studies is as follows.

4.1. Clinical trials in which there is a QOL Assessment

A QOL assessment is conducted only in phase-III trials. On the other hand, if the objective is to determine the feasibility of QOL assessment in clinical trials, it may be implemented in a single arm study.

4.2. Endpoint

QOL assessment should not be used as a confirmatory primary endpoint, but as an exploratory secondary endpoint.

4.3. Questionnaires

A questionnaire used for QOL assessment should be a self-reporting format and must have been previously validated.

The number of items on the questionnaire should be minimized as much as possible.

Consideration should be made in a study-by-study basis on whether to use a generic scale or a disease-specific scale (or both).

4.4. Analysis Method

The primary analysis method should be determined at the planning stage of the trial and described in the protocol.

Binary data analysis is recommended as the primary analysis method to compare the proportion of improvement exceeding a certain pre-specified threshold. If binary data analysis is used and there are missing data, they should be counted as negative values. (If a better method is available for QOL analysis in the future, the policy will be revised.)

After the primary analysis, an exploratory analyses should be performed using other methods to assess the validity of the results. When QOL results are reported in a research paper, it should be emphasized that the analysis be positioned as an exploratory analysis.

4.5. Publication of QOL Assessment Results

If QOL assessment is conducted as an ancillary study, publication of QOL assessment results should be done after completion of the primary analysis of the primary endpoint of the main trial. This is to avoid affecting the results of the clinical trial results if QOL results are published.

4.6. Review

The study hypothesis, questionnaires, and informed consent forms for QOL assessment should be reviewed and approved by the Protocol Review Committee (PRC) of JCOG, along with a review of the protocol of the main trial.

5. Required Resources and Methodology for a QOL Assessment

Follow the instructions below in conducting a QOL assessment in JCOG:

1) The sending and collection of QOL questionnaires should be arranged by the study group by appointing a QOL Study Coordinator. The work can either be performed by a few individuals or an individual whose activities are mostly dedicated to this task.
2) When selecting the QOL Study Coordinator, it is desirable to assign one QOL Study Coordinator for each group. From the perspectives of accumulation of know-how, communications with the Data Center, and assuring of quality of data, it is desirable to assign one QOL Study Coordinator for the entire JCOG and consolidate operations in the future.
3) Each QOL Study Coordinator should use the standard JCOG SOP as often as possible.
4) Entering the questionnaire responses into the database should be performed by the JCOG Data Center, or performed by the QOL Study Coordinator and then validated by the JCOG Data Center.

6. Revision of QOL Assessment Policy

This policy should be considered for revision by the Executive Committee approximately every 5 years (the Executive Committee met in March 2010). If a determination is made by the Executive Committee that revision is necessary, a discussion should be held at the Protocol Review Committee (PRC). If the Executive Committee recommends a review before the above date, the need for a revision will be considered at that time.