Pergamon

*European Journal of Cancer* Vol. 31A, Suppl. 6, pp. S8–S10, 1995
Elsevier Science Ltd
Printed in Great Britain
0959–8049/95 $9.50+0.00

0959-8049(95)00495-5

# Clinical Trials and Quality of Life Assessment: the Nurses' Viewpoint

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**The rationale for quality of life assessment has been largely developed in the literature. Quality of life is an important concept in the oncology environment because the physical, psychological and social wellbeing of patients are affected both by the disease and the related treatments. The relevance of quality of life assessment to nursing clinical practice has been discussed by several authors. There is a need to use more valid and reliable instruments to plan appropriate nursing care, to evaluate and document the effect of nursing interventions. In clinical trials, quality of life assessment is being used increasingly to predict patients' outcomes and to evaluate medical and nursing interventions. Nurses' viewpoints of potential benefits and pitfalls related to quality of life assessment are discussed. Among the benefits, it is usually considered that therapeutic interventions might be improved. These could be adjusted and individualised and the need for supportive care interventions might be evaluated more accurately. As for the pitfalls, the quality of life evaluation causes an extra burden if its implementation is not properly co-ordinated and if poor or incomplete guidelines are provided to patients and staff. Proposals for implementing effective quality of life assessment in clinical trials are discussed. Basic requirements, such as preliminary instructions, guidelines for administration of the questionnaire and proposals for reducing missing evaluations, are presented.**
*Eur J Cancer*, Vol. 31A, Suppl. 6, pp. S8–S10, 1995

## INTRODUCTION

ALTHOUGH THE major objective of cancer treatment is tumour control, it has been increasingly recognised during the last 10 years that effective cancer treatment should also include strategies to maximise patients' wellbeing or quality of life. As clinical trials have become the preferred means of evaluating new approaches in cancer therapy [1], a large variety of tools have been developed for the evaluation of positive effects (tumour control and increased survival) or of negative effects (temporary toxic effects or permanent sequelae). Recent advances in symptom and toxicity management and other supportive care interventions have modified the classical profile of studies. New tools are needed for objective evaluation of the effects. Quality of life assessment instruments have been recently introduced in the cancer clinical trials field.

Quality of life is influenced by a variety of factors. In health care research, the definition of quality of life contains a wide range of components/aspects which are related to health including the impact of the disease and/or medical interventions [2]. Although there is no standard definition, it is generally accepted that the core dimensions of health status or health-related quality of life include the physical, the psychological and the social domains [3–5]. This multidimensional approach makes it particularly important in the oncology environment because the physical, the psychological and the social wellbeing of patients are affected both by the disease and by related treatments. It is important in clinical trials too as it becomes an additional endpoint to classical endpoints such as tumour control and survival [6].

Most available measures of treatment outcome are focused on physical effects [7]. Although quality of life assessment enlarges the evaluation to other fields, Gill and Feinstein [8] indicated that current measurements are performed by using practitioners' perspectives of patient quality of life and therefore do not reflect the actual patient views. They suggest that instruments should allow patients to add supplemental items. Moreover, they recommend that the measurement of quality of life should be more than a health status rating, and also incorporate patients' values and preferences.

## RELEVANCE OF QUALITY OF LIFE TO NURSING PRACTICE

Quality of life is highly relevant to nursing practice as nurses are not only concerned with patient survival and decreased morbidity but with the patient as a whole. Padilla and Grant [7] reported that patients' quality of life is influenced by how well nurses are able to help patients to adjust to the changes induced by cancer and its treatments. The relevance of quality of life assessment to nursing clinical practice has been described by Varricho [6]. The nursing process includes the initial evaluation of patients' needs, the development of nursing plans, the implementation of nursing interventions and the evaluation of effects. Although the nursing process is currently used in nursing practice, nurses still demand valid and reliable tools to evaluate

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patients' needs, to plan appropriate nursing care and to evaluate the effect of nursing interventions. During the last few years, economical aspects have been taken more into consideration and nurses will have to increasingly justify their actions in terms of measurable objectives reached.

Potential benefits of health-related quality of life endpoints have been described by Moinpour and colleagues [4]. The authors indicate that the inclusion of quality of life measurement improves therapeutic interventions. These can be adjusted and individualised (although the degree of adjustment within a clinical trial is limited), and the identification of a need for supportive care can be more accurate.

## THE ROLE OF THE NURSE

As described by several authors [9, 10] the role of the nurse in the clinical trials field is expanding. It can differ according to the nature of the research, the setting in which it is performed, the available resources and the level of nurses' education. The European Organization for Research and Treatment of Cancer's Oncology Nursing Study Group is promoting the idea that nurses should be involved in the design and planning of clinical trials [10]. Furthermore, Ferell and Cohen [11] indicated that it is becoming more usual to have a nursing research issue investigated in the clinical trial as a companion study. Quality of life assessment is an excellent opportunity for these nursing studies [12]. Companion studies, which are usually initiated by a nurse investigator, are associated with an existing clinical trial. Both studies can start at the same time (preferably) and can be conducted either in parallel or independently. Performing companion studies demands a good interdisciplinary collaboration which should include the following factors: contribution, good communication, commitment, consensus, compatibility and credit [13].

## THE DESIGN AND PLANNING OF THE QUALITY OF LIFE STUDY

The design and planning of the study has to be carefully agreed upon before its initiation. The quality of life study can either be developed as part of a protocol or as an independent protocol. Investigators should not only ensure that selected instruments are valid and reliable [8, 14], but also take into account the time necessary to complete the forms (10–15 min is usually considered as acceptable). In addition, the instrument should be clear and easy to understand in order to avoid missing data. In order to ensure proper conduct of a quality of life study, rules and guidelines should be included in the protocol. A list of items is proposed in Table 1.

*Table 1. Proposed list of items to be included in the protocol*

- Who should be completing the questionnaire (patient, nurse or family)?
- Inclusion and exclusion criteria, rules for entering the quality of life study
- Importance of baseline evaluation
- Planning of measure points
- Schedule for distribution of the questionnaire
- Period covered
- Guidelines for eventual verification of questionnaire for completeness and consistency (when and by whom?)
- Patient informed consent rules and confidentiality issues
- Rules for the analysis of the results
- Organisation of the collection of questionnaires within each participating centre

The aim of the quality of life evaluation should be clearly explained in the protocol [8]. In addition, the instrument to be used, such as questionnaire or visual analogue scale, should be described [15].

Special attention should be paid to the selection of assessment points which have to be in accordance with the protocol, patient visits and nursing workload. Too frequent assesments result in a large amount of missing data [16] and this has a major impact on the analysis.

## AVOIDING PITFALLS DURING THE CONDUCT OF THE STUDY

Several authors have reported compliance problems due to missing data especially during the follow-up period. Recommendations on how to minimise this problem have been proposed [16–19].

Before the initiation of the study, staff nurses should be informed about the start date, the objectives of the study and the tools which will be used. The introduction of the study protocol to the staff is mandatory. All persons involved in the study should be provided with adequate information.

Patient information should be routinely performed. His/her participation in a quality of life study should follow the same ethical requirements as for any research protocol. The patient has to be fully informed and the confidentiality of the data to be guaranteed [16].

Careful attention should be paid to the organisation of the circulation of the information between the patient, the staff and the centre collecting the data for analysis. In order to increase patient compliance, the measurement points should be planned during the outpatient visits. It is important to create room and privacy for the patient to fill in the questionnaire and, if necessary, to help and give advice.

There is a need for co-ordinating the implementation of the study and for data collection in general. Nurses might have an important role in the verification of the questionnaire, the identification of missing data and the collection of the data before patients leave the clinic.

Gill and Feinstein [8] indicated that performing quality of life studies is a professional burden and is time consuming. In addition, Lindley and Hirsch [20] indicated that nurses had to overcome many obstacles to measure health-related quality of life in cancer patients. Lack of time, lack of valid instruments, physicians' lack of time, patients' lack of time, patients' refusal to fill in the questionnaires, and invasion of patients' privacy were the most frequently experienced problems.

## RESULTS OF QUALITY OF LIFE RESEARCH

Assessment of quality of life is a relatively new field of investigation. It remains a concept that in itself is subjective and difficult to measure. Quality of life assessment is used to document the effect of therapeutic interventions, counselling or supportive care measures [21]. While the negative impact of cancer treatment on quality of life has already been documented [22, 23], the positive impact of psychosocial and supportive care interventions is more difficult to measure [21, 24, 25]. This might either be related to the small value of the intervention or to the lack of sensitivity of the instrument used.

Quality of life research will have only limited value unless the study is well-designed, adequate measurement tools are used and data are reliable, collected on an adequate sample and correctly analysed. Results of quality of life studies show that special attention has to be paid to their planning and implemen-

tation [17, 21]. Compliance problems can be reduced by careful introduction of the concept to all participants involved in the study and by following recommendations made by several authors [4, 16–19]. Results of quality of life research have to be implemented into clinical practice. The information available on the impact of quality of life results on medical and nursing interventions is limited. Padilla and Grant [7] stated that at this stage quality of life remains for nurses an interesting theoretical measurement.

## CONCLUSION

Quality of life assessment has a major impact on nurses' workloads. It is therefore important that studies are carefully planned and that quality of life assessment is only performed for selected studies and under good conditions.

It is still unclear how the results of the quality of life studies will influence medical and nursing daily practice. Results should provide nurses with information which will enable them to improve the quality of life of patients and this has still to be demonstrated.


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