

*Editorial*

# How informed are patients after informed consent process

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Researchers in their pursuit of finding better treatment modalities or comparing newer treatments with older ones are in a dilemma of including endpoints such as survival or disease-free survival as they have found out that patients are increasingly no more getting benefitted from these traditional endpoints.<sup>[1]</sup> However, a better quality of life (QOL) is fast becoming a preferred endpoint for many oncology researchers. In general, health-related QOL (HRQOL) covers the subjective perceptions of the positive and negative aspects of cancer patient's symptoms, including physical, emotional, social, and cognitive functions and, importantly, disease symptoms and side effects of treatment.<sup>[2]</sup> Compared to a few decades ago, around 10% of current randomized cancer trials include QOL as their primary endpoint.<sup>[3]</sup> The QOL has been accepted as a major endpoint by the US-FDA and many other regulatory bodies in giving approvals for several anti-cancer drugs but the implementation of QOL has not been so smooth. One of the various reasons for this is the lack of patient understanding of the importance of QOL in cancer care and the very fact that many patients are not able to understand the contents of the questionnaire itself. Understanding the subjective nature of the results that HRQOL studies generate and the barriers to acceptance by clinicians is another major issue. Studies by Stephens *et al.*<sup>[4]</sup> have also shown that as compared to clinical examination by clinicians themselves, patient-reported outcomes showed a marked precise assessment of the functioning of the patient.

## CHALLENGES BEING FACED CURRENTLY

While there is increasing evidence for the value of QOL assessment, one of the biggest challenges is actually measuring it. Being subjective it's difficult to measure. The measurement process draws from many disciplines such as social functioning, psychology amongst others. Many researchers have now started focusing on specific domains pertaining to cancer patients rather than addressing generalized questions which the patient might find difficult to answer. The method

adopted by the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Group, whereby researchers are able to obtain both a single global score as well as detailed knowledge of the various domains has addressed such limitations to some extent.<sup>[5]</sup> The EORTC quality-of-life questionnaire, QLQ-C30, not only collects details on the domains, but also assesses two global HRQOL items independent of the domain scores. Global quality-of-life items are easier to interpret clinically, however they do have some shortcomings.<sup>[6]</sup> For example, Indian patients focus more on limited physical functioning and possibly spiritual or psychological issues as the disease condition worsens.<sup>[7]</sup>

The 20-item EORTC Quality of Life Questionnaire Brain Neoplasm (QLQ-BN20), a cancer subtype specific QOL questionnaire, was developed<sup>[8]</sup> and validated<sup>[9]</sup> for patients with primary brain tumours to supplement the QLQ-C30 core questionnaire. Similarly, a 35-item version (QLQ-H&N35) EORTC head and neck cancer-specific module was developed as per applicable guidelines.<sup>[10]</sup> A lung cancer-specific module has also been developed (EORTC QLQ-LC13) that assesses specific symptoms related to LC and its treatments.<sup>[11]</sup> The QOL data obtained using EORTC QLQ-C30 and EORTC QLQ-LC13 tools have been used as primary outcome measures in some of the randomized clinical trials.<sup>[12, 13]</sup>

## FUTURE DIRECTION

Compliance problem has been attributed to several factors, including the unique challenges of collecting HRQOL data from within a multinational, multi-language region or institution. In addition, collecting QOL data from patients with advanced and progressive disease may be challenging because of their failing health.<sup>[14, 15]</sup> Even though there is increasing participation of patients in the formulation of the QOL questionnaires, still a majority of them are formulated by healthcare personnel. Due to the difference

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in the psychological and cultural frames of the patients and health-care professionals, misinterpretation of the questions is rampant among patients which eventually leads to the collection of data that is not entirely a valid measurement of the HRQOL. This may result in severe compromising of the results of studies in which HRQOL is a primary endpoint. We must try to evaluate an issue that has rarely been investigated: Whether the questions and response categories in the self-assessment questionnaires are interpreted by the study subjects in the same manner as would the researchers and analysts who interpret and report the data. The very validity of the QOL questionnaires would be at stake if this is not the case.

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