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## Survey on Quality of Life Index: Importance and Acceptability by Industry Experts

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### Abstract

**Aim:** The objective of the study was to understand the importance and acceptability of Quality of Life (QoL) index from industry experts with average experience of 10 years.

**Methodology:** This pilot survey was conducted on 42 Clinical Research professionals with 12-item questionnaire.

**Results:** The results concluded that the medical practitioners are of uniform opinion of having QoL as one of the essential parameter in their routine daily practise out of which 64.3% are in favour of enforcement of QoL index as a parameter in all clinical studies. Further 57.1% and 47.6% felt that there is moderate level of acceptance by Investigators and Indian Regulators respectively. Though 54.8% respondents were aware of standardized QoL questionnaire used in the industry, it varies based on disease area resulting in lack of generic standardized QoL questionnaire due to number of challenges that act as a barrier in implementing this change in the industry.

**Conclusion:** Although literature shows that importance of QoL assessment has increased over the years, reporting it as end-point remains uncommon in clinical trials and it is particularly lacking in developing countries. The enforcement of standardization of QoL index in Clinical trials may be of particular value in future.

**Keywords:** QoL, HRQoL, clinical endpoints, importance of QoL

### 1. Introduction

The traditional way of assessing change in patient's well-being in modern medicine has been to focus on laboratory or clinical tests. While these give important information about the chronic and progressive diseases, it is impossible to separate disease from an individual's personal and social context.

The only way to capture the personal and social context of patients is to use QoL tools. 1

### Concept and Definition of QoL

QoL measures have become vital part of health outcomes appraisal and it provides a meaningful way to determine the impact of health care when cure is not possible.

The term QoL is often used vaguely and without clear definition mainly because of the broad nature of the concept.

World Health Organization has defined QoL as 'individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns'. There are various other definitions in the literature, which define QoL in similar ways.<sup>2</sup>

### **Measurement of QoL Scale**

The first 16-item instrument of Quality of Life scale (QOLS) developed by an American Psychologist John Flanagan measured<sup>2</sup>-

1. Material and Physical well-being
2. Relationships with other people
3. Social
4. Community and Civic activities
5. Personal Development and fulfillment
6. Recreation and Independence

The two outcomes namely Health-related quality of life and other Patient-reported outcomes are important to assess patient perspective and experience as they reflect patient satisfaction. It is vital to evaluate QoL during, at completion of therapy or even beyond therapy as a drug may only improve the QoL for short period. For juvenile rheumatoid arthritis and fibromyalgia, measuring of QoL have proved to be useful. <sup>2</sup>

The QoL measures are especially important in cancer clinical trials. One of the study showed survival increased by a median of 2.1 months in an analysis of 71 consecutively approved cancer drugs for solid tumours.<sup>5</sup>

Sanders C et al<sup>3</sup> evaluated the frequency and quality of reporting on QoL through Cochrane Controlled Trials Register (1980 to 1997) to identify trials from all disciplines from oncology and from cardiovascular medicine. Reporting on QoL increased from 1.5% to 8.2% for cancer trials, and from 0.34% to 3.6% for cardiovascular trials during 1980-97. The authors of 48 (72%) used 62 established QoL instruments from a sample of 67 full reports. Own measures were developed in 15 reports by 22% of authors as compared to 3% where methods were unclear.

The General Version of the Functional Assessment of Cancer Therapy (FACT-G) and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQC30) are two widely used multidimensional QoL instruments in oncology.

The most widely used and accepted scales for head and neck (H and N) cancers are EORTC H and N 35, FACT H and N and the University of Washington QoL Questionnaire (UW-QOL).

The authors have suggested using specific questionnaires in addition to general QoL scales for a complete assessment as scales are designed as per the unique group of patients with distinct concerns and issues.

Researchers in the clinical research field debate the relative utility of QoL. Investigators who use QoL measures believe it is a valuable tool, however, others contend that it seems to be indistinguishable from other measures which are routinely used to assess drug safety and efficacy.

Acceptance of QoL may include difficulties in both, the understanding of the underlying concepts as well as in the interpretation of the results as it is not routinely included in the medical curriculum and clinicians are not trained in analyzing and interpreting quality of life data.

National bodies such as the National Institute for Clinical Excellence (United Kingdom) and the Food and Drug Administration (United States) has increasingly value QoL in the drug approval process. There has been increase in number of published clinical trials assessing the QoL; however, evidence is growing that clinical trials published have failed to meet good scientific standards of reporting QoL.

Developed countries of North America and Europe constructed most of the instruments used for accessing QoL, however, their cross-cultural compatibility has not been demonstrated leading to direct application questionable in developing countries. 4

Assessment of QoL has been extremely rare in India, one of the important reasons being non-availability of a suitable instrument. 4

Hence, the study's aim is to understand the importance and acceptability of Quality of Life index from Industry experts through Questionnaire Survey method. The standardization of Quality of Life index will be particularly important for patients with life-threatening conditions who are likely to have impact on their physical, social, emotional and functional well-being and will help in prolonged life expectancy of the patient.

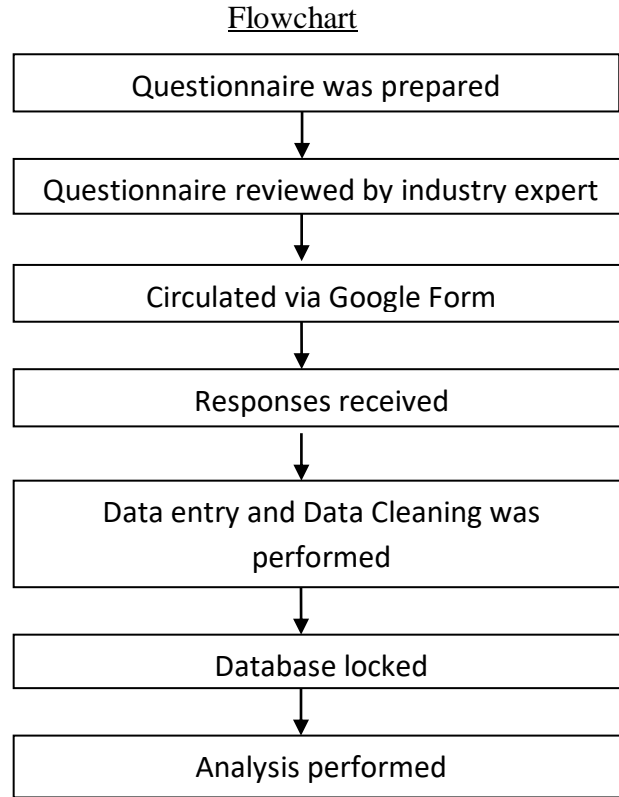
## **2. Method**

The study was survey based where questionnaire was prepared with 12 questions after referring to available literature and getting it validated from an industry experts which was then circulated with google form. Post that, for an ease, the form was converted into Google Forms just to maintain the ePlatform and link was shared with Clinical Research professionals.

The data collection timeline was set for two months (Oct to Nov 2020). The number of responses collected were 42, which was apt for this Pilot study.

Of the 12 questions, there were 10 closed-ended questions and remaining were open-ended questions.

The details procedure is explained in flowchart-

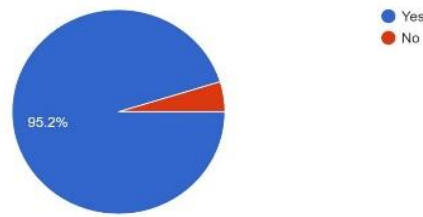


There was no need for assessment. The statistical level was based on percentage method and results were concluded.

**3. Results**

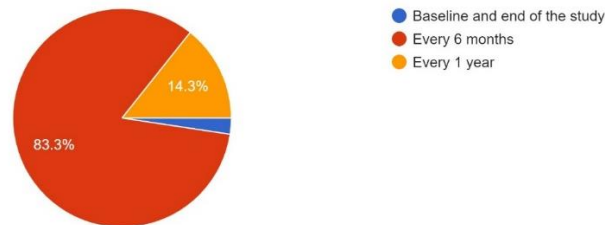
Forty-two responses received from Clinical Research professionals who had an average experience of 10 years (minimum 01 and maximum 16 years) and are currently working at various designations.

The survey shows 100% respondents (n=42) agreed to QoL being vital part of healthcare appraisal and 95.2% of the respondents (n=40) believe it needs to be assess at baseline as well as towards the completion of the trial (Figure 1).



**Figure 1: Need to assess QoL for all trials (baseline and completion of the trial)**

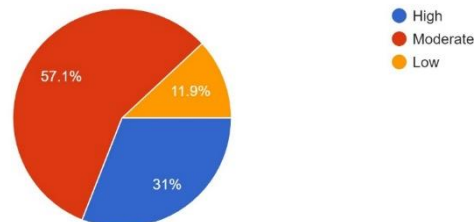
Further when asked the frequency for QoL assessment for longer duration of studies, 83.3% respondents (n=35) selected every 06 months as compared to 14.3% (n=6) for every 01 year and remaining 2.4% (n=1) for baseline and end of the study (Figure 2).



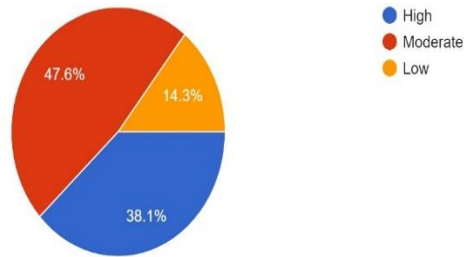
**Figure 2: Frequency for QoL assessment for longer duration of clinical studies**

From the literature collected from public database, the assessment of QoL has been extremely rare in India<sup>4</sup> and with our ultimate aim being standardization of QoL index in Clinical Research, it was important to understand the acceptability level by Investigators and Indian Regulators.

The level of acceptance by Investigators and Indian Regulators was selected as moderate by 57.1% (n=24) and 47.6% (n=20) respondents respectively in the survey (Figures 3 and 4).

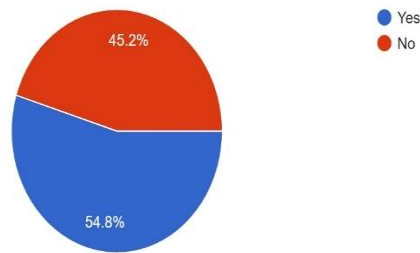


**Figure 3: Level of acceptance by Investigator**



**Figure 4: Level of acceptance by Indian Regulators**

54.8% respondents (n=23) are aware of standardized QOL questionnaire used in the industry (Figure 5). Commonly known questionnaires are listed in Table 1.



**Figure 5: Standardized QoL questionnaire awareness**

Table 1: List of standardized QoL questionnaire

Standardized Questionnaire	No. of Respondents
SF-36 Questionnaire	3
The Asthma Quality of Life Questionnaire	1
MacNew Heart Disease Health QOL	1
Quality Of Life Scale	1
WHO Quality of Life (WHOQOL)	3
Study specific QoL	1
PedQoL	1
EQ5D	4
EORTC QLQ-C30	1
VAS scale for Rheumatoid Arthritis patients	1
HRQoL	1
EORTC	1
EQ-5D-5L	1
Wisconsin QOL	1
Q6	1
QOL	1
PHQ-8	1
QOLs linguistic validation	1
HAQ-DI	1
DAS 28	1
Psychiatry scales	1
SF 20	1
Validation	1
Multiple Scales depending on Therapy area	1

61.9% respondents (n=26) used QoL index in their Clinical studies (Figures 6 and 7).

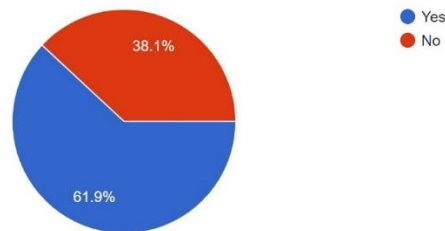
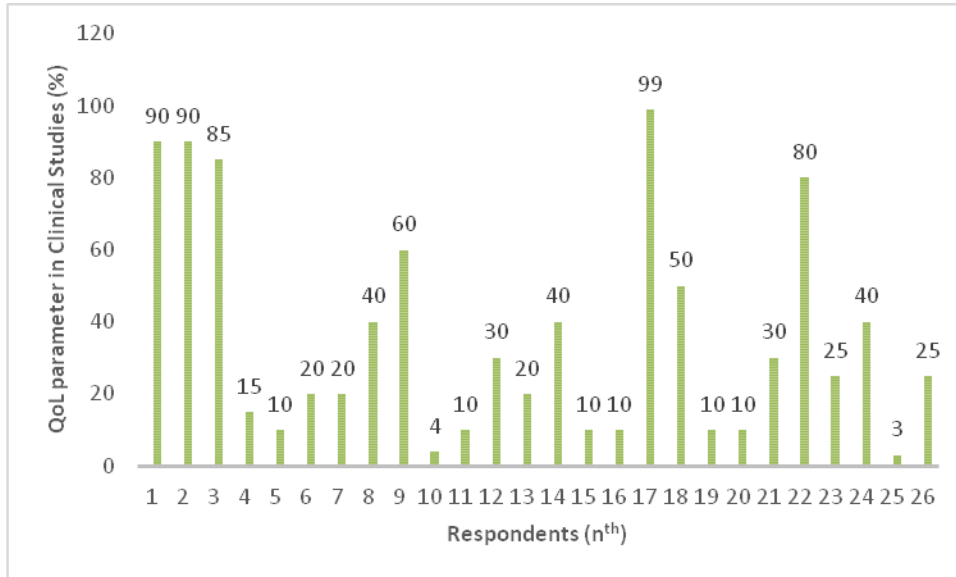


Figure 6: No. of respondents who have used QoL parameter

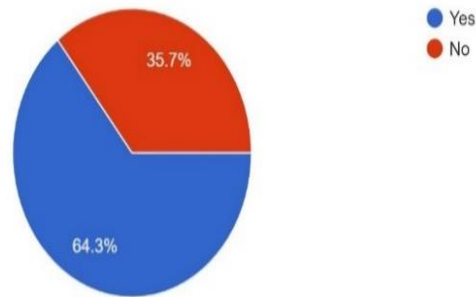


**Figure 7: Assessment of QoL parameter (Percentage of studies)**

As per the survey, 64.3% respondents (n=27) are in favour of enforcement of QoL index as a parameter in all clinical studies (Figure 8) and remaining 35.7% respondents (n=15) feel that only specific clinical studies as below should include QoL parameter -

1. Diseases and disorders that are chronic, degenerative, and/or lifestyle altering. Also in treatment/procedures for terminal diseases that may or may not cause functional side effects in long term
2. Life style diseases and studies involving elderly people
3. QoL could be mandatory for efficacy studies with terminal diseases
4. Studies done in indications where health condition could be either improved or deteriorated. The status of health may be endpoint or objective of the study
5. T2DM, Rheumatology, oncology, ailments impacting routine activities in any patient
6. Interventional
7. Oncology, Haematology and rare disease and pain studies should have QOL. DM, Ophthalmology may or may not have
8. It varies for each disease, life threatening diseases which impact your routine should be preferred Where the outcome is change in daily activity
9. Efficacy studies, Phase 4
10. Highly sensitive studies
11. Arthritis
12. Psychiatry O-42





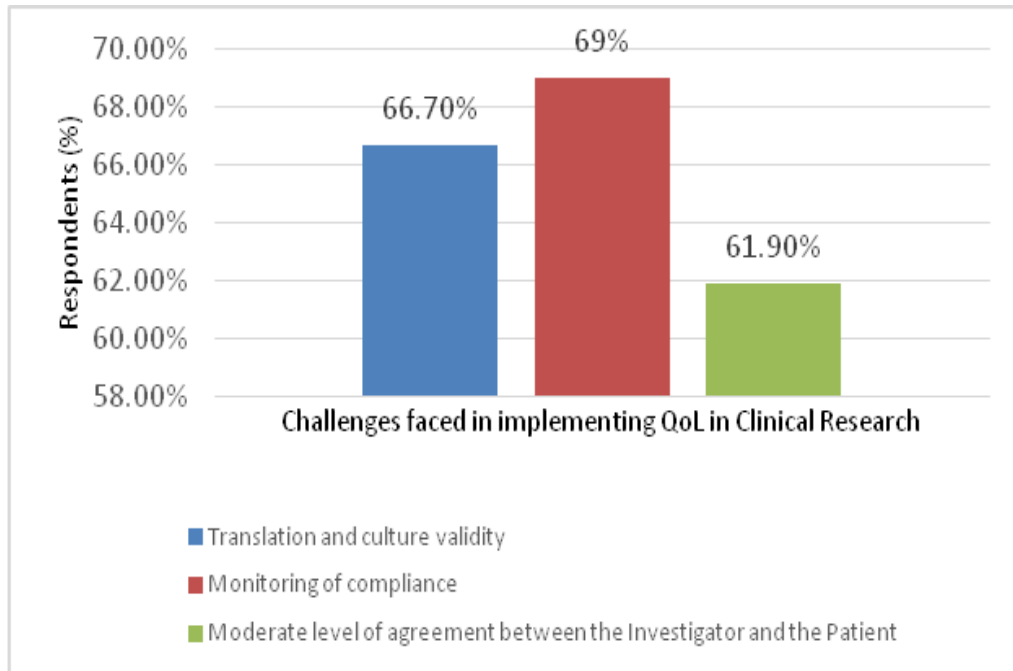
**Figure 8: Mandatory inclusion of QoL parameter in Clinical studies**

Following challenges were also evaluated which could act as a barrier in implementing QoL as a parameter in Clinical Trials (Figure 9).

The top challenge selected by 69% respondents (n=29) was monitoring of compliance followed by 66.7% (n=28) and 61.9% (n=26) for translation and culture validity and moderate level of agreement between the Investigator and the Patient.

Other challenges mentioned by 2.4% respondents (n=8) each were-

1. Interpretation of questions and available multiple-choice answers
2. During telephonic follow-up, patient cannot fill, as it is not on-site visit, ePRO they find difficult to fill, if patient is not educated
3. Subject's understanding and expression
4. Additional time needed by the patient, site staff, monitors as well as additional tools and system to evaluate data and results will add both time and cost to clinical trials
5. Strategy for preparing scale or questions
6. Awareness of its importance
7. Unfounded use of QOL in all studies. Should be used only if required and dictated by protocol
8. QoL linked to nature of disease and stage of disease. Cannot be parameter of trial



**Figure 9: Challenges in implementing QoL index in Clinical Research**

#### 4. Discussion

In clinical trials, the prevalence and quality of reporting on QoL is unclear, despite QoL being an important end-point.<sup>3</sup>

As mentioned by Burckhardt C et al. QoL is an important measure and is required part of health outcomes appraisal, which is also evident from our analysis where 100% respondents agreed on the same.<sup>2</sup>

There has been always been a concern in accepting QoL as one of the parameter for assessment in Protocol in India. When we approached the Clinical Research professionals to understand their point of view, we observed that highest percentage of 57.1 respondents mentioned moderate level of acceptance by Investigator that support the literature, which says clinicians are still reluctant to accept quality of life as an end-point. The reasons could be time-consuming issues such as randomisation, informed consent process, organisation of study medication; clinicians may consider this assessment as an additional burden to themselves and patients. It may be also due to difficulties in understanding the underlying concepts as well as interpretation of the results.<sup>10</sup>

Generally, QoL is considered as a concept that is too vague to be measured reliably with a structured questionnaire and is subject to too much variability across the cultures.<sup>4</sup>

Considering, regulatory body plays a vital role in drug approval process, it was important to evaluate the level of acceptance through Indian Regulators as well. As such, there is not much

literature; however, the current survey showed 47.6% respondents feel there would be moderate level of acceptance by Indian regulators.

Kazi R8 stated that QoL is a neglected domain in our country that was further analysed through our survey results where 35.7% respondents feel that QoL should not be mandatory for all clinical trials and needs to be specific for particular disease area. The survey results provided us with number of challenges that could act as a barrier in implementing QoL as a parameter in clinical trials such as monitoring of compliance, translation and culture validity, moderate level of agreement between the investigator and the patient, interpretation of questions, patient's understanding and lack of QoL.

Most of the literature include variety of scales for different disease areas in India.<sup>3</sup> This means there is a lack of standardized generic QoL questionnaire in India for all patients, which is in line with our survey results of 31 scales being in use by Clinical Research professionals.

The results from the survey has laid a strong foundation for my final thesis where the objective is to enforce generic standardization of QoL parameter in the clinical studies.

## **5. Conclusion**

In conclusion, although importance of QoL assessment has increased over the years, the reporting on QoL end-points remains uncommon in Clinical trials and quality of reporting is often poor. It is important to include QoL as an end-point in Clinical trials. This will show that a particular therapy improves QoL across the entire patient's life and not only during the treatment phase.

Currently, evaluation of physical and mental health is particularly lacking in developing countries where enforcement of standardization of QOL index in Clinical trials may come to be of particular value in future.

## **Acknowledgments**

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