



## **Quality of Life Index for Patients in Clinical Research – Patient’s Perspective**

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Received: 01 September 2023

Published: 15 September 2023

DOI:10.1027/marcr.2023.0373

**Abstract**

*The quality-of-life index is used to compare different medicines, therapies, interventions, or disease management strategies. Patients' cognitive, emotional, and social functioning are also impacted by diseases and their treatments in addition to how well they function physically and how much pain they experience. Assessments of sexual functioning, marital and family relationships, role performance, energy, sleep, health perceptions, and symptoms have all been included in QOL measures. Apart from providing clinical benefits, it also identifies the most effective treatments that enhance overall health and quality of life. This information can be very beneficial for decision-making between patients and healthcare professionals as it enables them to actively engage in their treatment decisions based on their own preferences and values. A complicated and intricate problem is the variation in QoL evaluation methods used in various clinical studies and illness areas. Assessment of quality of life is essential for determining how interventions and therapies affect patients' health and functioning. However, there is a large disparity in the way QoL is evaluated in clinical trials because to the diversity of diseases, patient demographics, and research objectives. Implementation and enforcement of QoL in clinical research require collaboration among various stakeholders including researchers, regulatory bodies, healthcare providers, and patient advocacy groups. Thus, it is essential to establish guidelines and best practices for the consistent integration of QoL assessments into research protocols and reporting standards.*

**Keywords:** *Quality of life, QoL index, General population, Standardization.*

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**Introduction:**

The perceived quality of a person's everyday existence, or QoL, is an evaluation of their well-being or lack thereof. This includes all of the individual's emotional, social, and physical facets. Health-related QoL (HRQoL) measures how a person's well-being may change over time due to a disease, disability, or disorder<sup>[1]</sup> The ability of QoL to offer an extra all-encompassing and nuanced understanding of human well-being is the number one reason for its importance. It fosters societal development towards extra egalitarian, sustainable, and satisfying life via providing facts for regulation, empowering people, and going past financial metrics to consider several dimensions<sup>[2]</sup>.

The idea of one's QoL is still important to consider in any healthcare environment. It is of the utmost importance in certain areas of medicine, such as hospice and palliative care, when the vigorous quest for a cure is put on hold instead of focusing on satisfying patient goals and making the patient's QoL as good as possible. It is essential that this point be made clear: studies reveal that there is considerable individual variation in the ways in which disease processes, symptoms, prognosis, and palliative treatments affect a person's quality of life. Given the current state of the relevant research, it is important to stress that it would be inappropriate to evaluate according to a constrained definition or to apply a single model to all patients. Although there is no shortage of definitions in textbooks, the description that the patient provides when they are sitting across from their doctor is likely the truest meaning of quality of life<sup>[3]</sup>.

The percentage of elderly people in the world's population is rising, while at the same time, survival rates for chronic noncommunicable diseases (CNCD) are getting better. Clinically, various CNCDs, the most prevalent of which are cardiovascular disease, diabetes, hypertension, dyslipidemia, and obesity, are associated with quality of life. Because of this, clinical and epidemiological research has a tendency to place an emphasis on the physical health components of quality of life, concentrating their attention on individuals' views of their living situations in the face of disease and their potential to lead a life that has meaning<sup>[4]</sup>.

Cancer is the most common cause of mortality worldwide. Cancer patients who are still alive may struggle with a wide range of symptoms. The QoL (QOL) is a major worry for cancer patients who are nearing the end of their lives. The symptoms impact their quality of life. The treatment of symptoms reduces distress and improves the quality of life. A survey was conducted by Malathi G Nayak et al<sup>[5]</sup> among 768 cancer patients in India selected by a convenient sampling technique. Data were collected from cancer patients by interview technique using a structured and validated interview schedule. These studies showed that Cancer patients experienced many symptoms that affected their QOL. There is a need to develop interventions for the effective management of symptoms that will empower the patients to have a greater sense of control over their illness

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and treatment and to improve the QOL.

The standardization of the Quality-of-Life index will be particularly important for patients with life-threatening conditions who are likely to have an impact on their physical, social, emotional, and functional well-being and will help in the prolonged life expectancy of the patient, especially in the case of oncology patients<sup>[6]</sup>

QoL evaluations are in line with the expanding emphasis on patient advocacy and quality of life in relation to health. It emphasizes how crucial it is to consider patients' preferences, worries, and general well-being when providing healthcare. Patients can express their experiences and difficulties through QoL assessment, giving healthcare professionals a forum to address these problems successfully. The impact of interventions on patients' everyday life is captured through QoL assessments, which aid in prioritizing patient-centred outcomes and enhancing overall care quality.

Additionally, long-term follow-up and survivorship treatment benefit greatly from QoL assessment. It aids in tracking and assessing how treatments affect patients' well-being after the initial phase of acute treatment. Researchers and physicians can spot late effects, treatment-related complications, and survivorship problems by tracking QoL outcomes over time. With the help of this data, customized survivorship care plans and support services may be created to cater to patients' continued requirements after their treatments are over.

Patient-centred care is a top priority in clinical trials and an essential element of this is the QoL assessment. This provides a comprehensive way to gauge treatment outcomes from the patient's viewpoint. Furthermore, it complies with regulatory requirements, promotes patient advocacy, streamlines course of treatment selection and permits long-term follow-up and survivorship care<sup>[7]</sup>. Adding QoL assessment to clinical trials empowers researchers and clinicians to achieve greater insight into how interventions impact patients' well-being, improving treatment outcomes and boosting patient-centered care.

## **Methodology:**

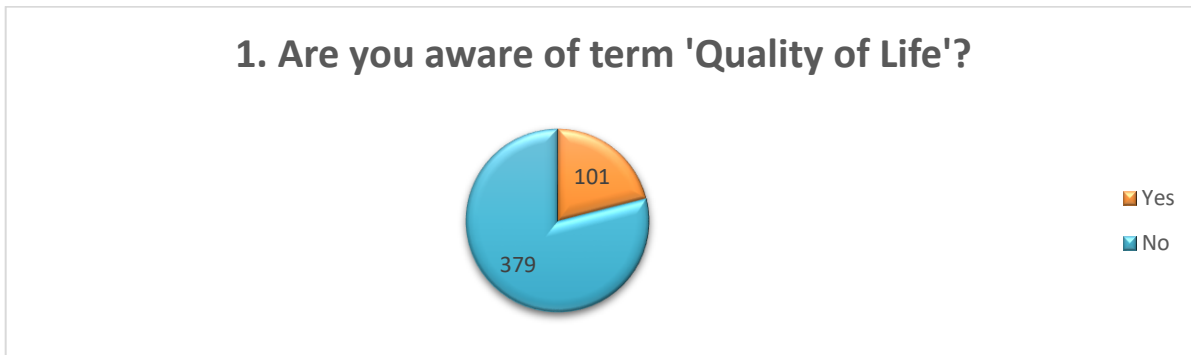
The research project was a survey-based model where we gathered information on the challenges and acceptability of the QoL index for patients within India using questionnaires. The survey was distributed to the general population as potential clinical research trial participants would be the best judges to share their views and expectations. The Questionnaires were developed with the help of available literature and by understanding the difference between existing questionnaires on QoL. Considering all the parameters including the challenges and barriers, these questionnaires were built. The questionnaires were distributed

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on a digital platform which helped us reach the target faster and proved to be of low cost. A web portal was built which was an easy-to-use website, which provided a variety of functions as per our requirement.

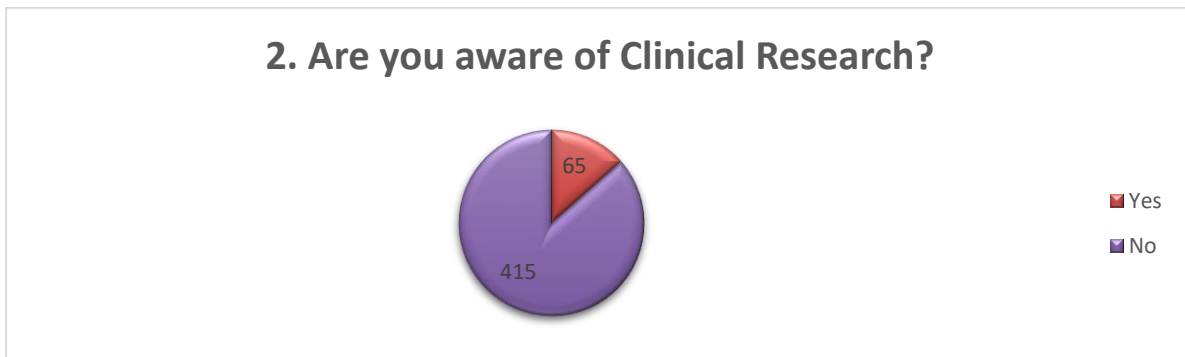
**Results:**

In order to assess the significance of QoL in clinical research, 480 patients were interviewed during the survey. Their responses are presented in the following section.



**Fig. 1:** Response of patients to Q1 of the survey

When the participants were asked if they were aware of the term ‘Quality of Life’, 79% said yes while 21% said no (Fig.1). However awareness of clinical research was low as only 14% said yes about being aware of clinical awareness.



**Fig. 2:** Response of patients to Q2 of the survey



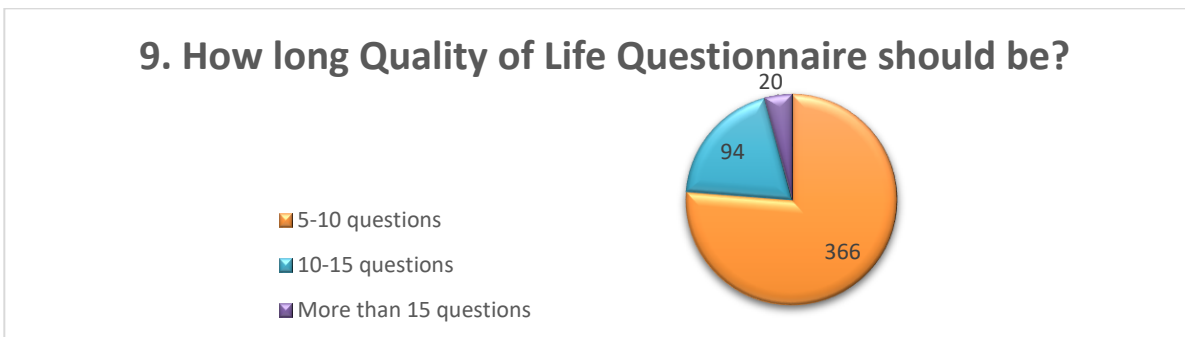
**Fig. 3:** Response of patients to Q3 of the survey

Those who had responded with yes, were then asked to self-evaluate how good their knowledge was about clinical research. The responses are presented in Fig. 36. When asked if they had ever participated in clinical research, more than 99% said no, with only 2 participants expressing unwillingness in sharing response.



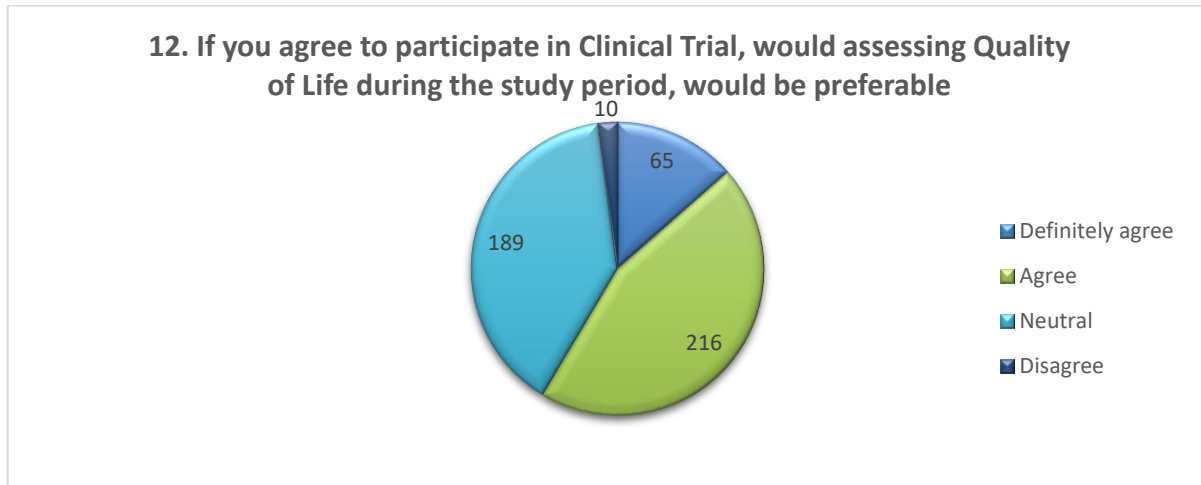
**Fig. 4:** Response of patients to Q8 of the survey

When participants were asked how comfortable were they participating in clinical trial, 86% were not sure about it. And only 2% were very comfortable in participating (Fig. 4).



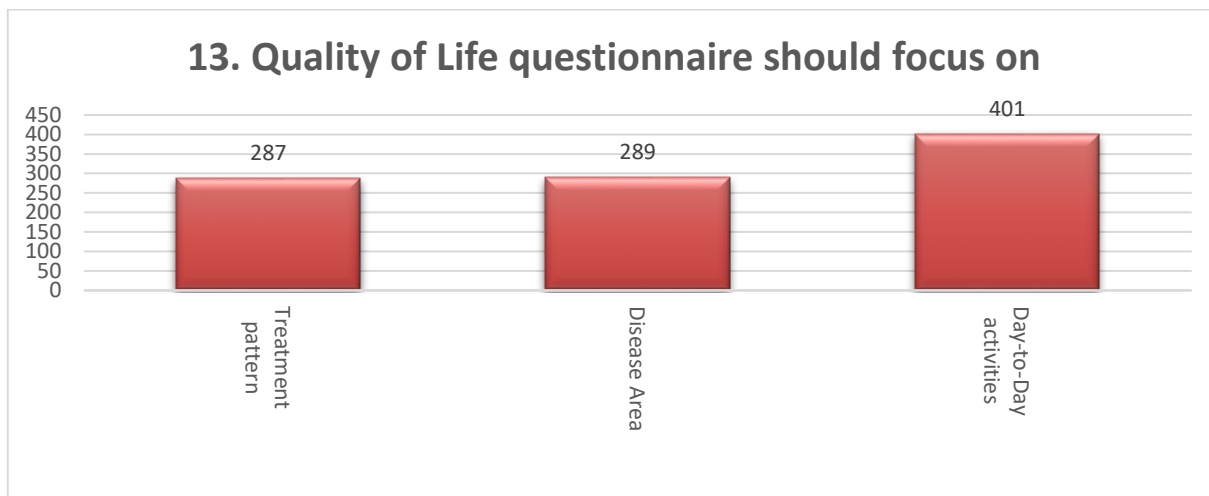
**Fig. 5:** Response of patients to Q9 of the survey

When the participants were asked how long the questionnaire should be, 76% stated that it should be between 5 to 10 questions. 20% said it should be between 10 to 15 (Fig. 5). In response to the next question, ‘Do you think Quality of Life Questionnaire should be available in local/regional languages?’, all of the participants said yes to this. Next they were asked, ‘Do you think that your physician should assess the Quality of Life before the start and end of the treatment?’. To this also all the participants said yes.

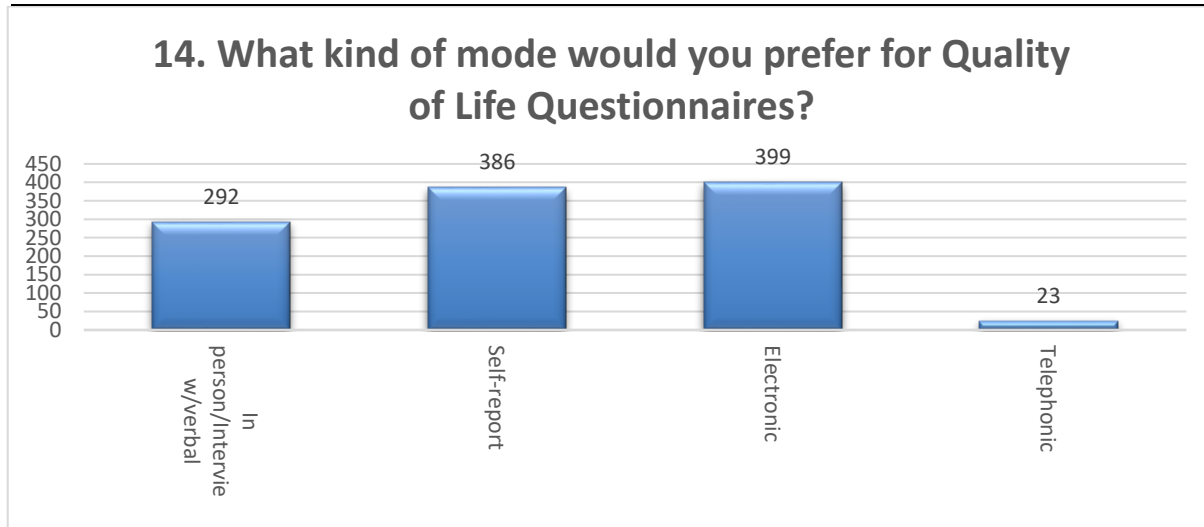


**Fig. 6:** Response of patients to Q12 of the survey

When the participants were asked, ‘If you agree to participate in Clinical Trial, would assessing Quality of Life during the study period, would be preferable’, 45% of the participants agreed to it. 39% chose to remain neutral, while 2% disagreed.

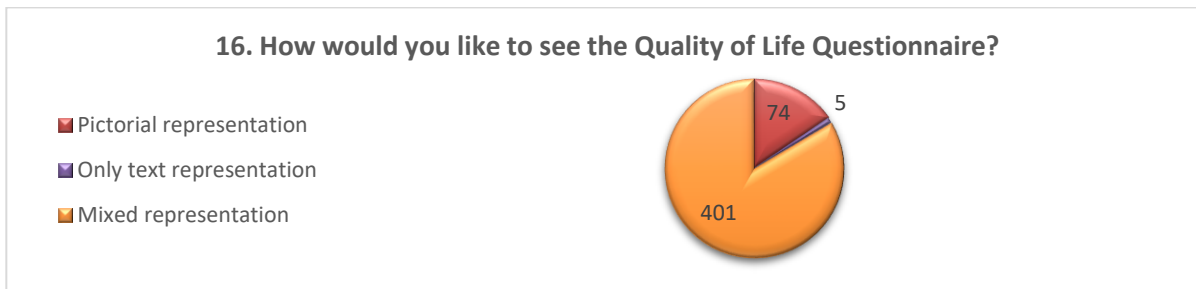


**Fig. 7:** Response of patients to Q13 of the survey



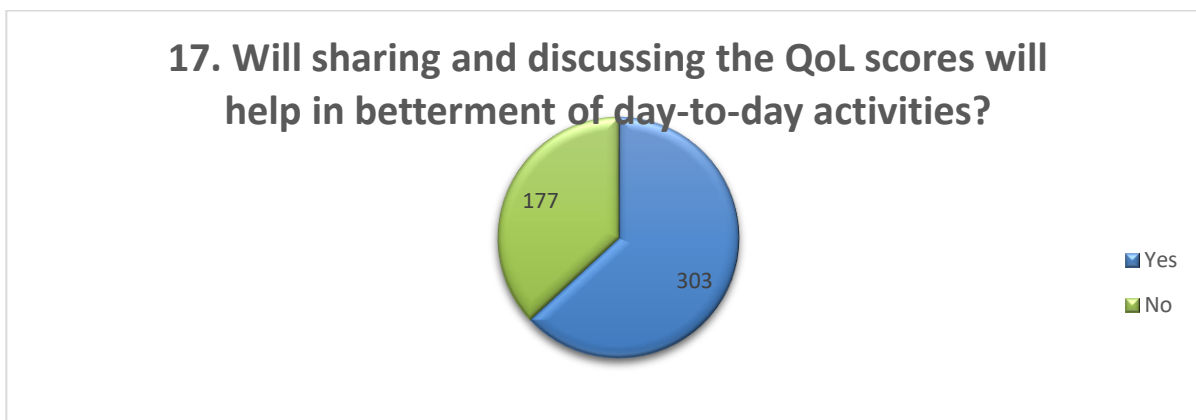
**Fig. 8:** Response of patients to Q14 of the survey

Majority of the patients (84%) stated that they thought that QoL should be mandatory for all clinical studies.



**Fig. 9:** Response of patients to Q16 of the survey

When the participants were asked about how they would like to see the QoL questionnaire, only 1% preferred a only text based representation. 15% opted for pictorial representation, while the majority at 84% preferred a mix of both (Fig. 9).



**Fig. 10:** Response of patients to Q17 of the survey

Next the patients were asked if sharing and discussing QoL scores will help in betterment of daily activities. To this 63% were of the negative opinion, while 37% agreed to it (Fig. 10).

## **Discussion:**

Developing a consistent and robust quality of life (QoL) index can overcome the difficulties associated with the variability of clinical research measures. It can also simplify the data collection and analysis process and enable meaningful comparisons between studies and patient populations, resulting in a more evidence-driven decision-making process. Standardized QoL indexes also significantly enhance patient-centered care by evaluating interventions based on clinical effectiveness and patient quality of life impact. This approach provides a better understanding of treatment outcomes and allows patients to be actively involved in their care choices. Stated QoL indexes can also help identify gaps in health care services and patient needs, which can guide resource allocation and the design of specific interventions to fill those gaps.

79% of the participants were aware of what is Quality of life. Quality of life is defined as an individual's perception 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. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their relationship to salient features of their environment<sup>[8]</sup>

Clinical studies that include QoL assessment encourage patient-centred care<sup>[9]</sup>. It values patient viewpoints and gives them the power to take an active role in choosing their own care. Patients can directly report on their experiences, symptoms, and functional abilities thanks to patient-reported outcomes, which serve as the cornerstone of QoL assessment. This patient-centered approach makes sure that therapies are personalized to meet the needs and objectives of each patient, which enhances patient satisfaction and treatment results.

The evaluation of the quality of life is crucial for choosing treatments and doing research on comparative efficacy. Beyond evaluating clinical effectiveness, QoL assessment assesses how interventions affect patients' QoL. Researchers and clinicians can make educated decisions by comparing QoL outcomes across various treatment options, taking into account both the clinical advantages and the therapies' effects on patients' daily life. By matching treatment choices with patient preferences, this information enhances patients' overall wellbeing.

By offering accurate and comparable data on patients' wellbeing, standardisation in QoL indices promotes clinical decision-making<sup>[10]</sup>. Healthcare professionals can monitor treatment outcomes, follow patients' quality of life over time, and make educated judgements about therapy modifications and supportive care interventions

with consistent measurement. By including patients' interests and views in the evaluation of treatment results, standardisation also supports patient-centred care by enabling more specialized and adapted healthcare actions. In order to achieve consistent and accurate measurement of patients' well-being in clinical trials, standardisation in QoL indicators is crucial. Using standardised QoL measurements provides researchers and clinicians with solid and useful data that ultimately results in more patient-centered care and better-informed healthcare decision-making. This also improves the comparability of QoL data, supports regulatory evaluations, accommodates cross-cultural studies, and eases meta-analyses. By utilising these measurement tools, the effects of treatments on patients' quality of life can be accurately assessed.

Most of the participants agreed that assessing QoL should be done during the study period. Both the significance and efficacy of measuring QoL in clinical studies have increased in recent times. The current situation shows a greater understanding of the complexity in the nature of patients' experiences and the growing need to document their personal well-being together with conventional clinical outcomes. One of the key developments in QoL assessment is the use of Patient-Reported Outcomes (PROs), which allow patients to provide their own QoL directly. PRO tools such as self-administered questionnaires or interviews have been designed to evaluate several aspects of QoL, including physical emotional well-being and social interactions, and overall satisfaction in life.

With the transition to patient-centered research, the use of QoL outcomes in clinical trial design has gained traction. While clinical objectives like survival or disease progression still matter the most, the addition of QoL endpoints emphasizes that the main aim of medical therapy should be to enhance patients' overall QoL. A person's subjective evaluation of their physical, mental, and social well-being in relation to their health status and the effects of a specific illness or intervention is referred to as their "health-related quality of life." It helps to understand how the different aspects of a person's health, including pain, exhaustion, mobility, emotional well-being, and social functioning, affect their overall quality of life.

Surveys or questionnaires that directly capture the patient's opinions on their health and treatment are frequently used to evaluate PROs. In clinical research and healthcare decision-making, HRQoL and PROs are both very important. They offer important details regarding how a specific procedure or therapy affects patients' life and can be used to evaluate the efficacy, security, and worth of medical procedures from the perspective of the patients.

HRQoL and PROs offer a more thorough understanding of the patient experience. They can aid medical professionals and researchers in choosing the best course of treatment, assessing interventions, and customizing care to meet the needs and preferences of particular patients.

Overall, incorporating HRQoL and PRO evaluations enables a more patient-centered approach, ensuring that patient viewpoints, satisfaction, and general well-being are taken into account alongside traditional clinical outcomes.

## **Conclusion:**

QOL measurements have been useful in understanding the subjective experiences and difficulties people with chronic illnesses and their families endure. These measurements offer a quantitative framework for evaluating and contrasting the effects of various chronic conditions on people's well-being, and they can aid in the creation of focused interventions and support plans. The efficient application of QoL metrics in clinical decision-making processes may be hampered by this disparity in knowledge and skill. To address these issues, efforts should be made to improve the knowledge of QoL concepts among medical professionals, foster interdisciplinary cooperation, and offer sufficient instruction on the interpretation and use of QoL metrics in clinical practise. Further study and the creation of particular QoL tools customised to particular patient populations can also aid in capturing the complete spectrum of patient feelings and worries.

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