Review Article:

**Simplification of Patient-Reported Outcome Measures in Oncology: A Narrative Review**

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**Abstract**

**Background:** Patient-reported outcomes (PROs) are reports provided by patients themselves detailing their medical health state or behavior related to an illness or medication use, without any interpretation by healthcare professionals. PROs are used to evaluate health status that cannot be quantified through tangible measures, for primary outcomes such as pain severity, and secondary outcomes such as quality of life. Patient-reported outcome measures (PROMs) are instruments or methods developed by professionals to assess data on PROs directly provided by patients during reporting procedures. In the oncology field, they are important to determine the impact of cancer and chemotherapy on patient’s physical symptoms, mental well-being, and social functioning. The health system turned towards using PROMs as tools for remote monitoring, conducting visits when needed, and alerting stakeholders at the right time. **Aim:** To describe the uses and types of PROMs in use in clinical practice and the simplified PROMs that have been developed in oncology. **Conclusion:** PROMs are widely used in oncology for data collection. It became necessary to simplify measures by using patients’ language, downsizing content, and promoting electronic PROMs through technological programs.

**Keywords:** Adverse reaction; Oncology; Patient-reported outcomes

**1. Introduction**

Patient-reported outcomes (PROs) are reports provided by patients themselves, detailing their medical health state or behavior related to an illness or medication use, without any interpretation by healthcare professionals (HCPs) (1 – 3). Throughout the treatment trajectory, patients can communicate their symptoms and any treatment-related side effects to their doctors. HCPs enter these data into the patient’s medical record and interpret them immediately. However, these entries were not considered PROs (4).

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Additionally, they play a vital role in qualitative and quantitative clinical trials, making the results more credible and acceptable (8). Patient-reported outcome measures (PROMs) are instruments or methods developed by professionals to assess data on PROs directly provided by patients during reporting procedures (3). PROMs were first used in clinical trials before being developed for a variety of uses, including decision-making involvement, enhancing patient-HCP communication, improving patient care services (9), assessing symptoms and severity, health-related quality of life (HRQOL), physical functional status, psychological status, and patient satisfaction. PROMs can be used to estimate one or more of these concepts (1, 10). Several studies have been conducted focusing on PROMs’ application in health systems and show a gradual increase in PROMs use in clinical trials, especially in the oncology field (11 – 13). This narrative aims to describe the uses and types of PROMs in use in clinical practice and the simplified PROMs that have been developed in oncology.

2. Patients Reported Outcome Measures (PROMs)

2.1. Uses of PROMs

PROMs could be used to illustrate various forms of self-assessment of health status and to describe several aspects including; symptoms and symptoms’ burden, quality of life, functional status, mental status, and patient satisfaction. PROMs can be used for assessing one or more of the aforementioned concepts or more than one (1, 14).

2.2. Types of PROMs

PROMs serve various purposes and could be broadly categorized into generic and disease-specific PROMs. Generic PROMs are health conceptual measurements applicable to a broad spectrum of patient populations, allowing for comparisons and aggregation in a variety of contexts and scenarios. (1, 15 – 18). Generic PROMs can be used to assess many components of general health, including physical function, pain, adherence, vitality, and mental health (19, 20). Research showed that the most commonly used generic PROM in clinical trials is EuroQol-5 Dimension (EQ-5D) which collects accurate information about the patient’s current health condition (21). It consists of questions related to the patient’s level of mobility, ability to do self-care tasks, engagement in regular activities, experience of pain or discomfort, and presence of anxiety or despair. It also has a scale to determine the level of severity (non, little, or significant issue) (22). Other widely used generic PROMs are short-form (SF) 36-item questionnaire, and shorter versions; SF-20, and SF-12 (23 – 25).

On the other hand, specific PROMs target populations with specific characteristics and/or with specific diseases (22). Disease-specific PROMs are specifically created to detect particular symptoms and assess their effect on the functioning of those particular diseases like cancer, such as the European Organization for Research and Treatment of Cancer Quality of Life questionnaire (EORTC QLQ-C30) (26), which assesses the general QOL for cancer and can be subdivided into many specific questionnaires according to the type of tumor (27). Similarly, Functional Assessment of Cancer Therapy – General (FACT-G) PROM is specific to cancer and assesses four categories of well-being: social, emotional, physical, and functional (28, 29).

Furthermore, specific PROMs are used for special population or conditions like geriatric, children and adolescents, smokers, drinkers, pregnancy, or any other conditions (9, 30). For example, the Child Health and Illness Profile—Child Edition Child Report Form (CHIP-CE CRF) PROM is used to assess the general health of children (31), and the Adolescent-Quality of Life Questionnaire (32) to assess QOL and satisfaction of treatment in adolescents (33).

In most researches, clinical investigations used a blend of generic and disease-specific PROMs. For instance, a research study including individuals with asthma may incorporate a PROM specifically assessing ‘asthma control’, in addition to a generic PROM like the EQ-5D, to evaluate patients’ quality of life (1). According to Churrucu et al., (2021) study, there is an increasing trend towards the utilization of PROMs. The disease-specific PROM, with the highest average annual citation count, was the mental health PROM. Followed by generic PROM, blood and metabolic, cancer, respiratory, skin, kidney and urinary, musculoskeletal, neurological, reproductive and maternal, cardiovascular, hearing and vision, gastrointestinal, endocrine, infectious, injuries, and trauma (9). The highest utilization of mental health PROM may be attributed to its reliance on self-reporting as a primary method for diagnosing and monitoring these diseases, as they often lack identifiable biological indicators. Consequently, some mental health PROMs are employed for screening and diagnosing these conditions (34).

2.3. Advantages and disadvantages of PROMs

Generic PROMs have the advantage that they are intended to be used for a population that consists of persons who are in good health or individuals with several coexisting medical conditions (35). It can evaluate various aspects of overall functioning, well-being, or QOL (36), and is convenient to make comparisons between patients and populations (37). On the other hand, generic PROMs are less effective than specific measures in detecting specific changes in disease status, making them less responsive to targeted change (24). Furthermore, they might not be able to adequately address significant specific conditions and are less commonly used in clinical trials (38).

Disease-specific PROMs are just like generic PROMs, in which they have their advantages and disadvantages. Disease-specific PROMs have the advantage that they are used if the intended population is a subgroup of patients with a certain illness or undergoing a prevalent treatment (35). Furthermore, they are used to assess symptoms that are anticipated to be directly targeted by a condition-specific intervention, a particular symptom, or a combination of symptoms that are specific to the illness (36). They also enable the differentiation of groups at the same level of specific symptoms or disease. Finally, they are more
applicable in clinical settings and trials, sensitive, and have more clinical detail than generic PROMs (9). However, disease-specific PROMs have their own disadvantages that include, increased assessment burden, and the difficulty in the comparison between different conditions or diseases (37, 39). Moreover, they are inappropriate to be used for general or coexisting conditions since they were designed and validated primarily for specific diseases or used in research investigations (40).

3. PROMs in Oncology

Oncology practices are seriously seeking to monitor tumor growth and the effects of chemotherapy drugs. There is a lot of research and studies that have proven the importance of PROMs in oncology (40 – 43). Accordingly, the demand for incorporating PROMs into cancer care has consistently increased patient satisfaction and communication between HCPs and patients (44), more than data related to HRQOL (45). Many studies have shown the beneficial effects of PROMs on health outcomes and offered long-awaited confirmation that the regular utilization of PROMs in cancer clinical treatment might enhance health outcomes, such as HRQOL and even survival (16, 46 – 48). In the oncology field, there are many PROMs used, which are classified into generic and specific PROMs (49). Generic forms like the European Quality of Life-5 Dimensions (EQ 5D) (50, 51), Short Form-36 (SF-36) (23), Short Form-12 (SF-12) (52), (EORTC QLQ-C30) (26), Functional Assessment of Cancer Therapy (FACT-G) (28), the MD Anderson Symptom Inventory (MDASI) (53), and the European Kid Screen-52 (KIDSCREEN-52) (54). Weingärtner et al., (2013) study showed that FACT, EORTC QLQ-C30, and EuroQoL 5D were the most popular PROMs used throughout the study’s duration between 2010 and 2013 (55). The EORTC QLQ-30 questionnaire, which is considered the most popular PROM in the oncology field, is used to assess QOL in cancer and may be targeted for different diagnosed types of cancer (EORTC QLQ-LC13) for the Lung Cancer Module (9, 56).

Disease-specific PROMs are also used in the field of oncology, e.g., EORTC QLQ-HCC18 for liver cancer and EORTC QLQ-STO22 for gastric cancer (25). Preston et al., (2015) study has shown that QUEST GY is most commonly used for pelvic cancer, EORTC QLQ-OV28 for ovarian cancer, EORTC QLQ-CX24 for cervical cancer, EORTC QLQ-EN 24 for endometrial cancer, and FACT-V for vulval cancer (57). The Van Rooij et al., (2023) study showed that the Eating Assessment Tool-10 (EAT-10), and EORTC Head and Neck Cancer Quality of Life Questionnaire (EORTC H&N35) (58) were used to assess the HRQOL in patients with head and neck cancer (59).

3.1. Limitations of the available cancer-specific PROMs

Despite all the benefits of cancer-specific PROMs, studies have shown some limitations of PROMs in clinical trials;

• Culturally sensitive PROMs can contribute to increased attrition rates and elevated levels of missing data (60).
• The use of translated PROMs in multinational clinical studies that include the patient’s health and cultural experiences is more responsive to environmental changes (61).
• The incorporation of translated as well as culturally validated PROMs into a more diverse pool of participants can lead to the absence of clear information, a decrease in the number of participants, and incomplete data (60).
• Insufficient transparency exists regarding the publication and reporting of data on some ethnic groups (5).
• The majority of PROMs were first designed and verified for application in collective settings for research purposes, thereby rendering them unsuitable for individual patient assessment (62 – 64).

3.2. PROMs simplification

Despite the positive impact of PROMs on patient monitoring and communication during cancer treatment, their recognition is not widespread (65). Among the downsides of currently in-use PROMs is the complexity of use since they use technical language that is hard to understand by lay person or needs assistance from healthcare professionals (66). Furthermore, they are time-consuming and tedious since they are long and many patients think that they are boring and may refuse to fill them (67). Moreover, long and demanding PROMs that depend on the patient’s recalling, may lead to worsening fatigue and malaise in patients with cancer who already complain of these symptoms, therefore, they are less inclined to fill these PROMs (68).

The review of the literature revealed a paucity of research conducted to simplify PROMs, therefore, research are necessary to explore the simplification process of PROMs to improve care outcomes, and understand patients’ experiences (69). Among the strategies that can be implemented to simplify and improve filling PROMs and overcome the barriers to their use, the following points have been suggested:

• The use of a common native language that facilitates detailed understanding and simplicity. This is crucial to overcome issues related to diverse linguistic backgrounds or non-native languages that can result in incomplete filling and data loss (70, 71).
• Content validity entails validating and condensing questions to match the target audience and research goal, in accordance with Food and Drug Administration (FDA) standards (72).
• Time for completing the questionnaire is crucial, as a lengthy one might be tedious and exhausting for people (73).
• Data gathering through the utilization of several methods of patient-reported data collection, such as the web (ePROMs), telephone, tablet, or paper (74).
• Implementing strategies to minimize missing data by training site staff, patients, and physicians and monitoring adherence in real time (75).
• Using specific PROMs since they are more accurate and focused on gathering the necessary information (76).
3.3. PROMs’ applicability across the diverse patient population

To ensure that these tools are understood and achieve the desired benefit from their use around the world, PROMs should be translated into a language that is familiar to the target population (5). If the questionnaire is not clearly understood or filled out incorrectly by patients, it can result in inaccurate or incomplete reporting. This can compromise the validity and reliability of the collected data, as well as the quality of medical information needed for monitoring and health assessment (77). Utilizing translated and culturally adapted PROMs enables the incorporation of a more diverse group of participants. In contrast to culturally inappropriate PROMs, which can lead to a decrease in the number of participants and incomplete data (5), participants may not understand or find relevance in some items, which hinders the capacity to build a common understanding of the value of combining patient-centered data in clinical trial outcomes (78). Many guidelines emphasize that validation and translation procedures are meticulous and accurately represent the necessary cultural viewpoints. Nevertheless, it remains uncertain whether translated and culturally validated PROMs are being utilized in clinical trials that have PRO endpoints (61).

3.4. Examples of the widely used simplified PROMs in Oncology

3.4.1. EORTC QLQ-C30

The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Group proposed the creation of a significant tool in 1986 that assesses HRQOL (79). The result was the EORTC Quality of Life Questionnaire-core module (EORTC QLQ-C30). This questionnaire is cancer-specific comprises 30 items, and is widely used in clinical practice (80). The main module is accompanied by subspecialty modules for certain diseases that provide in-depth information that is pertinent to assessing the HRQOL in particular patient groups, such as lung cancer (QLQ-LC13) (71), and breast cancer (QLQ- BR23) (81), evaluating symptoms associated with a particular tumor site, such as urinary, sexual, and bowel symptoms in prostate cancer (EORTC QLQ-PR25) (82). Complications that may arise in head and neck cancer patients, such as speech and feeding difficulties can also be measured (83, 84).

In 1987, researchers modified the initial version of the EORTC QLQ-30 (75) to make it more specialized to cancer, multifaceted in design, suitable for self-administration, can be used for different cultural groups, and can be applied for specialized modules related to types or treatments of cancer. (85). Later, the EORTC QLQ-30 was further modified based on the original fundamental concepts, to make it more concise and condensed (84, 86, 87). Due to its importance and usability, EORTC QLQ-30 was translated into more than sixty languages (73), including all the main Western languages, as well as numerous African and Asian languages (88). It only requires 11 minutes on average to complete, without needing any help (75).

3.4.2. Functional Assessment of Cancer Therapy-General (FACT-G)

The FACT-G questionnaire form is a cancer-specific questionnaire; it is validated, reliable, and widely used in clinical trials and the oncology field (89). This PROM was created in 1987 with the invention of a generic CORE questionnaire and used to encompass various chronic illnesses and conditions (90). It consists of 27 general questions categorized into four domains related to quality of life (91): physical well-being, social/family support, emotional well-being, and functional well-being (92). This PROM was simplified to the FACT-G7, which is a rapid 7-item version of the FACT-G (93), to assess the patient experiences within the past 7 days and requires less than 15 minutes to complete (94, 95). It is designed for self-administration, but it can also be completed through an interview. This PROM is suitable for patients with any type of cancer and has been tested and confirmed for use with other chronic conditions like HIV/AIDS and multiple sclerosis, as well as with the general population with some adjustments (96). It has been translated into more than 45 languages, including; Asian, European, and African languages (97).

3.4.3. Hospital Anxiety and Depression Scale (HADS)

Zigmond and Snaith introduced the HADS as a self-assessment tool in 1983 (98). It was validated and translated into more than 30 languages and it is considered as a brief measure that can be filled quickly, as it takes 2 to 5 minutes (99). It is considered the gold standard for mood scales in oncology and palliative care (100).

The HADS was initially developed to assess anxiety and depression in patients, even though it has been extensively used in screening and case-finding research. It can identify depression in patients with concurrent somatic illness, who have sleeping disturbances, lack of energy, or concentration difficulties due to their somatic illness (101). This PROM has also been modified, in which it had been separated into HADS-A for anxiety and HADS-D for depression, enabling separate measurements of these disorders (102).

3.4.4. The Short Form-36 (SF-36)

The SF-36 questionnaire is a generic, self-administered questionnaire with multiple dimensions (103). It is a validated and reliable PROM (104). HCPs widely use this PROM for burden diseases like cancer, especially for comparative purposes to assess health improvements (105, 106). It has been translated into more than 50 languages and it took approximately 7 minutes to fill (107). This tool assesses two main aspects of subjective well-being: physical and mental health, using 36 questions and 8 multi-item scales (108). The SF-36 was simplified to the SF-12, which is a condensed form of its previous version SF-36, that has been developed to reduce the load of responding and the burden on the respondent (109).

3.5. A comparative assessment between EORTC QLQ-C30, FACT-G, HADS, and SF-36

All of these PROMs are reliable, validated, and exhibit strong psychometric features. However, the selection of a certain
PROM is dependent on the specific clinical inquiry and the intended purpose of its utilization (110). Since both EROTC-QLQ-30 and FACT-G are specific PROMs for cancer, they have a high level of patient compliance, are user-friendly, and pose no major challenges (111), with a minimum rate of error or missing data. Both are quick and take less than 15 minutes to fill (112).

Despite the great closeness between EROTC-QLQ-30 and FACT-G, studies have found some differences between them. Compared to FACT-G, the EORTC QLQ-C30 items often contain negative words, potentially leading to confusion among respondents and unsatisfactory item attributes, as they are harder to understand (113). King et al., (2014) study found that the total score of the FACT-G was more effective than the global scale of the EORTC QLQ-C30 in assessing the overall HRQOL (114). However, Iravani et al., (2018) study found that EORTC QLQ-C30 offers the benefit of generating symptom scores more specific than FACT-G (115).

Despite that HADS and SF-36, both are widely used in oncology, they are not specific to cancer. HADS is most suited for screening rather than case-finding (76). It is considered a distinctive measure that assesses only simple cases of anxiety and depression associated with cancer. On the other hand, the SF-36 has been proven to have content validity as a general assessment tool. However, it is acknowledged that it may not cover all the relevant content areas for specific populations. Additionally, the SF-36 has not been used in the context of palliative care, possibly because it does not address the specific concerns of patients with advanced disease (116).

3.6. Electronic PROMs (ePROMs)

To enhance the role of PROMs in the health system, in addition to conserving physician time since physicians’ time is very tight (117), the health system shifted towards using PROMs as tools for remote monitoring, conducting visits when needed, and alerting stakeholders at the right time (46). By shifting from using old-fashioned PROMs that utilize pens and papers to the use of electronic PROMs (ePROMs). In which data are collected electronically through devices such as smartphones, tablets, or personal computers (118, 119). Moreover, ePROMs have the advantage of being completed either directly or through a telephone interview by the patients or their caregivers. The use of electronic devices has significantly reduced the time required to fill, collect, and organize information (117). Furthermore, the outcomes can be immediately shown at the location of treatment and examined on a visual representation (46).

Basch et al., (2016) study was conducted at Memorial Sloan Kettering Cancer Center, used ePROMs, and applied on patients with solid tumors who received chemotherapies distributed randomly into two groups. The first group, known as the intervention arm, was required to electronically report 12 commonly experienced symptoms during chemotherapy. The second group, known as the control arm, received standard follow-up care as usual. After a 6-month follow-up, the study findings indicated a significant improvement in HRQOL among patients in the intervention group as compared to the control group. Furthermore, individuals in the intervention group experienced a decrease in emergency department visits and hospitalizations and also adhered to scheduled chemotherapy treatments for a longer duration (120). Furthermore, during long-term observation, the median overall survival rate was enhanced by 5 months when utilizing weekly ePROM monitoring as opposed to the standard periodic follow-up visits (121). Using ePROMs complying with local laws requires prioritizing data privacy and security (122). The use of ePROMs is also associated with some disadvantages:

- Cost: This is a significant obstacle to the implementation of ePROMs. Typically, ePROMs have a higher cost compared to conventional PROMs (123).
- Security: An additional significant disadvantage of ePROMs is their susceptibility to data breaches, which pose a risk to the confidentiality of sensitive information (124).
- Complicated programs: ePROMs necessitate computer programming, which might pose difficulties for inexperienced users and elderly patients, and may limit their utilization in some establishments (125). The McCleary et al., (2013) study showed that geriatric patients needed help to finish ePROMs due to computer illiteracy, while patients who could do the paper questionnaire needed less support (126).
- In another study, patients requiring assistance were notably older than 70 years old (127). In a different study, cancer patients who declined ePROM or preferred phone calls instead of ePROMs were around 10 years older. Elderly or technologically inexperienced patients encounter more obstacles with ePROMs and require training courses to become acquainted with the devices (128).
- Infrastructure requirement: Patients may vary in internet access, and compatible devices to run the ePROMs (129).

3.6.1. Examples of the widely used ePROMs in oncology

3.6.1.1. The McGill Pain Questionnaire (MPQ):

In cancer populations, the MPQ is a widely used, reliable, and validated ePROM used as a measure of pain. It quantifies the neurophysiological and psychological domains of pain, making it a valuable tool for cancer research. However, it is considered time-consuming, since it takes about 25–30 minutes to fill (130). Furthermore, the MPQ has further limitations as it has readability issues for some descriptors, and its three pain patterns are not adequate to account for changes in pain experienced by cancer participants (131).

To overcome these limitations, the MPQ was modified, simplified, and transformed into an electronic Short-Form McGill Pain Questionnaire (eSF-MPQ), which can be filled in 15 minutes (132). Cook et al., (2004) study compared the eSF-MPQ with the conventional (non-electronic) version of the SF-MPQ and found that responses to both versions’ testing modalities for the SF-MPQ showed strong agreement. Furthermore, patients suffering from chronic pain were widely embraced and often favored the electronic version (133).

3.6.1.2. Electronic New Patient Intake Questionnaire (e-NPIQ):

The electronic New Patient Intake Questionnaire (e-NPIQ) is a systematic electronic questionnaire used in clinical care for large-scale data collection and screening of patients for health
and lifestyle factors affecting treatment. The e-NPIQ allows patients to fill out the online questionnaire from any personal device, phone, or tablet, and it has been recorded and saved in the electronic health system. The physicians would be notified when the data are collected and analyzed to implement the appropriate health interventions (134).

4. Conclusion

PROMs are used frequently in the oncology field and for research data collection. These measures were developed greatly by researchers and oncology organizations, to achieve the desired benefit, along with increasing the patient sample size in a short period and avoiding missing patients’ data. It became necessary to simplify the available measures by; using patients’ language, downsizing the content, easily completed by patients themselves, not time-consuming, in line with the level of society’s culture, and using technological programs to encourage the using of ePROMs.

Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

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