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Flexibility in patient-reported outcome and health-related quality of life measurement: The EORTC Quality of Life Group measurement strategy

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ABSTRACT

The development of the first European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Group (QLG) health-related quality of life (HRQoL) questionnaires contributed to the systematic uptake of HRQoL as an endpoint in cancer clinical trials, and to the measurement of HRQoL for individual assessment in routine care. Following a modular approach, these patient-reported outcome (PRO) measures (PROMs) ensure that both generic and disease-specific issues are assessed, enabling comparison of PROs across groups and studies. The application of a comprehensive and continually refined methodology for developing and updating these PROMs has been crucial in supporting their psychometric and cross-cultural validity, and their continued implementation in clinical research. However, the advancement of measurement science, the more widespread implementation of PROMs, and the significant evolution of anti-cancer therapies over the last decades have highlighted the need to adopt more flexible approaches to PRO assessment to ensure that PROMs remain relevant and fit-for-purpose. The QLG has responded to this call by implementing more tailored PRO measurement

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approaches through the development and release of the computerised adaptive test (CAT) version of the EORTC QLQ-C30 (i.e., the EORTC CAT Core) and the EORTC Item Library. The EORTC Item Library is an interactive online platform that allows for the creation of customised questionnaires (item lists) from the pool of available items derived from established EORTC QLG PROMs. The aim of this article is to describe the current EORTC QLG approach to PRO measurement in oncology, covering important historical developments and best practice recommendations.

1. Background and aims

The European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Group's (QLG) approach to health-related quality of life (HRQoL) assessment and other patient-reported outcome (PRO) measurements has evolved considerably since the publication of its first HRQoL measure, the Core Quality of Life Questionnaire, QLQ-C30 [1]. These latest developments reflect changes in cancer research and practice, including the advent of new therapies, developments in measurement science, and the more widespread implementation of PRO measures (PROMs) within research and clinical care. Here we aim to describe the EORTC QLG's current, state-of-the-art approach to PRO measurement, providing historical context and highlighting current practices, with a focus on tailored application of PROMs, and future directions.

2. The EORTC QLG modular approach to PRO measurement

Development of the first EORTC HRQoL questionnaires began in the 1980s, when it was recognised that patients' HRQoL should be considered when evaluating the impact of anti-cancer treatments in clinical trials [2]. HRQoL is a multidimensional construct comprising physical (e.g., disease-related symptoms and treatment side-effects), emotional, social, and functional health (e.g., physical functioning and role functioning) [3,4]. As anti-cancer therapies evolved over time, with more patients being cured or experiencing longer periods of disease-free and overall survival, the need to better understand treatment-related toxicities and the impact of disease and treatment on HRQoL became more pronounced. This need also better reflected the World Health Organisation's seminal conceptualisation of health as not only the absence of disease and symptoms but also the presence of physical, social, and emotional well-being [5].

The first version of the EORTC QLQ-C30 [1] was developed alongside the first disease-specific module for patients with lung cancer, the QLQ-LC13 [6]. It was published in 1993 following international validation and later updated to its current version 3.0 [7]. Since then, the QLQ-C30 has been translated into more than 120 language versions [8,9] and has undergone extensive psychometric [10–12] and cross-cultural [13] validation. A recent international evaluation confirmed the current relevance of the 15 domains covered by the QLQ-C30 [12].

The development of the QLQ-C30 and QLQ-LC13 formed the basis for the EORTC QLG's modular approach to PRO measurement, whereby generic core HRQoL issues are captured within the QLQ-C30 and disease- and treatment-specific issues are included in separate modules administered in addition to the QLQ-C30 (e.g., QLQ-CR29 for colorectal cancer) [14,15]. This comprehensive and integrative approach to PRO measurement was designed to be general, allowing for comparison within and across studies (including between groups and over time), while remaining specific enough (through the EORTC modules) to address relevant research questions and ensure content validity.

2.1. Expanding the EORTC QLG modular approach

The establishment of a rigorous methodology for questionnaire development paved the way for subsequent EORTC modules. The EORTC QLG Module Development Guidelines, currently in their 5th edition [16], continue to be refined and serve as an important reference. They ensure that new questionnaires (modules) are developed and updated, following a four-phase approach (including qualitative and quantitative methods) within an international context with input from relevant patient subgroups (e.g., covering different disease stages and treatments), healthcare professionals, and PRO methodologists. This approach helps to ensure patient-centredness and high levels of psychometric (including content) and cross-cultural validity. Currently, over 50 modules are available for use [9].

2.1.1. QLQ-C30 derivatives

Over time, the EORTC QLG PRO measurement strategy expanded to include other PROMs derived from the QLQ-C30. The QLQ-C15-PAL [17] is a 15-item shortened version of the QLQ-C30 for patients in palliative care and the QLQ-F17 [18] contains the 17 functional scale items from the QLQ-C30 to facilitate its use alongside other symptom-specific PROMs. Designed for cancer survivors, the Survivorship Core (QLQ-SURV100) [19] incorporates all QLQ-C30 items, making it possible to conduct longitudinal studies with a combination of both the core items and additional scales specific to the survivorship setting. Additionally, the QLU-C10D [20], a preference-based health utility measure scored from the QLQ-C30, is now available to support health economic evaluations, which represent an important aspect of health technology assessment (HTA).

2.1.2. Stand-alone questionnaires

Stand-alone questionnaires were developed to capture specific aspects of HRQoL in detail (e.g., sexual health and spiritual wellbeing) [21,22] and can be administered independently of the QLQ-C30. These questionnaires also include patient-reported experience measures (PREMs) that assess patients' satisfaction with care and services [23].

The EORTC QLG PROMs described above are all static in nature, meaning that for each PROM, the same set of items is administered in a fixed order to all patients regardless of setting or intent.

3. Towards a more flexible and adaptive approach to PRO measurement

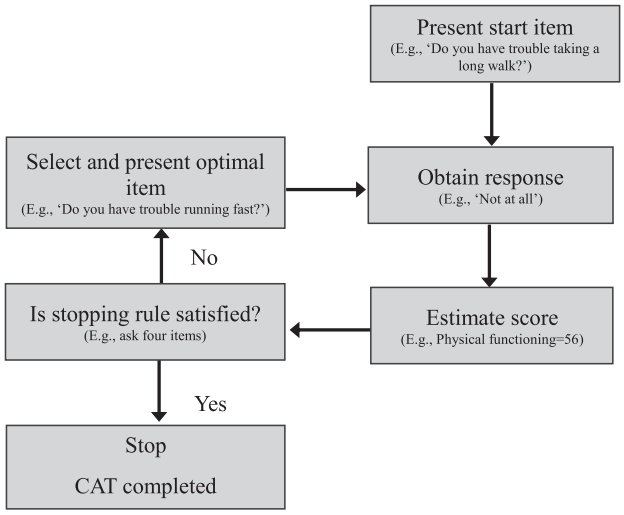
Over time, it became clear that more flexibility was needed in terms of how PROMs are administered as well as their coverage.

To support alternative administration modes beyond traditional paper-and-pencil assessment, a validated voice script was developed for telephone administration of the QLQ-C30 [24]. Moreover, guidelines were developed to support the migration of EORTC PROMs to electronic (ePRO) platforms [25].

In order to target additional, important aspects of PROM coverage: [1] measurement range and precision (for more in-depth measurement of certain domains) and [2] content, two new tools were developed, the computerised adaptive test (CAT) version of the EORTC QLQ-C30 (the EORTC CAT Core) [26] and the EORTC Item Library [27].

3.1. The EORTC CAT Core (for computer adaptive testing)

When developing PROMs that are intended to be relevant for a given population, the scores of individuals with particularly high or low levels of symptom burden or functioning may not be adequately captured by static questionnaires. In contrast to static PROMs, CAT measurement



Start item: The item initiating the CAT assessment, i.e., the first item being asked.

Stopping rule: The criterion determining when a CAT assessment should end. For example, it should stop when a specified number of items has been asked or once the standard error of the score estimate is below a predefined threshold.

Figure 1. Computer adaptive testing (CAT) logic.

systems select items 'dynamically', one at a time from a set of calibrated items (an item bank) measuring the same domain and developed using item response theory (IRT). Based on the patient's response to previous items, a CAT algorithm selects the next best-fitting item (Figure 1). In this way, item selection is tailored to the individual respondent to optimise relevance, measurement precision (reducing sample size requirements), and range of measurement (reducing floor/ceiling effects, increasing sensitivity), while preserving comparability of PRO scores across and within studies [26,28].

The CAT Core covers the 14 functional and symptom domains of the QLQ-C30, with an item bank for each domain. Given that all QLQ-C30 items are included within the item banks, the CAT Core is compatible with the QLQ-C30. In addition to its computerised adaptive application, CAT items can also be administered as static short forms, whereby specific items from an item bank are preselected. The results obtained from these static short forms are scored using the same methodology, preserving many of the advantages of CAT, while allowing for paper-and-pencil administration. A standard set of short forms is available for each QLQ-C30 domain, with a brief and long version for mild, moderate, and severe symptoms, respectively [29]. It is also possible to request custom-made short forms, and work is underway to create sub-divisions of existing CAT Core item banks [30].

3.2. The EORTC Item Library

The EORTC Item Library was originally created as a database to store all existing EORTC QLG items and their translations, available to QLG members to facilitate the development and standardisation of new PROMs. Since then, it has been updated to become an integrated online platform, accessible to users upon request [27]. It currently includes over 1000 items from 75 EORTC questionnaires, all of which have completed at least Phase 3 of questionnaire development [9]. Within the EORTC Item Library, users can obtain detailed information about items and their source questionnaire(s), including development phase, scale structure, translations, and relevant publications. It is also possible to search for items using the Common Terminology Criteria for Adverse Events (CTCAE) framework, with over 200 different adverse events (AEs) currently linked to EORTC items (Figure 2) [31]. An important feature of the EORTC Item Library is that it allows user-created customised questionnaires (item lists) to capture, for example, issues relevant to a specific clinical or research setting, not covered by, e.g., the QLQ-C30 and a relevant module.

The need for customised item lists was prompted in large part by the development of new cancer treatments, since updates of EORTC disease-specific modules and their subsequent validation are time intensive. This highlighted the importance of incorporating item lists to ensure that symptomatic AEs and other HRQoL issues related to novel treatments are captured. While historically patients tended to be administered cyclical intravenous cytotoxic chemotherapies in hospital settings, many patients today are treated as outpatients with oral immunotherapy and targeted therapies (also as part of combination therapies) that have different mechanisms of action and safety profiles [32]. These new treatments can cause prolonged, heterogenous, and complex AEs affecting different organ systems. Indeed, regulatory authorities have called for increased flexibility in PRO measurement, highlighting the shortfalls of using static PROMs alone [33–35].

Even beyond changing therapeutic standards, many stakeholders have pointed to the importance of increased flexibility to ensure, for example, that PROs can be measured in patients for whom standard disease-specific PROMs may not be available (e.g., rare disease groups) without necessitating the full development of a new PROM. Customised item lists may also help minimise patient burden in cases where large sets of different static PROMs are required, leading to overlapping HRQoL domains and/or redundant items [36]. Further, in early phase dose finding and optimisation trials, when less is known about the possible impact of treatment, a more tailored approach to PRO use can help capture important aspects of tolerability [37].

Finally, an open-ended PROM, the Write In three Symptoms/Problems (WISP) measure, has recently been released [38]. It allows patients to report up to three additional symptoms and problems not covered by the assessment battery, which may be especially useful when shorter

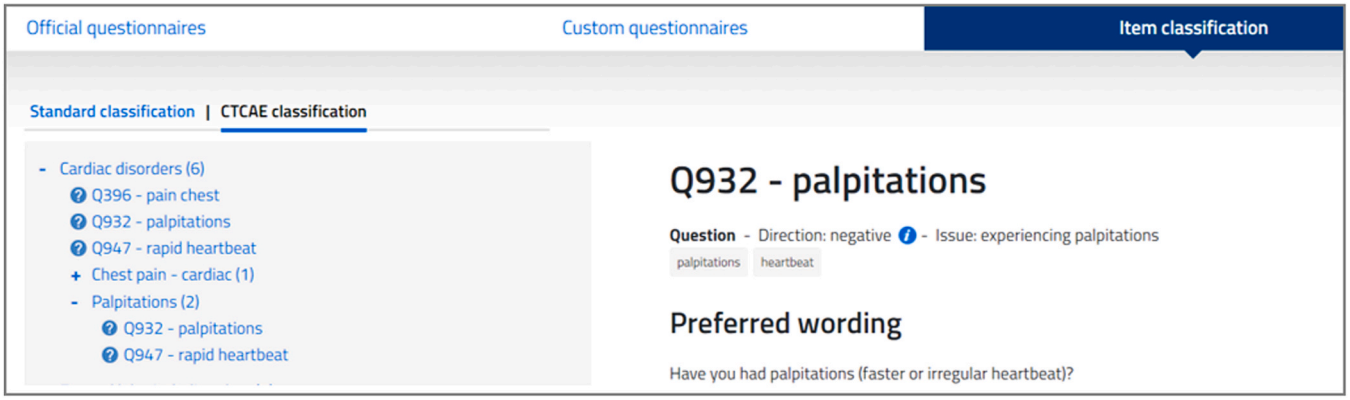


Figure 2. CTCAE-EORTC item mapping example from EORTC Item Library.

Table 1
Example settings and approaches for EORTC item list use.

Rationale for Item Library approach – examples	PRO measurement strategy – examples	Considerations	Key recommendations
Symptoms/issues missing from core + module	Core + module + item list	Item lists can be used to capture the impact of, e.g., novel treatments when symptoms/issues are not covered (or not sufficiently covered) within the core + module	1. *Regardless of the specific PRO measurement strategy used, it is the **responsibility of the user to ensure that an adequate approach with clear rationales is provided**.*
Scale(s) from a module are not relevant (e.g., scale measuring surgical issues when there is no surgical treatment in the trial/setting)	Core + item list (module subset)	A module can provide a good starting point for an item list, and the EORTC QLG PRO measurement strategy (via the EORTC Item Library) provides the possibility to remove scales that are not relevant within a given context. However, the resulting measure is considered an item list as it no longer contains all the original items/scales from the source module, and content validity may be hampered.	2. *Especially when the recommended QLG core + /- module + /- item list measurement strategy is not applied or when an item list is formed through modification of a static PROM, **users should carefully justify and provide evidence to support their approach**.*
No module available (e.g., for specific disease- and population-type)	Core + item list	When there is no module that corresponds to a specific disease-type and/or population, this pragmatic approach can help to ensure that relevant symptoms/issues and other HRQoL concepts are included within an item list. However, special care must be taken to select symptoms/issues relevant for the respective patient group to ensure content validity.	3. *Regarding the selection of items for inclusion within item lists, it is **important that users consider appropriate methods to ensure content validity** by, e.g., involving patients/patient representatives, healthcare professionals and other relevant stakeholders, and consulting available literature and guidance.*
Symptom monitoring context where only symptoms (and no other HRQoL domains) will be measured	Item list	In a symptom monitoring context, when only symptoms will be measured and other HRQoL domains are not relevant, an item list may be suitable to cover the targeted symptoms.	

Table 2
Key recommendations and considerations for EORTC item list use.

Stage	Recommendation	Rationale and explanation
PRO measurement strategy design	Available PROMs should be reviewed to help determine if an item list is necessary	Reviewing available PROMs can help to determine if an item list is necessary, with modules often providing an informative starting point, given their relevance for specific populations and the methods used to identify and refine their content
	When HRQoL measurement is the goal, it is important to use a core measure (e.g., QLQ-C30, EORTC CAT Core) and module (where relevant)	It is important to consider the over-arching aims and objectives when choosing a PRO measurement strategy. Namely, if HRQoL measurement is the goal, then it is important to consider its multi-dimensional nature by including relevant domains
	In a symptom monitoring context, use of an item list comprised of items covering relevant symptoms/issues should be considered as part of the PRO measurement strategy	In a symptom monitoring setting, where the goal is to monitor specific symptoms repeatedly, the entire HRQoL measurement may not always be necessary, and a subset of relevant symptoms or issues (in the form of an item list or item lists) may be sufficient
	When an item list is used as part of a PRO measurement strategy, a rationale should be provided (as for static PROMs)	It is important to provide a convincing rationale for why and when item lists need to be used, e.g., because of context (e.g., population, research design), new treatments, or particular settings
Item list format and item selection	Items should generally be used at the scale level (where relevant), respecting the underlying validated scale structure	Given that items are often validated as part of a multi-item scale, it is important to use this scale structure (where relevant) to preserve the intended scale and facilitate scoring, comparisons with previous research, and future data analysis. In case only a subset of items is used (i.e., not all items of the original multi-item scale), this can no longer be considered a valid scale
	When an item list is formed by removing a specific subset of items from a questionnaire (e.g., from a module), a rationale should be provided for this approach	Given the patient-centred methods used to identify and structure the content of the extant questionnaires, it is important to provide a convincing rationale for why and when certain items are not relevant or required within a given setting
	In general, the methods used to build and design an item list, including the process for selecting items, should be reported in detail	In order to gauge whether an item list is patient-centred, valid for the context of use, and designed in line with relevant guidelines, it is important that the methods used to guide item selection are shared in a transparent way
Item list testing and implementation	Content validity should be prioritised in the evaluation of item lists	Since item lists can be created by combining items from different source questionnaires, potentially validated in different populations, it is essential to evaluate content validity [44]. Different methods may be considered to identify relevant issues and ensure that these are assessed in a way that is comprehensive and understood by patients, especially if the items have not previously been validated within a specific population. Since other types of psychometric properties cannot be established without content validity, it should be prioritised [45]. When evaluating psychometric properties, it is also important to consider health technology assessment (HTA) guidance where relevant [46]
	Within multi-arm clinical trials, the same item list(s) should be administered to all treatment groups	Administering the same item lists to patients in all treatment groups (while ensuring coverage of treatment impact for all) helps to minimise the potential for bias and underreporting of AEs, and ensures comparability across groups

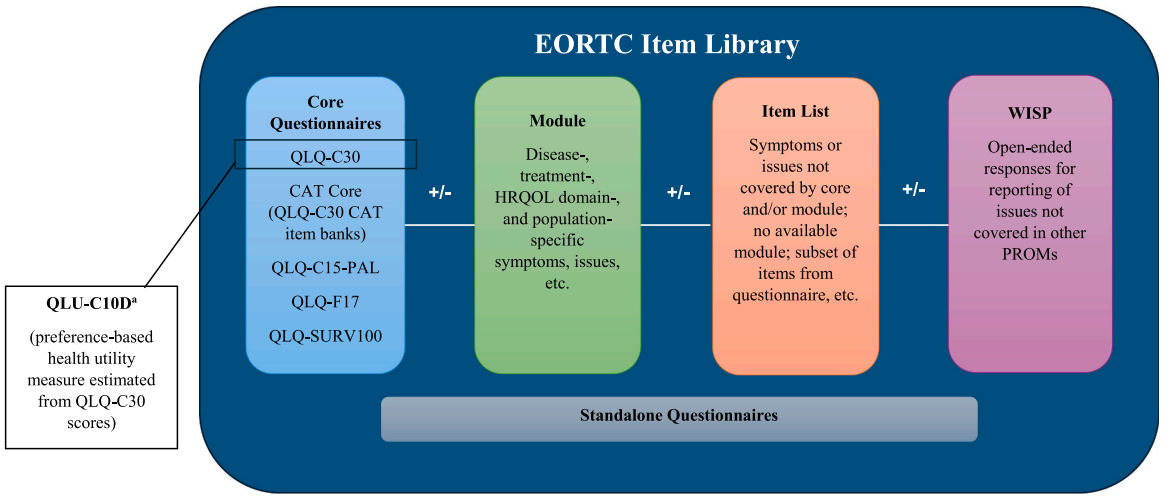


Figure 3. EORTC QLG PRO Measurement Instruments. [a]Given that the QLU-C10D provides a scoring algorithm for the QLQ-C30, to calculate utility values from the QLQ-C30 scores, it is classified separately and distinguished from the PROMs which are stored within the EORTC Item Library.

PROMs are used (e.g., in palliative settings) and to capture unexpected symptomatic AEs (e.g., linked to novel therapies and in early phase trials).

3.2.1. Recommendations for the creation and use of item lists

The EORTC Item Library facilitates different ways of creating and using item lists. Table 1 provides considerations and examples of different approaches. The EORTC QLG has published guidelines to support both the use of the EORTC Item Library platform [39], as well as the design and implementation of item lists [40] and work is currently underway to build upon these guidelines and tailor them to specific settings (i.e., clinical trials and routine care) [41]. An international, multi-stakeholder working group has also published general recommendations for the use of PRO item libraries in cancer clinical trials [36].

When HRQoL measurement is the aim, it is crucial to respect the multidimensional nature of the concept, implying that all relevant dimensions should be assessed. This is generally best achieved through use of a core measure, module, and item list, where relevant. However, if monitoring of specific symptoms is the goal, comprehensive HRQoL measurement may not be necessary. In both situations, the principles of questionnaire development should be kept in mind when designing customised item lists to minimise bias, ensure patient-centeredness, and promote scientific rigour. While not exhaustive, we strongly recommend adhering to the recommendations listed in Table 2.

3.3. Summary of the current EORTC QLG approach to PRO measurement

The current QLG approach (Figure 3) allows for flexibility to ensure that PRO measurement remains feasible and relevant, especially as therapeutic approaches and clinical research designs evolve. Core outcomes can be measured using a variety of static and flexible PROMs, including the CAT Core, and there is an extensive and growing range of modules and stand-alone questionnaires. In addition, the EORTC Item Library allows for the creation of customised item lists from a large pool of available items. The EORTC QLG recommends the use of a core measure (e.g., QLQ-C30 or CAT Core) and module (where relevant), supplemented by an item list to capture missing relevant issues, when needed. Still, the research objective(s) and settings (e.g., clinical trial vs. routine care) should ultimately guide the choice of PROMs within the PRO measurement strategy.

4. Conclusions

Through the development of new measures and administration modes, and the release of the EORTC CAT Core and Item Library, the EORTC QLG PRO measurement strategy continues to evolve, preserving many of the benefits of static measures while increasing the accessibility and coverage of PROMs, with the view to amplify patients' voices in clinical research and care. When designing a PRO measurement strategy, the selection and design of PROMs should reflect the research objectives, the population under investigation, and the context of use, considering relevant regulatory [42,43] and HTA guidance.

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests

- Fabio Efficace had a consultancy or advisory role for AbbVie, Incyte, Novartis and JAZZ Pharmaceuticals and Research support (institution) from Daiichi Sankyo, all outside the submitted work.
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- Galina Velikova received honoraria from Pfizer, Novartis, Eisai, and Lilly, consultancy fees from AstraZeneca, Roche, Novartis, Pfizer, Seagen, Eisai, Sanofi, and Daiichi Sankyo, and an institutional grant from Pfizer. She was also part of an AstraZeneca working group (unpaid) in April, 2024. All of these declarations are outside of the submitted work.
- All remaining authors have declared no conflicts of interest.
- The EORTC Quality of Life Group business model involves license fees for commercial use of their instruments. Academic use of EORTC instruments is free of charge.

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