EORTC Item Library Guidelines Project Protocol

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Amendment history	Changes
V1.1_18.10.2023	Narrative review: Double title and abstract screening confirmed as 10% MMAT to be used for critical appraisal. CONSORT-PRO review criteria to be used as a basis in data extraction. Data synthesis paragraph amended.
V1.2_20.11.2023	Narrative review: Quality assurance section aligned with Prospero registration which was approved 30.10.2023. Section provides greater detail about quality assurance.
V1.3 03.01.2024	Collaborators contact details updated. Clarified including routine care use, including audit as well as research. Clarified the review is systematic rather than narrative and covering 2 years only.
V1.4 18.09.2024	Updated collaborator list (3 have left/changed jobs)

Study summary

This study aims to create internationally agreed guidelines for the development and utilisation of the European Organisation for Research and Treatment of Cancer (EORTC) Item Library. This outcome will be achieved through combining the following elements, 1) narrative literature review, 2) analysis of existing patterns of item library usage, 3) Delphi survey of multiple stakeholders, 4) creating a guidelines framework and guidelines.

Study background

The European Organisation for Research and Treatment of Cancer Quality of Life Group (EORTC QLG) develops patient-reported outcome measures (PROMs) for use in quality of life research, clinical trials, and increasingly routine cancer care. A key resource in the development of these measures is the EORTC Item Library, an online and interactive resource, currently comprising over 1,000 unique items from the EORTC QLG's portfolio of scientifically based quality of life questionnaires and modules specific to cancer tumour sites and types of treatment. A growth area for the Item Library is supporting flexible usage of PROMs through creation of customised item lists, capturing symptoms and issues which may not be covered by existing questionnaires e.g., related to new treatments or techniques or different clinical settings.

In the recently updated EORTC module development guidelines, the use of the Item Library is mandated for all new projects. However, currently there are no EORTC QLG guidelines or internationally agreed consensus-derived standards on how best to approach incorporating individual items or multi-item scales from the Item Library into a research project/routine care, or how to develop official QLG item lists and validate the developed item lists for use within different settings. Although the main use of the Item Library is currently within clinical trials, the application within routine care is an important growth area within the QLG.

This study aims to create internationally agreed guidelines for the development and utilisation of the EORTC Item Library, item lists, and multi-item measures for all users 1) the EORTC Quality of Life Group 2) clinical trials (including different trial phases) and 3) routine care. The guidelines will need to address content selection and validity as well as how the items are analysed, interpreted, and reported which will vary according to setting and whether another PRO instrument is used. EORTC QLG refers to the use of the Item Library for the creation (including development, validation, and reliability) of official item lists aligned with QLG module development guidelines; for example, for module updates, extensions, or modifications to current modules for novel treatments/change in practice, novel agent symptom lists. This distinction is made from use of the Item Library in research projects (e.g., in clinical trials, routine care).

Multiple stakeholders (patients, researchers, clinicians, industry, and regulators) within and outside the EORTC who use the Item Library will be involved in the consensus process to ensure the guidelines and recommendations produced are relevant to all users. This work will build on the previously conducted international stakeholder workshop outcomes and use the existing EORTC QLG module guidelines as the starting framework; proposing to follow a similar structure as applicable (i.e., Phase 1/2/3/4).

Aims:

1. To develop a standard approach to the implementation of the EORTC Item Library for the development and validation of item lists by the EORTC QLG
2. To develop agreed standards for all users of the EORTC Item Library, on how to approach the flexible use of single items/multi-item scales within cancer research in two key clinical settings: clinical trials and routine care.

Objectives:

Work Package 1 (WP1): Systematic literature review

This review will ascertain how flexible as compared to static PRO measures are used in cancer clinical trials and routine care. The review will focus on mapping the different uses of the Item Library and other PRO cancer systems in different settings to establish the breadth

of use and to identify examples of where and how they have been used, analysed, and published.

Work Package 2 (WP2): Analysis of Item Library use

1) Examine existing patterns of usage of the EORTC Item Library (using routinely collected data) to identify areas of strength, areas for development, missing items, and needs of different stakeholders to establish a method to prospectively identify areas requiring updates within the Item Library.
2) To use this method to develop an iterative process, in collaboration with the EORTC QLD, to identify existing modules in need of an update, new research areas, and missing issues.

Work Package 3 (WP3): Delphi survey

Use Delphi consensus methods to establish key criteria for use of the Item Library within the EORTC QLG, and for development, implementation, and analysis of individual EORTC items/scales for clinical trials and routine care, including identification of issues and selection of items; how to address missing items within existing modules and across the whole Item Library; and how to determine levels of validity and reliability for item lists (aligning with work within SISAQOL). The statements for consideration within the consensus process will be derived from a combination of the preliminary workshops undertaken prior to this study and findings from WP1 and WP2.

Work Package 4 (WP4): Guideline development

Create a clear framework presented as guidelines for use of the EORTC Item Library for all users and publish the process and final recommendations in peer-reviewed journals.

Methods

WP1: Systematic literature review

The literature review will build on the Item Library workshop topic outcomes, existing recommendations from SISAQOL, SPIRIT-PRO and CONSORT-PRO and recommendations identified in the preliminary scoping review. The following topic areas were identified as important within the workshops and the literature review will contribute towards answering these questions:

- Which methods should be used to drive item selection?
- When should single items vs. multi-item scales be used and what are the benefits and limitations of both?
- How should different types of psychometric properties be considered and tested, based on the item list/measure and the context of its use?
- How can bias be minimized in the design of item lists?
- How can unexpected issues be measured?
- How should item lists be ordered?
- How should appropriate recall periods be selected?
- What are some of the determinants of patient burden and how can it be minimized?
- How should item lists be used in conjunction with static measures and/or other measurement systems?

Aims

1. To identify how Item Libraries are used in trials, routine care audit and research and by the EORTC QLG to identify key areas which can be developed into statements to be considered in a Delphi Consensus survey.

2. To establish trends in current practice, mapping the different uses of the Item Library and other PRO cancer systems in cancer clinical trials and routine care to establish how often researchers/trialists use item lists, add extra items or scales to questionnaires, and to examine which concepts or domains are usually added to the core EORTC Quality of Life questionnaire (QLQ-C30) and its modules in these trials, as well as published examples using PRO-CTCAE and FACIT Item Libraries for comparison.

This approach aims to ensure we develop Item Library Guidelines specific to EORTC QLG measures but aligned with current international practice and usage of other cancer PRO item libraries, while also revealing any missing important areas of consideration.

Review questions

1. How are 'Item Library questionnaires' used in cancer clinical trials and routine care research?
   With the following data to be extracted where possible:
   a. How frequently are they used?
   b. Single or multiple items?
   c. What do they measure?
   d. Electronic vs paper?
   e. How were unexpected issues measured? E.g., WISP Write in three symptoms.
   f. How were they analysed?
   g. What study design was used? E.g., RCT, cross-sectional
   h. What methods were used to drive item selection? E.g., how the items were selected E.g., do they use literature, ask patients, picked ad hoc?
   i. How are designed? E.g., length (patient burden); order; validity
   j. How many additional items were added? Eg on average people are adding in (no of items)
   k. Use in conjunction with static measures or other measurement systems?

The main outcome of the review is to identify and assess how item libraries are used to construct PROMs (both at the item and scale level) in cancer clinical trials and routine care research. We will describe current practices (over a 2 year period) including how often researchers and trialists add extra items or scales, and which concepts or domains are usually added to the QLQ-C30 and its modules. We will also identify and describe published examples using PRO-CTCAE, FACIT and other item libraries. These findings will inform a subsequent Delphi Survey to establish international consensus guidelines on the use of PRO item libraries. Findings from the review will inform the statements to be considered in the consensus process.

Literature search development

Aim to create a broad search, which reduces the potential of missing papers in which an item library was used. Several pilot searches were conducted and tested, and the decision made to conduct a two-concept search of Cancer AND Item Library (V3.4search) using a mix of key words and MeSH terms.

This search was tested at title/abstract screening and then full paper until we had established a broad screening approach and a wide range of indicator words for item library at title/abstract stage. At full paper screening candidate papers were read closely to establish where the additional items had originated from. We continued with this process until we had a high level of certainty that the screening approach was picking up all potential item library usage at full paper stage. Fifty papers were screened in this process.

Item library at title/abstract screening includes any reference to the use of additional items such as single item, section of questionnaire, sub-items, subscales, additional PRO items, modified, bespoke, development of new instruments, flexible use of validated PROs, novel non validated item(s) added to questionnaire.

Population	Cancer, all ages with cancer; cancer survivors; proxies for people with cancer e.g., parents
Intervention	Use of Patient Reported Outcome (PRO) item library from any PRO system: EORTC, Functional Assessment of Chronic Illness Therapy (FACIT), MD Anderson Symptom Inventory (MDASI), Patient Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE), Patient Reported Outcomes Measurement Information System (PROMIS) in cancer clinical research, routine care research or for use by EORTC QLG. Use includes construction of item lists or questionnaires to measure PRO, develop new questionnaires, or screening tools.
Limits:	For 2 years (October 2021- 2nd October 2023) In English

Eligibility criteria

1. Is the study about cancer in humans?
2. Are the population patients, or survivors?
3. Is the study about patient reported outcomes?
4. Is an item library used or flexible use of validated PROs?
5. Is the study from October 2021 inclusive?

Tag in screening (for consideration for exclusion or inclusion):

1. Mixed populations i.e., not only cancer
2. Patient proxies
3. Non-QOL PRO e.g., communication difficulties in cancer patients
4. Qualitative studies

These papers will be tagged in the first 10% screened at title/abstract stage. The decision will be made as to whether to fully include or exclude.

Exclusion criteria

1. Not cancer: title or abstract makes no reference to cancer.
2. Not cancer patient, survivor, or patient proxy
3. No reference to a PRO(M) in title or abstract
4. Before October 2021
5. Abstract only, conference abstracts.
6. Protocol
7. Opinion piece or editorial
8. Not in English

Databases

1. Medline using OVID.
2. EmBase using OVID.
3. Cinahl using EBSCO Host

Screening

All studies identified in the searches will be imported into Covidence software where all review decisions will be recorded. Duplicates will be removed. The review team will comprise of three reviewers.

Screening will be carried out in two stages. Title and abstract will be screened against eligibility criteria followed by full text review of potentially relevant papers. Both reviewers will assess 20% of the studies, the remaining studies will be divided between two reviewers and screened independently. The full texts of potentially relevant studies will be assessed for inclusion using the same process and eligibility criteria. Disagreements will be resolved between the reviewer and a third reviewer involved should this not resolve the issue.

Data extraction

Data extracted will be:

a) Study details including design, setting, sample size, duration, location, PRO (questionnaire & module) and data required by CONSORT-PRO reporting guidelines. Population details, all outcome measures relating to quality of life primary and secondary outcome findings, methods of analysis and conclusion.
b) Specific information relating to item library: item library used, items used, domains used, single items and scales, level of validation, combined with other PRO.

The data extraction form will be covering key areas included in CONSORT-PRO Review Criteria (Mercieca-Bebber et al., 2022) for trials and other quantitative study designs such as observational studies and mixed methods studies. Data will be extracted by a single reviewer and checked by a second reviewer using Covidence software. A third reviewer will be involved if there are any difficulties reaching consensus. All data will be collected from published papers, supplementary materials and published protocols, missing information will not be sought from study investigations.

Quality assessment/critical appraisal

As the review aims to include a range of study designs the Mixed Methods Appraisal Tool (MMAT) v 2018 will be used at the study level. This tool assesses the quality of quantitative, qualitative, and mixed method study design. It has 2 screening questions " Are there clear research questions" and "Does the collected data allow to address the research questions", further appraisal will not be appropriate if one or both of the questions are answered “No” or “Can't tell”. After screening, studies are assessed against five detailed methodological criteria for each study design i.e. qualitative, quantitative RCT, quantitative non-randomised, quantitative descriptive, or mixed methods. Studies will either meet each criterion (yes), not meet the criteria (no), or can't tell if the criteria are met. The MMAT is not designed to calculate of an overall score from the ratings of each criterion, instead a detailed presentation of the ratings of each criterion will better inform the quality of the included studies. Data will be extracted by a single reviewer and checked="checked" value="1" by a second reviewer using the Covidence software. A third reviewer will be involved if there are any difficulties reaching consensus.

Synthesis

Previous scoping review has established that there were very few existing guidelines specific to item library usage and it is not currently included in frameworks such as CONSORT-PRO or SPIRIT-PRO. A descriptive synthesis of the data will summarise existing practice in the use of item libraries in cancer clinical trials and routine care research. The studies will be mapped using the published framework from Piccinin et al (2023) to identify methodological categories considered important for the

selection of items, tests of validity, reliability, and responsiveness to change, measurement of unexpected symptoms, item order, patient burden and use in conjunction with other PRO questionnaires. The mapping will identify the extent to which studies report in these areas, identify most common approaches taken to item usage, gaps in current processes and where data is missing.

Illustrative examples from published studies about current practice will be compiled and evaluated against CONSORT-PRO evaluative review criteria (Mercieca-Bebber et al., 2022). It will include how often researchers/trialists use item lists, add extra items or scales to questionnaires, and which concepts/domains are usually added to the QLQ-C30 and its modules in these trials, as well as published examples using PRO-CTCAE and FACIT Item libraries for comparison. The synthesis will be presented in tabular and narrative form.

The findings from the review will assess the value of item library usage methods and will inform a Delphi survey (WP3) which will identify importance of different aspects of item selection. This will establish consensus about quality usage of item libraries by clinicians and researchers to help them choose the most appropriate ways of using PRO item libraries.

The review protocol will be registered with Prospero or similar.

Development of Delphi Statements

In combination with findings from the Item Library database usage (WP2), statements will be drawn up addressing the questions identified in the preliminary workshops supplemented by statements relating to gaps identified in the review. A format for statements will be agreed by the PI in conjunction with study collaborators.

WP2: Analysis of the EORTC Item Library based on existing use.

Descriptive analysis of the data routinely collected from all users of the EORTC Item Library will be conducted to identify differences in use for stakeholder groups, trial phases, items requested in context, frequency of use and missing items highlighted/requested by researchers. This analysis will evaluate whether current usage of the Item Library follows published research practice and guidance.

Data collected will include:

- User type; study design/context of use; protocol number (where relevant).
- Study population (e.g., advanced), number of patients; disease site; treatment type (extracted from study name and protocol number, using https://clinicaltrials.gov/).
- Use of other EORTC questionnaires (e.g., QLQ-C30, module).
- For the item lists, data comprises composition/usage, frequency of use of EORTC item lists and individual items.

Through the data search of the Item Library, we will also identify illustrative examples, from clinical trials and routine care to exemplify the recommended approach, for inclusion in the final guidance document.

In addition, existing item lists and patterns of usage will be reviewed to establish a method to prospectively identify areas requiring updates within the Item Library. In collaboration with the EORTC HQ QLD Item Library team, we will use this method to develop an iterative process we can implement prospectively to allow changes in need and practice to be highlighted. This method may be used to indicate the need for a module update, new module/item list/research project or individual missing items to address within the EORTC QLG.

WP3: Multi-Stakeholder Delphi Consensus Survey

Aims

The primary aim of the Delphi survey is to derive a framework to approach the use of the EORTC Item Library within:

1. EORTC QLG to develop official item lists/module updates.
2. Clinical trials.
3. Routine care.

In addition, through the process of aligning EORTC QLG strategy with multiple international stakeholders, the Delphi process aims to establish internationally agreed, consensus recommendations for the creation of custom PRO lists using individual items or multi-item scales from (instrument agonistic) PRO item libraries within cancer clinical trials and routine care settings.

Design

The Delphi method is a structured communication technique in which participants answer questions over the course of multiple rounds until consensus is reached. In this study, the Delphi survey method will be used to establish consensus, between multiple international stakeholders, on the selection of information proposed for inclusion in the new item library guidelines. The Delphi survey will be conducted online using Jisc Online Survey software. The approach taken will be to ask Delphi panel members to rate the importance of predetermined statements derived from WP1 and WP2.

Delphi survey development

First round statements will be generated from the findings from WP1 and WP2 based on the frameworks devised by Piccinin et al., (2023) and SPIRIT-PRO. The total number of statements has not been determined; however, the first survey is planned to take approximately 20-25 minutes to complete to reduce participant burden, anticipating a range of between 30-60 statements.

The survey will be created using JISC Online Survey platform. The first page of the survey will provide information about the study, consent, and registration to the survey. Appropriate identifying logos, REC approval and contact details of the research team will also be included. After consent participants are asked to provide their name and email address, demographic data, and stakeholder group membership information. This will be followed by instructions for completion of the survey, if required. The decision about whether to include instructions will be made after conducting a pilot. Once this is completed the participant will be taken to the first question in the survey. If participants chose not to participate, they will be automatically routed to an end of page thanking them for their time.

Questions will be copied from a Word document into the survey tool, selecting questionnaire type, response options and formatting. A compulsory response will be considered to ensure a complete data set, the decision on this feature will be made through conducting a pilot. An additional field for comments will be included after each domain or group of statements and for overall suggestions.

Statements will be assessed on a 9 point labelled scale, adopting the approach taken by GRADE to assessing the importance of evidence. All outcomes must be rated using this 1-9 scale, labelled as 1-3, 4-6, 7-9 where 1-3 not important; 4-6 important but not critical, 7-9 critical or unable to rate.

The survey will be structured in two parts: core questions and specific questions. Core questions are general questions about using an item library and will be presented to all survey participants. The specific questions are about the use of the Item Library by the EORTC Quality of Life Group for

members of this group. A branching question structure will be used to route participants indicating they are active QLG members to the QLG questions.

Distribution of survey rounds

The first round will be distributed to mailing lists via an invitation email containing a URL link to the survey. For each round, emails will be scheduled for distribution with up to three follow up reminder emails to non-responders each round. The list of responders from each round will be copied into new recipient lists for the next round.

Jisc Online Survey has the functionality to track completion and send automatic reminders. There are pros and cons about whether to use the tracking functionality and automatic reminders. The decision about whether to use the software's system or devise a more manual researcher-driven approach to distribute and track survey completion will be decided once we have undertaken training in using the software and piloted the survey.

Once a participant completes the survey, they are automatically assigned an ID number by the software. Participant names and email address will be separated from the ID number (pseudonymised) when the data is imported into the spreadsheet for analysis.

Each round of the survey will be held open for a month (as stated in PIS). The survey will need to be sent out at the same time by the mailing list gatekeepers as the analysis of the first round has to be completed to present as feedback for subsequent rounds. Further communication with gatekeepers will establish appropriate timetables and arrangement for giving them advance notice of the survey.

The survey will be piloted to test survey and data collection processes with volunteers from PCOR and RAG.

Identifying Delphi panel participants

Potential participants will be identified because they have relevant experience and expertise; and will be identified from the literature review, professional networks, advisory, national, international and research groups, including EORTC QLG, SISAQOL, EUonQOL, ISOQOL, PROTEUS, PCOR RAG and relevant PPIE groups. The whole mailing list for some organisations will be very large, in these cases consultation will be undertaken with gatekeepers to draw up a targeted section of their mailing list, examples below.

- EORTC QLG
    - Active members
    - People running a project
    - Grant committee members
    - QLG early career research group
    - Patient reps at committee level
    - Attendees at Item Library section of QLG (Sept 2023, March 2024, Sept 2024)
    - Named collaborators
- PCOR RAG
- PROTEUS: Limit to steering committee or whole list if not too big
- ISOQOL: Limit to Core Group, Board
- SISAQOL: Limit to Work-package Leads
- EUonQOL
- Professional networks of Alex Gilbert, Galina Velikova (to identify healthcare professionals with a PRO research interest)

Written email approval from gatekeepers will be obtained to access their mailing list to provide information about the study and ask potential participants whether they would like to take part. Gatekeepers will be asked to distribute the study information on the study team's behalf or mail the individual directly if they have given permission for this. Following the distribution of the study information, prospective participants interested in taking part will be able to use the link provided to sign up to the study. This helps prevent any potential coercion as it is up to the individual to determine whether to join the study. By using the relevant members of each network as the gatekeepers for their members' personal information, we comply with privacy and GDPR regulations to limit the sharing of personal data.

Approaching participants

Participants will self-identify to participate in the study by having responded to the invitation email. Upon their initial approach, the invitation email, an information sheet, including a link to the privacy notice, will be provided to ensure they are fully aware of what the study entails. Personal information such as email addresses will be used to arrange for them to take part in the study and will not be used in any research output. For those who do not respond after their initial contact with the researcher, an invitation email will be sent up to a maximum of three times.

Recruitment of participants

Once participants have provided informed consent and agreed to take part, they will be recruited to the study. We will respond to participant interest in the study on a first come first served basis, aligned with our proposed purposive sampling strategy to ensure a balanced group is recruited. Email reminders to complete the questionnaire during subsequent rounds will be sent a maximum of three times. Reminders will not be sent to those who have responded.

For a Delphi survey the number of participants needed to generate knowledge is unclear, the process is built around consensus of participants after giving feedback. Purposive sampling will be used. Participant recruitment will continue until it is determined there is enough participation to provide meaningful input into the Delphi process. This will be agreed upon by the study steering group in conjunction with the PI. The aim is for an initial sample of 50-60 to ensure between 15-20 for each use of the Item Library i.e., EORTC QLG, clinical research and routine care. We will invite approximately 65 panel members, assuming a rejection rate of 20% and allow for panel members to send invitations to other relevant participants to join. We will monitor response rates, recommending a response of 75% for each round. Reasons for withdrawal will be collected to assess for threats to validity.

We aim to recruit from the three/four key stakeholder groups identified (clinical and academic researchers; healthcare professionals, patient researchers/representatives and technical experts including regulators and industry). We aim to have at least 10 participants (not mutually exclusive) in each group.

Stakeholders will be approached to take part in the topics relevant to their practice e.g., EORTC QLG participants involved in clinical trials and routine care will be invited to feedback on all three topic areas; those only involved with one or two areas will only be invited to contribute to these. This will ensure the work is carried out in an effective, streamlined manner to maximise the relevance and applicability of the work and reduce burden to participants.

Providing feedback to panel members

After each round participants will be provided with structured anonymised summary feedback regarding the previous round. After consideration of this feedback participants will be encouraged to

review their answers with the aim of the group converging towards consensus. The feedback will provide information about the degree of consensus for each statement together with a summary of comments by participants. The summary document will be emailed directly to each panel member, as this cannot be achieved via Online Survey (as the email collector is limited to distribution of emails containing the survey URL link and to collection of responses).

The threshold for consensus and number of rounds will be pre-determined, although it is anticipated that around 3 survey rounds will be required, with feedback from the steering committee (comprised of named collaborators) on aggregate scores provided to participants in between. Statements which reach consensus will not be included in the next round.

Data analysis

The round one survey panel responses and qualitative feedback will be analysed for consensus. The format of the feedback from each round is to be further explored and decided. One way might be to utilise stacked bar charts depicting colour coded response choices for the importance scale of statements, grouped within domains (group of statements). The free text comments will be included for thematic analysis. Comments will be categorized into themes, the scope or area of practice, suggestions for changes to the wording of existing statements, and new concepts. This process will result in the revision of the survey for the next round.

In Online Survey each round is developed as a separate survey. This means that data need to be exported to other software to undertake data analysis between/across rounds or data sets. Data will be exported into Excel and descriptive statistics will be used to report and review the panel demographic characteristics. Stability of panel responses between rounds two and three surveys will also be assessed**.**

Ethical considerations

Ethical approval will be sought from University of Leeds Ethics Committee for the Faculty of Medicine and Health. Participants will be provided with written information about the study via the participant information sheet (PIS). Contact details of the researchers involved in the study will be provided in the PIS so that prospective participants can ask questions or for additional information about the study. The PIS will provide a link to the University of Leeds Privacy Statement.

Participants willing to take part will be encouraged to register using a link provided to access the Online Survey software. Here they will be provided with information about the study and how their data will be looked after. Online informed consent will be sought. As part of the consent process participants are informed that they can choose to withdraw from the study at any time and no further contributions will be made. Participants do not have to give a reason for withdrawing from the study. However, survey responses up to the point of withdrawal will be retained and used in the analysis. This is to maintain the integrity of the results, because for the next stage of the questionnaire all participant responses will be used to give a group response to the questions.

They are then asked to indicate their consent to participate in the study and receive email notifications about the study. If they tick YES, they can proceed to completing the demographic questions and the survey questions. Participants who tick NO will not be included, or able to complete the survey. The survey does not ask about sensitive questions and we intend to limit the burden of completing the questionnaire to approximately 20-25 minutes.

All the information collected during the study concerning individual participants will be treated in the strictest confidence. Participant survey responses and identifiable data will be pseudonymised. All the information collected and stored will be kept according to the Data Protection Act and GDPR.

The demographic data collected in this study will be pseudonymised and stored confidentially. No reference to personally identifiable information will be made in any publication. After each round of the questionnaire the responses to questions will be downloaded onto a secure Leeds server as a spreadsheet. This will allow group analysis and contain no personal information and thus preserve anonymity. Electronic data will be stored on password protected, firewalled computers on the secure University network, including secure University M drive or OneDrive. No data will be stored in hard copy. The principal investigator and members of the research team at the University of Leeds will carry out data analysis on pseudonymised data.

Survey will be conducted using Jisc Online Survey software which is compliant with GDPR requirements and is approved by the University of Leeds for conducting online surveys. The Jisc Online Surveys licensee (University of Leeds) acts as the Data Controller. Jisc acts as the Data Processor, only processing the survey data in accordance with the research team's instructions. Online Surveys is certified to ISO 27001, the recognised information security standard. All Online Surveys user and respondent data is stored in the EU.

WP4: Guidance development and publications

Consensus meetings

Draft guidelines based on the results of WP1, WP2 and WP3 will be distributed to the named collaborators and key stakeholders, who participated in the Delphi for each of the three applications: EORTC QLG, clinical trials and routine care.

Three consensus meetings will be held (via videoconference) to finalise and agree on the key recommendations for development of customised item lists for (1) EORTC QLG, (2) clinical trials and (3) routine care. These recommendations will be amalgamated into a final Item Library Guidance document for use by all stakeholders.

Publications

In addition to the EORTC QLG Item Library guidance document, we will produce at least two peer-reviewed publications: describing an international consensus on the use of flexible PRO instruments, including the Item Library, within cancer (1) clinical trials and (2) routine care.

References

Mercieca-Bebber, R., et al. (2022). "Knowledge translation concerns for the CONSORT-PRO extension reporting guidance: a review of reviews." Qual Life Res 31(10): 2939-2957.

Piccinin, C., et al. (2023). "Recommendations on the use of item libraries for patient-reported outcome measurement in oncology trials: findings from an international, multidisciplinary working group." Lancet Oncol 24(2): e86-e95.