EORTC QUALITY OF LIFE GROUP
Item Library:
Technical Guidelines

First Edition

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March 2018
Contents

Introduction to the Item Library: history and development .................................................. 4
Item Library overview ........................................................................................................... 4
Access ................................................................................................................................ 4
  Types of accounts: .............................................................................................................. 5
Logging in ............................................................................................................................. 5
Item Library home page ....................................................................................................... 6
  Footer ................................................................................................................................. 7
Overview of the Official questionnaires library ................................................................... 8
  Types of views .................................................................................................................. 8
    Questionnaire view .......................................................................................................... 8
    Item view ......................................................................................................................... 12
  Other elements – response scales, time scales, conditions, instructions, domain scales .... 14
Searching .............................................................................................................................. 15
  Home page search box ....................................................................................................... 15
  Search results .................................................................................................................... 17
  Keywords .......................................................................................................................... 17
Overview of the Custom questionnaires library ................................................................. 18
  Types of custom questionnaires: ....................................................................................... 18
    My questionnaires ........................................................................................................... 18
    Questionnaires from community ................................................................................... 18
Custom item list flow .......................................................................................................... 19
Make your own item list ....................................................................................................... 19
  Custom item list details ..................................................................................................... 21
Add items to a custom item list .......................................................................................... 22
Delete items from a custom item list .................................................................................. 24
Re-order items ...................................................................................................................... 24
Add response and time scales .............................................................................................. 24
Submit an item list for approval .......................................................................................... 26
Modify a submitted item list ........................................................................................................................................ 27
Published item lists ...................................................................................................................................................... 27
Custom questionnaire translations .............................................................................................................................. 27
Use of custom item lists ............................................................................................................................................... 28
Abbreviations used in the document

EORTC – European Organisation for Research and Treatment of Cancer
IL – Item Library
QLD – Quality of Life Department
QLG – Quality of Life Group
Introduction to the Item Library: history and development

The main aim of the Item Bank, as it was originally called, was to create a database of items that could be used, mainly by the QLG members, during the process of new questionnaire development. It enabled investigators to browse through validated items, identify questions covering relevant issues that they wanted to include, and use them in new instruments with consistent wording. This way the Item Bank also saved time and effort spent on the translation process by re-using previously translated items.

With technological advances requiring updates of the software, the Item Bank underwent subsequent refurbishments in 2009 and 2016.

The most recent development, which took place in 2017, turned the Item Bank as a database of items into the Item Library by adding the option of making a custom item list and creating a library of such user-made item lists.

Item Library overview

In its current form, the IL enables users to:

1) Browse through the existing official EORTC instruments as well as user-created custom item lists
2) Find existing items for new item lists from the pool of items developed by the QLG
3) Make a custom item list by adding new items to existing questionnaires, modifying existing questionnaires or creating new item lists

Access

How to get access to the Item Library:

1. Go to http://www.eortc.be/itemlibrary
2. Fill in the request access form, specifying your name, institution/company where you work, your e-mail address, motivation for accessing the IL and the type of account you are requesting (academic, commercial or for an active QLG member).
3. Your request is automatically sent to the IL admin, who will prepare an access agreement and send it for your signature.
4. Upon receipt of a fully executed agreement, the IL admin activates the account.

Types of accounts:

1. QLG: full access to all features (searching English items and all translations), limited in time by the duration of the active membership in the QLG
2. Academic: full access to all features (searching English items and all translations), 6 months
3. Commercial: access to English items, 3 months

Logging in

The login page’s address is [http://www.eortc.be/itemlibrary](http://www.eortc.be/itemlibrary)
On the login page, you can:

1. request access by filling in the access form;
2. log in with your e-mail address and password chosen during the registration process;
3. receive a new temporary password by clicking on “Forgot your password?”. The process is fully automatic and is the only way to get a new password, since the IL admin does not have access to the password database.

Item Library home page
The home page of the IL consists of the following elements:

- The total number of questionnaires (official EORTC instruments) and unique items included in the Item Library
- Search box
- Tab with the official EORTC questionnaires and with the custom-made questionnaires library
- List of types of official questionnaires – clicking on the category acts as a filter to display only the chosen category:
  - Core – the C30 as the core questionnaire with 30 items relevant to the general population of cancer patients and the C15-PAL, an abbreviated version of the C30 for palliative patients. The C15-PAL questionnaire is shorter to focus on the issues relevant in a palliative setting and to diminish patient burden
  - Stand-alone questionnaires – questionnaires which can be used on their own, without the C30
  - Modules – site-, population- and symptom-specific questionnaires that complement the C30 and should always be used together with the core
  - Previous versions – previously developed questionnaires which have been updated ever since
  - CAT – the Computer-Adaptive Testing version of the 15 domains of the QLQ-C30 questionnaire. This category includes full item banks and short forms

Footer

The footer consists of two columns:

- Information on how to obtain official questionnaires – both for academic and commercial use
- Contact information for sending suggestions of items that were not found in the existing pool of questions
Overview of the Official questionnaires library

Types of views

Questionnaire view

You can see the full questionnaire in its validated form by clicking the icon on the homepage or a title of a questionnaire. You can also search with the name or other keywords in the search box and select the questionnaire of choice.

The questionnaire view includes the following elements (see screen shot on next page):

- General information on the questionnaire (see p. 10)
- List of the items – clicking on an item shows its basic information view (see p. 12)
- All other elements included in the questionnaire – conditions, instructions, response scale(s), time frame(s), and domain scales with the option of filtering
- Additional information about the questionnaire (if available – under all items)
<table>
<thead>
<tr>
<th>Questions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>31. Did you have a dry mouth?</td>
<td></td>
</tr>
<tr>
<td>32. Did food and drink taste different than usual?</td>
<td></td>
</tr>
<tr>
<td>33. Were your eyes painful, irritated or watery?</td>
<td></td>
</tr>
<tr>
<td>34. Have you lost any hair?</td>
<td></td>
</tr>
<tr>
<td>35. Were you upset by the loss of your hair?</td>
<td></td>
</tr>
<tr>
<td>36. Did you feel ill or unwell?</td>
<td></td>
</tr>
<tr>
<td>37. Did you have hot flushes?</td>
<td></td>
</tr>
<tr>
<td>38. Did you have headaches?</td>
<td></td>
</tr>
<tr>
<td>39. Have you felt physically less attractive as a result of your disease or treatment?</td>
<td></td>
</tr>
<tr>
<td>40. Have you been feeling less feminine as a result of your disease or treatment?</td>
<td></td>
</tr>
<tr>
<td>41. Did you find it difficult to look at yourself naked?</td>
<td></td>
</tr>
<tr>
<td>42. Have you been dissatisfied with your body?</td>
<td></td>
</tr>
<tr>
<td>43. Were you worried about your health in the future?</td>
<td></td>
</tr>
<tr>
<td>44. To what extent were you interested in sex?</td>
<td></td>
</tr>
<tr>
<td>45. To what extent were you sexually active? (with or without intercourse)</td>
<td></td>
</tr>
<tr>
<td>46. To what extent was sex enjoyable for you?</td>
<td></td>
</tr>
<tr>
<td>47. Did you have any pain in your arm or shoulder?</td>
<td></td>
</tr>
<tr>
<td>48. Did you have a swollen arm or hand?</td>
<td></td>
</tr>
<tr>
<td>49. Was it difficult to raise your arm or to move it sideways?</td>
<td></td>
</tr>
<tr>
<td>50. Have you had any pain in the area of your affected breast?</td>
<td></td>
</tr>
<tr>
<td>51. Was the area of your affected breast swollen?</td>
<td></td>
</tr>
<tr>
<td>52. Was the area of your affected breast oversensitive?</td>
<td></td>
</tr>
<tr>
<td>53. Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?</td>
<td></td>
</tr>
</tbody>
</table>

**Description**

**QLQ-BR23 Breast cancer module**

The module is fully validated. It is to be used with the QLQ-C30.

**Conditions**

- Answer this question only if you had any hair loss.
- Answer this question only if you have been sexually active.

**Instructions**

- Please indicate the extent to which you have experienced these symptoms or problems during the past week.
- Please go on to the next page.

**Response scales**

- Not at all, A little, Quite a bit, Very much

**Time scales**

- During the past week
- During the past four weeks

**Domain scales**

- Body Image - functional scale
- Sexual Functioning - functional scale
- Sexual Enjoyment - functional single
- Future Perspective - functional single
- Systemic Therapy Side Effects - symptom scale
- Breast Symptoms - symptom scale
- Arm Symptoms - symptom scale
- Upset by Hair Loss - symptom single
Detailed questionnaire view:

1) Basic information

- Gender – specifies the gender of the population in which the questionnaire was originally validated
- Type – type of questionnaire: core, module, standalone, CAT, previous version.
- Contact – e-mail address for any questions related to the questionnaire
- Testing – phase of development following the EORTC Module Development Guidelines:
  o Phase III completed – pilot-testing phase finished and approved
  o In Phase IV – undergoing Phase IV field-testing
  o Phase IV completed – fully validated with the Phase IV field-test finished and approved
- “Last modified” date

2) Main description – basic information on the questionnaire

3) Filter view for:
   - Conditions – for items which should be answered only under certain conditions
   - Instructions
- Time scale
- Response scale
- Domain scale

Clicking on the “filter” button shows which items are defined by each element. Clicking on “clear” turns off the filtered view.

4) Language version – list of all available linguistically validated translations. Selecting a language shows all elements in the chosen language with English version underneath.

5) Other information:
   - Any additional details on the questionnaire and its use
   - References of development and validation publications
   - References of other publications on the questionnaire and its translations
The basic information on an item is shown in the “Question details” tab and includes:

- Number in the questionnaire
- Wording in the questionnaire
- Direction of scoring – negative (symptom scale) or positive (functional scale)
- Underlying issue of the item
- Recommended wording for the item (if set)
- Response scales associated with the item in the context of the questionnaire
- Time frames associated with the item in the context of the questionnaire
- Domain scale to which the item belongs in the context of the questionnaire
- See all info – button to see the detailed information page on the item.
Switching back to the questionnaire view is possible by clicking on the “Questionnaire info” tab.

**Detailed item view**

**Code**

[Q70 - dry mouth]

**Short name**

Issue having a dry mouth

**Keywords**

dryness, thirsty, parched, xerostomia, lack of saliva, sticky saliva, salival

**Recommended wording**

Have you had a dry mouth?

From Cachexia, Chronic Lymphocytic Leukaemia, Chronic Lymphocytic Leukaemia, and 16 others...

**Other wordings**

Did you have a dry mouth?

From Breast, Colorectal, Meta Breast, and 4 others...

**Similar questions**

The following questions have a similar wording.

- Has acid or bile coming into your mouth been a problem?
- Do you have any trouble lifting a full cup or glass to your mouth?
- Have you had a sore mouth or tongue?
- Have you had a dry cough?
- Have you experienced a dry vagina during sexual activity?
- Did you have a dry vagina or other problems during intercourse?
- Did you have a dry vagina or other problems during intercourse?

**Specified by**

This question is typically specified by:

- During the past week:
- Not at all, A little, Quite a bit, Very much
- Systemic Therapy Side Effects - symptom scale
- Symptom Burden - symptom scale
- Dry Mouth - symptom single
- Side Effects of Treatment - symptom scale

**The full item view page includes:**

- Code – unique code for each item
- Short name
- Direction of scoring – negative (symptom scale) or positive (functional scale)
- Underlying issue
- Keywords
- Language versions – a drop-down list of all available translations of the item
- Wordings – all wordings for the item as used in various questionnaires over time.

Recommended wording (if set) is based on linguistic aspects (such as the use of a more suitable grammatical tense) and comprehensibility (simpler terms etc.). For other
wordings, the top one is the most recently added. Wordings are marked as gender-specific, if they originate from a gender-specific questionnaire. The same mechanism is used to show wordings in other languages, with a possible recommended wording and the top wording being the most recently added (thus from the most recently finalized translation).

- Add a wording to a custom questionnaire
- Other elements describing the item – a list of other elements that are used with this item in all questionnaires and scales in which the item is included.
- Similar questions – a list of similarly worded questions. The similarity is computed as a percentage of overlapping words, thus is not based on similarity of meaning. It can help make items consistent and re-use parts of translations.

Other elements – response scales, time scales, conditions, instructions, domain scales

In the questionnaire view it is possible to filter additional elements such as response scales to see which items they describe in the questionnaire. Clicking on the element shows its full information page.
The full information page includes:

- Name and code
- Category
- Language versions
- Wordings – all wordings used for the particular element in all questionnaires. The recommended wording is marked for the wording that should be used in new item lists
- List of items this element specifies
- Similarly worded elements

Searching

Searching is the basic function of the Item Library. It enables you to find items or questionnaires that are of interest and cover the relevant issues.

General searching in the Item Library can be done two-fold:

- with the search box on the home page, or
- by browsing through the questionnaires and items.

Home page search box

The search box on the Item Library home page can be used in several ways.
When you start typing your search words, a dropdown list appears with the following options:

- existing keywords
- items that match the typed word(s) because the name or wording includes them or the word matches one of the keywords associated with this item
- questionnaires that match the typed word(s)
- other elements of questionnaires that match the typed word(s).

When you type a search word, you can do two things:

a) Type your search term and click Enter to get search results;

b) Choose from the list of the existing keywords and items/questionnaires/etc. the one that matches your search criteria. If you choose a keyword (term with a looking glass), you will arrive at the results page for a search performed with that term. If you choose a matching item/questionnaire/etc., you will see a page with the information on that item/questionnaire/etc.

The icons to the left of the term represent the category of the entry:

- Condition
- Instruction
- Question
- Questionnaire
- Response scale
- Domain scale
- Time scale

Each entry in the IL has its code (for example, Q151, RS5, TS3) and it is possible to use it as a search term.
Search results

Search results are displayed with a predefined filter on questionnaires and items, so that only questionnaires and items that fulfil the search criteria are shown. It is possible to show other types of results by enabling and disabling filters by ticking respective boxes on the right-hand side.

Search results for "pain"

Keywords

Each item has a list of associated keywords that help the search engine. Keywords are shown in the item view and can be used to trigger a search action. Clicking on a keyword leads to a search results page listing all elements associated with this keyword.
Overview of the Custom questionnaires library

Types of custom questionnaires:

The Custom questionnaire library is divided into two sections:

- My questionnaires
- Questionnaires from community.

**My questionnaires**

There are three types of item lists in the My questionnaires section:

- Drafts – visible only to the user who created them
- Waiting for approval – visible to the user who created it and to the content manager/admin
- Approved – visible to all users

**Questionnaires from community**

The Questionnaires from community section includes two types of questionnaires:

- Approved custom item lists made by other users,
- Approved custom item lists made by you.
Custom item list flow

In order to make a new custom item list you should follow these steps:

1) Make a new questionnaire – fill in the basic information form
2) Add items
3) Add response scale, time scale, instructions, conditions if necessary
4) Submit for approval
5) Content manager/admin checks the information and the questionnaire – in case of problems contacts the user and edits if necessary. There is also a user agreement sent for signature.
6) Questionnaire is approved – it becomes visible to all users and can be downloaded as a .csv file.

Make your own item list

There are a few ways to create a custom item list.

1. By making a copy of an existing questionnaire and adding/deleting items – in order to make a copy you should choose the questionnaire to be copied and click on the “Copy as new custom questionnaire” button visible in the questionnaire’s view

2. By creating a new questionnaire from the home page – simply click on the “Create a new questionnaire” button
3. By creating a new item list in the “Custom questionnaires” library

4. By adding search results to a new questionnaire – once search results have been selected, you can click on “Add X selected to questionnaire” and from the drop-down list chose “New questionnaire”

5. By adding an item from the questionnaire view – if an item from a particular questionnaire seems of interest, you can click on the three dots and add it to an empty item list by selecting “New questionnaire”
6. By adding a wording from the item view – if a particular wording in an item view seems of interest, you can click on the three dots and add it to an empty item list by selecting “New questionnaire”.

Custom item list details

When creating a new item list, you have to fill in some basic information about your questionnaire. The following information can be filled in:
Add Questionnaire

Your questionnaire will be saved as a draft.
If you wish to export this questionnaire for use, you will first need to submit it for approval.
Once a content manager approves it, it will be visible to the entire community and everyone will be able to export it for use.

Name – chosen name (can be changed later)

Type – a drop-down list to choose from Module, Standalone, CAT.

Gender – gender of the population for which the item list is intended.

Molecule – name of the molecule that will be tested with the item list. It is not obligatory.

Description – place for any information deemed necessary. The more information you can provide, the easier it is for the IL admin to review your item list.

NOTE: name of the author of custom-created questionnaires is not stored or visible to other users, regardless of their profile and status of the questionnaire. If the author wants to mark authorship, any information on the questionnaire can be added in the description.

Add items to a custom item list

There are various ways to add an item to an already created item list:

1. In the custom item list view in the Custom Questionnaires library
2. From search results by clicking the three dots icon and selecting the item list of choice (see p. 17)
3. From questionnaire view by clicking the three dots icon and selecting the item list of choice (see p. 20)
4. From item view by clicking the three dots icon and selecting the item list of choice (see p. 21)
Delete items from a custom item list

In order to delete any item from an item list you have to click the garbage bin icon and confirm that it should be deleted.

Re-order items

While it is not advisable to change the order of items, it is possible to re-order them in a custom item list. In order to move an item to another location in the list, you have to click on the dots to the left of the wording and drag the item to its new place. The numbering of the list should update on its own, but in case it has not, it will be updated when you reload the page.

Add response and time scales

It is important to add the correct response options and time frames to the item list. It is recommended to use the response options and time frames with which the items were originally validated.

In order to add the response options and time frames you should:

1. Click on Choose a response scale to see the available options
2. Select the appropriate option and click +Add

3. Choose the items to which the chosen option relates.
You can type a range:

or single numbers separated by commas.

Submit an item list for approval

Once a draft is ready for use, it can be submitted for approval to the IL admin.

The IL admin checks to see if the basic information on the item list has been added correctly and includes all the necessary elements, and prepares a user agreement for the use of the item list.

After the user agreement has been fully executed, the IL admin approves the item list for publication in the system.
Modify a submitted item list

An item list that has been submitted for approval cannot be modified. If you would like to modify the submitted draft, you have to first cancel the submission.

Once the submission has been cancelled, the submitted item list reverts to draft status and can be modified by adding, deleting and re-ordering items.

Published item lists

All approved item lists are visible in the Custom questionnaire library. They are accessible to all users of the IL. Only an approved, published item list can be exported.

In order to export an item list, you have to click on the export button.

An exported item list is available as a .csv file that can be opened in, for example, Microsoft Office Excel.

Custom questionnaire translations

It is possible to have the custom item list available in languages other than English. In order to get a translation, you have to follow these steps:

1) Choose the required language. The drop-down list includes all possible languages – not necessarily available languages for the items. It also includes different names for the same language, so it is best to check the naming convention used for the EORTC questionnaires in the questionnaire or item view.

2) View the translation of the custom item list. Translations are collated automatically from different questionnaires and often from different wordings that are available for one item. The following options are possible:
- If a recommended wording in this language has been set for a particular item, it is chosen for the item.
- If there is no recommended wording chosen, the most recent translation will be added.
- If no translation exists, you will see “No translation available” above the English version.

3) Review the translation. Because of the fact that translations are pulled from different questionnaires and might be inconsistent, all translations must be reviewed together with the IL admin. Gender-specific items are marked with a gender symbol, because in some languages the translation developed for one gender only will not fit the other gender or a mixed population.

4) Export the translation. All language versions can be exported into a .csv file.

Use of custom item lists

The use of custom, user-created item lists is subject to the conditions specified in the user agreement and to the user requirements available on the QLG website: http://qol.eortc.org/

More specific information can also be obtained by e-mail: itemlibrary@eortc.be