

The QLQ-C30 cut-off project

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Symptom screening with the EORTC quality of life scales

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Overview

1. Background
2. Ongoing study on cut-off development
 - Objectives
 - Methods
 - Preliminary results
3. Outlook on follow-up project

Symptom monitoring and screening in daily oncological practice

- It is well-known that many cancer symptoms and treatment side-effects are undetected and therefore undertreated (e.g. Weingart 2005 JGIM, Pakhomov 2008 AJMC)
- Often limited time for patient-clinician communication (i.p. in outpatient unites)
- This makes systematic symptom monitoring important for adequate symptom management
- The QLQ-C30 and the EORTC CAT measures appear to be suitable for symptom monitoring as they cover important functioning domains and key cancer symptoms

Symptom monitoring and screening in daily oncological practice

- To date, much research has been done on minimal important differences/changes for the QLQ-C30, but only very few studies on interpretation of absolute scores
- Interpretability of absolute scores (in the context of screening) relies on the availability of cut-off scores, i.e. thresholds that allow a clinician to tell whether the severity of a symptom is “normal“ or not
- **Cut-off scores should not reflect if a problem is a “disorder“ but if it should be included in the conversation with the patient**

Recent studies on developing cut-off scores

Content-based approaches:

(determine cut-off scores according to response categories)

Johnsen et al (2009): symptom prevalences for haematological patients based on QLQ-C30: “not at all” – no symptom; “a little” – symptom present; “quite a bit” or “very much” – severe symptom;

Distribution-based approaches:

(relate PRO scales to score distributions in reference populations)

Velikova et al. (2004): symptom screening using general population mean as cut-off score

Gulbrandsen et al. (2004): age- and sex-adjusted general population means

Recent studies on developing cut-off scores

Anchor-based approaches:

(relate PRO scales to external criteria)

Snyder et al. (2009; 2010): anchoring QLQ-C30 scales to the Supportive Care Needs Survey (external criterion); patients with unmet needs considered as positive cases

Snyder et al. (2011): asked for the two most bothersome issues to classify positive cases

Johnsen et al. (2012): supplemented the QLQ-C30 with questions on problem intensity, problem burden, and felt need, i.e. the Three-Levels-of-Needs Questionnaire (3LNQ)

Why not using the anchor items directly for screening?

Anchor items used for developing cut-offs could be used directly for screening instead of relying on cut-offs for the EORTC domains.

Disadvantages of using anchor items directly:

- very limited measurement precision with regard to changes over time
- non-comparability of results to the large body of literature available on the EORTC measures
- substantial limitations to the use of the collected data for research purposes

Ongoing cut-off study: Objective

To determine cut-off scores for the EORTC physical functioning, emotional functioning, pain and fatigue scores to identify moderately and severely impaired patients

These cut-off score should help to highlight domains that should be included in clinician-patient communication

Methods - Sample

- Patients will be recruited (mail survey) at the NKI (NL), at Innsbruck Medical University (AT), at the Jagiellonian University in Krakow (PL) and at the Mount Vernon Cancer Centre (UK)
- Recruitment status: n=355
 - Amsterdam n=240
 - Innsbruck n=65
 - Krakow n=50
 - London – obtaining ethical approval
- Inclusion criteria:
 - any cancer diagnosis
 - any treatment
 - no brain metastases or serious cognitive impairment
 - patients aged 18-80

Methods – Screening scales

EORTC QLQ-C30

- Physical Functioning (5 items)
- Emotional Functioning (4 items)
- Fatigue (3 items)
- Pain (2 items)

EORTC item banks (IRT-based)

Additional items were taken from the EORTC item banks for the above domains to reach a total number of 7 per domain

Items were selected to maximize measurement precision in between the 75th and 90th percentile of score distribution in Dutch general population

(van de Poll-Franse LV 2005 EJC)

Methods – External criterion

Anchor items asking patients for burden, limitations and need for help to develop thresholds for **moderate** and **severe** impairments

Has your PF/EF/FA/PA been a burden to you?

None – Mild – Moderate – Severe

Has your PF/EF/FA/PA limited your daily activities?

None – Mild – Moderate – Severe

Have you needed any help or care for your PF/EF/FA/PA?

No help – A little help from family or friends –

Quite a bit of help from family or friends – Professional help (e.g. physicians, nurses)

A patient is considered to be a „positive case“ if s/he selects at least ONE of the orange/red response categories

Methods – Analysis

- Statistical analysis relies primarily on Receiver Operating Characteristic (ROC) curves which investigate how well a metric scale predicts a dichotomous criterion
- For every possible cut-off score of the scale sensitivity and specificity are determined. Each pair of sensitivity and specificity values are plotted in a chart (X-axis: 1-specificity; Y-axis: sensitivity) to obtain the ROC curve
- Area under the curve (AUC) is a measure of diagnostic accuracy of the scale (values range from 0 to 1). AUC is the probability of a positive case having a higher score than a negative case
- **An AUC of 0.50 reflects chance level, an AUC between 0.70 and 0.80 indicates acceptable discrimination and an AUC above 0.80 excellent discrimination (Hosmer and Lemeshow, 1989).**

Preliminary results – Patient characteristics

Analysis of **267 patients**:

Sex: 54.7% women – 45.3% men

Age: mean 60.1y (SD 12.1y)

UICC stage:

I 6.4%

II 28.9%

III 27.8%

IV 36.9%

Cancer site:

Breast cancer 39.9%

Lung cancer 15.1%

Colorectal cancer 14.9%

Preliminary results – Physical Functioning

	External Criterion	
	Moderate	Severe
Prevalence	73.8%	65.5%
QLQ-C30 PF	AUC 0.87	AUC 0.85
Optimal cut-off	90 points	74 points
PF CAT item bank	AUC 0.88	AUC 0.85

Preliminary results – Emotional Functioning

	External Criterion	
	Moderate	Severe
Prevalence	44.1%	19.9%
QLQ-C30 EF	AUC 0.80	AUC 0.81
Optimal cut-off	71 points	63 points
EF CAT item bank	AUC 0.83	AUC 0.84

Preliminary results – Fatigue

	External Criterion	
	Moderate	Severe
Prevalence	73.4%	33.7%
QLQ-C30 FA	AUC 0.91	AUC 0.91
Optimal cut-off	28 points	39 points
FA CAT item bank	AUC 0.96	AUC 0.93

Preliminary results – Pain

	External Criterion	
	Moderate	Severe
Prevalence	38.6%	14.9%
QLQ-C30 PA	AUC 0.88	AUC 0.91
Optimal cut-off	8 points	25 points
PA CAT item bank	AUC 0.93	AUC 0.93

Preliminary conclusions

- ROC analysis suggests that the QLQ-C30 scales and CAT measures for PF, EF, FA and PA are highly predictive for limitations, burden and need for help in these domains (all AUCs > 0.80)
- The CAT measures are somewhat more predictive than the shorter QLQ-C30 scales
→ the EORTC scales may be highly suitable for symptom screening in daily clinical practice

Future Perspective

The presented project is developing cut-off scores for 4 QOL domains using pre-defined anchors

Further extension in follow-up project:

- Including all QOL domains covered by the QLQ-C30
- Improving anchor criteria based on expert and patient interviews
- Improving cross-cultural validity
- Investigating stability of cut-off scores across patient groups (defined by e.g. tumour stage, treatment phase)

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