



EORTC QLQ Meeting, Opatija, September 2018

Reaching new horizons

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Dear readers,

International funding is accelerating as never before, as is the translation of cancer research into new treatments. This is great news for patients and great news for the Quality of Life Group! Our mission is to embed quality of life assessment into every aspect of cancer care. For our Group this begins and ends with the patient. It is easy to step away from the patient - to get caught up in micro and macro political and socio economic uncertainty. But if we are to harvest the fruits of all our work for the assessment of health related quality of life (HRQoL) and highlight even the marginal changes that can have a big effect on a person's life, we need to continue to work powerfully with patients to guide our work and define our quality of life metrics. We need to continue developing some of the best science in the world of Quality of Life and get this to patients faster than ever before.

We successfully continue to reach out and collaborate with our partners in other Disease Oriented Groups (DOGs). This exchange is crucial.

This issue of our Newsletter carries this strong message and focuses on exciting new projects, achievements and the wonderful members from across the world that make the Quality of Life Group so unique. Our theme 'Reaching new horizons' includes brief reports of work in different cultures including newly industrialized India and global north Australian perspectives on quality of life. Reports also reflect different organizational cultures including industry and academia in their response to our Item Library.

One of the joys of the Newsletter is that it offers opportunities to relive attendance at past meetings in glorious Technicolor and to anticipate

future meetings. As well it is a chance to reboot on priorities and direction and to share ideas amongst the Group. This is crucial to retain our cutting edge in QoL science and you can read in Anne-Sophie's piece about a revamp to our active members Business Meeting to put discussion at the heart of our Group processes.

The next edition of the Newsletter will be Anne's baby! Do let me know if you have an idea for a new section of the Newsletter - an 'opinion piece' perhaps?

We thank Christopher Courtois for his excellent work in getting the Newsletter out in time for EGAM. Happy reading!

[Anne-Sophie Darlington](#)
[Anne Lanceley](#)



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A few words from the outgoing and incoming chairs

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Fabio Efficace, Past Chair of the EORTC Quality of Life Group, Head of Health Outcomes Research Unit, Italian Group for Adult Hematologic Diseases (GIMEMA), Rome, Italy

Fabio: It has been a tumultuous year in the world of patient-reported outcome measures and quality of life measurement. Directives from many directions are encouraging us to be flexible and share our work more widely.

Our group has been expanding and we are seeing exciting new developments with proposed work in regions of the world such as India and Japan, which bring with them interesting cultural issues and disease profiles. Our FDA qualification process is in full swing. The EORTC item library is now being used increasingly and we have also appointed a research fellow in the QLD to guide this process. In light of our comprehensive item library, we are increasingly encouraging new grant applicants, to incorporate its use as an integral part of their project. This seems to be an appropriate solution to the rapid development new treatments, allowing us to respond to these with our flexible measurement approach. Hopefully, we will be able to also start fruitful discussions over the coming several months with EMA, in order to further value our measurement portfolio.

Anne-Sophie: Fabio has been able to do a fantastic job of leading us through this year and, being recently elected as Chair of the QLG, I am now delighted to continue this work and closely collaborate with all of you over the coming years. The current Executive Committee with two new members – a warm welcome to Olga Husson and Anne Lancelley - is a strong team with very committed people. There is particular strength in ensuring we streamline processes to make things easier and clearer, for all of us. We notice each year we get better at organising things, with invaluable input from the Quality of Life Department, the GRC,

PMDC and our statistics group. And this is entirely right as everything has become more complex: coordinating with the HQ, organising contracts with universities, organising our meetings in convenient locations, and accommodating our growing number of projects, particularly together with the different disease oriented groups.

Given the increasing competition that we have been facing over the last years, it becomes even more important for us as a group to demonstrate the value, history and legacy of our work. At the core of our work is a commitment to produce patient-reported outcome measures with the highest quality processes, clearly aligned with clinical needs and to have the patient voice at heart. We do have quite a few challenges ahead of us but our multidisciplinary approach and the diversity of our membership is a key strength and I have no doubts we will succeed.

In order for us to keep making strong progress and be agile, we need and value your point of view. To this end, we will make sure that business meetings are used to have active and informed discussions in order to accelerate decision-making and progress!

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News from the EORTC Quality of Life Department

Andrew Bottomley, EORTC Quality of Life Department Representative, EORTC, Brussels, Belgium

2018 has been a busy year for the EORTC Quality of Life Department. The good news is that, unlike in the past years where we experienced significant staff turnover, this year we have had **no staff changes**. We have very highly skilled and motivated researchers, all working on new large-scale and challenging projects. You can read about many of these projects in more detail in other parts of the newsletter. The EORTC is constantly changing, and we are adapting to both the external clinical trials environment and also the internal changes.

We have continued to work hard on **refining the QLG grant process**, to ensure that it fits well within the existing EORTC internal procedures. Rules and procedures have changed again this year, so please keep up-to-date on the QOL website to find out more.

The drive from within the QLG Executive Committee and the Project and Module Development Committee to have **better quality assurance procedures for all on-going QLG-funded projects** is having an impact. This has meant tightening up our procedures and developing new ways of working which has, of course, placed a greater demand on the investigators. However, with this extra effort, we expect to see projects delivering high quality results, which we hope will lead to improvements in patient care.

Our Translation Team was exceptionally busy in 2018. Over 160 new translations were finished with 120 out of these requested by pharmaceutical companies. This brought in a **major increase in the revenues for translations** in comparison to 2017. With so many ongoing grants for new modules, new translations are always needed and keep the team busy.

We had **many users contacting the department to use EORTC QOL tools**. Over the last year, more than 5000 academic users from over 100 countries contacted us mostly to use the core tool or the lung or breast cancer modules. Furthermore, there was an increase in industry users, with more than 240 agreements signed with industry partners, a record number since we began over three decades ago. More than a hundred of these partners used one module or more, with the lung cancer (QLQ-LC13) and multiple myeloma (QLQ-MY20) modules still being the most used. Commercial and academic interest in the Item Library has continued to grow, with over 170 access request in 2018. You can read more about it on [p. 9](#).

We are undertaking the **5th QOL Clinical Trials Conference in mid May 2019**. We invite you all to attend, as attendance will be free for academics thanks to a grant from the QLG and support from the HQ. To those readers from industry who wish to support our initiative, additional funding opportunities still exist, and past conferences provided great online training for QOL and PRO researchers (see <http://events.eortc.org/qol-conference/final-program/>).

The **QOL website underwent a total overhaul** and is now completed, after a slight delay. Prof. Anne-Sophie Darlington and Melodie Cherton worked extremely hard over the last year with an external company. We now have a brand new website that better suits the needs of all types of users.

Given all these activities, one can easily forget that the department is involved in **scientific activities** too. For example, our staff have had an impressive scientific output, co-authoring over 10 peer-reviewed papers in journals like JCO and The Lancet Oncology, often co-authored with QLG

members, and frequently in collaboration with EORTC Disease Orientated Groups (DOG) such as the Breast, Brain or Melanoma Groups. For example, Madeline Pe was the lead author on a Lancet Oncology review of QOL in metastatic breast cancer with the SISAQOL group, and the SISAQOL Consortium members also authored a paper on setting standards on clinical trials analysis in Clinical Trials, Jammbe Musoro published a paper on interpreting QLQ-C30 scores in an adjuvant melanoma setting in EJC, and at least four other publications on MIDs across different disease sites are planned for this year. Furthermore, a new QLG funded project "Cancer Clinical Trials Pooling of Quality of Life Data (CATAPULT)" was recently initiated by the department. This project will build a user-ready HRQoL database on the QLQ-C30 from published trials, which will be used to investigate critical topics to better understand HRQoL in cancer patients and to educate clinicians, healthcare providers and policy makers.

Many of the staff were invited to **speak at prestigious international conferences and meetings**, to share their knowledge and experience with the FDA, EMA, Japanese Clinical Oncology Group and other academic societies (e.g. the ISOQOL or European Cancer Patients Coalition, ISPOR, ESMO). The staff also had some noteworthy recognition last year for their scientific work. We would like to congratulate Madeline Pe for being selected as a finalist for the new investigator award, and Irina Ghislain for being selected as a finalist for the poster presentation award at ISOQOL. Jammbe Musoro had his poster ranked in the top 10% of the poster presentations at ISPOR and I was very much honored to receive the 2018 ISOQOL Presidents Award.

One of the key roles of the QOL Department is to act as a **centralized resource to help ensure the smooth integration of QOL endpoints in EORTC clinical trials**. We have been actively working with many DOG and QLG members to ensure that protocols are developed quickly, consistently and robustly

In 2019, of the 16 EORTC projects which are currently under development, all but one contain QOL as an endpoint. We have also 9 CTs with QOL that are about to start (regulatory in process). Most of these 9 trials use EORTC questionnaires as main tools, except for 2 (2/9=22%) using the Skin Index and VAS Pain. In addition to that, QoL is an active endpoint in 22 recruiting trials using mainly EORTC questionnaires except for 3 (3/22= 14%) using SF36, SF12 and EQ-5D. Also, 2 studies led by the QLG, with the collaboration of a DOG, are currently managed at the EORTC HQ: 1 follow-up study of gynecological cancer survivors (Principle Investigators (PIs): Eva Greimel, and Antonio Casado from the GCG) (1514); and Follow-up in Early and Locally Advanced Breast Cancer Patients (PIs: Vesna Bjelic-Radisic, and Fatima Cardoso from the BCG) (1617).

In summary, the QOL Department is **adapting well to the challenges**, and has an **ever growing portfolio of activities** in support of the EORTC HQ, QLG, and DOGs.



Clinical validation of the EORTC CAT Core

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Computerized adaptive testing or CAT is an innovative approach for collecting patient reported outcomes. CAT tailors the questionnaire to the individual patient, thereby maximising the obtained information and measurement precision. This means that studies using CAT may include fewer patients while preserving the same power.

The EORTC CAT Core is a CAT version of the EORTC QLG's core quality of life questionnaire, the EORTC QLQ-C30 [1]. The EORTC CAT Core includes item banks for the 14 QLQ-C30 symptom and functional domains. The individual banks comprise between 7 and 34 items with a total of 260 items. The QLG has also developed software for conducting online CAT assessment, and an upgrade of this software is expected to be released shortly. If online computer-based data collection is not feasible, the item banks may also be used to construct customised static questionnaires, so called short forms.

During the development of the item banks, favourable measurement properties have been found for the EORTC CAT Core compared to the QLQ-C30. However, the validity of the CAT instrument should be verified in independent data. Therefore, the EORTC QLG has conducted a clinical validation study comparing the EORTC CAT Core and the QLQ-C30. A heterogeneous sample of 699 cancer patients initiating chemotherapy and/or radiotherapy was recruited across seven European countries. Participants were assessed before and after initiating treatment allowing assessment of the ability to detect group differences and changes over time.

The validation confirmed that the EORTC CAT Core measures the same domains as the QLQ-C30 and facilitates the use of smaller samples without loss of power compared to the QLQ-C30. Detailed results of this validation study will be presented in an upcoming scientific paper. A recent clinical trial also confirmed improved measurement of emotional function using an EORTC CAT Core based short form [2].

The EORTC QLG website provides more information on the current use of the EORTC CAT Core and short forms at [http://www.eortc.org/qlg](#).

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Determination of European Utility Weights for the EORTC QLU-C10D - a Cancer-Specific Preference-Based Quality of Life Measure Derived from the QLQ-C30



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For many readers of the newsletter the words utility weights, preference-based and QLU-C10D may still sound rather unfamiliar. And those who remember that there has once been an article on a “new born” EORTC instrument (EORTC QLG Newsletter Spring 2015) may wonder how the “child” is getting on. Here we want to give you some information on both issues.

Utilities, QALYs, and the QLU-C10D

New cancer treatments are expensive; some monoclonal antibody therapies even cost a fortune. Is the expected increase in survival time or in quality of life (QoL) worth such an expenditure? To deal with such questions, the utility concept tries to link QoL, survival and costs. Periods in a patient’s life with high QoL are weighted by a high utility, periods with low QoL are weighted by a low value. This is the basis for quality-adjusted life years (QALYs), which play a key role in cost-utility analyses.

One way to obtain utilities is by means of utility instruments. Once utility weights for the instrument have been determined, it can be applied like a normal questionnaire. Utilities for patients are obtained by a simple formula. The QLU-C10D is a cancer-specific utility instrument based on the QLQ-C30. It covers 10 dimensions, some of which are generic, e.g., Physical Functioning or Pain, while others are cancer-specific, like Fatigue or Nausea.

Determination of utility weights for the QLU-C10D – our first EORTC utility project

Main purpose of our project was to determine utility weights for the QLU-C10D for five European countries. For each country, we obtained the required information from a sample of 1,000 people of the general population. Respondents were asked to complete an online survey covering socio-demographic and clinical items and, most importantly, questions on health preferences

where the participants had to pick one of two health states A and B – both combinations of the 10 dimensions, but with different severity levels (see Figure 1).

Similarities and differences between countries

Our project covered QLU-C10D valuations for Germany, France, Italy, Poland, and Austria. Figure 2 shows how much each of the 10 dimensions contributed to the total utility, broken down by country. Similarities between countries: Physical Functioning (PF) was considered most important by respondents of all countries, usually followed by Pain and Role Functioning. Among the cancer-specific dimensions, Nausea received the highest utility weights. Differences: French and Italian respondents regarded Emotional Functioning as much more important than those of the other countries. Polish participants focussed very much on Role Functioning, next to PF.

Figure 1: Example of a choice set used to determine utility weights for the QLU-C10D

	Situation A	Situation B
In taking a long walk	You have a little trouble	You have a little trouble
In taking a short walk	You have a little trouble	You have a little trouble
You are limiting in pursuing your daily activities	Quite a bit	Quite a bit
Your physical condition interferes with your social or family life	Quite a bit	A little
You feel depressed	Quite a bit	Quite a bit
You have pain	A little	Very much
You feel tired	A little	A little
You have trouble sleeping	Not at all	Not at all
You lack appetite	Quite a bit	Quite a bit
You feel nauseated	A little	Quite a bit
You have constipation or diarrhoea	Not at all	Quite a bit
You will live in this health state for	2 years and then die	5 years and then die
Which situation would you prefer?	O	O



Qualitative research to explore the content validity of the EORTC QLQ-C30

Kim Cocks, PhD, Adelphi Values, UK
Colin Johnson, Professor of Surgical Sciences, University of Southampton, UK

Practical use of the QLU-C10D - Manual

Utility weights for the QLU-C10D in the first five EU countries are in principle “ready for use” in clinical trials or cost-utility analyses. They will soon be published to make their use more official. A manual on the QLU-C10D is presently in work.

Follow-on projects

Psychometric properties of the QLU-C10D are investigated in an EORTC project led by Eva Gamper. Moreover, a second QLU-C10D valuation project has started covering three further European and two East-Asian countries.

Acknowledgements

Many thanks to all our collaborators, in particular to Madeleine King and the MAUCa Consortium, to the members of the HTA/Utility work group, and to the EORTC QLG for the generous funding!

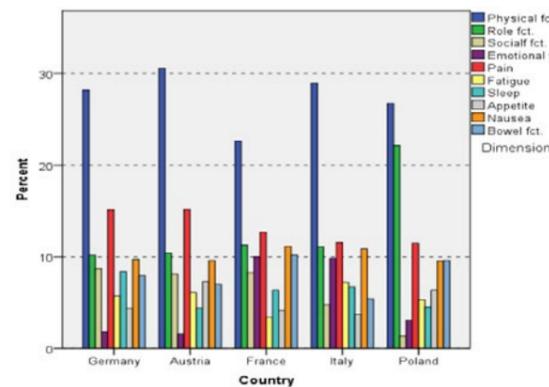


Figure 2: Contribution of each of the ten QLU-C10D dimensions to the total utility decrement (in %) – comparison across country

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The EORTC QLQ-C30 has been in existence for over 30 years and is now the most commonly used patient-reported outcomes instruments in oncology. As the treatment landscape has changed drastically over this time period, it is key for continued success of the QLQ-C30 that the concepts it covers remain important and relevant to cancer patients today. Indeed, there is also increasing pressure for those who invest in QLQ-C30 licenses to provide regulatory-standard evidence that any patient-reported outcome measure is content valid for their study population. To continue to offer the highest standard of measurement tools in the field we need to publish this evidence for the QLQ-C30. The purpose of this project, funded by the EORTC QOL Group, is to generate additional evidence using best practice guidelines¹ to support the relevance and patients’ understanding of existing items in the QLQ-C30, and to identify if there are additional concepts relevant for patients today.

Semi-structured concept elicitation and cognitive debriefing interviews are being conducted followed by in-depth qualitative analysis of transcripts. The interviews aim to explore the patient experience and encourage spontaneous elicitation of new concepts; they also discuss the relevance of existing items in the QLQ-C30 and patient understanding of those items and the recall period. A sample of 120 patients is targeted across a broad range of clinical and demographic characteristics. The four most common cancer types are included (breast, colorectal, prostate, lung) plus a group of patients with any other cancers in order to generalise findings across a broad spectrum of cancer patients. Patients across different disease severities, treatment types, ages, and gender, from a range of international locations are being recruited to the study (UK, Poland, Netherlands, Italy, Denmark, Germany and the United States).

The first stage of the work was presented at ISOQOL in 2016. A review of existing EORTC disease-specific modules was carried out to consider which concepts appeared to be common across a range of cancer types, which may therefore warrant inclusion in the core questionnaire. Initial findings from the interviews were then presented at the EORTC QOL Group Autumn meeting in Opatija and at ISOQOL 2018.

To date we have 9 participating sites. Around half of the interviews have been conducted (59 as of early January), and all interviews will be completed before April 2019. Key discussions will take place at the EORTC QOL Group meeting in March ahead of sharing the analysis results. The findings will be presented at international meetings and published after discussion with the EORTC QOL Group Executive Committee and the QOL Group as a whole.

If you would like more information about this project, please contact the Principal Investigators, Kim Cocks (kim.ocks@adelphivalues.com) and Colin Johnson (c.d.johnson@soton.ac.uk).

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Development of a health-related quality of life module specifically for patients with anal cancer treated with chemoradiotherapy: EORTC QLQ-ANL27

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Anal cancer is rare, accounting for 2% of all gastrointestinal malignancies and the current standard of care is concurrent chemoradiotherapy (CRT)¹. While treatment outcomes are promising with overall survival rates reaching 75%², associated toxicities are common, potentially long lasting, and impact health-related quality of life (HRQoL). Potential complications include radiation enteritis, diarrhoea, proctitis, skin desquamation, stenosis, sexual dysfunction, pelvic fractures, urgency and frequency of defecation, stool incontinence, and urinary tract dysfunction. There is limited information on HRQoL and in particular late effects. Furthermore, there is no anal cancer specific HRQoL measure.

In 2013, the EORTC QLG supported the development of an anal cancer module to supplement the EORTC QLQ-C30. This study is guided by the EORTC QLG framework for module development: Phases I-III have been completed and Phase IV international validation work of the questionnaire is underway.

We carried out a systematic review of the literature³ and interviews with patients recruited across the disease and treatment spectrum (on treatment / acute, early and late) and health care professionals (HCPs). We found that bowel function issues, particularly diarrhoea, and sexual problems were the most commonly reported QoL concerns for these patients.

Phase I recruitment of 43 patients took place from seven centres across five countries (Canada, Cyprus, Germany, Poland and UK). A total of 197

quality of life issues, categorised under 19 sub-headings, were captured across the 43 interviews. Again, bowel function issues, in particular diarrhoea and constipation, were the most commonly referred to across all centres. Skin issues, in particular burning and itchy skin, were also frequently mentioned by patients. After further interviews with HCPs and a separate group of 10 patients, a list of 65 issues was operationalised, with guidance from the EORTC QLG Item Library, into items to form the pilot questionnaire. This was tested in Phase III.

Our Phase III pilot testing involved a wider group of collaborators as we welcomed additional centres from Greece, Italy, and Norway to recruit 100 patients from 11 centres spanning 8 countries. Participants were asked to complete the draft questionnaire as well as the EORTC QLQ-C30 and then rate each anal cancer specific question for relevance and importance. Our analyses led to the modification and removal of questions resulting in a 27 item questionnaire, the EORTC QLQ-ANL27 with the following hypothesised subscales: bowel function, pain or discomfort, sexual function (male and female), and stoma, with five individual items (frequent urination, keeping clean, proximity to toilet, lower limb oedema, planning activities) and a sexual activity screening question. For full details about the development of the EORTC QLQ-ANL27, please see our work published in Radiotherapy and Oncology⁴.

The EORTC QLQ-ANL27 is currently available in 10 languages and is suitable for use in clinical practice in promoting engagement and ongoing regular

contact with HCPs. The measure is designed to be sensitive to both the acute and late effects of anal cancer and its treatment. In addition, the EORTC QLQ-ANL27 is also appropriate for use in clinical trials and is currently used to assess HRQoL and symptomatic toxicity for all anal cancer patients enrolled in the PLATO trial⁵.

We are currently working on the international validation of the EORTC QLQ-ANL27 with a target recruitment of at least 375 patients. This Phase IV study opened in December 2017 and recruitment is scheduled for completion this year. We have so far reached 1/3 of our target recruitment. Please get in touch if you can contribute to this module; we always welcome new collaborators!

From the very beginning of the development of this module, there was notable enthusiasm for an anal cancer specific measure and the work has attracted widespread interest and drawn on the expertise from world leaders in the field.

For more information about the EORTC QLQ-ANL27 or for any expressions of interest in becoming involved in the Phase IV International Validation Study, please contact either

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Update on the Item Library

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On 25 October 2017, the new Item Library set sail, starting a new chapter in the history of our instruments. The interest in the Item Library and all it has to offer, with its 954 unique items, has grown steadily since its launch, with over 170 new users registered in 2018. Each academic and commercial user is sent an agreement, specifying the terms of access. If they decide to use an item list created with the Item Library, a user agreement has to be signed as well. Given the volume of agreements to handle, print and scan, we were happy to move to an electronic signature system in September 2018.

Since the launch, 29 item lists have been created and used in research, trials, and clinical practice. New item lists are discussed with users on a case-by-case basis, to help ensure that the content and formatting are appropriate, and to aid in the selection and organization of items. Item lists are then exported in the required languages (which sometimes involves launching new translation projects) and formatted to reflect the mode of administration: pen-and-paper or ePRO.

Extensive discussions with users on various issues related to the item lists pointed to a number of topics that needed to be covered by our User Guidelines. Further discussion involving Item Library working group members, during group meetings in Kiel and Paris, helped to refine these topics, which were then translated into a written document and further revised. Existing guidelines from the FDA, EMA, and CONSORT PRO Extension were also consulted for relevant guidance and helped us identify gaps to bridge with our new document.

The User Guidelines accompany the Technical Guidelines that we now share with each new user. Both documents will be updated on a regular basis to make sure that they answer all of the most frequently asked questions related to the Item Library, while promoting good scientific practice.

Research on Item Library-related topics was also present at the 2018 ISOQOL Annual Meeting in Dublin. We presented two posters – one on the content analysis of the items, and another on the translation process for item lists. Both were well received and the entire conference provided excellent opportunities for networking, discussion, and training.

In 2019, the new horizon for the Item Library is to present it more globally. The first conference we are aiming for is the ISPOR meeting in New Orleans, USA, where we submitted two abstracts focusing on the general strategy of the QLG and the development of User Guidelines. With this meeting, we would like to reach a more US-based public and make them aware of our instruments. Later this year, we would also like to go east and present our work at a meeting in Asia. While we are well known in Europe, we believe we can improve our visibility on a more global level. Hopefully, 2019 will be the year of sailing into the horizon to make the Item Library a worldwide name.



European norm data study now published in European Journal of Cancer

Sandra Nolte, Department of Psychosomatic Medicine, Charité – Universitätsmedizin Berlin, Germany

On behalf of my wonderful collaborators, I am delighted to inform you that we successfully finished our European norm data study. As part of this project, we collected general population norm data for both the EORTC CAT Core and the QLQ-C30 from 15,386 people across 15 countries, including 11 EU countries, Turkey, Russia, Canada and the United States.

As you have all witnessed over the past several years, the QLG (led by Morten Petersen and Mogens Groenvold) has been developing a computer-adaptive test (CAT) version of the QLQ-C30. The EORTC CAT Core assesses the same 15 content areas as the QLQ-C30 and was recently published [1] with the publication of the validation study to follow soon (for further details on the CAT Core, please see previous QLG newsletters, e.g., Spring 2018 – Issue 18).

The main idea behind computerised adaptive testing is that it avoids the administration of irrelevant items by tailoring the instrument to the individual respondent. By making use of the information on individual item parameters, respondents only fill out those items that are more relevant to them, while less relevant items are omitted. Thus, CATs enable the assessment of patients' health-related quality of life scores with increased precision, efficiency and flexibility compared with traditional instruments.

Using item response theory methods, the item parameters for the CAT Core have already been established. However, as these are based on several mixed clinical datasets [1], scores thus far were on "arbitrary" metric hampering their interpretation. Meaningful and sensible interpretation can be obtained by linking the CAT Core to general

population data. Hence, our study was aimed at collecting normative data to establish the European Norm for the EORTC CAT Core and to generate updated QLQ-C30 norm data.

Funded by the QLG, we devised an international study to generate these normative data. The final country selection was based on several criteria, including population size and balance of geographical location, whilst considering budgetary constraints. Of the final 15 countries selected for our study, 11 EU countries formed the European Norm, while the remaining four countries were included for comparative purposes. To ensure a consistent data collection method across countries, data collection was subcontracted to GfK SE, a panel research company with vast experience in multi-national online surveys. Data were collected in March/April 2017 with a total of 15,386 respondents completing the survey.

The study has now been finalised by establishing the official European Norm for the EORTC CAT Core [2] and generating updated general population norm data for the QLQ-C30 [3] across aforementioned countries. These normative data can now be used globally and facilitate valid intra- as well as inter-country comparisons and score interpretation. Furthermore, the new norm data document and quantify important differences between men and women, across age groups and between countries.

Links to both articles that were published open access in the European Journal of Cancer:

<https://www.sciencedirect.com/science/article/pii/S0959804918315223>

<https://www.sciencedirect.com/science/article/pii/S0959804918315211>

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Co-investigators:

(in alphabetical order): Neil K. Aaronson, Anna Costantini, Peter M. Fayers, Mogens Groenvold, Bernhard Holzner, Colin D. Johnson, Georg Kemmler, Gregor Liegl, Morten Aa. Petersen, Matthias Rose, Krzysztof A. Tomaszewski, Annika Waldmann & Teresa E. Young



Revision of the EORTC QLQ-BN20 brain tumour module

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Background

The European Organisation for Research and Treatment of Cancer (EORTC) QLQ-BN20 brain tumour module was developed and validated in 1996, with a phase IV validation in 2010. The aim of this module was to evaluate the effects of the tumour and its treatment on symptoms, functions and health-related quality of life (HRQoL) of brain tumour patients, both in clinical trials and clinical practice.

Since the publication of the QLQ-BN20 in 1996, we have observed an increase in the use of this questionnaire, not only in glioma patients whom this questionnaire was developed in and validated for, but also in patients with other types of brain tumours, such as meningioma patients and patients with brain metastases from systemic cancer. Despite the fact that use of the QLQ-BN20 has tremendously contributed to insight into the quality of life of brain tumour patients, certain items of the questionnaire have raised issues (e.g. underestimation of symptoms due to poor formulation of the items), and new treatments have been introduced with different toxicity profiles not covered by the current measure. These observations have led to the recognition that a revision of the QLQ-BN20 is warranted.

Working plan

The recently received grant from the EORTC Quality of Life Group will enable us to revise the current BN20 module for both primary and metastatic brain tumour patients. To do so, we will follow the Quality of Life Group guidelines for updating existing modules, including a literature review and interviews with patients and health care professionals for the identification

of items relevant to current/new treatments (phase I), creation of a revised item list (phase II), and psychometric pilot testing (phase III). In addition, we will explore if it is possible to have a more flexible approach with this module, in which a standard set of items could be complemented with validated scales from the item library depending on the research question.

Project progress

In May 2018, Marthe Peeters started as a PhD student on the BN20 project. Marthe is a medical student and she was halfway through her residency when we asked her to coordinate the BN20 project. As a medical student, Marthe was already interested in Neuro-Oncology and involved in several studies. She investigated the prediagnostic symptoms and signs of brain tumour patients in the year before their diagnosis, and she was involved in a systematic review evaluating HRQoL issues of patients with a benign brain tumour. Her experience and motivation make her the perfect candidate to coordinate the BN20 project.

At this moment, we have completed the literature review and extracted all possible relevant HRQoL issues for brain tumour patients. The next step will be to conduct interviews with patients and health care professionals to evaluate the relevance of the 288 identified issues,

and to identify if relevant issues are missing. The interviews have started in the Netherlands, and will commence in the United Kingdom and Italy as soon as ethical approval is obtained. In phase III of the project, collaborators from Germany, Switzerland and Japan will join the project. We are still searching for collaborators from an Eastern European country.

Co-investigators:

(in alphabetical order): Neil Aaronson, Florian Boele, Andrew Bottomley, Corneel Coens, Robin Grant, Peter Hau, Ulrich Herrlinger, Yoshitaka Narita, Andrea Pace, Jaap Reijneveld, Andrea Talacchi, Martin Taphoorn, Hitomi Sato, Michael Weller

(...)certain items of the questionnaire have raised issues (...), and new treatments have been introduced with different toxicity profiles(...)"



Development of an EORTC module assessing fertility issues and patient care needs (Phase 1-3)

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 Andrea Kiemen, University Medical Center, CCC-F, Freiburg, Germany
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 Roxana Schwab, University Medical Center, Mainz, Germany
 Annette Hasenburg, University Medical Center, Mainz, Germany

Introduction

Reproductive toxicity of anti-tumour therapies often lead to decreased fertility in patients, which causes many psychosocial issues and impairments to later quality of life of cancer survivors. Most patients diagnosed with cancer in the reproductive age and their relatives or partners wish to receive information related to fertility protection and preservation (FP). Fertility is a priority survivorship concern for women and men at risk for cancer-related infertility. However, knowledge and utilization of FP services remain low. Lack of information can negatively influence decision-making and increase decisional conflicts, which can be associated with emotional distress and decisions' regret in the future. More than 80% of women counselled, reported that time constraints presented a challenge for undergoing the fertility preservation (Assi et al., 2018) and those being referred timely to fertility preservation counselling were grateful to the time given to fully investigate the different fertility preservation methods (Ussher, Parton, & Perz, 2018).

Women and men report a need for information on FP strategies and decision support while reflecting their options during the brief, stressful window of time before initiating cancer treatment. Later in life, after treatment and during survivorship, psychological distress and fertility issues are still evident.

Aims and objectives

This is a cooperative project between ESGO (European Society for Gynaecological Cancer) and EORTC Quality of Life Group (QLG). Initiated by the ESGO and EORTC QLG the project will

be carried out in collaboration with several Disease Oriented Groups (DOGs) within the EORTC and ESGO partners. The primary objective of this project is the development of a validated questionnaire instrument that covers all fertility related quality of life (QoL) issues including the individual patients' need for information and counselling. In addition, information and support needs about FP with cancer will be included. The questionnaire is designed for measuring fertility issues in clinical trials and for evaluating patient care needs in daily practice. The module will cover issues of fertility in various cancer types (associated with fertility preserving issues) for both genders and in different medical treatment settings (surgery, systemic therapy, radiotherapy). The module will be developed as a 'stand-alone' questionnaire in accordance with the EORTC QLG guideline (Johnson et al., 2011). Since this fertility questionnaire should be applicable to patients with various cancer types, we will include a broad range of cancer patients affected by fertility preserving issues focusing on gynaecological cancer, bladder cancer, colorectal cancer, testicular cancer, prostate cancer, breast cancer, sarcoma in the pelvic region and lymphoma. Female patients in pre-menopause and younger than 45 years are eligible. For male patients there is no age limitation for inclusion. Patients in any treatment affecting fertility are included focusing on surgery, systemic therapy or radiotherapy (alone or combined) with curative intention. In addition, newly diagnosed patients under treatment and in the post-treatment follow-up will be included in the module development process.

Development of issues

We performed a systematic literature search concerning the following keywords: fertility (/preservation), infertility, oncofertility, cancer/neoplasm, QoL and available QoL questionnaires/scales. The selection of issues was guided by a strong a priori conceptual framework regarding the important dimensions of need for information and counselling, dimensions that are warranted in most of the publications concerning fertility in patients with cancer. Our literature research includes also the review of all existing related tools and questionnaires addressing fertility issues, and formal needs assessment with patients and health care providers (HCPs). There are only two existing scales specifically designed to measure reproductive concerns of cancer patients (Gorman, Su, Roberts, Dominick, & Malcarne, 2015; Wenzel et al., 2005) both focusing solely on female cancer patients. In addition, some existing questionnaires or modules include single items on fertility or reproductive issues in certain diagnoses (e.g. EORTC Life Situation Questionnaire among Hodgkin Lymphoma survivors, [van der Kaaij et al., 2012]). Common items include loss of control over reproductive future, sadness about inability to have children, concerns about fertility potential, partner disclosure, becoming pregnant, the acceptance of potential infertility, personal health and child's health.

Based on the literature review and the discussion within the fertility working group at the EORTC QLG autumn meeting we generated a pool of 52 issues for the phase 1 item list. We included various items related to counselling, partnership, family planning, financial aspects, QoL dimensions,

decision making process and coping strategies. In phase 1 we will interview HCPs with multi-professional background, patients and partners. They will be asked to rate the relevance and priority of the issues and potential issues that are still missing in the list.

Statistical methods

Data from the patient and HCP interviews and questionnaires will be analysed using basic quantitative analyses, including generation of descriptive statistics (e.g. missing data, means and standard deviations, floor and ceiling effects, etc.), prevalence ratings, priority ratings and range of responses for each item. The data from the debriefing questions will be reported both quantitatively and qualitatively. Preliminary testing of the hypothesized scales structure will be carried out based on the concept of item response theory (IRT). As we do not yet know how long the item list of the preliminary module will be, we calculated the sample size (n=260 patients in phase 3) assuming that the module will not exceed more than 40 items. In case of missing data we will use multiple imputation procedures.

Perspectives and milestones

The project started in August 2018 and has been scheduled for three years (2018-2021). In all phases we will include ESGO and EORTC DOCs listed below. The update of the literature and the issue list for interviews and all study forms will be finalized in February 2019. In parallel, ethical approval has been applied in the study centre Freiburg. We will start HCP interviews during the EGAM meeting in March 2019. The conceptualization of the questionnaire, ethical approval in all centres, translation of issue list, patient and HCP interviews are intended to be finalized by the end of 2019. Analysis of data and the phase 1-2 report will be completed in March 2020 and submitted to the MDC. We intend to start with phase 3 in June 2020.

Collaborating partners:

ESGO	Annette Hasenburg, Roxana Schwab, Dominik Denschlag (Germany); Vesna Kesic, Snezana Mijalkovic (Serbia)
EORTC Quality of Live Group	Vesna Bjelic-Radicic (Germany), Eva Greimel (Austria), Juan Ignacio Arraras (Spain), Teresa Young (UK), N.N
EORTC Lymphoma Group	Paul Meijnders (Belgium)
EORTC Gynaecologic Cancer Group	Nelleke Ottevanger, Elenora van Dorst (Netherlands)
EORTC Breast Cancer Group	Katarzyna Pogoda (Poland); Fatima Cardoso (Portugal)

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New horizons in working closely together with disease-oriented groups - The Late Tox Project



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The Late Tox Project ("Late Toxicity and Long-term Quality of Life in Head and Neck Cancer Survivors") is a joint project between the Quality of Life Group (QLG) and the Head and Neck Cancer Group (HNG). It is a concrete, successful example of the EORTC's aim to create more connections between the QoL Group and the various disease-oriented groups within the organization. As would be expected with any major project, the Late Tox Project has experienced challenges as it has progressed, but the overall picture looks promising at what is essentially half-time for the project.

With variations depending on tumour site, the five-year survival for head and neck cancer is about 50%. Both the treatment and the disease itself have an impact on quality of life (QoL), and some of the known issues for these patients include impairments to salivary function, breathing, swallowing, and speaking. Given the central role of these functions in daily life, head and neck cancer treatment carries considerable, unfortunate side effects with it within the first years after treatment. However, very little is known about how these survivors fare in terms of quality of life and the presence of toxicities at five years or more post-diagnosis. This is worthwhile investigating as it is possible some late sequelae may develop initially after treatment and then disappear, lessen, or even worsen after longer periods of time. The long-term survivors may therefore also have different QoL issues compared to more newly diagnosed patients.

The aim of the Late Tox Project is to make a significant contribution to this knowledge gap. The project plans to enrol 1200 head and neck cancer survivors and have them complete the EORTC QLQ-C30 and the EORTC QLQ-H&N35 as well as non-EORTC questionnaires on their use of medical services, loss of productivity at work and home, and supportive care needs. A clinical exam follows,

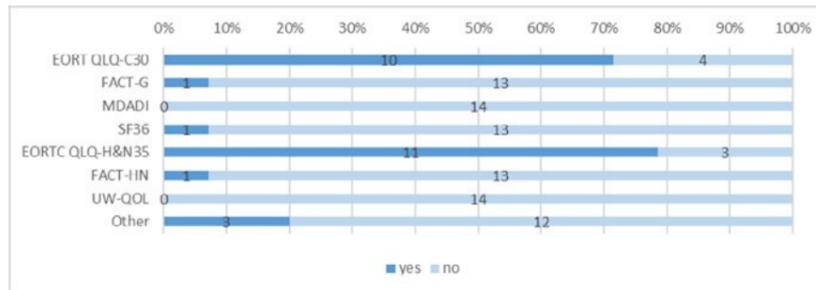


Figure 1: Instruments used to measure QoL in the institutions. Other instruments were: SF12, anamnesis only, Tschiesner screening tool

in which the collaborating physicians assess each patient for 33 toxicities. The project also includes a sub-project specifically on the oral health of survivors, and for the survivors invited to collaborator centres that are participating in this, there is an additional oral examination by a dentist and the EORTC's quality of life module for oral health.

The first steps for this project began in 2014 when members of the HNG and the QLG began to design the study. We wanted to follow-up survivors from EORTC head and neck studies in addition to a "real-world" survivor population. A grant application to the QLG was submitted in February 2015, and we also had a teleconference with Denise Lacombe to clarify how HQ employees could be involved and funded. However, this grant proposal was not endorsed by the EORTC board and the QLG. The main criticism was that there would be too few survivors from the EORTC trials, and hence the sample size would be too small.

We therefore redesigned the study and excluded the part with the survivors from EORTC trials. Moreover, we conducted a survey among HNG and QLG members about the feasibility of this project. Twenty-three colleagues replied (11 from HNG, 12 from QLG) and 22 declared they would like to participate. We also asked potential collaborators about whether they already had quality of life data on their patients and if so, which instruments they had used. Results showed that the majority of the participants who had collected such data had used the EORTC instruments; however, other tools were used as well (Figure 1).

The new study proposal was submitted in March 2016. It was approved by the EORTC board and protocol review committee in January 2017, who requested a reduced budget. The new version of the grant proposal was submitted in February 2017 and finally approved. The contracts were ready in July 2017, and the research fellow was hired in September 2017. By that time, we had already started drafting the study protocol and 24 institutions had committed themselves to enrolling survivors into the study. Now, in January 2019, 34 sites are involved.

During the first 18 months of the study (since September 2017), the main tasks have been completing the study protocol, pilot testing questionnaires, translating questionnaires into the languages required by the considerable range of countries involved in the study, and working with Bernhard Holzner and his team to create CHES instances in English and German. Questionnaire translations into Slovenian, Greek, Italian, French, German, Dutch, Norwegian, Portuguese and Arabic are largely complete, and five other languages are still in the earlier phases of the process. The many collaborators (and their colleagues) involved in this important, necessary process deserve a special thank you; your time and effort are very much appreciated. From the translations necessary for the Late Tox Project, the EORTC has benefitted directly by now having official Slovenian and Arabic (Arabic is not quite complete) translations for the EORTC-QLQ-OH15. Thank you to Dagmara Kulis for coordinating the process for these two translations and organizing the final proofreading so that the EORTC recognizes them!



Cancer Clinical Trials Pooling of Quality Life Data (CATAPULT) initiative

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To date, most collaborators are still involved with the at-times complicated process of obtaining ethical approval. However, two German sites and the collaborators in Oslo have started to enrol survivors. As of the end of January 2019, data for 56 survivors have arrived at the coordinating centre in Mainz, Germany, and as more sites obtain their approval in next few months, enrolment will rise considerably.

That the project has benefitted from close collaboration between QoL experts and clinical experts is indisputable, but the benefits come with the drawbacks of the logistics of trying to coordinate two groups, each of which have two (usually separate) meetings a year. At the start of the project, it was decided that the location of the "official" Late Tox Project meeting would alternate between being held at the QoL Group Meeting and the Head and Neck Group Meeting, although the project is presented at each of the four meetings a year. In reality though, some collaborators only attend Head and Neck meetings, some only attend QoL meetings (both of which are understandable), and some do manage to attend both. The upshot is that face-to-face meetings never involve a majority of collaborators, making email and telephone communications all the more important when decisions need to be made. For the main PI and study coordinator, it means twice as much travel every year.

This challenge is more than compensated for by the advantage of the involvement of a more pointed clinical perspective right from the inception of the study idea. In addition, a happy side effect of the consistent contact with the Head and Neck Group has been the development of friendships and other professional opportunities that likely would not have otherwise occurred. Regular attendance at Head and Neck meetings has also provided an opportunity to continually learn about the on-going clinical studies within the group, and opportunities where QoL could be added as an additional endpoint have been noted. As is the case with group meetings, the discussions that happen outside the official program are often just as important, and ideas for new projects between the QoL Group and the HNC Group are under discussion.

2019 will be an important year for the Late Tox Project, and we expect to be able to report on considerable enrolment in the project at the Fall meetings of the QoL Group in Naples and the Head and Neck Group (location not yet determined). For more information about the project, feel free to contact Kathy Taylor, the study coordinator, at kataylor@uni-mainz.de.

Patient-centered care is a critical component in quality health care; and patient-reported health-related quality of life (HRQoL) is one of the best ways to capture patient-centeredness. The utility of patient perspective and HRQoL can enable the investigation of significant but neglected topics relating to HRQoL in various areas of clinical cancer trials research. To respond to this need, the EORTC spearheaded the Patient-Reported Outcomes and Behavioral Evidence (PROBE) initiative. PROBE combined HRQoL data from over 17,000 individual patients from different cancer randomized clinical trials (RCTs) and disease stages, offering a robust resource to address research questions relating to HRQoL (Bottomley, et al. 2009). Although the insights gained from PROBE have been pivotal in moving the research on HRQoL forward, there are still some remaining issues, which should be addressed. Thus, the CATAPULT project aims to investigate whether;

- baseline or change in HRQoL adds prognostic value beyond clinical measures and therefore improve prognostic accuracy in cancer RCTs
- HRQoL domains form three factors (physical, psychological and gastrointestinal) which are interrelated
- the different HRQoL domains form one factor and yield a single, valid summary score

Furthermore, one major limitation of PROBE was that the majority of the data were mainly from the EORTC and the Canadian Cancer Trials Group (CCTG) closed clinical trials, and were limited to specific disease sites. Therefore, the CATAPULT project presents an opportunity to: (a) include data from other institutions and different cancer sites (b) validate the findings from PROBE to make results more generalizable and (c) address new arising questions that were not addressed in PROBE. The CATAPULT project will build on PROBE, which has been proven to be scientifically fruitful in providing a greater understanding of psychosocial issues in improvement of care, services and practice.

Findings from CATAPULT will help to promote a better understanding of HRQoL of cancer patients in RCTs, which will be helpful for educating clinicians, healthcare providers and policy makers.

The kick-off meeting for CATAPULT took place in September 2018, during the QLG meeting in Croatia. The project is currently in the data collection phase. The basis of the dataset will be formed by the already established PROBE dataset, which will be updated with recently closed EORTC trials. In addition, external data sources such as Canadian Cancer Trials Group (CCTG), Project Data Sphere, Mayo Clinic USA, Cancer Research UK, and key pharmaceutical companies such as AbbVie, Bristol-Myers Squibb, Merck, and Pfizer will be solicited to provide additional data. Please do not hesitate to contact us in case you wish to collaborate in this project by sharing data.



Improving Health-Related Quality of Life in Metastatic Breast Cancer

Taking stock of achievements and delivering better measurement?

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Fatima Cardoso, Champalimaud Clinical Centre Lisbon, Portugal (BCG)

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Andrew Bottomley, Assistant Director, EORTC, and Head of Quality of Life Department, Brussels, Belgium

Significant progress has been made in the management of Metastatic/Advanced Breast Cancer (MBC/ABC), and an increasing number of patients live with their disease for years rather than months [1]. MBC is very different to early breast cancer, not only biologically and clinically, but also in the wider psychosocial impact it can have on patients and their families. MBC is an incurable albeit treatable disease which can affect multiple organs and requires continuous therapy, resulting in a wide range of physical symptoms and psychological burden. To address these unique experiences, and the urgent need for specific quality of life evaluation tools, we aim to develop a disease-specific questionnaire for assessing Health Related Quality of Life (HRQOL) in this patient group.

The project is led by Professor Galina Velikova from EORTC Quality of Life group at the Patient Centred Outcomes Research group, University of Leeds, UK and Dr Fatima Cardoso from the EORTC – Breast Group, at the Champalimaud Clinical Centre, Lisbon, Portugal and builds upon the EORTC-BR23 module update. The development of the MBC questionnaire provides an ideal opportunity for collaboration across the EORTC. Members of both the Quality of Life (QLG) and Breast Cancer Groups (BCG) have been invited to work together on the project, with the aim of combining the methodological and clinical expertise of members. The project remains in its early stages, but has already received a high level of interest from both groups with over 50 sites from 14 countries expressing an interest in participating. We are currently in the process of selecting centres for Phase I.

Working within the framework of EORTC QLQ module development guidelines, relevant HRQOL issues will be generated by systematically reviewing the literature and conducting semi-structured interviews with patients and healthcare professionals from centres across Europe and the rest of the world. A comprehensive search of bibliographic databases, such as PubMed and PsycINFO, is currently being conducted to identify relevant physical and psychosocial HRQOL issues for MBC patients. A purposive sample of patients and healthcare professionals will take part in semi-structured interviews, in which the list of issues generated from the review will be assessed for its relevance and breadth of coverage. We aim to have the issues prepared for review at EGAM in March and will continue to follow the development guidelines as the project progresses into Phase II and III.

For additional information about the MBC module development project or if you are interested in collaborating, please contact either Galina Velikova (g.velikova@leeds.ac.uk) or Christopher Bedding (umcmb@leeds.ac.uk).

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Establishing thresholds for clinical importance for the EORTC QLQ-C30 and EORTC CAT measures

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Results from patient-reported outcome (PROs) instruments are often challenging to interpret for health professionals and researchers that are not familiar with instruments such as the EORTC QLQ-C30 questionnaire. To foster the use of the QLQ-C30 and to improve interpretability, in particular regarding its use in daily clinical practice, we have conducted a research project developing thresholds for clinical importance (TCIs) for the individual QLQ-C30 scales. TCIs will allow use of the QLQ-C30 for symptom screening as well as for calculating prevalence rates for symptoms and functional impairments in clinical studies.

In the first part of the project, a mixed method study [1] including 150 cancer patients and health professionals from six countries, we have identified a variety of individual aspects of clinical importance that were discussed in a consensus session at a biannual Quality Life Group Meeting to define criteria for establishing TCIs. This comprehensive process for developing the criteria underlying the thresholds allowed us to include the perspectives of cancer patients with mixed diagnoses and treatment types and of health professionals with different professional backgrounds (e.g. oncologists, nurses, surgeons, psycho-oncologists). This process distinguishes the current project from previous studies that used criteria defined a priori by experts. The final criteria defined for establishing TCIs in the second part of the project were: the patient's need for help or care, limitations of daily

life, and worries about a symptom or problem by the patient, his/her partner or her/his family.

In the second part of the project, we collected data from 500 cancer patients in six countries and established the TCIs for the QLQ-C30 scales and for the recently released EORTC CAT measures. We found that the QLQ-C30 scales provide high diagnostic accuracy in identifying clinically important symptoms and functional impairments. In addition, we found that the established thresholds are consistent with those from a pilot study on four QLQ-C30 scales [2], although external criteria in that study were somewhat different. This indicates a fair degree of robustness of the TCIs with regard to variations in the underlying external criteria.

Future research should investigate how the methodology developed in this project can be applied to symptoms and health issues covered, not by the QLQ-C30 and the EORTC CAT measures, but by the various EORTC modules and the EORTC Item Library (www.eortc.org/itemlibrary/). Furthermore, it will be of interest to investigate how the TCIs relate to clinicians' gradings of adverse events.

I would like to thank all patients and health professionals who participated in this study as well as the study collaborators (Neil Aaronson, Juan Arraras, Giovanni Caocci, Fabio Efficace, Mogens Grønvold, Bernhard Holzner, Jacobien Kieffer, Marieke

van Leeuwen, Morten Petersen, John Ramage, Krzysztof Tomaszewski and Teresa Young). Sincere thanks also go to the EORTC Quality of Life Group for funding this project (grant number #008 2014).

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“We have conducted a research project developing thresholds for clinical importance (TCIs) for the individual QLQ-C30 scale”

Global perspective



CURRENT STATUS OF QOL RESEARCH IN JAPAN AND FUTURE PERSPECTIVE

Mitsumi Terada, MD, EORTC, Brussels, Belgium
Naomi Kiyota, MD, PhD; Kobe University Hospital Cancer Center, Japan

It is our great pleasure to have an opportunity to introduce our perspective on Quality of Life (QoL) and Patient Reported Outcome (PRO) research in Japan.

Approximately three decades ago, the Japan Clinical Oncology Group (JCOG), one of the largest multi-institutional cancer clinical trial groups in Japan, started QoL assessment in their trials. However, the quality of QoL data collection from 1990s to 2000s was poor due to a lot of missing data and low completion rate. Furthermore, there were concerns for QoL research such as the burden for patients, investigators and data center staff and uncertainty with regard to interpretation of QoL data. Despite a long struggle for implementation of QoL assessment in JCOG cancer clinical trials, QoL research in cancer patients and not prevail in Japan. As a result, an organized nationwide platform for QoL research was not established in Japan.

However, even after going through difficult times, some Japanese investigators did not

lost their enthusiasm for QoL research. They started attending the EORTC QLG meetings and working together through new module development, updates of existing modules (e.g. QLQ-H&N43, THY34, and STO22), a project to implement ePRO (CHES). In the meantime, EORTC and JCOG have strengthened the scientific ties since 2015 and started conducting collaborative studies and projects. As one of



such collaborations between EORTC and JCOG, the first ever PRO/QoL workshop took place at National Cancer Center Hospital, Tokyo, Japan in September 2018. From EORTC QLG, Francesca Martinelli, Madeline Pe, and Galina Velikova were invited as guest speakers. Many stakeholders on cancer research such as JCOG investigators, physicians, research nurses, patient advocates and pharma industry took part in the workshop. We deepened mutual understanding from each perspective, shared issues about QoL data management and interpretation, and discussed the way of getting over them and future collaborations between the EORTC QLG and Japanese QoL researchers. After this successful workshop, JCOG has decided to found the PRO/QoL ad-hoc committee that aims to establish efficient platform for PRO/QoL research in Japan and encourage sustainable cooperation with the EORTC QLG.

Finally, the door to new era of appreciation for PRO/QoL research is opened by your sincere support. We are really looking forward to more cooperative studies and projects with you, which will contribute to improvement of cancer care.

HOW'S THE QUALITY OF LIFE IN AUSTRALIA?

Imogen Ramsey, Marion Eckert, Nadia Corsini and Greg Sharplin, on behalf of the Rosemary Bryant AO Research Centre, University of South Australia

Health-related quality of life is an emerging research area in Australia. While exciting and innovative work is occurring in many places, patient-reported outcomes are not yet embedded in routine measurement at a regional, jurisdictional or national level. One of the barriers to enacting a coordinated approach to collecting PROMs across our eight states and territories is the lack of a robust digital health system. The shift to electronic health records as part of Australia's

National Digital Health Strategy for 2018-2022 is still in the early stages of implementation. There is also no normative data for the QLQ-C30 available for the Australian population.

The Australian organisations most frequently engaged in the development and implementation of PROMs are academic institutions and research centers in collaboration with clinicians (e.g. Psycho-Oncology Co-operative Research Group, University of Sydney) and university-based clinical registries. Several well-established groups provide leadership in this field with a focus on benchmarking. For example, the Australian Commission for Safety and Quality in Healthcare is developing a national work program to support the consistent and routine use of PROMs to drive quality improvement. Meanwhile, other peak government bodies including Cancer Australia and the Medical Research Future Fund have incorporated elements of HRQOL reporting into their new strategic plans.

Using patient-reported outcome data to inform and improve health services in Australia is one of the key goals of the Rosemary Bryant AO Research Centre, which is a partnership between the Australian Nursing and Midwifery Federation and the University of South Australia. We really value the opportunity to be involved in the work of the



QLG and are currently recruiting colorectal, lung, melanoma and prostate cancer patients for the development of the EORTC generic cancer survivorship questionnaire. We are also working with the Royal Australasian College of Surgeons to pilot a PROMs module as part of their Breast Surgeons of Australian and New Zealand Quality Audit.

We sincerely appreciate the warm and welcoming reception we have received from the QLG and look forward to our ongoing involvement in its research activities!

PAVING A FUTURE

Manas Chakrabarti, Columbia Asia Hospital, Kolkata, India

Hello everyone! Writing for the newsletter has given me a unique opportunity and I am truly thankful for that. The opportunity to look back at what we have been doing in this part of India. When I took an obsessive sabbatical to come to India to develop evidence based gynae-oncology and QOL in cancer care, after more than a decade of training in England, the start was cold and lonely in this tropical country of 1.2 billion. Then quite slowly but steadily several QOL enthusiasts flocked together. Ranging from professors to medical



students and from a cancer surviving tea-kiosk owner to a newspaper journalist who experienced cancer in their family. It appeared they all were striving for provision of QOL for own life or others. Yet, it is not a very formal approach here.

Decades since the independence, India got bogged down firefighting basic problems. We nearly forgot to look at the headlines of care. Literacy was more important than lymphoedema. But, a modern India has emerged now and poised to overtake US economy by 2030. Young India has become QOL aware.

That is why, when we took part in EORTC Quality of Life cancer survivorship questionnaire study as one of the 20 countries, it was in the headlines of newspapers with cumulative readership of more than 10 million.

This study was far beyond of being just a study. For us, the start of a new beginning. The concept of QOL is no less than a social revolution. There is scope for significant improvements in India in spreading the values and ethos of EORTC-QLG in sync with the aspirations of modern Indian population. We already have started 5 pilot projects. Being the first active EORTC QLG member working in this subcontinent I am ambitious that one day QLG will spread the wings further beyond geographical boundaries. I am looking forward to joining more collaborations and meaningful projects that can transform QOL of survivors in this part of the world.



The future of cancer therapy



SAVE THE DATE

5th EORTC Quality of Life

Cancer Clinical Trials Conference
16 & 17 May 2019, Brussels, Belgium



WE ARE PLEASED TO INFORM YOU THAT THE 5TH EORTC QUALITY OF LIFE CANCER CLINICAL TRIALS CONFERENCE HAS BEEN ACCREDITED BY THE EUROPEAN ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION (EACCME) FOR A MAXIMUM 9 EUROPEAN CME CREDITS.

Practical Information

Registrations

Open until 2nd May 2019

Key Dates

Early Registration from 3.12.2018 to 3.04.2019

Late Registration from 4.04.2019 to 2.05.2019

Venue

Crowne Plaza, Le Palace
Rue Gineste 3,
1210 Brussels, Belgium

Dear Colleagues,

It is our pleasure to invite you to the 5th EORTC Quality of Life in Cancer Clinical Trials Conference which will be held in 2019. This event will give participants the opportunity to learn about the latest topics in quality of life (QOL) and patient reported outcomes research. The two-day conference aims to bring together over 30 of the world's most influential QOL researchers. There will be presentations on current state of the art methods for instrument development and QOL measurement in international cancer clinical trials, addressing a variety of topics from designing robust measures to understanding their clinical meaning. Discussions will be held on new tools and emerging technologies that have the potential to change the way we measure QOL, as well as on the rapidly growing field of electronic questionnaire administration.

This event is meant to stimulate progress and ensure greater patient involvement in cancer clinical trials, hence, patients and patient advocates will be speaking and providing their unique vision on QOL. All academic attendees will be able to participate for free.

Finally, we would like to thank our sponsors, including the EORTC Quality of Life Group, for supporting this conference.

We are looking forward to welcoming you to our conference and participating in an engaging exchange of ideas.

Dr. Andrew Bottomley (Conference Chair), and Drs. Jaap Reijnen, Michael Koller, Henning Flechtner, Krzysztof Tomaszewski and Eva Greimel (Conference Co-Chairs)

EORTC QLG Meeting Opatija, September 2018





From the City of Lights to the Seaside Home of the Maiden with the Seagull

Christopher Courtois, Quality of Life Department, EORTC, Brussels, Belgium

2018 gave us, once again, beautiful destinations for our Group Meetings that offered the members everything from culture and refinement to a seafront and sunburns.

Anne Brédart and Sophie Parnalland organized the Spring Meeting in the beautiful "City of lights", Paris, which provided a very inspiring setting for our gathering.

Traditionally, the meeting opened with a few words from the Chair, Fabio Efficace and the Head of the QoL Department, Andrew Bottomley, before kicking off the parallel sessions where all members could sit down and talk about ongoing and new projects. As always, these sessions provided a great platform for all members to push ideas and find common ground and shared interests. The QoL Department participated in many of these sessions in order to see where we could offer support. It is always a pleasure for us to meet new members and to reconnect with the EC and other members. After a full day of sessions, everyone was happy to tour around the beautiful, sunny Paris on open-air buses and to do a bit of sightseeing. We then enjoyed a lovely meal in a traditional restaurant "Brasserie Mallard", before heading back out and seeing Paris by night. Our last day in Paris was filled with

plenary sessions and a business meeting. We said goodbye to Paris and closed the meeting with a lovely laid-back dinner in "L'Auberge du Moulin Vert", where we once again enjoyed the famous Parisian food and wine.

For the Autumn Meeting, Karin Kuljanic and Duska Petranovic brought us to Opatija, a coastal town on the Adriatic Sea and a well-known 19th century health resort in Croatia.

The meeting was kicked off with workshops that provided a smaller platform for members to dig deeper into certain projects and participate in hands-on activities under the guidance of fellow group members. Our first full day was, as per tradition, opened by the Chair of the Group and the Head of the QoL Department, followed by parallel sessions. Our social event of the evening was an amazing dinner topped off with a world-class live performance from the QLG superstar Karin, offering members a very classy yet relaxed opportunity to dance and sing. All of us left the venue totally exhausted after hours of dancing to the live band music and looking forward to getting some rest before the final day of plenary sessions. Some members used their free time before the final evening event to work on their suntans (or burns), go kayaking, and get a few free diving lessons in the beautiful azure sea.



Karin and Duska went above and beyond to offer us an extra day of Istrian activities after the meeting ended, which involved a visit to a place of inspiration for Jules Verne novels, a boat ride and visit of the beautiful Brijuni National Park, and a real Croatian feast at an olive grove. The magical day ended with locally made refreshments in Hum, the charmingly quaint smallest town in the world!

I think we can all agree that this year was a great success, as much for the organisers as it was for the attendees. People came from all over the world to join our meetings and were welcomed as long-time friends and colleagues. As always, it was a pleasure seeing you and we look forward to working with you all in the near future as well as welcoming you to Brussels for EGAM and a taste of the Belgian local specialties!!



EORTC QLG Autumn Meeting 2019 Naples, September 26-27, 2019

Monica Pinto, Istituto Nazionale Tumori IRCCS "Fondazione G. Pascale", Naples, Italy

It's a great pleasure for me to invite you all to Naples for the 2019 EORTC Quality of Life Group (QLG) Autumn meeting. The meeting dates are September 26-27, 2019 at the Royal Continental Hotel, one of the nicest seafront congress hotels in the centre of the magnificent Bay of Naples.

Naples is the largest city in Southern Italy, it is rich in history, art, architecture, unforgettable songs, glorious food, and unexpected panoramas. The legend says that the ancient Greek city of Naples was built on the land where the siren Parthenope landed. During the last 3000 years of its history from the Romans to the 21st century it never lost its spirit as cultural and artistic capital of Southern Italy.

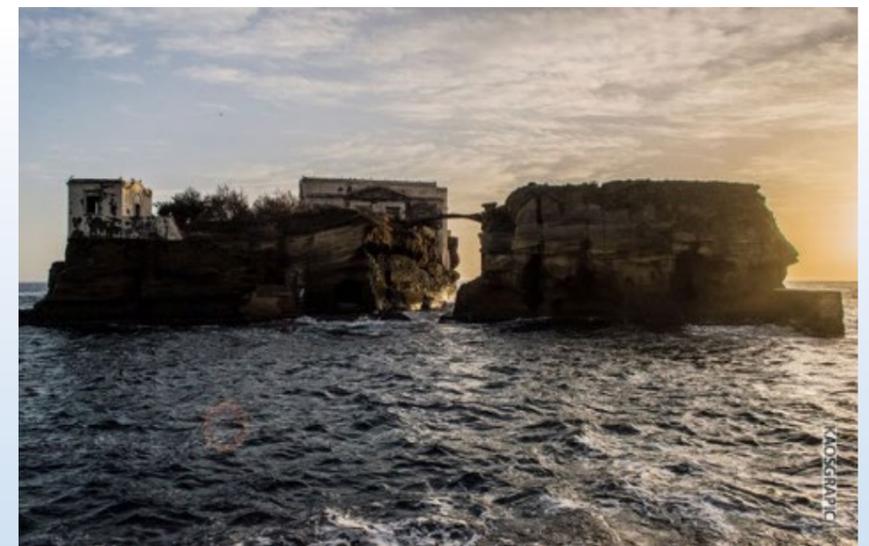
On Thursday evening we will visit the city centre and in particular the Sansevero Chapel, with the famous Veiled Christ. The Chapel is one of the most mysterious and timeless places in Naples. After this tour we will enjoy a typical Neapolitan pizza. On Friday evening we will visit the Roman Villa of Publio Vedio Pollione, built in the 1st century B.C., followed by a dinner in the panoramic restaurant "Le Arcate" where you will taste great food and have a wonderful view!

If you extend your stay to enjoy a Neapolitan weekend, there are plenty of places to visit. Naples has 2 royal palaces, 3 castles, and the ancient ruins of Ercolano and Pompei towns. Not to mention the Neapolitan streets and courtyards which are dotted with art craft shops and nice boutiques, selling everything from high fashion dresses and impeccable suits, shirts and ties to the characteristic pastori (nativity-scene figurines), to rare Neapolitan lithographs and gourmet local food and wine.

Naples is relatively compact and easy to be explored on foot. Buses, funiculari and metros

run all over the city. It is easily accessible by plane and train. The Naples International Airport of Capodichino is located 7 km northeast of the city centre and it serves many domestic and European flights.

Looking forward to meeting you all in Naples!



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As part of the EORTC Fellowship Program, we are currently recruiting two QOL research fellows

Learn about patient-reported outcomes and quality of life in cancer clinical studies
by participating in the activities of the Quality of Life department
and being immersed in the activities of an international academic research organization.

More information at: <https://www.eortc.org/education-training/fellowship/>