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

Reaching new horizons

Anne-Sophie Darlington - Newsletter Editor
Chair of the EORTC Quality of Life Group, School of Health Sciences, University of Southampton, UK

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Content

Reaching new horizons 1
A few words from the outgoing and incoming chairs 3
News from the EORTC Quality of Life Department 4
Clinical validation of the EORTC CAT Core 5
Determination of European Utility Weights for the EORTC QLU-C18D 6
Qualitative research to explore the content validity of the EORTC QLQ-C30 7
Development of a health-related quality of life module, EORTC QLQ-ANL27 8
Update on the Item Library 9
European norm data study now published in European Journal of Cancer 10
Revision of the EORTC QLQ-BN20 brain tumour module 11
Development of an EORTC module assessing fertility issues and patient care needs (Phase 1-3) 12
New horizons in working closely together with disease-oriented groups - The Late Toe Project 14
Cancer Clinical Trials Pooling of Quality Life Data (CATAPULT) initiative 15
Improving Health-Related Quality of Life in Metastatic Breast Cancer 16
Establishing thresholds for clinical importance for the EORTC QLQ-C30 and EORTC CAT measures 17
Global perspective 18
Events: Save the date 20
Paris & Croatia; From the City of Lights to the Seaside Home of the Maiden with the Seagull 21
EORTC QLG Autumn Meeting 2019 - Naples, September 26-27, 2019 22
NEWS 23

A few words from the outgoing and incoming chairs

Anne-Sophie Darlington, Chair of the EORTC Quality of Life Group, School of Health Sciences, University of Southampton, UK

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 it 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 streamline processes to make things easier and more efficient.

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 high-quality processes, clearly aligned with the highest quality processes, processes, and best practices. And this is entirely 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 it 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 year. The current Executive Committee with two new members – a warm welcome to Olga Husson and Anne Lanceley - 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 organizing 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, organizing contracts with universities, organizing our meetings in convenient locations, and accommodating our growing number of projects, particularly together with the different disease-oriented groups.

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.

Quality of Life Group Executive Committee

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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 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-MM10) modules still being the most used. Commercial and academic interest in the Item Library has continued to grow, with over 170 access requests in 2018. You can read more about it on page 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 Méridine Cheron 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, Madelaine Pe was the lead author on a Lancet Oncology review of QOL in metastatic breast cancer with the SISADOL group, and the SISADOL Consortium members also authored a paper on setting standards on clinical trials analysis in Clinical Trials. Jambimbe Musoro published a paper on interpreting QLQ-C30 scores in an adjacent 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 HDRQ database on the QLQ-C30 from published trials, which will be used to investigate critical topics to better understand HDRQ 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 Oncology Group and other academic societies (e.g. the ICDHCL or European Cancer Patients Coalition, SPOR ESMO). The staff also had some noteworthy recognition last year for their scientific work. We would like to congratulate Madelaine Pe for being selected as a finalist for the new investigator award, and Irina Ghislan for being selected as a finalist for the poster presentation award at ISQOL. Jambimbe Musoro had his poster ranked in the top 10% of the poster presentations at IPOR and I was very much honored to receive the 2018 ISQOL Presidents Award One of the key roles of the QLG 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 (registry in process).

Most of these trials use EORTC questionnaires as main tools, except for 2 (2/9=22%) using the Skin Index and EORTC CAT Core included for the EORTC CAT Core in an ongoing study of gynecological cancer survivors (Principle Investigators: Ph.1: Eva Greimel, and Antonio Casado from the GCG) (15/14); and Follow-up of Early and Locally Advanced Breast Cancer Patients (Ph.6: Vesna Bjelic-Radisic, and Fatima Cardoso from the BCG) (16/17).

In summary, the QOL Department is adapting well to the challenges, and an ever growing portfolio of activities is support of the EORTC: HRQOL web-site, QLG QOL website underwent a total overhaul!

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 short form (2).

The EORTC QLG website provides more information on the current use of the EORTC CAT Core and short forms at .

References

News from the EORTC Quality of Life Department

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

Clinical validation of the EORTC CAT Core

Morten Aa. Petersen and Mogens Groenvold
The Research Unit, Department of Palliative Medicine, Risseløgård Hospital and Department of Public Health, University of Copenhagen, Copenhagen, Denmark
Determination of European Utility Weights for the EORTC QLU-C10D
- A Cancer-Specific Preference-Based Quality of Life Measure Derived from the QLC-C30

Georg Kemmler, Medical University of Innsbruck, Innsbruck, Austria

For many readers of the newsletter the words utility weights, preference-based and QL-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 QL-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 was linked to 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 utility, with high QoL are weighted by a high utility, peri-

Determination of utility weights for the QL-C10D – our first EORTC utility project
Main purpose of our project was to determine utility weights for the QL-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 out of two health states A and B – both combinations of the 10 dimensions, some of which are generic, e.g., Physical Functioning or Pain, while others are cancer-specific, like Fatigue or Nausea.

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 QLC-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.

One can thus determine the utility weights for the QLU-C10D in 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 out of two health states A and B – both combinations of the 10 dimensions, some of which are generic, e.g., Physical Functioning or Pain, while others are cancer-specific, like Fatigue or Nausea.

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

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 SIOQOL 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 SIOQOL 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.cocks@adephyseval.com) and Colin Johnson (c.johnson@notre-dame.ac.uk).

References
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Professor Colin Johnson, University Hospital Southampton, UK
Associate Professor Anne-Sophie Darlington, University of Southampton, UK
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Update on the Item Library

Dagmara Kulis, Quality of Life Department, EORTC, Brussels, Belgium
Claire Piccinin, Quality of Life Department, EORTC, Brussels, Belgium

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 178 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 ISPOR 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 Item Library-related topics. 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 Item Library-related topics. Both were well received and the entire conference provided excellent opportunities for networking, discussion, and training.

5. PLATO Trial Personalising anal cancer radiotherapy: eDelivering ACTS, ACT4 and ACTS. Available at: http://medhealth.leeds.ac.uk/vls/4383/ solid_tumours/2210/plato.
European norm data study now published in European Journal of Cancer

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

O n behalf of my wonderful collabora-
tors, 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 text-
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 relevant 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 can now be used globally and facilitate valid intra-
criency 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 interpreta-
tion. 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 establish-
ing the official European Norm for the EORTC CAT Core [2] and generating updated general population norm data for the QLQ-C30 [2] across aforementioned countries. These normative data can now be used globally and facilitate valid intra-
criency as well as inter-country comparisons and score interpretation. Furthermore, the new norm data document and quantify important differences between main and women, across age groups and between countries.

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

References

Co-investigators:

Revision of the EORTC QLQ-BN20 brain tumour module

Linda Dirven, PhD Department of Neurology & Radiation Oncology, Leiden University Medical Center, Leiden, The Netherlands

Marthe C.M. Peeters, PBS Department of Neurology, Leiden University Medical Center, Leiden, The Netherlands

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 clini-
cal 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 vali-
dated 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 for-
mulation of the item) and new treatments have been introduced with different toxicity profiles not covered by the current measure. These observa-
tions 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 met-
astatic brain tumour patients. To do so, we will follow the Quality of Life Group guidelines for updating existing modules, including a litera-
ture 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 com-
plemented 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 medi-
cal 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 system-
atic 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 litera-
ture 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 evalu-
ate 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:
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Development of an EORTC module assessing fertility issues and patient care needs (Phase 1-3)

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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 surviving 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 (Asi et al., 2018) and those being referred timely to fertility preservation counselling were grateful to be seen and given the opportunity to fully investigate the different fertility preservation methods (Usher, Pantor, & Perez, 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’ needs 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, oncology, 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 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 DOGs 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 questionnaires, 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.
New horizons in working closely together with disease-oriented groups - The Late Tox Project

Susanne Singer and Kathy Taylor
Mainz, Germany

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 represents a considerable, unfortu- nate side effect 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 investigat- ing as it is possible some late sequelae may develop initially after treatment and persist for many years, which instruments they had used. Results showed that the majority of the participants (about 50%) had committed themselves to enroll- ling 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 CES 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 project. The many collaborators (and their colleagues) involved in this important, necessary process deserve a spe- cial 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 an official Slovenian and Arabic (Arabic is not quite complete) translations for the EORTC QLQ-HNC. Thank you to Dagana Rula for coordinating the process for these two translations and organizing the final proofreading so that the EORTC recognizes them.

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.

In which the collaborating physicians assess each patient for 3 toxicities. The project also includes a sub-project specifically on the oral health of survi- vors, and for the survivors invited to collaborate 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 from the professional team. The 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 poten- tial collaborators about whether they already attended Head and Neck meetings, and 18 (73%) stated they would like to do so.

As is the case with group meetings, the discus- sions were lively and often just as important, and ideas for new projects and the many challenges that likely would not have otherwise occurred. Regular attendance at Head and Neck meetings has also provided an opportunity to continually look for new and other professional opportunities.

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 spe- cific 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.

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

Jammbe Musoro, Justyna Mierzynska, Mekdes Taye, Madeline Pe and Andrew Bottomley, Quality of Life Department, EORTC, Brussels, Belgium

Hans-Henning Flechtner, Medical Faculty, Otto-von-Guericke-University Magdeburg, Magdeburg, Germany

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 randomised 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 if you have any questions or 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?

Christopher Bedding, Kate Absolom, Galina Velikova, Section of Patient Centred Outcomes Research, University of Leeds, UK
Fatima Cardoso, Champalimaud Clinical Centre Lisbon, Portugal (BCC)
Katarzyna Pogoda, Maria Sklodowska-Curie Institute – Oncology Center, Warsaw, Poland (BCC Liaison)
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 symptoms and psychological burden. To address these unique experiences, and the urgent need for improving HRQOL, the development of the MBC module update. The development of the MBC module update. 

The project is led by Prof. Galina Velikova from EORTC Quality of Life group newsletter and Kate Absolom from Section of Patient Centred Outcomes Research, University of Leeds, UK and Dr Fatima Cardoso from the EORTC, Champalimaud Clinical Centre Lisbon, Portugal. The project is being developed at the Champalimaud Clinical Centre, Lisbon, Portugal and builds upon the EORTC-BR23 Group, at the Champalimaud Clinical Centre, Lisbon, Portugal and the EORTC Quality of Life group at the Patient Centred Outcomes Research, University of Leeds, UK and the EORTC Item Library (www.eortc.org/itemlibrary/). 

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In the first part of the project, a mixed method study [1] including 150 cancer patients and healthcare professionals from six countries, we have identified a variety of aspects of clinical importance that were discussed in a consensus session at a biannual Quality of 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 patients with cancer who consulted the EORTC Item Library for component thresholds for clinical importance (TCIs) in that study. The criteria collected from this study are consistent with those from a pilot study on four QLQ-C30 scales (1), 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/).

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

References
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 EORTC QLG.

Finally, the door to a new era of appreciation for PRO/QOL research is opened by your single-minded commitment! 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 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 straining 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 fighting 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-QLQ 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 pursuing more collaborations and meaningful projects that can transform QOL of survivors in this part of the world.
SAVE THE DATE

5th EORTC Quality of Life
Cancer Clinical Trials Conference
16 & 17 May 2019, 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, patient 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 Reijneveld, Michael Koller, Henning Flechtner, Krzysztof Tomaszewski and Eva Greimel (Conference Co-Chairs)

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

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.
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 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 experience. 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!!

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

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

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!!

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

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

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 were 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 Publico Vedo 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, funicolari 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!
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/