



EORTC QoL Group Meeting, Cyprus, spring 2014

Building planes and teaching how to fly them

Jaap C. Reijneveld – Newsletter Editor

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It is an honour for me to present the 2015 issue of the Newsletter of the European Organisation for Research and Treatment of Cancer (EORTC)'s Quality of Life Group.

This annual newsletter is the ultimate opportunity for people inside and outside the EORTC to get acquainted with the structure and activities of our Group. With that in mind, our new chair, Lonneke van de Poll, will kick off by introducing herself and touching upon a number of strategically important activities of the Group.

Our Group was reviewed by the Scientific Audit Committee (SAC), instituted by the EORTC board, in early 2014. The overall conclusion was very positive, but a SAC wouldn't be a proper SAC if there wasn't room for improvement. One of the observations was that our Group is excellent at building planes, but should invest in teaching people how to fly them. In other words: the Group is one of the worldwide authorities on the development of questionnaires for measuring quality of life, but should liaise more intensively with the disease-oriented groups (DOGs) within the EORTC in order to improve implementation and analysis of quality of life research in future clinical trials.

When I joined the Quality of Life Group back in 2010, I was very warmly welcomed by everyone and found a lot of experience regarding psychometry and questionnaire development, but sometimes missed a platform to discuss the problems encountered when applying these tools in clinical trials and interpreting the outcomes. As a clinician who is also a member of a DOG, I would very much appreciate a platform for such issues within our Group. The plan is to institute a Clinical Project Development Committee (CDC, equivalent to the Module Development Committee (MDC)), and in this issue Eva Greimel will present the initial ideas on that. Furthermore, quality of life liaisons from a few selected DOGs will explain the way it works in their particular group.

This issue will also inform the readers on the progress made regarding the strategic projects of the Group; in a few years from now we will monitor HRQoL in our clinical trials, and during routine clinical practice, through Computer-Assisted Testing (CAT) on the Computer-based Health Evaluation Software (CHES) platform, of course with a special focus on long-term survivors. The coordinators of all these strategic projects will

update you in this issue, and we will also highlight the projects that received funding through the Group in last year's grant round.

The QLQ has always had an excellent track record regarding its own QoL, and this was not different in 2014. Meeting venues were even a bit over the top, as for some reason both the spring and autumn meetings were in Mediterranean countries. Please keep in mind, when reading the reports on those meetings, that they did have a very dense workshop schedule from early in the morning till late in the afternoon. This year's meetings will be in Brussels, where EGAM provides an excellent opportunity to catch up with members of other groups; and in Krakow, and this issue will provide some information on that beautiful Polish city.

Last but not least, I would like to thank Cheryl Whittaker, who has succeeded Sheila Scott Sanderson as the Newsletter's Assistant Editor based at the EORTC Headquarters, for her assistance, and all the contributors for their efforts, including Dirk Hofmeister for his photographs of the meetings. I hope you will enjoy reading this 2015 Newsletter!

Table of Contents

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Editorial	1
Chair's welcome	3
Facts & figures	4
QLG Website: New Members' Area	5
News from the EORTC Quality of Life Department	6
Members' news	7
The importance of liaison (Brain Tumour Group)	8
Collaboration is key (Leukemia Group)	9
Having a heart for patients (Head and Neck Group)	10
Brainstorming from experience	11
The MID Project	12
New kid on the block	13
Developing thresholds for clinical relevance	14
Determination of European utility weights for the QLQ-C30	15
Measuring I-ADL in Patients with Brain Tumours	16
Developing an EORTC cancer survivorship QoL questionnaire	17
CAT Project	18
CHES.EORTC Project	20
Look back: Cyprus QLG Meeting Spring 2014	21
Look back: Venice QLG Meeting Autumn 2014	22
Next QLG Meeting: Come to Krakow in Autumn 2015	23

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Lonneke van de Poll-Franse



Welcome from the new chair

Lonneke van de Poll-Franse, Tilburg University and Netherlands Comprehensive Cancer Organisation

There are numerous reasons why I quickly responded with 'yes' when asked to consider succeeding Mogens Grønvold as chair of the Quality of Life Group (QLG). Although, I have to admit that my predecessor wrote a pretty convincing letter citing all the wonderful aspects of this chairmanship, and that helped too.

An important reason why I find it appealing to now become chair of the QLG is the recent broadening of the research strategy of the EORTC to include cancer survivorship research. As an epidemiologist working in the field of cancer epidemiology and survivorship, I am personally committed to this area of research. I also think that cancer survivorship research will provide a good opportunity to link the success of the QLG more closely to the whole EORTC. With improving survival rates after cancer diagnosis (due to better treatments, but also earlier detection), the importance of maintaining quality of life has received increasing attention in the past decade. But satisfaction with care, communication and information provision have also gained importance for when we want to evaluate quality of care provided to cancer patients and survivors. As our QLG develops instruments to assess all these types of patient-reported outcomes, I see many opportunities to strengthen our collaboration with disease-oriented groups (DOGs) and contribute to the new strategy of the EORTC.

A direct response to the survivorship strategy is the initiative of our group to start the creation of an EORTC survivorship module. With a group of 25 researchers and clinicians we are currently developing this much-needed questionnaire to evaluate the long-term impact of cancer and its treatment on a broad range of patient-reported outcomes. The new survivorship instrument will

increase the EORTC's profile in survivorship research, and will ensure that generic survivorship issues can be measured accurately and with the same EORTC-compatible measure across EORTC trials. Furthermore, we have set up a QLG survivorship coordination committee that collaborates with the EORTC survivorship initiative, coordinates QLG group initiatives in survivorship, and aims to help standardize and improve assessment across EORTC survivorship trials.

Although we have a long-standing collaboration with several clinical groups, we would like to revitalize and intensify our interaction and collaboration with all DOGs. We therefore recently invited all chairs of DOGs to discuss their needs and views in relation to QoL research, and how the QLG can play a greater role in the planning of new clinical trials and increase the 'QoL profile'. It is positive to notice that recently a few members of clinical groups also approached us to become new members of the QLG. Dual memberships of DOGs and the QLG can be very fruitful for strengthening collaboration. The QLG is exploring different ways to support members of all groups to develop clinically relevant inter-group projects. In order to fuel the initiation of these projects, in our 2015 grant application call we have given extra priority to projects aiming to strengthen liaisons between the QLG and the DOGs.

On a more personal note, it is the enthusiastic, inspiring scientific atmosphere with many dear colleagues which is another very important reason for me to be actively involved in the QLG. I first contacted the EORTC QLG in 2007 as I was searching for a disease-specific questionnaire to evaluate symptoms and health-related quality of life (HRQoL) in endometrial cancer survivors. I was invited to join

a meeting and instantly became hooked on the open and friendly, but nevertheless critical, scientific atmosphere. Researchers from different disciplines (medical and nursing backgrounds, psychologists, statisticians, epidemiologists and social scientists), countries (members come from 17 European countries as well as from North and South America, Australia and Asia), and cultures are collaborating with great spirit to develop instruments to measure symptoms and quality of life in cancer patients and survivors. In recent years I have been involved in the development of an endometrial cancer module, hemato-oncological modules, a melanoma module and, as mentioned earlier, more recently the start of a cancer survivorship instrument. It is stimulating to know that many researchers will use these modules to evaluate the impact of new therapies or other promising interventions on quality of life.

I am looking forward to presiding over the QLG, and support and encourage all QLG members as well DOG members to truly create a strong collaboration and ultimately improve the standard of cancer treatment and survivorship care. Although science can be highly competitive, my personal experience is that the best advances are accomplished when people collaborate and share their knowledge and information.

Irma Verdonck de Leeuw



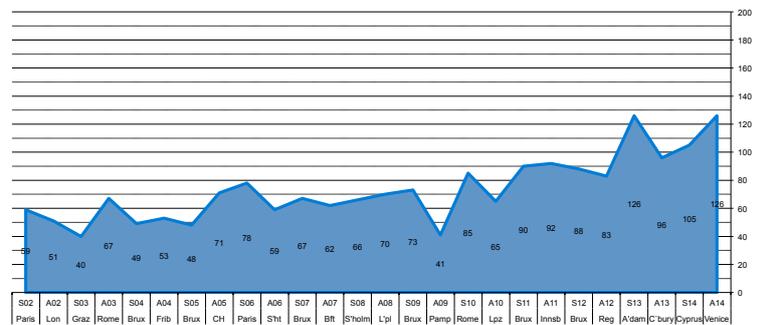
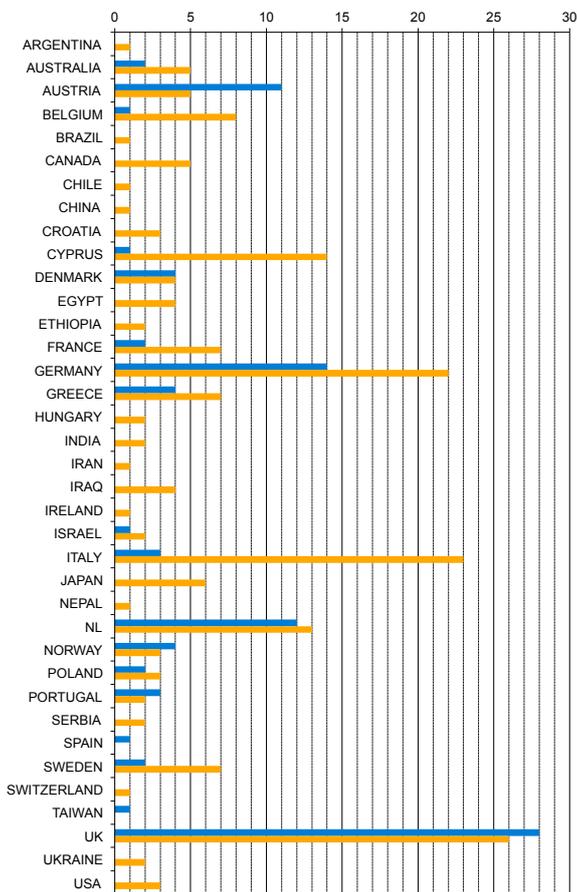
EORTC Quality of Life Group – facts & figures

Irma Verdonck de Leeuw, VU University Medical Center, Amsterdam, The Netherlands

At this moment we have 301 members (174 corresponding, 117 active and 10 from the department) all over the world, as you can see below.

A total of 105 members of the EORTC QLG were present at the spring 2014 meeting in Limassol, Cyprus and 126 at the autumn 2014 meeting in Venice, Italy. You can see the steadily increasing attendance of QLG meetings below.

■ active ■ corres



HOW CAN I BECOME A FULL ACTIVE MEMBER ?

To become a full active member of the EORTC Quality of Life Group, you must attend two meetings (within two years) and be actively involved in research in the Group.

On the third meeting you become an active member.

To maintain active membership you have to continue with research activities and attend two meetings every two years.

If you are not able to attend meetings regularly, you can become a corresponding member.

LEFT TO RIGHT Anne-Sophie Darlington, Mélodie Cherton



Welcome to the intranet: the members' area of the QLG website

Anne-Sophie Darlington, QLG Executive Committee Web Representative, University of Southampton, UK

Mélodie Cherton, Executive Assistant & Web Administrator, Quality of Life Department, EORTC Headquarters, Brussels, Belgium

We are very excited to announce that on 25 April, 2014 the Members' Intranet of the EORTC QLG website was successfully launched.

At the EORTC Quality of Life Group meeting in Cyprus in April 2014, we introduced this new members' area, which aims to provide access to documents and communication opportunities for active members in order to facilitate more collaborative working.

The main features of the website include a forum, document access and meeting registration. Within the forum (see Figure 1), active members now have the opportunity to post comments and engage in running ideas through shared discussions. Building on this open access format, the document section will give access to a host of useful documents to aid project management.

Another feature is online access to forms that active members can use to register for meetings and submit expenses claims (see Figure 2). Having these forms easily available all in one place should help reduce the time it takes to carry out these administrative tasks.

Currently we are also working on a new comprehensive flowchart aimed at guiding collaborators through the process of module development by outlining the requirements in each phase in terms of carrying out the research and reporting back to the Module Development Committee. In addition, in the near future, members will also be able to apply for funding by uploading the relevant documents in this area.

These endeavours are all aimed at reducing email traffic and streamlining procedures to reduce the need to ask questions, especially

in light of the increasing number of members active in the QLG.

After the launch in April 2014, active members were able to register for the site, a process which was monitored by Mélodie. Feedback was welcomed to help improve the functionality of the site. After this, a more intuitive hierarchy was implemented, including general documentation, such as the Group's statutes, access to account details to change passwords or update personal information, and so on.

We continue to welcome feedback in order to keep improving the site – and we encourage you to visit and use the area. Please also feel free to send us feedback on the general EORTC Quality of Life Group website, and do not hesitate to contact us with any news you would like to see posted on the site.

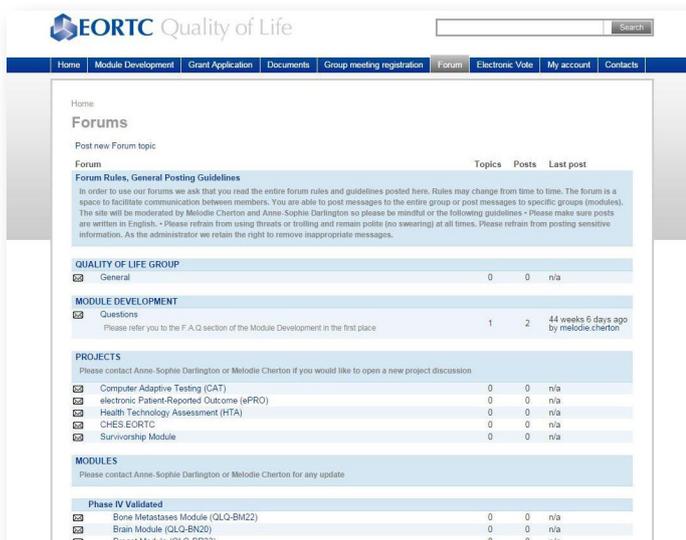


Fig. 1

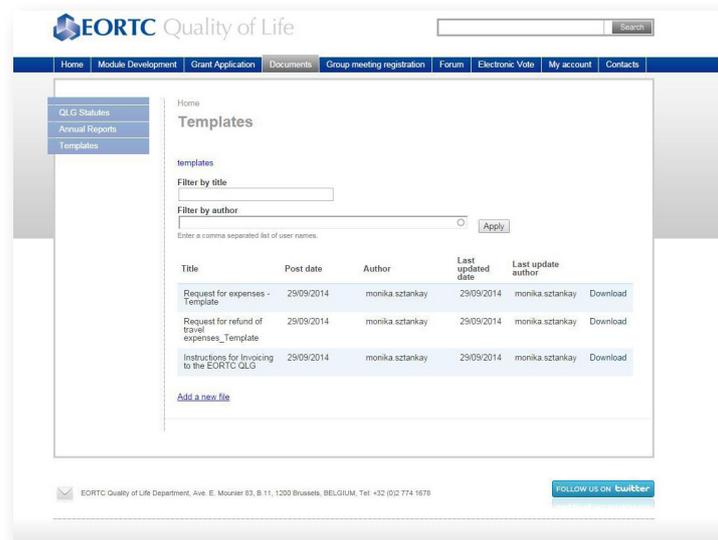


Fig. 2

Andrew Bottomley



News from the EORTC Quality of Life Department

Andrew Bottomley, Head of Quality of Life Department, EORTC Headquarters, Brussels, Belgium

2014 was a busy year for the Quality of Life Department (QLD). We started less clinical trials with quality of life (QoL) in the protocols, but managed to publish a number, in collaboration with several clinical groups such as the Brain Tumor Group and the Head and Neck Cancer Group. We have an active ongoing methodology program, looking at prognostic factor analysis and also a small number of systematic reviews looking at the impact of QoL data. In total, 2014 saw around 16 papers authored or co-authored by department staff. We often work with the QLG and have provided comments on regulatory or policy documents, for example from the European Medicines Agency (EMA), or reviews of PRO. Over 14 abstracts were presented at ASCO, ISOQOL and other meetings.

The PROBE project funding is limited due to the coming to an end of several years' grants and this year saw the end of Divine Ediebah's three-year fellowship under the Belgium Cancer Foundation, and his move in spring to work in industry. We were sorry to see him go but the good news is that we keep on working with Divine, as he is still working towards his PhD in collaboration with the VU University Medical Center in Amsterdam, The Netherlands. We were also able to secure a grant for three years to look at clinical significance of QoL scores, and hope to recruit a new researcher for three more years in 2015.

The Data Repository Project has gone well and much of the QoL data is uploaded. We are making rules for the use of the data and harmonizing that with EORTC policies. The EORTC QLG website was updated for a final time, now with an all-new membership area. It was Anne-Sophie Darlington and Mélodie Cherton who led this, so please make sure you use it and do

keep us informed of your publications before you publish. We can then make these available for members on the website.

The Translation Team, led by Dagmara Kuliś, has experienced their workload expanding, with both the usual translation projects and new ones, for example the new translation guidelines. Over 55 new translations were developed in 2014. The new business model has simplified the administrative process, and it ensures high-quality translations, as a benefit generating income for the QLG to cover costs of quality assurance and translations of newly developed modules. To keep integrating the department with other departments within the EORTC, training has been offered to project and data managers, as well as all new staff at the HQ, who undergo an introduction to, and are provided with a dossier on, QoL.

The number of academic users of and demands for use of the tools increase each year, dealt with by Mélodie Cherton. Julie Walker dealt with a huge increase in demand of user agreements from commercial companies up to the end of 2014, to well over 100, putting us in an excellent financial situation and making us a key partner with pharma across the globe. However, changes are afoot: with the EORTC having a more advanced financial and contracting department than the QLD, some of the finance roles will move there, although Julie's post will still manage the bulk of the requests and questions. It is a pity that after four years' service to the HQ Julie has had to return to the UK, and that is truly our loss, but we wish her all the best in her new role. In addition, the newsletter may have a different feel to it this year, as Sheila Scott Sanderson steps back and takes her first step into retirement. She hands the task over to Cheryl

Whittaker to work as Assistant Editor to Jaap Reijneveld, the QLG member responsible for editing the Newsletter.

With the QLG we were involved in the EORTC Scientific Audit Committee (SAC) review, and we received positive comments about our collaboration with the QLG. It was noted that this had improved over the last few years, and that we are among the most scientifically productive departments, producing papers with EORTC clinical groups, obtaining independent research grants, and fostering research outside the EORTC, as research in QoL is now truly global. We are currently looking at reviewing the old "liaison" model of support we use and working with the QLG to see if we can make this more efficient and support clinical groups better. A new committee, the Clinical Project Development Committee (CDC), will be set up to foster projects and collaboration between the Quality of Life Group and disease-oriented groups with the support of the Quality of Life Department.

I'd like to take this opportunity to give special thanks to Professor Meunier, EORTC Director General, who after 24 years of dedicated leadership of EORTC's pan-European cancer research will move on as Director of Special Projects at the EORTC, beginning in April 2015. Professor Meunier, who had the vision back in 1993 that quality of life would be a key factor in the success of the EORTC, was pivotal in setting up the EORTC QLD. But was she right to create such a department in 1993? Well, without her vision, spirit and foresight, patients' views would not have been so well understood. Indeed, since the QLD was created by Professor Meunier in 1993, we have published over 250 papers, had grants of over 2.5 million euros, performed studies to create

QoL measures in 30 different disease sites such as lung, breast, and head and neck cancer, and involved over 15,000 patients in over 120 clinical trials. Another 8,000 patients have helped develop our measures, which are now the most used in the world. We have even trained doctoral students, who have gone on to have brilliant careers as high-flying academics.

So was Professor Meunier's idea to create the department a good one for patients, or not? I have to say that it was brilliant: she predicted the future before others managed to. For that, both patients and I myself have to thank her. Now we look to the future, on secure foundations and with a vast network and reputation built up over these 20 years.

We expect a lot of changes and challenges in 2015 with this end of an era, but it also means we get to welcome the newly promoted EORTC Director General, Doctor Denis Lacombe.



LEFT TO RIGHT: Doctor Denis Lacombe, Professor Françoise Meunier

Members' news

- **Deborah Fitzsimmons** was awarded a personal chair (Professor in Health Outcomes Research) at Swansea University in October 2014. It has been largely based on Deborah's working in collaboration with colleagues and friends in the QLG and QLD since, in her own words, "starting out as a very novice research nurse" who joined the QLG in 1996 in order to co-ordinate the pancreatic cancer module development. Deborah says: "I feel privileged to be one of many others whose careers have been supported so well by the QLG. There are many to thank for their support and good advice over the years but a special thank you must go to Colin Johnson who has been a fantastic mentor throughout. Dioch yn fawl!"

- In recognition of his contributions to the assessment and treatment of acute pancreatitis, and clinical research in pancreatic cancer, together with his programme of work with the QLG, **Colin Johnson** was appointed Professor of Surgical Sciences in the summer of 2014. This coincided with his Presidency of the European Pancreatic Club, with 650 delegates attending the annual EPC meeting in Southampton. Colin was Chair of the QLG Module Development Committee from 2006–2012 and is currently collaborating on a module for anal cancer and on the development of "symptom-based" questionnaires.

- In October 2014, **Andrew Bottomley** became a Fellow of the British Psychological Society.

- If, as a QLG member, you have some **news to share with the QLG**, we want to hear from you! Send an email to Cheryl: cheryl.whittaker@eortc.be

Erratum

With apologies to Sally Wheelwright of the University of Southampton, whose surname was misprinted as 'Wainwright' (p.10, winter 2014 edition).

Jaap C. Reijneveld



The importance of liaison: how the Brain Tumor Group has benefited from increased cooperation

Jaap C. Reijneveld, VU University Medical Center, Amsterdam, The Netherlands

Over the last few decades, the Brain Tumor Group of the EORTC has been successful in improving treatment not only for patients with primary, but also for patients with metastatic, brain tumours. In a number of large multi-centre randomized controlled trials, the group has demonstrated the value of, for example, addition of chemotherapy to post-operative irradiation for glioblastoma and anaplastic oligodendroglioma patients, which has had practice-changing impact.

Relatively early, the Brain Tumor Group realized that for patients with brain cancer, maintaining quality of life throughout the disease course is crucial. Particularly as cure for most patients is not an option, it is even more important that treatment regimens with only limited impact on survival time do not interfere dramatically with patients' perceived quality of life. Therefore, measurement of quality of life through both the EORTC QLQ-C30 and the QLQ-BN20 was introduced in the larger Brain Tumor Group trials before this was state-of-the art in many other EORTC disease-oriented groups. Furthermore, the position of Quality of Life Liaison Officer was introduced within the Steering Committee of the Group, in order to guarantee a strong link between both Brain Tumor and Quality of Life Groups and the Quality of Life Department (QLD) at the EORTC Headquarters.

Since then, the goal of this liaison has always been two-fold. First of all, this Liaison Officer, who should be a clinician from an actively recruiting centre within the Brain Tumor Group, coordinates the implementation of QoL measurement in the clinical trial protocols and monitors the collection of QoL data throughout the trial, obviously in close collaboration with the EORTC QLD. The second goal is to introduce new tools and insights from the QoL experts in the EORTC Quality of Life Group and the Department to the Brain Tumor Group, and vice versa. Collection and interpretation of QoL data from brain tumour trials has been shown to be rather complicated. No different from other cancer subgroups, compliance rates tend to drop during the follow-up in these trials, and we have other issues, such as response shift and the impact of cultural differences, in common as well.

One thing, however, is very different: the fact that these patients per definition suffer from a disease of the organ which is required to understand and report one's situation complicates things very much. Patients' perception of their own quality of life might therefore be hampered. Not infrequently, a brain tumour patient reports a very satisfactory quality of life to me during a visit at the neuro-oncology outpatients' clinic, while the face of the patient's partner tells a completely different story. The impaired cognition

of patients also influences their ability to fill in the questionnaires.

For this reason, the search for better (patient-reported) outcome measures is constantly ongoing. Proxy-reported outcomes might be a means to obtain more objective information on patients' QoL, and therefore, in close collaboration with the QLD, concomitant patient and patient-by-proxy measurements have been introduced in two recently started Brain Tumor Group trials. Another strategy could be to integrate QoL scores and objective cognitive testing, and for that purpose cognition is tested in selected centres in some trials. Furthermore, in this Newsletter issue, Linda Dirven, Martin Taphoorn (who is the former Liaison Officer) and I report on the recently started project on developing a tool to measure the performance of brain tumour patients regarding instrumental activities of daily living (I-ADL), which is funded by the Quality of Life Group.

Altogether, cross-talk between the Brain Tumor Group, Quality of Life Group and the QLD is crucial for improving quality of life research in the brain tumour field. The well-defined position of QoL Liaison Officer within the Brain Tumor Group and the warm welcome such a Liaison Officer experiences from the Quality of Life Group are very helpful in this respect!

“Relatively early, the Brain Tumor Group realized that for patients with brain cancer, maintaining quality of life throughout the disease course is crucial.”

LEFT TO RIGHT Fabio Efficace,
Frédéric Baron

Collaboration is key: the Leukemia Group

Fabio Efficace, GIMEMA Data Center, Rome, Italy
Frédéric Baron, C.H.U. Sart-Tilman, Liège, Belgium

Thanks to our collaboration over the years, the EORTC Quality of Life Group (QLG) and the EORTC Leukemia Group are strongly linked. Dr Fabio Efficace, long-standing member of the EORTC QLG and former Secretary of the QLG, has been actively involved in the research activities of the EORTC Leukemia Group for many years. Dr Frédéric Baron is Chairman of the EORTC Leukemia Group.

The Italian Group for Adult Hematologic Diseases (GIMEMA) and the EORTC Leukemia Group have been conducting joint clinical trials for more than two decades. Results of these joint trials have been published in top-ranking medical journals and have contributed to setting new standards of care for patients with acute leukemia. As an example, one of our pivotal earlier findings stemming from this outstanding collaboration was the first evidence-based data of the value of allogeneic and autologous bone marrow transplantation as post-remission therapy for patients with acute leukemia published in the *New England Journal of Medicine* in 1995 (1). Later on, effects of these post-remission strategies on patients' quality of life (QoL) were also investigated and published in a separate publication (2).

Fabio Efficace regularly attends EORTC Leukemia Group bi-annual meetings and closely collaborates with the Leukemia Group in the design of studies where a QoL endpoint is planned. Recently, for example, he designed the QoL assessment, in collaboration with colleagues in the EORTC QLG, of a new large multicentre Phase III randomized study whose primary objective is to assess the effect of 10-day decitabine versus conventional induction chemotherapy on overall survival (OS) in

older acute myeloid leukemia (AML) patients (EORTC-GIMEMA AML21).

Another important recent collaboration is the "SPARTA Platform" (A **S**urvivorship **P**roject to underst**A**nd and to imp**R**ove long-T**E**rm outcomes for **A**cute myeloid leukemia patients – SPARTA). The main objectives of this large survivorship study are: 1) To update clinical outcomes (e.g. OS, LFS, response to therapy, late adverse effects, second cancers); and 2) To investigate the long-term QoL and socioeconomic status of AML patients included in previous EORTC/GIMEMA studies.

This project will take advantage of three previously conducted EORTC/GIMEMA Trials (1,3,4) performed in young patients with AML enrolling, overall, some 5,000 patients. This is a challenging and ambitious initiative under the larger framework of the survivorship research agenda of the EORTC, and was made possible through the full support of the EORTC Headquarters. It is also financially supported by the GIMEMA. We are coordinators of the project and a dedicated research fellow has been appointed to work on this project at the EORTC Headquarters in Brussels. The project will also take advantage of the outstanding expertise of EORTC QLG members who have been making major efforts to improve long-term QoL of cancer patients.

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LEFT TO RIGHT Susanne Singer,
Johannes A. Langendijk



Having a heart for head and neck cancer patients

Susanne Singer, University Medical Centre Mainz, Institute of Medical Biostatistics, Epidemiology and Informatics (IMBEI), Mainz, Germany
Johannes A. Langendijk, University Medical Centre Groningen, Department of Radiation Oncology, Groningen, The Netherlands

It all started in 2009, at one of the EGAM meetings. We, two people interested in Quality of Life (QoL) in head and neck cancer patients, met and realized that we were fighting for the same goal: better incorporation of QoL into head and neck cancer trials. We felt it would be best to join forces, as the EORTC Quality of Life Group (QLG) and the EORTC Head and Neck Cancer

Group (HNG) could benefit from mutual exchange. The HNG created a QoL subcommittee, with Susanne Singer representing this subgroup in the Executive Committee of the HNG, allowing close collaboration and excellent exchange.

The update of the EORTC QLQ-H&N35 started by discussing together the pros and cons of such an undertaking. It was followed

by many members of the HNG helping perform Phase I interviews and resulted in a joint publication by the QLG and HNG (Figure 1).

Quality of life in patients with head and neck cancer receiving targeted or multimodal therapy - Update of the EORTC QLQ-H&N35, Phase I

Susanne Singer, PhD,^{1*} Juan I. Arraras, PhD,² Ingo Baumann, MD,³ Andreas Boehm, MD,⁴ Wei-Chu Chie, PhD,⁵ Razvan Galalae, MD,⁶ Johannes A. Langendijk, MD,⁷ Orlando Guntinas-Lichius, MD,⁸ Eva Hammerlid, MD,⁹ Monica Pinto, MD,¹⁰ Ourania Nicolatou-Galitis, DDS,¹¹ Claudia Schmalz, MD,¹² Mehmet Sen, MD,¹³ Allen C. Sherman, PhD,¹⁴ Karin Spiegel, MD,⁸ Irma Verdonck de Leeuw, PhD,⁸ Noam Yarom, MD,¹⁵ Paola Zotti, PhD,¹⁶ Dirk Hofmeister,¹⁷ on behalf of the EORTC Quality of Life and the EORTC Head and Neck Cancer Groups

Fig. 1: The first joint publication of EORTC Quality of Life and EORTC Head and Neck Cancer Group (Head Neck 35: 1331–1338, 2013).

Susanne Singer went regularly to the HNG meetings and members of the HNG became active members of the QLG. Together we performed Phase III of the QLQ-H&N35 update, resulting in a second joint publication (Figure 2).

New studies are now planned together and we invite each other to conferences and meetings, in this way broadening the scope beyond EORTC. We presented at ASCO 2013 together, resulting in an educational paper on supportive care in head and neck cancer

(full text available on <http://meetinglibrary.asco.org/content/248-132>).

We both believe that we took the right decision six years ago. It was the beginning of an extremely fruitful collaboration, and a good friendship too.

Measuring quality of life in patients with head and neck cancer: Update of the EORTC QLQ-H&N Module, Phase III

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Fig. 2: The second joint publication of EORTC Quality of Life and EORTC Head and Neck Cancer Group (Head Neck epub forthcoming).

Eva Greimel



Brainstorming from experience: EORTC QLG planning optimization of operational collaboration between EORTC clinical and speciality groups

Eva Greimel, Medical University Graz, Austria, Department of Obstetrics and Gynecology

The EORTC Quality of Life Group (QLG) has a leading role in developing the methodology for health-related quality of life (HRQoL) assessment and applying these measures in relevant trials in close collaboration with EORTC disease-oriented groups.

The implementation of HRQoL research into clinical trials started in the nineties (1). With the increasing number of randomized Phase III trials, the QLG established a liaison model to improve the application and practice of HRQoL assessments in clinical trials (2). Several liaison people from the QLG with expertise in the field of HRQoL research and knowledge about the specific disease site were appointed to help investigators design trial protocols with HRQoL as a relevant endpoint. Liaison activities require collaboration with the EORTC Quality of Life Department and involvement with the disease-oriented groups who undertake HRQoL assessment. There has

always been a close collaboration between the Quality of Life Department and the QLG, with the main aim to support the clinical trials coordinators in designing trial protocols with HRQoL endpoints.

Recently, the EORTC has shifted the research agenda from clinical trials to survivorship research, addressing second malignancies, cardiovascular disease, cognitive dysfunction, infertility/sexuality and psycho-social problems following cancer treatment. A Cancer Survivorship Task Force has been established with the mission of identifying the needs of cancer survivors and providing guidance on their proper management (3).

Moreover, the Scientific Audit Committee (SAC) encouraged the QLG to take a proactive role in inter-group projects, including the patients' perspective, which help clinicians and patients understand and manage both the short- and long-term consequences of the cancer and its treatment.

In response to the changed agenda of the EORTC and the SAC review the QLG Executive Committee suggested increasing the collaborative research with disease-oriented groups. For this reason a brainstorming meeting was held on 13 December, 2014 in Berlin with experienced QLG members (Henning Flechtner, former chair of the liaison committee; Andrew Bottomley and Francesca Martinelli from the Quality of Life Department; and Jaap Reijneveld, liaison for the Brain Cancer Group, and Eva Greimel, liaison for the Gynecologic Cancer Group, both members of the Executive Committee of the QLG). The aim of this brainstorming meeting was to discuss past successes and weaknesses, and to explore better ways of working within the EORTC with the QLG, the Quality of Life Department and the disease-oriented groups. A Clinical Project Development Committee will be proposed to better optimize collaborations following discussions in the QLG Executive Committee. Interested researchers from disease-oriented groups as well as members of the QLG are welcome to discuss their ideas with the newly established Committee. In the future more emphasis will be placed on developing inter-group projects related to clinically important research questions.

Brainstorming from experience; Berlin - December 13, 2014



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Corneel Coens



The MID Project: empirical evaluation of the appropriateness of an anchor and its use in establishing MIDs (Minimal Important Differences)

Corneel Coens, Quality of Life Department, EORTC Headquarters, Brussels, Belgium

Collaborators: Andrew Bottomley (EORTC QLD), Alexander Eggermont (EORTC Melanoma Group), Henning Flechtner (EORTC QLQ), Eva Greimel (EORTC QLQ/Gyneacology Group), Mogens Groenvold (EORTC QLQ), Madeleine King (EORTC QLQ), Martine Piccart-Gebhart (EORTC Breast Cancer group), Jaap Reijneveld (EORTC QLQ/Brain Tumor Group), Egbert Smit (EORTC Lung Cancer Group), Mirjam Sprangers (EORTC QLQ), Roger Stupp (EORTC Brain Tumor Group), Martin Taphoorn (EORTC QLQ/Brain Tumor Group), Galina Velikova (EORTC QLQ), Efstathios Zikos (EORTC QLD).

“SO WHAT DOES IT ALL MEAN?”

It is one of the most challenging questions that a statistician may face after having produced a 100+ page analysis report detailing the Quality of Life results of a clinical trial. All the estimates, confidence intervals, odds ratios, treatment effects, etc. may be described in the document up to and including individual patient listings, but at the end of the day, how does one make sense of it all? This problem is at the heart of an ambitious project proposed by the EORTC Quality of Life Department (QLD) and supported by many clinical groups who have a proven level of interest in QoL in the EORTC. The proposal was funded by the EORTC Quality of Life Group (QLG) in 2014.

Patient assessment of health-related quality of life (HRQoL) in cancer clinical trials has increased over the years. Consequently, there is greater need to attach meaningful interpretations to differences in HRQoL scores between groups, or over time. Determining what represents a minimal important difference (MID) in HRQoL scores is useful to clinicians, patients and researchers, and can be used as a benchmark for assessing the success of a health care intervention (e.g. a new treatment). It also has implications for the design of a clinical trial, in particular for establishing sample size and power calculations.

The added value of HRQoL data in clinical trials is dependent on how treatment differences

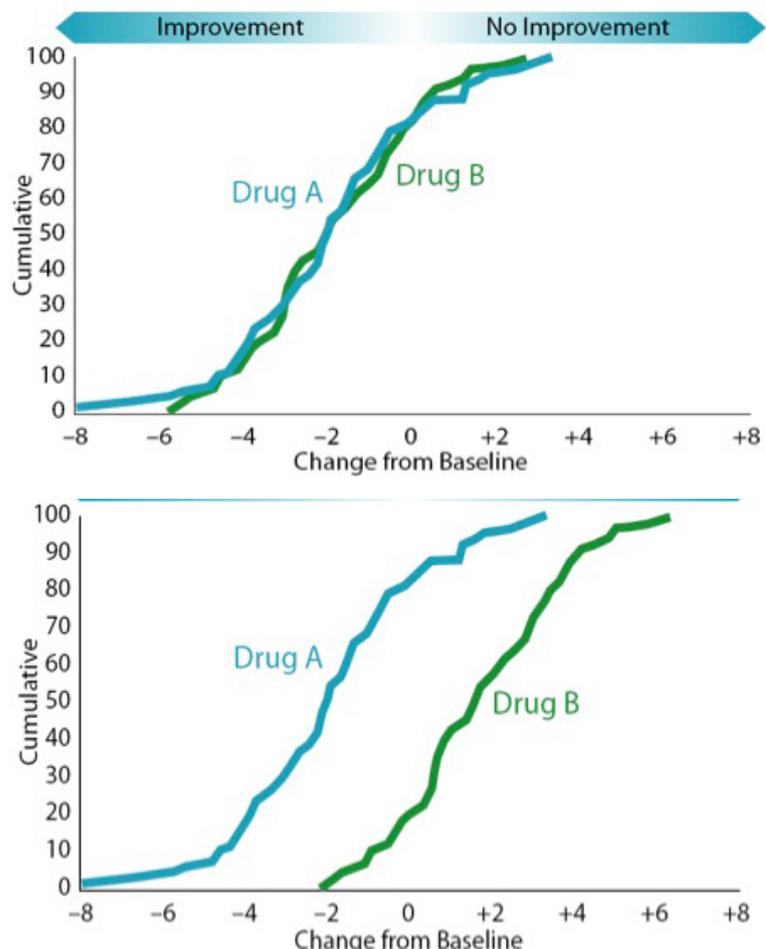


Fig. 1: example of HRQoL cumulative distribution function without treatment difference (above) and with treatment difference (below).



New kid on the block

Cheryl Whittaker,
Quality of Life Department,
EORTC Headquarters, Brussels, Belgium

“Patient assessment of health-related quality of life (HRQoL) in cancer clinical trials has increased over the years.”

can be interpreted. This is different from the use of HRQoL in an individualized clinical practice setting. Currently, in clinical trials, interpretation of treatment differences is still too focused on statistical significance and group differences rather than on patient benefit. This is reflected in such guidelines as the recommendation of the US Food and Drug Administration (FDA) to use cumulative distribution functions (see Figure 1). These functions give a range of the treatment effects, but ultimately do not reflect clinical relevance or individual benefit.

Our aim is to examine the relationship between HRQoL scores and clinical anchors, e.g. weight loss, performance status, etc. Such clinical anchors are commonly part of clinical trial data but are rarely taken into account when evaluating treatment effects. The appropriateness of particular anchors in the determination of MIDs will be investigated. How does the association between an anchor and HRQoL scores change over time? How is the evolution of the anchor profile related to the evolution of the HRQoL scores? These questions can be addressed using a joint model, flexible enough to model the evolution in time. We believe this approach can lead to more accurate estimation of the association between the anchor and HRQoL scores, which in turn can identify clinical anchors suitable to aid HRQoL interpretation: a clinical measure with clear medical interpretation, easily and reliably obtainable, sensitive to changes in health states,

and with shared content validity with its patient-reported counterpart. Once sufficiently strong and stable associations are confirmed through the joint modelling, MID estimates determined using that particular anchor would be more credible and can be confidently used in clinical practice.

The ultimate goal is to establish a library of MIDs on the EORTC QLQ-C30 across various patient populations as well as across stages of the disease. This should eventually cumulate in an overall guidance on the value, limitations and practical use of MIDs in the design, analysis and interpretation of clinical trials.

And, finally, a suitable answer to the question “So what does it all mean?”

Having worked for the majority of my career within research organizations, the collaborative nature of the EORTC Quality of Life Group is not new to me – and having already been working in the EORTC’s Quality of Life Department since the start of 2012, I am not exactly a new face here, either! But I am new to the QLG Newsletter: this issue I’ve taken over the position of Assistant Editor from Sheila Scott Sanderson, and it is already a pleasure to be working with Jaap on getting the latest news out to QLG members.

When I’m not contacting newsletter designers and printers, or sending annoying e-mails to newsletter contributors, you’ll find me working part-time in the QLD at the EORTC Headquarters in Brussels. Along with Dagmara Kuliš and Edite Fiskoviča, I coordinate the translation projects for the EORTC Quality of Life measures, which for my part involves, amongst other things, liaising with pharmaceutical companies as well as translation agencies, drawing up contracts, and dealing with invoices. You’ll also find me proofreading research papers and articles from time to time, and putting in my two cents’ worth as a native English speaker and qualified language editor when called upon.

This issue, it was a pleasure to interact with contributors (if only by e-mail) – and I look forward to future opportunities to do so.

Johannes M. Giesinger



Developing thresholds for clinical relevance to use the EORTC QLQ-C30 for screening in daily clinical practice

Johannes M. Giesinger, Netherlands Cancer Institute, Amsterdam, The Netherlands

The use of patient-reported outcome (PRO) measures for screening individual patients for clinically relevant problems requires thresholds (i.e. cut-off scores) for clinical relevance. Such thresholds for quality of life (QoL) measures found in the literature have often been developed on an ad hoc basis and are based on the wording of response categories, percentiles from reference populations, or other PRO measures.

The availability of methodologically sound cut-off scores for the EORTC QoL measures will increase their interpretability. It will also help to raise clinicians' awareness of symptoms and QoL aspects that require attention, and potentially an intervention or treatment adaptation. The EORTC QLQ-C30 appears to be especially suitable for symptom screening in cancer patients, as it covers a broad range of physical and psychosocial domains potentially requiring clinician awareness.

In a previous project funded by the Austrian Science Fund, we evaluated an anchor-based approach to develop cut-off scores for four key QLQ-C30 domains (physical functioning, emotional functioning, fatigue and pain). Development of cut-off scores relied on anchor items assessing burden, limitations or need for help in a particular QoL domain. Results

from 548 patients recruited in Austria, the Netherlands, Poland and the United Kingdom indicated that the QLQ-C30 scales show high diagnostic accuracy (i.e. sensitivity and specificity) in detecting patients who experience burdens, limitations, or need for help associated with these four domains.

Following this initial study, the EORTC Quality of Life Group kindly provided a grant in 2014 for our group to conduct a follow-up project. In this project we will develop clinical thresholds for screening in daily clinical practice for the 14 symptom and functioning domains included in the QLQ-C30 and for their corresponding EORTC CAT measures. This project will investigate what makes a symptom relevant for patient-clinician consultation, based on qualitative interviews with patients and health professionals. It will include a consensus process to develop an external criterion for the QoL scales based on the results from the interviews, and will then determine cut-off scores for the EORTC QoL measures. Patient recruitment will take place at centres in Rome, Pamplona, Krakow, Copenhagen, Amsterdam, Innsbruck and London.

The project will facilitate the use of the QLQ-C30 and the CAT measures for screening in daily clinical practice, based on valid cut-off scores to identify patients with problems in a certain

QoL domain. This will substantially increase interpretability of the absolute scores of these measures and foster the use of the EORTC measures in clinical settings. In addition, cut-off scores allow the conversion of score points to prevalence rates, which may increase the understanding of QoL data among clinicians and researchers who are less familiar with QoL data (and the EORTC measures in particular).

The author would like to thank the patients, health care professionals and collaborators involved in this project (Neil Aaronson, Juan Arraras, Fabio Efficace, Mogens Grønbold, Bernhard Holzner, Morten Petersen, Krzysztof Tomaszewski and Teresa Young) for their help.

“In this project we will develop clinical thresholds for screening in daily clinical practice for the 14 symptom and functioning domains included in the QLQ-C30 and for their corresponding EORTC CAT measures.”

LEFT TO RIGHT Georg Kemmler,
Eva Gamper

Determination of European utility weights for the EORTC QLQ-C30

Georg Kemmler & Eva Gamper, Innsbruck Medical University, Austria

Until fairly recently the topics of utilities and health technology assessment (HTA) received rather little attention and were even looked upon with some scepticism within the EORTC Quality of Life Group. Members may have asked, "Quality of Life and economics: do they fit together?"

However, we live in a time of increasingly scarce resources, both in everyday life and in the health sector. Financial considerations play a key role in the decisions made by health care providers and health authorities. The EORTC Headquarters has also emphasized the importance of HTA issues for clinical trials in oncology. Such considerations have led to the formation of an HTA working group within the EORTC QLG, led by Georg Kemmler and Eva Gamper.

In 2014 the EORTC Quality of Life Group decided to fund a research project on HTA led by us. The funded project deals with the determination of utilities for the EORTC QLQ-C30. So, what is the secret behind utilities? Conventional QoL instruments like the QLQ-C30 are not directly applicable for health economic evaluations. They require a special way of scoring by which each health state is translated into a number between 0 and 1, where 1 indicates optimal QoL and 0 means death. Health economists use these utilities as weights in order to obtain quality-adjusted life years (QALYs) for their cost-utility analyses.

One important mainstay of our project is close collaboration with Prof. Madeleine King from Sydney, Australia, who is leader of the Multi-Attribute Utility in Cancer (MAUCa) project, dealing with the determination of utility weights for the QLQ-C30 and the FACT-G. During the QLG meeting in Cyprus, Madeleine King and the QLG Executive Committee agreed on a name

for the new scoring algorithm. This "new baby" was called QLU-C10D: U for utility, C for Core Questionnaire, and 10D for the ten dimensions of the QLQ-C30 on which the algorithm is based.

The main part of our project will consist of the determination of utility weights for five European countries, across Northern, Southern, Eastern and Central Europe. It will be based on representative general population samples of N=1000 each. Recruitment and assessment will be contracted to a company specialized in conducting online surveys. We also plan to obtain valuations from a sample of 1,000 Austrian cancer survivors. This part of the study is a novelty: nobody else in the MAUCa group has included patients so far. Involvement of patients is supported by literature findings suggesting that utilities of chronically ill people may differ substantially from those of the general population.

How are the utilities obtained? In our study we will use discrete choice experiments (DCE), a method that has gained in popularity in recent years. Respondents are shown two scenarios, A and B (each combining a health state with a survival time), from which they have to select the one they would prefer. Each respondent has to complete 16 such choice sets. Although the task is not so easy, first results from the Australian study in the general population are promising, indicating that most respondents can deal with the challenge. Our study is due to start right away. We are grateful for the generous financial support from the EORTC QLG!

LEFT TO RIGHT Linda Dirven, Jaap Reijneveld, Martin Taphoorn

Development of a questionnaire to measure instrumental activities of daily living (I-ADL) in patients with brain tumours



Linda Dirven, Jaap Reijneveld, Martin Taphoorn, VU University Medical Center, Amsterdam, The Netherlands

Co-investigators (in alphabetical order): Neil Aaronson, Jonas Egeter, Robin Grant, Martin Klein, Sietske Sikkes, Günther Stockhammer, Andrea Talacchi, Bernard Uitdehaag

Traditional outcome measures in clinical trials for patients with primary or metastatic brain tumours are progression-free and overall survival, as well as tumour response assessed on magnetic resonance imaging. Apart from these outcome measures, information on the patients' functioning and wellbeing has become increasingly important, particularly since most brain tumour patients cannot be cured of their disease. Measures such as health-related quality of life (HRQoL) and cognitive functioning are frequently used in brain tumour research and although very valuable, they do not provide a complete picture of the patients' functioning in daily life. Therefore, an additional Patient-Reported Outcome (PRO) measure specifically aimed at measuring activities of daily living (ADL) is needed.

ADL are divided into two categories: basic activities of daily living (B-ADL) and instrumental activities of daily living (I-ADL). B-ADL include basic skills such as feeding, bathing and dressing. I-ADL, on the other hand, include more complex activities such as food preparation, ability to handle finances, shopping or using a computer or smartphone. These capacities are required for autonomous functioning. Because I-ADL are higher-order activities, they may be negatively influenced by cognitive decline, which is characteristic of brain tumour patients, in contrast with patients with other types of cancer. Therefore, limitations in I-ADL

in particular are informative of brain tumour patients' functioning in daily life.

Recently, a new proxy-based questionnaire was developed and validated to measure problems in I-ADL in patients with early dementia: the Amsterdam I-ADL®. Because there is no gold standard to measure I-ADL in brain tumour patients, and because of the expected similarities in problems in I-ADL between dementia and brain tumour patients, we decided to perform a pilot study to assess whether the activities in this existing Amsterdam I-ADL© questionnaire are also relevant for brain tumour patients.

The results of this pilot study showed that the Amsterdam I-ADL© questionnaire measures several activities that are relevant for patients with early dementia, but not for patients with brain tumours. On the other hand, the Amsterdam I-ADL© questionnaire also misses activities that are relevant for brain tumour patients. This pilot study thus indicated the necessity of developing an I-ADL questionnaire specifically for brain tumours rather than simply applying the already developed questionnaire to this population.

The recently received grant from the Quality of Life Group will enable us to develop an I-ADL questionnaire for both primary and metastatic brain tumour patients. We will start this project in the coming months.

The primary objective is to develop a reliable and valid questionnaire to measure I-ADL in both primary and metastatic brain tumour patients. Parallel versions of the questionnaire will be developed: one that is designed to be completed by patients, and another that is intended to be completed by a proxy. As we don't know which source is best, the second objective of this study is to determine the extent of congruence between patient and proxy ratings. Based on the results, decisions can be taken as to whether proxy measures are an appropriate alternative in cases where the patient is unable to complete the questionnaire, for example due to cognitive impairments or poor health status.

LEFT TO RIGHT Lonneke van de Poll-Franse, Neil Aaronson, Olga Husson, Marieke van Leeuwen



Phase I in developing an EORTC cancer survivorship quality of life questionnaire

Lonneke van de Poll-Franse¹, Neil Aaronson², Olga Husson¹, Marieke van Leeuwen²

¹Tilburg University and Netherlands Comprehensive Cancer Organisation, The Netherlands

²Netherlands Cancer Institute, Amsterdam, The Netherlands

Increasingly, clinical cancer trials are being designed to include long-term follow-up to assess not only survival, but also late effects and quality of life (QoL). Additionally, both observational and intervention studies are needed to identify and meet the long-term physical and psychosocial health needs of the growing population of cancer survivors.

Many of the QoL questionnaires designed for cancer patients, such as the EORTC QLQ-C30 and the FACT-G, with their supplementary condition-specific or symptom-specific modules, may not be entirely appropriate or sufficient for assessing the experience of cancer survivors. On the one hand, they include items assessing acute, treatment-related symptoms (e.g. vomiting or hair loss) that are probably not relevant in the post-treatment survivorship period. On the other hand, they may not address many of the mid- and long-term problems confronting cancer survivors.

This project on development of a cancer survivorship module represents the first step in a longer process of developing an appropriate EORTC measurement model and assessment strategy for assessing the QoL of cancer survivors. It is important to note that there is no universally accepted definition of “cancer survivor”. The working definition that is being used in this project is: any person who has been diagnosed with cancer, has completed primary treatment (with the exception of

maintenance adjuvant therapy), and is currently disease-free (i.e. no evidence of active disease). A central question that will be answered in this first phase is whether it is possible to develop one generic questionnaire covering all relevant survivorship issues or, rather, whether it is necessary to develop condition-specific survivorship modules. More specifically, two measurement models or strategies are possible: (1) development of a generic cancer survivorship module that could be used in conjunction with the current QLQ-C30 and the current portfolio of modules; or (2) development of a generic cancer survivorship questionnaire and cancer site-specific survivorship modules. The latter model/strategy would most likely involve modification of both the QLQ-C30 and the extant condition-specific modules.

Following standard phase I procedures, we will first complete a comprehensive literature review to identify all relevant QoL issues for all cancer survivor populations. We will also review studies that have used the QLQ-C30 in cancer survivor studies to understand how the questionnaire performs in this setting. We will then conduct semi-structured interviews with 110 adult survivors of breast, colorectal, prostate, bladder, gynecological, head and neck, lung, and testicular cancer, and lymphoma, melanoma, and glioma with no evidence of disease. Patients will be recruited from Germany, the Netherlands, Norway, Austria, Poland, Greece, Israel, Italy, Spain and the United Kingdom.

Respondents will first be asked an open question about their survivorship experience, and they will be asked to review the EORTC QLQ-C30 and a site-specific module, if available, for topic and item relevance. They will be encouraged to “think aloud”, providing feedback on the reasons for his/her ratings. They will also be asked to identify survivorship issues that they believe to be important that are not included in the current questionnaires.

The list of issues generated by the literature search and the semi-structured patient interviews will be consolidated into a comprehensive list of issues. This list will be presented to 660 cancer survivors, stratified by diagnosis, geographic region and time since primary treatment, and to 90 health care providers. Respondents will be asked to rate the relevance of the QoL issues on a 4-point Likert scale, and to identify the 10 most important issues in the list. They will also be asked if any relevant issues are missing. Both quantitative and qualitative techniques will be used to analyze the patient and health care provider data, and to inform the decision as to how best to move forward; either to develop a single, comprehensive survivorship module or to adapt the QLQ-C30 and the currently available condition-specific questionnaire modules to the survivorship setting.

Data collection is currently underway. We anticipate that this phase I study will be completed in April 2016.

Why not add items from the CAT item banks to your next study using the EORTC QLQ-C30?

Morten Aa. Petersen & Mogens Grønvold, The Research Unit, Department of Palliative Medicine, Bispebjerg Hospital, Copenhagen, Denmark

As described later in this text, it is now possible to improve the measurement of one or more of the domains in the EORTC QLQ-C30 by adding so-called ‘short-forms’ of, for example, five additional fatigue items to the paper-based (or electronic) questionnaire used. We argue that this is worth considering even though the clinical validation project has not yet been completed. This article gives a brief status update on the EORTC Quality of Life Group (QLG)’s development of a computerized adaptive testing (CAT) version of the EORTC QLQ-C30.

In CAT measurement the questionnaire is adapted to the individual patients by using the responses to the previously asked items to select the most informative next item from an item bank. Within the CAT project, we will develop such an item bank for each of the fourteen QLQ-C30 dimensions (except overall health/quality of life). This development consists of four phases (similar to QLG module development):

- Phase I: Literature search
- Phase II: Formulation of new items and expert evaluations
- Phase III: Pre-testing (patient interviews)
- Phase IV: Field-testing and psychometric analyses

These four phases have been completed for ten of the fourteen QLQ-C30 dimensions. The numbers of items in the resulting

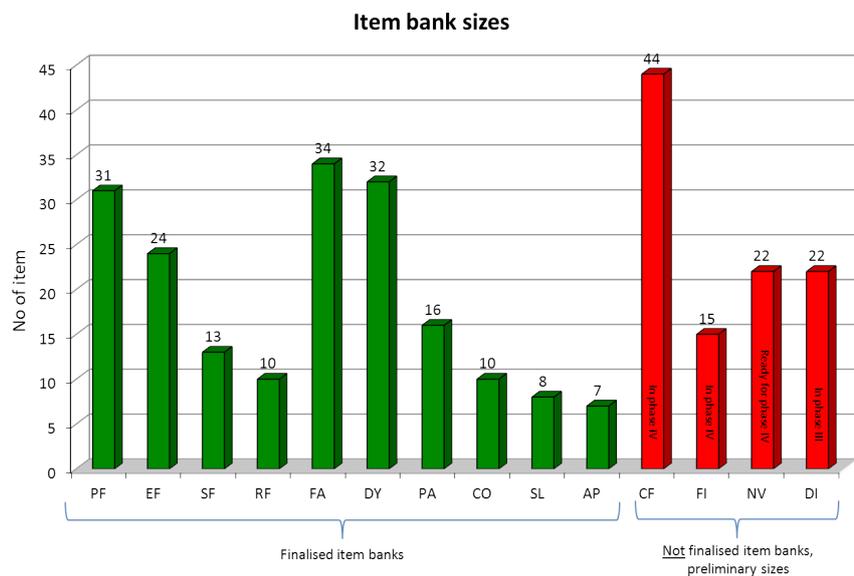


Fig. 1: Number of items in each of the 10 finalized item banks and in the four item banks still under development.

item banks are shown in Figure 1. The four dimensions still under development (cognitive functioning, financial difficulty, diarrhoea, and nausea/vomiting) are in Phases III or IV (preliminary item bank sizes are also shown in Figure 1). Preliminary validation of the CAT measures has been conducted based on the data used for the item bank development.

The results have been promising, indicating average potential savings in sample size requirements of 25–30% compared to using the QLQ-C30.

A clinical validation study has been initiated. It consists of two parts: a feasibility study investigating the acceptability, optimal design and logistics of web-based administration of the CAT, and a field study testing the “real-life” validity and measurement precision of the EORTC CAT with particular focus on evaluating the measurement precision of the EORTC CAT compared to the QLQ-C30 scales. There are participating centres from ten countries. For the feasibility study a total of 100 cancer patients will be interviewed. The field study is planned to include 1,000 patients,

“It is now possible to improve the measurement of one or more of the domains in the EORTC QLQ-C30”

LEFT TO RIGHT Morten Aa. Petersen, Mogens Grønvold



“The EORTC CAT will be released as a validated EORTC instrument when the validation study has been completed.”

assessed twice, before and after chemotherapy. We have currently completed the first 30 interviews of the feasibility study. When the feasibility study has been completed we will initiate the field study.

The EORTC CAT will be released as a validated EORTC instrument when the validation study has been completed. However, the current version of the EORTC CAT may be used already, although the QLQ-C30 should still be used as the primary outcome in the study until the validation study is completed. As is often stated, validation is an ongoing process, and concurrent use of the QLQ-C30 and EORTC CAT might give important evidence concerning the performance in various disease groups, in relation to additional treatments and so on.

A simple alternative to the electronic, adaptive use of the EORTC CAT is to use so-called short-forms. That is, additional items selected from the items banks may be added to the QLQ-C30 to improve measurement precision for selected dimensions. Scores based on such short-forms are directly comparable with scores based on the EORTC CAT.

Standard solution: The EORTC QLQ-C30 only.

Standard solution plus short-forms: The QLQ-C30 plus additional items selected from the item banks to improve measurement for one or more dimensions (e.g. five additional fatigue items when fatigue is the primary outcome).

CAT solution: QLQ-C30 asked as CAT plus additional items for one or more dimensions using CAT.

Figure 2 shows the information obtained with the standard solution (the three C30 fatigue items only) and with a hypothetical 8-item fatigue short-form (the three C30 fatigue items + five additional items). Due to the increased information/reliability obtained,

the ability to detect differences between groups and changes over time (and hence, the power of the study) is expected to increase.

For more information on the EORTC CAT please visit <http://groups.eortc.be/qol/eortc-cat>

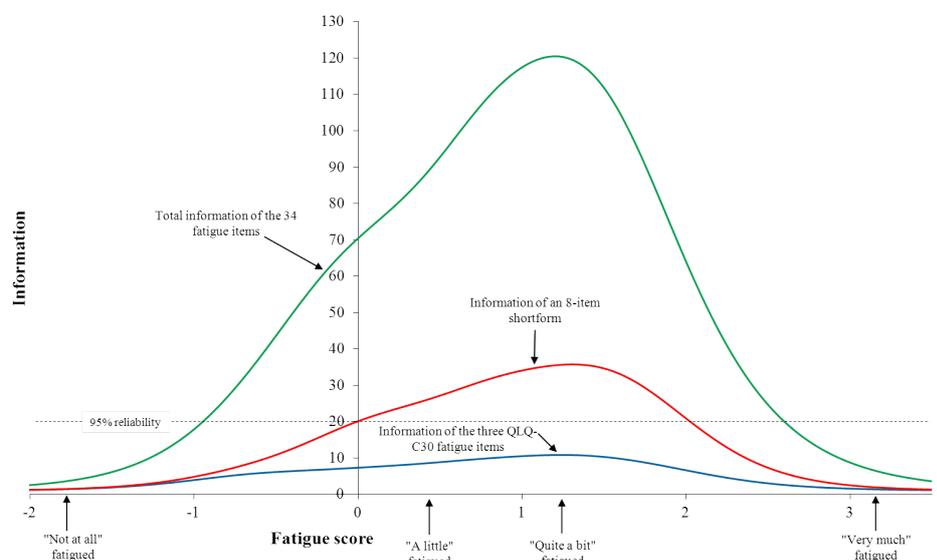


Fig. 2: Information obtained with the full fatigue item bank (asking 34 items), an 8-item short-form, and the standard 3-item QLQ-C30 fatigue scale, respectively.

LEFT TO RIGHT Bernhard Holzner, Johannes M. Giesinger, Gerhard Rumpold



Update on CHES

Bernhard Holzner, University of Innsbruck, Austria

Johannes M. Giesinger, Netherlands Cancer Institute, Amsterdam, The Netherlands

Gerhard Rumpold, Evaluation Software Development, Rum, Austria

Over the last few years, we have continuously developed and refined our Computer-based Health Evaluation Software (CHES.EORTC) and evaluated its use in different EORTC Quality of Life Group projects. To date, it has been used for routine patient-reported outcomes (PRO) monitoring, and also for module development studies and feasibility testing of the EORTC CAT measures.

In the previous newsletter, we reported on our experiences with the use of CHES.EORTC in the Phase IV validation study of the testicular cancer module (EORTC QLQ-TC26). A further, current example for its use is the Phase IV study on the validation of the breast reconstruction module (EORTC QLQ-BRR15/24). Here, CHES.EORTC is being used for data collection at 32 centres in Europe and Australia. To date, 280 patients have been assessed electronically.

To meet the specific requirements of this study, CHES.EORTC was extended to include debriefing questionnaires and standardized electronic case report forms. We also implemented features such as a BRR-specific study logistic (so that patient questionnaires can no longer be assigned incorrectly), refinement of the export module, and a translation module for local investigators to translate the home-monitoring website for patients. A major advantage of the use of CHES.EORTC in module development studies is immediate access to the collected data from all centres,

allowing constant monitoring of recruitment progress and missing data.

The ongoing EORTC CAT validation study is using CHES.EORTC for CAT administration and electronic capture of medical and other data. An interface has been programmed to link the engine containing the CAT algorithm and settings with CHES.EORTC. This joint system is currently being assessed for feasibility and first results are positive. The CAT engine is basically stand-alone software that can be run on Windows PCs. It includes all CAT-related calculations and allows the creation of static short-forms.

An important line of development is the enhancement of the graphical presentation of results from EORTC PRO measures for health care professionals and patients alike. An easy-to-interpret presentation of individual results is crucial for facilitating the use of PRO in daily clinical practice. In a study within this ongoing project, we investigated the graphical presentation of PRO results to patients. We found that patients had substantially different preferences about the presentation style. In a preliminary analysis, patients differed in preferences for chart types, and also in their choice of reference populations. About one in six patients would like to see how his/her scores compare to the general population, a third would like to be compared against other cancer patients, and about 40% wanted to be compared with their own previous assessments (patients could select multiple options).

Using these findings, we plan to develop a new feature for CHES.EORTC that allows easy individualization of score reports for patients.

We expect that the availability of sophisticated software for PRO data collection and presentation of results will contribute to the integration of the EORTC QLQ-C30 and its modules into daily oncological practice. CHES.EORTC will also facilitate the future distribution and use of the EORTC CAT measures and the implementation of EORTC module development studies.

Asalet Yener



EORTC QoL Group spring 2014 meeting in Limassol

Asalet Yener, University of Southampton, UK

The 2014 spring meeting of the EORTC Quality of Life Group was hosted by Dr Vasilis Vasiliou from 24 to 25 April, 2014 in sunny Cyprus. Limassol was the perfect location for the event: situated on the southern coast of Cyprus, it offered beautiful scenery overlooking the sea and pleasant warm weather which starkly contrasted with the cooler and grey climate of England. The meeting venue was the Four Seasons Hotel, a luxury hotel and beach resort, and the event allowed for many opportunities to enjoy this amidst the busy meeting schedule.

The parallel sessions were not at all how I imagined they would be. Essentially, everyone is welcome to participate and/or be an observer. Nothing is frowned upon – there is no pressure to contribute, yet it is encouraged. Hence, even though I thought I would be too intimidated to make any active contribution to any module, the Group's common enthusiasm for research instigated confidence in all attendees, allowing active contribution to any of the meetings. This was the strength of this EORTC event and the driving force behind the excellent and successful reputation of the QLQ.

The next day started with a meeting of the Module Development Committee, discussing progress of module development and ideas for future modules, and the Group's Business Meeting. During the plenary session in the afternoon, presentations were delivered with regard to the Data Repository Project, CAT project, QLQ-C30 cut-off project, the I-ADL in brain tumour patients' project, and discussions on the autumn meeting in Venice.

The hospitality was simply perfection and it appeared that every intricate detail was carefully planned, from catering and atmosphere to social events and entertainment. We were rewarded with a great variety of buffet foods encapsulating authentic Cypriot cuisine at breakfast, lunch and dinner. On the evening of 24 April we were taken by bus to the old town and had dinner at the Carob Mill restaurant, which is located next to the Mediaeval Castle. Entertainment after dinner was sensational: an acrobatics and fire show with beautiful dancing. Guests were invited to participate in a traditional Cypriot glass-stacking game.

On 25 April, we travelled to the Intercontinental Aphrodite Hills Resort and stopped off at the site of Aphrodite's Rock to enjoy the view on our way. At the resort we were welcomed



with a cocktail reception at the sunset bar and enjoyed the spectacular views outside. Again, entertainment was exceptional: traditional Cypriot dancing followed by everyone joining in and dancing the night away.

The social events were a fantastic opportunity to network and gain new collaborators and insight into possible future steps to ensure high-quality research. Every opportunity was thus relished to have coffee breaks, lunch buffets and dinner with exciting entertainment.

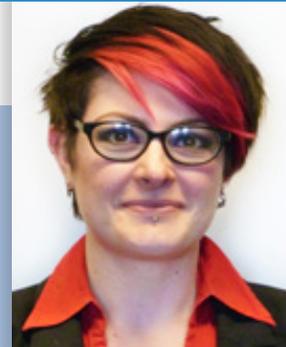
I discovered that EORTC QLQ consists of amazing people with a passion for research. They have a fantastic work ethic and have formed real friendships – all of these positive attributes are reflected in their continuous success. They truly live up to the saying "work hard, play hard!". It is a pleasure and privilege, as a medical student, to experience such a high-quality research meeting and meet driven individuals from all over the world united in a common cause – the drive to make a difference in patient care.

Despite the fact that this was only my first experience of an international meeting, the bar has been set high for the future. I was reassured by many of the collaborators that this was one of the best locations visited by the EORTC Quality of Life Group. I would like to take the opportunity, on behalf of the QLQ, to thank all the administrative team and organizing committee, chaired by Dr Vasiliou, for all their efforts!



The meeting started with a brief introduction by the chair of the QLQ, Mogens Grønvd, and the Head of the Quality of Life Department, Andrew Bottomley. After this introduction the parallel sessions began, with a total of 4 sessions running on 23 different modules in different phases of development. Parallel sessions were well accommodated for in the impeccable Four Seasons conference & meeting rooms. Almost all the sessions had a high degree of lively debate and contribution, which was encouraged by the coordinators. In addition, feedback and discussions were encouraged and issues were openly discussed. Therefore, they were very rewarding meetings for the collaborators and the study leads.

Cheryl Whittaker



EORTC QoL Group autumn 2014 meeting in Venice

Cheryl Whittaker, Quality of Life Department, EORTC Headquarters, Brussels, Belgium

September 2014 saw Andrea Tallachi and Fabio Efficace host the EORTC Quality of Life Group autumn meeting in the spectacular and sumptuous setting of Venice. The meeting venue was the exclusive island of San Servolo in the Venetian lagoon, only accessible by a 10-minute boat journey every morning, and with a tranquility that turned out to be highly conducive to collaboration. With the waves lapping at the walls of the island, and despite the not-so-occasional buzz of a passing water taxi, the conference rooms at San Servolo felt a million miles away from the bustle of everyday life.

As always, the first day was dedicated to the parallel sessions, following a welcome to Venice by Andrea and an introduction to the meeting by outgoing chair Mogens Grønvd and Head of the Quality of Life Department Andrew Bottomley.

Mogens welcomed incoming chair Lonneke van de Poll, and spoke of his fond memories of his time as chair. The parallel sessions themselves involved lively debate, and a clear desire was shown by all involved to reach mutual agreement and move the projects on.

During the second afternoon's plenary session, we got to hear Dr Claire Snyder, from the Johns Hopkins School of Medicine, present on an ePRO system currently in use at her institution. The second guest speaker was Dr Matthias Rose, who talked animatedly on the use and applicability of CAT systems in the future. In addition, the audience was given overviews of a joint research centre (Luciana Neamtii), HRQoL Trials (Eva Griemel and Jaap Reijneveld), the Data Repository Project (Francesca Martinelli), the QLD translation team's work (Dagmara Kuliš), the CAT project (Mogens Grønvd) and the CHES project (Bernhard Holzner). We were also addressed by new chair, Lonneke van de Poll, who warmly thanked Mogens for his work and looked forward to her post.

Thanks to the local expertise of the hosts, the social program was first class. Attendees were instructed to meet at the end of the first day in the Piazza San Marco, in the shadow of the Basilica. While watching tourists feeding the pigeons, QLG members were whisked off in groups for a private evening tour of the Basilica, given by truly excellent tour guides who were all very eloquent and proud of the stories of their heritage. That evening's dinner,

served in the Antico Pignolo Restaurant, was a seemingly endless stream of courses, featuring lots of wonderful fresh fish. QLG members filled the whole place, and the atmosphere was warm and friendly, made even more enjoyable by the delicious food.

At the end of the second day those guests still in Venice boarded a private boat that took them to the Lido, where a team of people at the Pachuka Beach Bar – including two smiling musicians who serenaded members at their tables with folk and modern music alike – put on a pizza party, and we ate, drank and danced the night away. Meanwhile an enormous storm raged overhead – the perfect dramatic ending to a wonderfully sunny, warm and friendly two days. Thank you to Andrea Tallachi and Fabio Efficace and all the organizing committee for their dedication in bringing us to such a thrilling place!



LEFT TO RIGHT Iwona Tomaszewska,
Krzysztof Tomaszewski



EORTC QoL Group autumn 2015 meeting in Poland

Iwona Tomaszewska & Krzysztof Tomaszewski, Jagiellonian University Medical College,
Krakow, Poland



Panorama of Krakow

We are pleased to invite you to Krakow in Poland for the 2015 EORTC Quality of Life Group (QLG) autumn meeting on the 10 & 11 September, 2015. Poland, a member of the European Union since 2004, is located in central Europe, and is the ninth largest country of the "Old Continent". Its landscapes encompass, in the north, beautiful golden beaches on the Baltic Sea coast; in the north-east, vast lakes (Masurian Lake District) and forests (Białowieża Forest); and in the south, the breathtaking Tatra mountains. The people here are open and welcoming.

Our meeting will be held in Krakow – the second-largest and one of the oldest cities in Poland, home to the Wawel Royal Castle, St. Mary's Church, the Jagiellonian University, and the largest mediaeval town square in Europe. It is here that we are going to have our bi-annual meeting – in the very heart of this vibrant city where numerous tourist attractions intertwine with cozy cafés and lively pubs. The sessions will be held at the Grand Hotel (<http://www.grand.pl/>) – a palace dating from 1887, and today a 5-star hotel, situated only 100m from the Main

Market Square, allowing for extensive sightseeing both before and after the sessions.

For those looking forward to sightseeing, we have planned several guided tours both in Krakow and nearby. On 9 September (Wednesday) we will see the Old Jewish Quarters (Kazimierz) and visit a museum located in Oscar Schindler's Factory (portrayed in the movie *Schindler's List* by Steven Spielberg). On 10 September (Thursday), after finishing the lively parallel session discussions, we will board electric power cars to see Krakow's Old Town, and finish with a dinner at the oldest and most famous restaurant in Krakow – Wierzynek (<http://wierzynek.com.pl/galeria.html>). On 11 September (Friday), the scientific part of our meeting in the afternoon will come to an end at around 4 or 5pm, and leave some time for more sightseeing before we go to dinner at a typical Polish restaurant to taste pierogi, bigos, barszcz and other Polish specialities. For those participants wishing to stay for the weekend, after the meeting is finished we plan to organize extra excursions, for example to the Wieliczka Salt Mine (<http://www.wieliczka-saltmine.com/>).

Group members and meeting attendees will be sent information by email on how they can book their hotel rooms. Apart from the venue hotel there are excellent 3-, 4- and 5-star hotels nearby that can be used. Reservation forms and other information will be sent to all members for all hotels in due time. Krakow in September tends to be busy in terms of tourist traffic, so group members and attendees are advised to book their hotels early on. We hope to see you all in Krakow!

Krakow Airport (<http://www.krakowairport.pl/en/>) can be easily reached from almost every part of Europe by plane. From there a trip to the city centre takes about 20–30 minutes by taxi (about 20–25 Euros for a 4-seater car) or 40 minutes by public transport (ticket price 1 Euro; the bus station is about 200m from the airport terminal).

More information on Krakow can be found at: http://www.tripadvisor.com/Attractions-g274772-Activities-Krakow_Lesser_Poland_Province_Southern_Poland.html <http://en.wikipedia.org/wiki/Kraków> <http://wikitravel.org/en/Kraków>
Photograph by www.fly4pix.pl

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