



30

years
of
achievement



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Report on the EORTC QoL Group Meeting Innsbruck, Austria, September 2011

Looking back at 30 years of progress from methodological developments to making a real impact on oncology practice

G Velikova, A Bottomley On behalf of EORTC Quality of Life Group and EORTC Quality of Life Department

HRQOL outcome measures have been an integral part of EORTC (European Organisation for Research and Treatment of Cancer) clinical trials for the last 30 years. The EORTC created the Quality of Life Group (QL Group) in 1981 with the mission to develop measures of patient-reported outcomes in cancer, including HRQOL, and to promote clinical studies concerning the quality of life of cancer patients. In parallel, the EORTC Quality of Life Department (QL Department) at the EORTC Headquarters was established to provide administrative, practical and scientific support to co-operative groups to implement HRQOL measures in their clinical trials.

The QL Group has a multi-disciplinary membership with representatives from medical and nursing backgrounds, as well as psychologists, statisticians and social scientists. Members come from seventeen European countries as well as from North and South America, Australia and East Asia.

Our scientific programme focuses on three major areas:

- 1) Methodological research: to develop and refine questionnaires for assessing the HRQOL of cancer patients.
- 2) Implementation of HRQOL in clinical trials.
- 3) Scientific research in patient-reported outcomes: to study the effects of cancer and its treatment on the HRQOL of diverse populations cancer patients.

Methodological research

In the 1990s the EORTC QL Group introduced the concept of *modular HRQOL measurement* in oncology, based on a core cancer questionnaire and cancer site-specific modules covering specific symptoms, treatment side-effects and functional problems. The QL Group was the first to publish detailed guidelines on the development of questionnaire modules that have set the standard internationally and have been widely used by researchers and clinicians worldwide. These have been regularly updated and are now in their Fourth edition available online.

The most notable achievement of the QL Group is the development and validation of the core EORTC HRQOL questionnaire, known as the EORTC QLQ-C30. The EORTC QLQ-C30 was validated in multiple European countries and published in 1993. The EORTC QLQ-C30 represents the most widely known example of the influence of the EORTC on international cancer research (EORTC QL Group Scientific Advisory Committee review report 2010). The EORTC-QLQ-C30 has been one of the most widely used cancer questionnaires in randomised trials in oncology, as demonstrated by systematic reviews. User agreements for the EORTC QLQ-C30 have been signed off in more than 9,000 clinical trials and academic studies worldwide.

In addition to the EORTC QLQ-C30, there is a portfolio of supplementary questionnaire modules cancer site-specific or symptom/ quality of life domain-specific. This is an active area of research with ongoing development of questionnaires for haematological malignancies, melanoma, doctor-patient communication, and updates to existing modules to capture the effects of new treatments.

A truly unique feature of the EORTC questionnaires is the attention paid to cultural and linguistic issues from the beginning of the developmental process. All our questionnaires are developed simultaneously in at least three European languages. The QL Group is an international leader in developing guidelines for translations. All validated questionnaires are available in at least eight key European languages. The EORTC QLQ-C30 has been translated and linguistically validated into more than 60 languages.

The EORTC QL Group created the EORTC *Item Bank*, a searchable database that contains all questions (items) from validated modules with their translations. It is a rich resource for developing questionnaires, as it ensures compatibility between different EORTC questionnaires, avoids duplicating work and makes possible creation of ad-hoc trial/research specific questionnaires.

Implementation of HRQOL measures in EORTC trials

HRQOL is an integral part of most EORTC clinical trials, and has been systematically implemented over the last 15 years. Over 130 EORTC clinical trials have a HRQOL element. There are numerous trials we could mention, but we note just two examples below.

In patients with glioblastoma, we studied the addition of concomitant and adjuvant temozolomide to the standard treatment with radiotherapy, and demonstrated that temozolomide significantly improved survival without a negative effect on HRQOL. This treatment is now the standard of care in newly diagnosed patients with glioblastoma.

Dose-intensive chemotherapy had generated much interest in the treatment of patients with locally advanced breast cancer as it might offer a survival benefit. We compared the effects on HRQOL of dose-intensive with standard chemotherapy. Patients assigned the intensified treatment had a significantly lower overall HRQOL score during the treatment, but scores returned to near baseline, with no difference between groups one year later. This was the first randomised trial to show that dose-intensive treatment may lead to a temporary reduction of HRQOL, followed by recovery, thus enabling clinicians to give accurate information to their patients.

The QL Department, on behalf of the EORTC Clinical Groups, undertook the largest meta-analysis of HRQOL data using the EORTC QLQ-C30 (n=7417 patients, 11 different cancers from 30 trials). The HRQOL parameters physical functioning, pain, and appetite loss, provided significant prognostic information in addition to socio-demographic and clinical variables.

Scientific research in patient-reported outcomes

The QL Group undertakes successful methodological research in a number of key areas.

Cross-cultural differences between populations in HRQOL assessment. Using Item Response Theory and Differential Item Functioning analysis in a large database of over 30,000 individuals from 50 countries, we demonstrated differences in reporting of pain and social function for Eastern European and Asian countries, when compared with the original English version. The reasons for Asian countries were primarily cultural, in contrast with Europe, where response patterns followed linguistic lines.

We are developing a *Computer-Adaptive Testing (CAT) Version of QLQ-C30*, which will allow increased measurement precision and adaptation of the questionnaire to the individual study or patient, thus reducing respondent burden.

Electronic administration of EORTC QLQ-C30. This project will provide a web-based platform for electronic administration of our questionnaires, based on a software solution called Computer-based Health Evaluation System (CHES).

Summary scores for EORTC QLQ-C30. Further research is being undertaken to recommend the generation of EORTC QLQ-C30 summary scores for Physical and Mental Health. In clinical trials, summary scores will simplify certain analyses and minimize the chance of Type I errors through multiple comparisons.

“The EORTC created the Quality of Life Group (QoL Group) in 1981 with the mission to develop measures of patient-reported outcomes in cancer and to promote clinical studies concerning the quality of life of cancer patients.”

Conclusion

The EORTC QoL Group and QoL Department have been international leaders in the development of patient-reported outcome measures in oncology and their implementation in oncology trials. Our most notable achievement is the development and dissemination of the EORTC QLQ-C30, which is one of the most widely used cancer HRQOL instruments. We established internationally accepted guidelines for questionnaire development. Our translation procedures set the highest standards for questionnaire translation and are used worldwide. These world-leading achievements have contributed to bringing HRQOL assessment to the fore in many international trials conducted by the EORTC and other groups, which have changed oncology practice and brought in patient perspective to clinical cancer research. The Group now looks to the future by developing ways to use information technology to improve precision of HRQOL assessment and accessibility to web-based interface ■

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Thoughts of the Departing Chair of the Group

Galina Velikova



I am grateful to the newsletter editor for inviting me to write this piece. It made me stop and think back about what went on during the last three years.

This was a busy, challenging, but ultimately enjoyable time. Leading the group was not a hard task, as the group was full of energy, enthusiasm and new ideas. As a chairperson, I felt my task was to support every group member to fulfil their potential and encourage them to share and shape their ideas. I tried to create an atmosphere where every member of the group felt valued and welcome to join different activities. The chair also represents the Group to the EORTC Headquarters and Board. In 2010, we updated the statutes of the group, to bring them into line with the ongoing Group changes and the regulatory environment. We had a challenging, but positive, Scientific Advisory Committee review, which resulted in a frank discussion about

where the group is now, where it is going, and how to address the challenges of running quality of life studies outside the EORTC data centre.

When I took over chairing the group, I mentally set up myself several tasks. The first was a conscious effort to improve and enrich the collaborative work with the Quality of Life Department. I am pleased that we developed the idea of the Data Repository project, leading to standardisation of our data collection and data storage for all Phase 4 studies. This is a truly joint endeavour, with a close working relationship between the Quality of Life Department, the Executive committee and the research fellow leading the project.

I invested time and effort in supporting discussions about closer collaboration with researchers in the United States, particularly in the PROMIS project. These conversations are ongoing and, whereas we have not got a solution to many of the issues, we now have specific plans about small joint projects. Mogens will take over this task and we look forward to a fruitful collaboration.

I tried to work hard on increasing the engagement of all group members and involve them more actively in the management of the group. We introduced web based voting for officers of the Executive committee, which allows all members to vote in elections. I was really pleased that we had several excellent candidates to choose from for both the position of chair and of treasurer. I believe it is really healthy for any organisation to have people who are willing to contribute their time and to work for its success.

Finally, as chair, I feel I was blessed with an excellent Executive committee. All members contributed enormously to the management of the Group, generated ideas, and were engaged in all initiatives throughout the three years. I am really grateful for their support, hard work and initiative.

I wish our new chair, Mogens Groenvold to have as enjoyable and stimulating a time, as I have had.

My intention is to continue to be part of the group and undertake new projects in the future ■



Thoughts from the new chairman of the EORTC Quality of Life Group: **Greenhouse or Strategy?**

Mogens Groenvold

During the more than 20 years I have been working at a university department we have been discussing the same theme every few years:

Greenhouse. Should the ideal university research department be a greenhouse where the individual researchers have optimal conditions for growing many totally different plants?

Strategy. Should everybody be working together on the same, common strategy, thus using all resources to grow a single plant species?

As my university department is typically Danish (and Danes are usually consensus-seeking) it has never chosen an either/or solution but has instead followed a gradual development towards greater emphasis on research groups than individualistic research.

When I took over as chair of the EORTC Quality of Life Group after having been involved in the Group's work for 22 years I wondered whether the same discussion could and should be applied to the Group. Had the Group followed the Greenhouse or the Strategy approach? And was the Group on the right track?

Having watched the development over many years, having discussed the Group's work with the Executive Committee and many other members, and having read the contributions in this Newsletter describing the Group's past and current activities, I think it is evident that the Group (often working in collaboration with the QoL Department) is truly a Greenhouse: It nurses the growth of many entirely different plants. This is one of the things I have always particularly liked: a very large number of enthusiastic researchers with many different backgrounds and ideas who work hard to develop a lot of very different research projects and implementation activities. They typically use the Group as a source of inspiration and for establishing international contacts thus transforming local ideas into successful, international, collaborative projects.

However, it is also clear that the Group has been consistently working on the single, common Strategy developed in the 1980s: the multidimensional, health-related quality of life model using the combination of a carefully cross-culturally developed core questionnaire and supplementary module questionnaires. This common strategy has proven extremely useful for obtaining scientifically robust insights into cancer patients' experiences, and still forms the basis for all activities in the Group.

I do not think this combination of the Greenhouse and Strategy approaches needs any adjustment, but clearly there are a lot of exciting challenges in the years to come. Among other things we will see:

- new and up-dated modules targeted even more cancer diagnoses and therapies,
- new translations and cross-cultural validation of instruments,
- new important clinical trials,
- web-based administration of questionnaires,
- an interactive, computer-adapted version of the EORTC QLQ-C30
- an even better documentation of all protocols and results of the careful development and validation our questionnaires

I really look forward to watching and taking part in this work and many other activities in the Group in the coming years.

I will do what I can to help keeping the conditions for healthy growth in the greenhouse intact, while at the same time continuously refining and elaborating the strategy. In this way the Group will continue producing important new knowledge about how cancer patients' lives with cancer can be improved. ■



Present and future of electronic patient-reported outcome data capture in clinical trials and daily clinical practice

Bernhard Holzner, Johannes Giesinger, Medical University of Innsbruck, Austria

Advantages of electronic data capture

Electronic patient-reported outcome data capture (ePRO) in daily oncological practice or clinical trials allows the convenient measurement of subjective physical health status and psychosocial burden with validated measures such as the EORTC quality of life (QOL) instruments. Within clinical routine patient-reported outcomes (PROs) provide additional information for medical decision making within individualized cancer treatment. In a research context, PROs have become an important outcome measure supplemental to clinical parameters such as survival and time to tumour progression.

ePRO will help to further increase the use of PRO measures within clinical trials and daily clinical practice. In a trial setting ePRO reduces data collection costs and increases data quality, since patients enter data directly into a database themselves which also reduces data entry errors. Also, the problem of a high percentages of missing PRO data in studies may be partially overcome, as a central database allows providing information on missing PROs at certain centers or in specific patient groups at any time. Within paper-pencil data collection analysis of missing data can only be done at various intervals, thereby not allowing immediate response to study logistic problems. In addition, ePRO can include automatic e-mail or SMS reminders to patients or study nurses in the case of omitted assessments. An important requirement for software packages used in clinical trials is compliance with the Good Clinical Practice (GCP) guidelines. These require for example a protocol system tracking data entry and any changes to the database.

A persuading method for ePRO is data collection via a web-interface which guarantees simple implementation of ePRO logistics, e.g. in hospitals participating in international multi-centre studies. Instead of potentially laborious, local implementation of ePRO software, a computer with web-access is sufficient to administer questionnaires.

With regard to daily clinical practice the relevance of ePRO may be even higher, since ePRO is necessary not only for reduction of resources required for data collection, but also for intuitive, graphical presentation of PRO results of individual patients to the medical staff.



CHES-EORTC

To convey electronic data capture with the EORTC QOL instruments the EORTC Quality of Life Group has funded a 2.5-year project to develop an EORTC version of the Computer-based Health Evaluation System (CHES-EORTC). In December 2011 the latest version of CHES-EORTC (4.0) was released and made available to the QLG via the CHES website (www.ches.at). This release included e.g. a web-interface for questionnaire administration, a basic feature for CAT administration, and multilingual questionnaire versions. In addition, a web-interface for eCRFs has been developed to be used in international multi-center studies. Currently, the web-interfaces for the questionnaires and the eCRFs are being used in the phase IV study of the testicular cancer module. CHES is also planned to be used for ePRO in a trial of the Austrian Breast and Colorectal Cancer Study Group (ABSCG) investigating the impact of physical exercise on re-currency rates in colorectal cancer patients. To foster collaboration within the EORTC there are ongoing discussions with the IT section of the EORTC headquarters concerning the possible use of CHES-EORTC in EORTC trials. In the case of a favourable decision, CHES-EORTC would be used alongside the eCRFs provided by the EORTC-owned software Vista RDC.

Further ePRO projects

Besides the ongoing CHES-EORTC project several members of the EORTC Quality of Life Group are engaged in national projects on ePRO. In the UK, Galina Velikova is involved in developing the ePOCS system (Electronic Patient-reported Outcomes from Cancer Survivors) which links PRO data to existing cancer registries. In the Netherlands, Lonneke van de Poll-Franse has set up PROFILES (Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship registry). This project has a strong focus on psychosocial aspects of cancer survivorship and also includes a large general population sample to gain reference scores for interpretation of the results from cancer survivors. Also in the Netherlands Irma Verdonck-de Leeuw has developed OncoQuest, a touch screen computer system to monitor quality of life of patients in clinical practice. Also, she is developing the OncoCompass, a personal e-health portal that supports cancer survivors by finding and obtaining optimal supportive care, according to stepped care programs and adjusted to their personal health status and situation.

Future developments and challenges

For the future, we expect that electronic PRO data capture will become more widespread, which will help to further increase the use of PRO measures in clinical studies and daily oncological practice. Within the EORTC Quality of Life Group, ePRO via a web-interface will facilitate conduction of module development studies. Also, the use of the EORTC CAT measures, which is likely to increase within the next years, relies on the availability of ePRO software packages. Concerning the use of PROs within daily clinical practice, ePRO software packages have helped to overcome a number of logistic barriers. However, other challenges still persist, e.g. limited evidence on the benefits of PRO data in individual patient treatment, the attitude of the medical staff towards this type of subjective information, and the lack of familiarity with PRO scores. This emphasizes the need for further research on the impact of ePRO in daily clinical practice, for specific training of the medical staff, and for further consolidation of PRO research within the oncological field ■

Web-connected devices offer possibilities for electronic data capture

EORTC Quality of Life Group Membership statistics

Since the beginning of our research activities some 30 years ago, EORTC Quality of Life Group (QLG) meetings have been attracting many collaborators from throughout Europe and beyond, and the numbers are constantly increasing. Official documentation of the number of attendees started at the Spring meeting in 2001, where 32 colleagues were present.

At the following Autumn meeting, there were 43 participants, and the numbers have been increasing up to our last meeting, Autumn 2011, with 92 attendees (see Fig. 1 for details).

Currently, the QLG has 83 active members who are actively involved in research activities and who are attending at least one meeting within two years. Another 112 colleagues are corresponding members who are interested in the group's activities without being able to attend the meetings regularly. Our members are from 31 different countries with the UK, Germany, Austria, Italy, and The Netherlands the five "top contributors" (see Fig. 2).

Fig. 1 Number of QLG meeting participants from Spring 2001 to Autumn 2011.

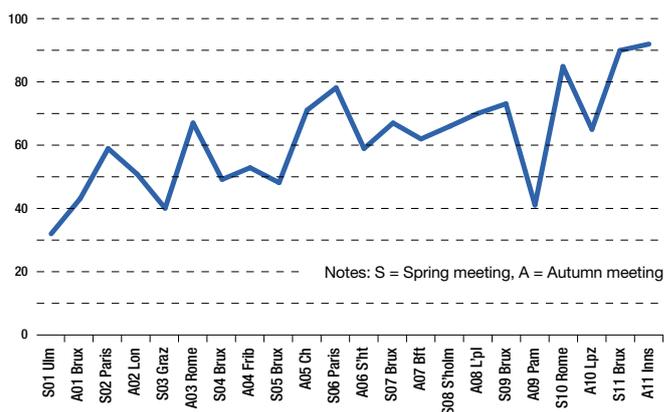
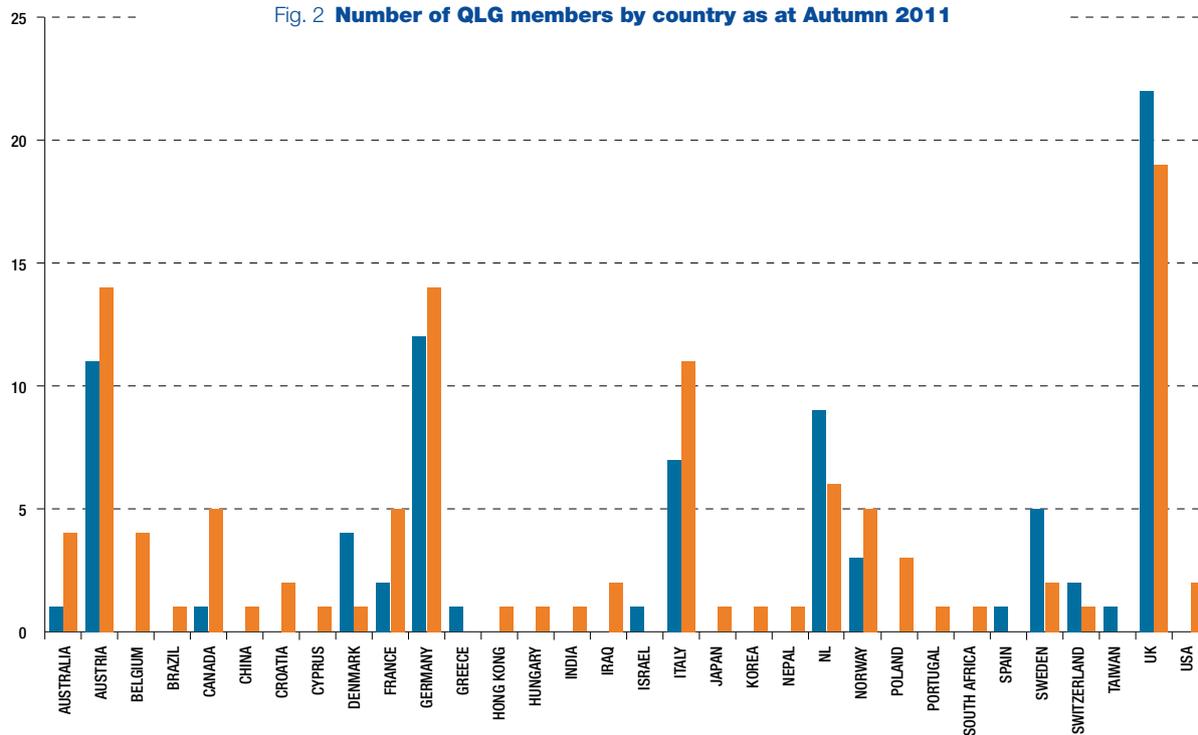


Fig. 2 Number of QLG members by country as at Autumn 2011



The EORTC
QoL Group
has

83

Active
Members

in

31

Different
Countries



Six years as Treasurer...a reflection

Teresa Young, Lynda Jackson Macmillan Centre Mount Vernon Hospital, Northwood, Middlesex, UK



For those of you with a good memory, or who hoard old documents and newsletters you may remember back in Spring 2004 I wrote an article for the QLG Newsletter. The article was written as I came to the end of my term as Honorary Secretary and it reflected on my membership of the group since November 1992. I recounted tales from the 13 cities that I had visited in that time – Brussels, Edinburgh, Trondheim, Warsaw, Pamplona, Besancon, Istanbul, London (my home city), Paris, Oslo, Ulm, Graz & Rome. I mentioned how communication and travel had changed between 1992 and 2004 when internet and e-mails were rare, the Channel Tunnel had not been built and cheap flights (unless they included a Saturday overnight) were non-existent. So what has changed since 2004 – well most of us now have smart phones on which we can read our e-mails and surf the internet almost anywhere. Few of us have to spend time in the library searching for paper copies of journals when we can download them onto our PCs. There are more high speed trains connecting major European cities but sadly although there are more airline flights they never seem to be very convenient and there are longer delays for security and passport checks, so international travel still often means hours spent in airports. The impact of all these on our own quality of life is debatable!

In my previous article I also discussed the unique nature of QLG meetings. As a small 'working' group it is possible to recognise and know almost everyone at each meeting. During the day we work hard in our parallel sessions and learn much during the plenary sessions from the expert speakers we are able to invite. But in the evenings we have the opportunity to learn about our host city and sample the local food and drink. It is during these walks and dinners that some of the most creative ideas originate and are nurtured into new cross-cultural research projects. I am sure that in our daily jobs there are some meetings and conferences we attend from a sense of duty, aiming to arrive at the last possible moment and leave as soon as possible. But I always look forward to QLG meetings – they provide a wonderful opportunity to meet with colleagues (some of whom I have now known for almost 20 years) and to find out about European history and culture in a way that is often not available as a tourist. I think it is also true to say that QLG meetings are almost always met with unseasonably good weather!

So what are some of the most memorable moments from the last six years as Treasurer? The Tivoli Gardens in Copenhagen in Autumn 2005, the 25th Anniversary meeting in Paris in Spring 2006 and a trip into the New Forest near Southampton in 2006. A journey to Belfast in 2007 – a city we have probably all heard lots about for all the wrong reasons. The docks and harbour area in Stockholm and Liverpool. (In Liverpool one of our social events was a visit to the Beatles Museum followed by dinner and entertainment from a Beatles 'tribute' band – during the interval someone sought me out with the message, 'Paul McCartney is looking for you, he wants to know when he we will get paid!'). Then back to Pamplona and Rome. Our two most recent meetings have been in Leipzig and Innsbruck and interspersed with all these were four trips to Brussels for EGAM meetings.

What have I learnt whilst being the Treasurer of the EORTC QLG? There is an English expression, "Look after the pennies and the pounds will look after themselves." Perhaps in our case it should be, "Look after the cents and the Euros will look after themselves?" Given all the stories in the newspapers about the imminent collapse of the European money market that may not be so easy. During my time as treasurer we seem to have defied the common wisdom that everyone is making cuts and our income would fall. The increasing recognition of the importance of collecting PRO data has meant that our income has increased enabling us to fund more research. And it is in this area that perhaps the role of the Treasurer has changed most in the last six years. Clinical and Research Governance has seen a huge increase in the legal documentation that is required before a study can commence. It is no longer sufficient for the treasurer to be good with numbers and accounts, they also need to be familiar with Good Clinical Practice and the regulations around Sponsorship and Funding. I wish Bernhard well as he takes on this responsibility. ■

Teresa Young

“Paul McCartney is looking for you, he wants to know when he will get paid!”

Translation Activities

Dagmara Kuliś, Eva Greimel, Michael Koller

As from January 2012 the EORTC Translation Unit has three team members, with Maria Arnott, as Translation Officer running most of the translation projects, and Dagmara Kuliś, Translation Team Leader supervising the overall activities, they have been joined by Cheryl Whittaker, who will be responsible for contact with commercial clients and the administration of new translation requests within the framework of the new business model. The Translation Unit is a truly international team with its members hailing from Spain, Poland, and the United Kingdom.

The EORTC Quality of Life Group (QLG) has a long tradition in translations of PROs and translation methodology research with numerous publications, including Translation Manuals, papers, conference posters and oral presentations. The seminal Translation Manual was published in 2002 (ISBN2-930064-28-5).

The Translation Unit is extremely interested in maintaining an international network of language service providers, especially by fostering collaboration with three selected vendors, namely TransPerfect, Pharmaquest and MAPI, as well as with the scientific world. With respect to the latter, collaboration with the International Society for Quality of Life Research (ISOQOL) and its Translation and Cultural Adaptation Special Interest Group is of major importance. Representatives of the QLG and the Translation Unit have attended the past three meetings of the TCA-SIG in New Orleans (2009), London (2010), and Denver (2011). They contribute to the TCA-SIG's scientific agenda, especially with the paper on the reconciliation process, and take part in the exchange of knowledge and experience during the meetings.

Special Interest Group (TCA-SIG)

Translation and Cultural Adaptation

Katrin Conway, MAPI Research Trust, Lyon, France

The Translation and Cultural Adaptation Special Interest Group (TCA-SIG), established in 2004 during ISOQOL's annual meeting in Hong Kong, strives to identify and advance research in the fields of translation and cultural adaptation of Patient-Reported Outcomes (PRO) measures.

The TCA-SIG is chaired by Donald Patrick, University of Washington, Seattle, WA, USA, and Katrin Conway, MAPI Research Trust, Lyon, France. The annual focus of the group is decided by the steering committee comprising Donald Patrick, Katrin Conway, Mona Martin, Health Research Associates Inc, Seattle, WA, USA and Sonya Eremenco, United Biosource Corporation, Bethesda, MD, USA. The TCA-SIG's 26 members are divided into three subgroups, each pursuing individual objectives to meet the overall aim:

1. The cross-cultural issues subgroup led by Sonya Eremenco addresses issues related to the access of copyrighted instruments, the translation of PROs and their use in e-format.
2. The Translation Methodology subgroup is chaired by Mona Martin and pursues a research agenda for the development of methodologies in the field of translation and cross-cultural research.
3. The PRO Translation Certification subgroup coordinated by Mona and Katrin aims at establishing an international certification program for PRO translations.

After conducting exploratory work during the first five years of its existence, the group decided to focus its efforts on the publication of findings. The following six topics were identified:

1. Copyright of translations of PRO measures, rules, and applications. Senior author: Caroline Anfray, MAPI Institute, Lyon, France. Submission target: 1st Quarter 2012
2. Translation of Patient Reported Measures: What type of certification should be offered? Senior author: Mona Martin, Health Research Associates, Inc., Seattle, WA. Submission target: 1st Quarter 2012
3. The process of reconciliation in the translation of quality of life questionnaires: Evaluation of existing procedures, criteria and outcomes. Senior author: Michael Koller, Center for Clinical Studies, University Hospital, Regensburg, Germany. It will appear in the April 2012 issue of Expert Review of Pharmacoeconomics & Outcomes Research
4. Efficiency of Translation Methodology in Error-Reduction for new Language Versions of PRO Instruments. Senior author: Mona Martin, Health Research Associates, Inc., Seattle, WA. Submission target: 2nd Quarter 2012
5. Translation Difficulties. Senior author: Catherine Acquadro, MAPI Research Trust, Lyon, France. Submission target: 2nd Quarter 2012
6. Pooling cross-cultural PRO data in global clinical trials: How much can a poor measure in a cultural subgroup affect the estimation in the overall population? Senior author: Antoine Regnault, MAPI Values, Lyon, France. Submission target: 1st Quarter 2012.

The TCA-SIG had its annual meeting during the ISOQOL conference in Denver Colorado on 27 October. 47 ISOQOL attendees participated in the lively discussion around the two presentations which were the highlight of the meeting: 1). "Spanish DTSQ: multiple translations and same language adaptations" by Annarita Felici from Health Psychology Research Ltd, University of London, London, UK; 2). "Pilot testing translations of PRO measures with populations who are difficult to interview" by Darren Clayson from PharmaQuest, Banbury, Oxfordshire UK.

The TCA-SIG's focus for 2012 will be decided and communicated by the end of the first quarter 2012. Please contact Tatiana Gauchon (tgauchon@mapigroup.com) for more information about our group or consult the ISOQOL website (www.isoqol.org).

EORTC Quality of Life Group

Development of Measures to assess Quality of Life in lymphoproliferative disorders: Chronic Lymphocytic Leukemia (CLL), Non-Hodgkin's Lymphoma (NHL) and Hodgkin's Lymphoma (HL)

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Rationale for the development of EORTC lymphoproliferative disorders modules

In contrast to the large number of quality of life (QOL) studies in patients with solid tumors, relatively few QOL studies have been conducted in patients with hematological malignancies, i.e. Chronic Lymphocytic Leukemia (CLL), Hodgkin (HL) and non-Hodgkin lymphomas (NHL)¹. The American Society of Hematology (ASH) has recently voiced concern about the lack of data in this area, advocating urgent efforts to raise the standards of QOL research². International recommendations for various hematologic diseases are paying greater attention to QOL issues and are advocating more research into this area²⁻⁶. The treatment of patients with these diseases has witnessed dramatic changes in the last two decades and this has resulted in better survival rates. The number of trials including QOL outcomes is expected to increase rapidly in this area and it is important to include condition-specific QOL questionnaires to describe patients QOL in more detail.

Objective and how many modules to develop?

The primary study objective is to conduct Phases 1, 2 and 3 of module development of CLL, HL and NHL to be used in conjunction with the EORTC QLQ-C30. As differences in age of onset, treatment and prognosis between these haematological cancers may influence QOL, an important question was raised at the Spring 2011 QLG meeting. Namely, is it possible to develop one module covering CLL, HL and NHL issues, or are the QOL issues surrounding these diseases sufficiently different to warrant the development of separate modules? For example, one could develop modules for indolent NHL and CLL, and one for HL and aggressive NHL. This decision will be made only after Phase 1, when a sufficient number of health care professionals and patient interviews have been conducted. Based on these preliminary interviews a more informed and evidence-based decision can be taken by the research group. We suggest now that when the issues of Phase 1 overlap 50% or more we will develop a haematology mini-core part, with disease specific sub parts for HL, NHL and CLL. If the issues of Phase 1 overlap less than 50% we will develop separate modules. It is also possible that HL and NHL issues will be combined in one module and a separate module will be developed for CLL. The advantage of this approach is that we will efficiently develop what is actually necessary for these three populations.

Project to date (December 2011)

A systematic review of the literature on the general QOL of HL and NHL survivors has been conducted, and has resulted in a publication in *Annals of Haematology*⁷. The first version of the issue list has been developed and we have also used information from two focus group meetings among HL and NHL survivors held at the Comprehensive Cancer Centre South in The Netherlands. Furthermore, we included previous work, which has been conducted by group members that resulted in the EORTC QLQ-CLL16. Centres in five countries will participate in Phase 1: Germany, Italy, The Netherlands, Taiwan and the United Kingdom.



More information or questions?

For additional information or interest in participation in the development of these modules please do not hesitate to contact us.

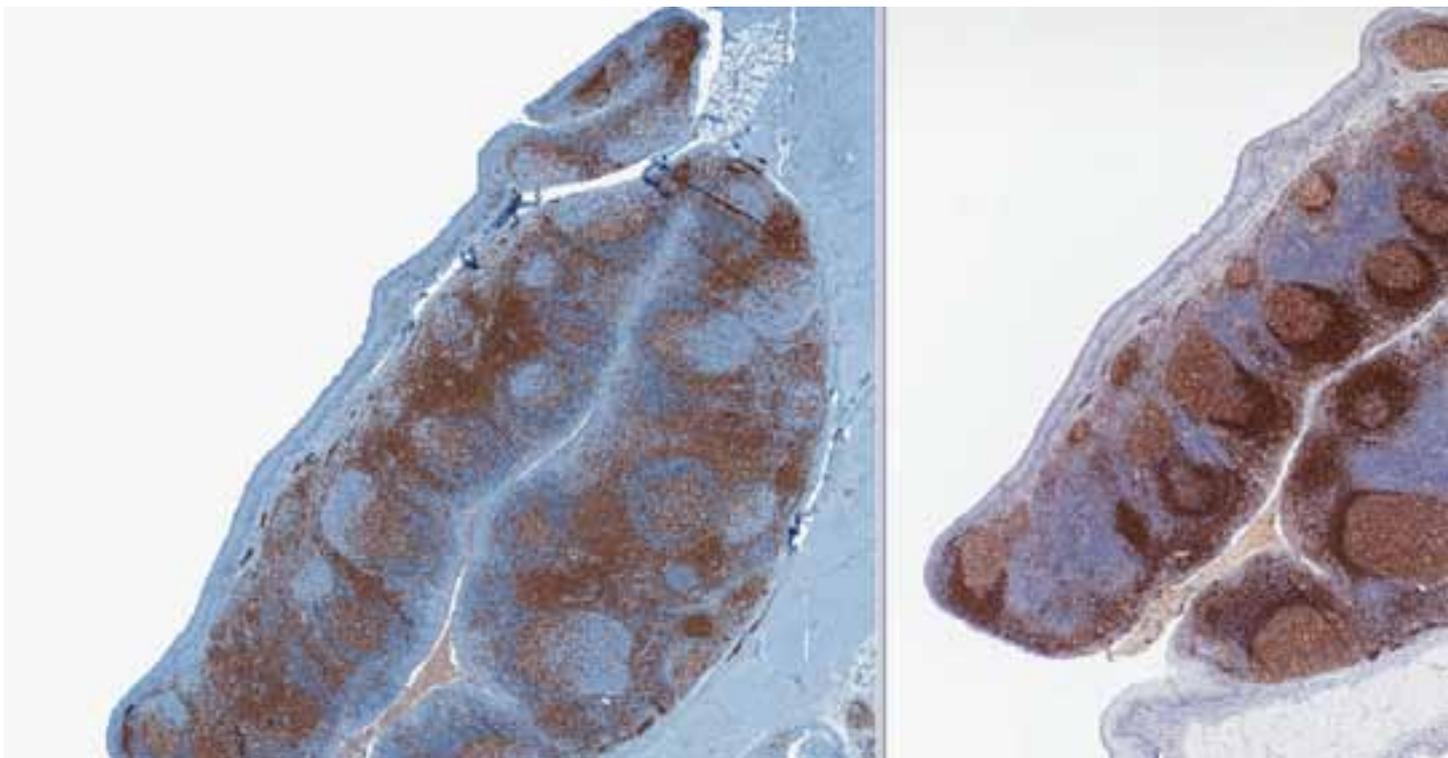
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Relatively few QOL studies have been conducted in patients with hematological malignancies

Development of the **EORTC Testicular cancer module (QLQ-TC26):**

a phase IV study including multi-centre electronic PRO data capture with CHES-EORTC
Bernhard Holzner, Johannes Giesinger, Medical University of Innsbruck, Austria



Introduction

Testicular cancer (TC) is characterised by a low prevalence (<1% of all male malignancies), a low mortality rate (<5% within 5 years), a young patient population (about two thirds <40 years), short hospitalisation, and increasing incidence rates¹.

As mortality rates are low most patients diagnosed with TC become cancer survivors and then have to cope with cancer survivorship problems, related either to the malignancy itself, its treatment or both². Furthermore the majority of TC survivors are men at an age when fatherhood is a very important consideration. Therefore, the toxicity of a therapy and the possibility of infertility have to be kept in mind³. Because of their age and the high cure-rate, evaluation of long term QOL is an important issue in this patient group⁴.

For the assessment of QOL in TC patients the EORTC Quality of Life Group has developed the EORTC QLQ-TC26. The QLQ-TC26 module is comprised of issues pertaining to symptoms of testicular cancer, treatment-related issues and additional dimensions of QOL specific to testicular cancer not sufficiently covered by the EORTC QLQ-C30, i.e. treatment side effects, infertility, body image and sexuality. The items are applicable to patients under treatment as well as to cancer survivors. Phase I-III of the module development process have been completed between 2006 and 2011 and the QLQ-TC26 module development report has been approved by the EORTC Module Development Committee in April 2011.

Objectives

The main aim of this project is to determine the psychometric characteristics and the validity of the EORTC QLQ-TC26 in a phase IV field study.

Another aim is the evaluation of CHES-EORTC (Computer-based Health Evaluation System – EORTC version) with regard to its use for web-based PRO data collection and study monitoring in international multi-centre studies. As TC patients are a young cancer population, web-based questionnaire administration is likely to show high feasibility.

Patient recruitment

The phase IV field study is planned to start in December 2011 and will last until November 2014. We plan to recruit 360 TC patients at the participating centers and assess them at two time points. Patients will be recruited in Australia, Austria, Italy, Spain, Norway, and the UK (see list of collaborators). In addition to these centers, we will seek additional collaborators from the newly reconstituted EORTC GU Group (we have already contacted them and expect that they will be willing to collaborate).

The sample should cover the most relevant patients groups in testicular cancer patients, that is patients undergoing surgery only, surgery and chemotherapy, or surgery and radiotherapy [1, 5]. Given the very high survival rate, a survivor group appears to be of special importance, and will also be included. Baseline assessment will be done in the hospital (electronically or paper-pencil), whereas follow-up assessments will be done either in the hospital or at home on the Internet.

Electronic data collection with CHES-EORTC

As noted above the secondary objective is the investigation of the use of CHES-EORTC for web-based PRO data collection in international multi-centre studies. Those centers willing and able (depending on ethical approval and required IT infrastructure) to participate in electronic data capture will be provided access to the CHES-EORTC data collection website. Our initial discussions with our collaborators indicate that at least five centers (Amsterdam, Innsbruck, London, Southampton, and Sydney) will be able to use this system. The website provides forms for entering clinical and socio-demographic data and allows the patient to complete the EORTC QLQ-C30 and the EORTC QLQ-TC26. For questionnaire administration, participating centers have to provide patients access to either a desktop computer or preferably a tablet-PC with touch screen.

We will evaluate the use of the electronic version in terms of results from the QOL measures, but also seek feedback from users (i.e. collaborators) and patients via debriefing forms. At institutions not participating in electronic data capture, data will be collected conventionally (follow-up assessments via mail survey).

Conclusion

The EORTC QLQ-TC26 will allow the EORTC QLG to have an additional validated measure that will increase the portfolio of tools that the QLG has on offer and appeal to future research groups, academics, and industry partners alike.

Furthermore, as this study includes longitudinal, international, multi-centre PRO data collection in a young patient group, we consider it an excellent opportunity to investigate benefits, barriers, and requirements of web-based electronic PRO data capture with CHES-EORTC. Such knowledge is likely to facilitate future PRO data collection within further EORTC studies. Electronic PRO data capture may improve questionnaire completion rates, reduce percentage of missing items, and reduce costs related to data collection and entry. Therefore, we consider such a combined project on module development and electronic PRO capture particularly beneficial with regard to further enhancement of the EORTC measurement system.



Current Collaborators:

- Neil Aaronson - Division of Psychosocial Research & Epidemiology, The Netherlands Cancer Institute, Amsterdam, The Netherlands
- Juan Arraras - Medical Oncology Department, Hospital of Navarre, Pamplona, Spain
- Andrew Bottomley - EORTC Headquarters Quality of Life Department, Brussels, Belgium
- Fabio Efficace - Health Outcomes Research Unit, Italian Group for Adult Hematologic Diseases (GIMEMA) Data Center, Rome, Italy
- Marianne Hjermsstad - The Cancer Center, Oslo University Hospital, Ullevål, Norway
- Colin Johnson - University Surgical Unit, Southampton University Hospitals, Southampton, UK
- Madeleine King - Psycho-Oncology Co-operative Research Group, School of Psychology, University of Sydney, Sydney, Australia
- Hannes Steiner - Department of Urology, Innsbruck Medical University, Innsbruck, Austria
- Teresa Young - Lynda Jackson Macmillan Centre, Northwood, UK

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As TC patients are a young cancer population, web-based questionnaire administration is likely to show high feasibility.

Patient Reported Outcome Measurements Over Time In ONcology (**PROMOTION**) Project.

Investigating the evolution of reporting quality of life/patient-reported outcomes over time in cancer clinical trials and the use of EORTC QLQ measures.

Fabio Efficace



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What is this PROMOTION Project about?

Randomized controlled trials (RCTs), play a key role in cancer research as they provide the scientific evidence needed to adopt the best treatment for all cancer patients. The provision of quality care depends on the ability to make choices from robust scientific data. Health-related Quality of Life (HRQOL) and other types of Patient Reported Outcomes (PROs) are now a standard component in various trials. Including HRQOL as an endpoint in a RCT setting could provide invaluable information related to functional ability as well as treatment side effects from the patients' perspective. However, assessing HRQOL requires making a number of challenging decisions with regard to, for example, data collection, appropriate timing of assessment, adequate statistical analysis as well as outcome interpretation. Inadequate or poorly designed and reported HRQOL investigations in the context of RCTs can mislead clinical decision making, as it hampers a clear appraisal of the validity of the outcomes. Cancer patients require information not only related to survival estimates, but also regarding HRQOL issues. Therefore providing patients with such information, from a methodologically sound research basis, is of paramount importance.

Some ten years ago an editorial published in *Journal of Clinical Oncology* by Mark N. Levine and Patricia Ganz, entitled "Beyond the development of quality of life instruments: where do we go from here?" raised an important issue in this area of research. The authors stated that it is "disappointing" that, despite the fact that thousands of patients have been enrolled in cancer clinical trials with a HRQOL component, "there are relatively few examples of formal quality of life measurement that have influenced individual patient decision-making or treatment policies". *Is this still entirely true after 10 years of research in this area?*

What are the Objectives?

The broad scope of the EORTC QLQ PROMOTION Project is to investigate the quality of HRQOL/PRO reporting in oncology RCTs to establish whether this has improved over time. This is a large project and we expect several publications out of this work, so we are happy to have the contributions of additional EORTC QLQ members. Please, do not hesitate to contact us for additional Information. We will investigate the consistency of patterns of reporting of HRQOL/PRO over time to help answer the following question: what are we still missing to bridge the gap between HRQOL/PRO research and clinical practice applications?

Some of the main goals:

- 1) To investigate whether there has been a learning curve in terms of the quality of HRQOL-PRO assessment in RCT reports. Such evaluation will be performed separately for each cancer disease site where the EORTC QLQ has modules (i.e. solid tumours and hematologic malignancies)
- 2) To investigate the robustness (in terms of psychometric properties) of HRQOL/PRO instruments used in these trials and evaluate the proportion of those that have used the EORTC QLQ measures. This will be performed according to recently published standard criteria.

How we will reach this goal?

There will be three main steps.

- 1) **Collecting evidence-based data.** Systematic literature searches on all cancer RCTs will be performed. Any RCT including HRQOL as an endpoint (either primary or secondary) will be considered.
- 2) **Data extraction.** Each RCT will be evaluated on a number of criteria including study design, study sponsorship, and methodological issues (including the forthcoming CONSORT HRQOL/PRO criteria). A large electronic database will be developed for the purpose of this research to store data collected from literature reviews.
- 3) **Data analyses and manuscript writing.** Statistical analyses will be performed to investigate reported quality trends over time. Several manuscripts are envisaged from this project, including a series of systematic reviews. All publications will be on behalf of the EORTC QLQ Promotion project.



The EORTC Brain Tumour Group; the value of proxy-reported QOL measurements.

Jaap C. Reijneveld^{1,2}, Martin J.B. Taphoorn^{1,3}, Andrew Bottomley⁴



The Brain Tumour Group (BTG) of the EORTC has a longstanding reputation in the incorporation of quality of life measurements in their clinical studies. The Brain Module is one of the first developed cancer specific modules^{1,2} and is, together with the generic EORTC QLQC-30, part of the tools of many completed and still running trials of the group.

The BTG has been very successful in performing phase 2 and phase 3 clinical trials during the last decade. Most of the activities of the BTG are focused on patients with glioma, primary brain tumours arising from the supporting tissue of the brain. Glioma patients eventually inevitably die of their disease. Patients with a WHO grade 2 glioma have a median survival of approximately six years, whereas the prognosis for patients with WHO grade 3 (or anaplastic) glioma and WHO grade 4 (or glioblastoma multiforme; GBM) is even poorer, with a median survival of approximately three years and one year, respectively.

Among the achievements of the BTG are the observations that early postoperative radiotherapy of WHO grade 2 glioma patients results in prolonged progression-free survival compared with delayed radiotherapy³, that addition of concomitant and adjuvant temozolomide chemotherapy to the postoperative radiotherapy of GBM patients prolongs survival⁴, and that the addition of chemotherapy to postoperative irradiation prolongs progression-free survival of patients with WHO grade 3 oligodendrogliomas and oligoastrocytomas⁵. We are still awaiting the results of, amongst others, a phase 3 trial assessing the effects of replacement by, or addition of chemotherapy to the routine postoperative radiotherapy in patients with WHO grade 3 gliomas, and a phase 3 trial comparing postoperative chemotherapy and irradiation for WHO grade 2 gliomas. Apart from the primary survival endpoints of these trials, translational research utilizing both tumour tissue and blood of these patients is coordinated by the BTG, and has resulted in improved classification systems of gliomas based on molecular markers.

The efforts of the BTG have thus led to increased survival for many glioma patients, but unfortunately, these patients still inevitably die of their disease. Awareness of this fact emphasizes the importance of a sound balance between treatment and perceived QOL, different from that in cancer patient groups with a reasonable percentage of cured patients. This awareness has resulted in the implication of QOL measurements in all phase 3 and most phase 2 clinical studies of the BTG during recent years^{6,7}. Although many aspects of health-related QOL are very similar to those of patients with other types of cancer, glioma patients are unique due to the impact of cognitive disturbances. Almost all glioma patients suffer from cognitive deficits to some extent, and these cognitive deficits may hamper adequate reporting of QOL by the patients themselves.

A challenge for QOL research in glioma patients in the near future is, therefore, to improve assessment of QOL in cognitively disturbed glioma patients. We have realised that what clinicians see is not always the same as what patients report. A more adequate assessment might be achieved by combining patient-reported outcomes with information retrieved from proxies of the patient. Whilst a handful of published peer-reviewed studies have been conducted using proxy-reported outcomes, the EORTC thus far has not, in the 140 clinical trials with QOL-measurements incorporated, undertaken any work in this area. The added value of incorporation of proxy measurements in EORTC BTG studies might be many fold: the use of the validated EORTC measures, robust data collection procedures, relatively large samples sizes, and, importantly, prospective data collection rather than cross-sectional snapshots. For this purpose, QOL proxy-reported measurements have now been incorporated into two recently started BTG studies. As BTG members have all shown an impressive degree of motivation in the past for getting good compliance, and QOL papers of our group have been published in high impact journals, we are very hopeful that these proxy-studies may be a test bed for other groups. Perhaps groups where they have patients with advanced cancer and where proxy-reported outcomes may also have additional value. We hope that the results of these studies will improve our knowledge on the value of proxy-reported measurements and the way they should be implemented in future trials ■

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2nd EORTC Symposium: Quality of Life, Symptom Research and Patient-Reported Outcomes in Cancer Clinical Trials

The 2011 EORTC Symposium held at the European Parliament in Brussels last 7-9 September confirmed the international attention paid to Quality of Life for cancer patients. The event enhanced the previous Symposium by introducing innovations on health related quality of life, symptom research and cancer clinical trials, including their design, implementation and analysis. Thanks to an extraordinary collaboration with the Portuguese Member of the European Parliament Marisa Matias, it was possible to give an institutional framework to the scientific gathering and engage a constructive debate with the European legislators and policy makers.

During the three-day event 31 Faculty, international leaders in their fields, presented diverse perspectives on HRQOL. All the different stakeholders in clinical research were involved including European patient groups. Patricia Garcia-Prieto and Šarūnas Narbutas from the ECPC (European Cancer Patient Coalition), Jan Geissler from CML Advocates network and Louis Denis from Europa Uomo gave an insight into the patient experience, addressing difficulties such as access to international clinical trials, survivorship issues etc.

The figures fully confirmed the success of the event, with 240 attendees from 44 different countries and the positive feedback from the participants wishing to repeat the experience. Andrew Bottomley, Head of the QOL Department and Symposium Chair, announced a 2012 Conference (17-19 October) co-funded by a European Commission grant with the aim to give continuity to this initiative.

In order to facilitate the participation of young investigators and those from developing countries the EORTC created a Travel Fellowship program. Hundreds of applications were submitted, and the QOL Scientific Committee selected with scrupulous care the 30 awarded from many worthwhile candidates with promising CVs. The awarded Fellows represented 23 countries, bringing a particular and fresh view. We asked the Fellows to talk about their Symposium experience and here are accounts of young investigators from Poland, Portugal, Malaysia, Egypt and China describing not only the scientific value but also the networking opportunities the Symposium represented for them.

Rossella Guzzo Foliaro

I am a 26 year old medical doctor from Poland. I am currently in my internship year and working at the J. Dietl Specialistic Hospital in Krakow, Poland. As for next years' plans I am going to start my PhD studies at the Jagiellonian University in Krakow and continue my work as a physician.

My scientific interests focus mainly on health-related quality of life and overall physical and mental well-being of patients. As a medical doctor I am trying to popularize the concept that though fighting to cure patients is of great importance, doctors cannot forget that for some patients good quality of life is more important than prolonging life "no matter the cost".

Currently I am involved in a series of projects focused on translating and validating the EORTC's tools for health-related quality of life assessment in cancer patients. Even though most of EORTC's tools have been translated into Polish, not all of them have been psychometrically validated. So there is still lot of work ahead.

Quality of life concepts are quite popular in my country and many researchers work in that field. Quality of life starts to be seen as a possible outcome measure in clinical trials in Poland, thus the need for appropriate instruments. That is why we are currently working on translating and validating the EORTC tools.

Taking part in the 2nd EORTC Symposium on Quality of Life, Symptom Research and Patient Reported Outcomes in Cancer Clinical Trials was a great experience for me. It gave me the chance to meet people from all over the world and exchange ideas about working on and with patients reported outcome measure. It has beyond doubt proven to me that the quality of life concept is popular all over the world. Things that I have learned at the Symposium will certainly contribute to my future work, especially the Translation Workshop and the talk by Prof. Eva Greimel about designing quality of life questionnaires.

Once again I would like to say that attending the Symposium was a fantastic experience. It was great to meet the EORTC staff in person.

Krzysztof Tomaszewski
Jagiellonian University Krakow, Poland



I work as an attending physician and lecturer at the Department of Clinical Oncology, Tanta Faculty of Medicine, Egypt. I also spent 2-year fellowship at the Department of Oncology, Massachusetts General Hospital, Harvard Medical School, Boston USA. I have shared in many peer-reviewed articles and I also edited two chapters in the book entitled "Breast Cancer: A Multidisciplinary Approach to Diagnosis and Management".

The quality of life in patients undergoing treatment for cancer is greatly underestimated in Egypt and I think this is one of the major defects in our practice. I learned about the EORTC symposium from the website and I was so happy to know about the travel awards. I applied and I was lucky enough to have the fellowship.

Attending this meeting was a unique experience to me since the topics were so much different from any other meetings I used to attend. This has been a very powerful life experience for me. The different people I met from diverse countries and culture has made my learning experience more meaningful and real. I've seen how diversity can result to immense synergies, fruitful learning, and strong friendships. Also, meeting the experts in this field was an excellent chance to exchange thoughts with the potential for future collaboration.

The EORTC quality of life symposium opens me to new perspectives in my career. I really enjoyed it very much and I look forward to attending future EORTC meetings concerning with quality of life in cancer patients as far as travel fellowships would be granted!

Mohamed Abd El – Hamid Alm El- Din
Department of Clinical Oncology
Tanta Faculty of Medicine, Egypt

I'm a 30-year-old Portuguese Medical Oncology resident, at the verge of becoming a specialist. Health-related Quality of Life (HRQOL) was the motto for the clinical research I undertook during my Master in Oncology. Presently, I await the public defense of the dissertation entitled "Assessing the information given to cancer patients attending Day Hospital in a comprehensive cancer centre", where I used EORTC QLQ-C30 and its information module EORTC QLQ-INFO25 as measurement instruments.

Attending the EORTC QOL Symposium, while writing my dissertation, was fundamental to contact directly with major experts in QOL worldwide, learning valuable tips and advice from them, and also for the opportunity to make contacts with other young researchers working in the field, which I believe will be most useful to me in the future, as I plan to continue working on this subject, namely developing a clinical trial where QOL will be an important endpoint.

Ana Catarina Pinto
Resident in Medical Oncology
Portuguese Institute of Oncology
Coimbra, Portugal

Hi, I am Chloe from China. The 2nd EORTC symposium was truly rewarding and educational. I benefit a lot from these topics of designing, conducting and analyses of HRQOL in clinical trials, also gained a lot useful information in my own research area of gynecological cancer. Those topics in genetics and HRQOL were very impressive and encouraging. The unique nature of this symposium included hearing the voice from patient perspective. That's truly meaningful.

From this symposium, I met many top researchers and scientists from all over the world, the Gala dinner was well organized as well!

Ying Chun Zeng
The Hong Kong Polytechnic University,
School of Nursing, China

When I was at the preliminary stage of planning my current research on the outcome of tumour-related hemipelvectomy, a colleague suggested including Quality of Life (QOL) assessment into it. It was something new to me, but from there on, I came across with the EORTC QOL-30 Questionnaire, and was invited to attend the symposium in Brussels. It was an amazing experience! The lectures were inspiring, some of the speakers made the whole idea on QOL research sound very interesting and meaningful.

I can still remember my short discussion with Corneel Coens during one of the breaks. I would like to specially thank him for his willingness to spend time to discuss and giving his sincere and motivating suggestions on my research. Back in Malaysia, the last decade had seen a boom in health related quality of life (HRQOL) research. This may be related to researchers' readiness to use the generic HRQOL by World Health Organization (WHO). With the increasing improvement in the management of incurable or chronic illnesses, HRQOL is gradually incorporated to assess the quality of service, cost utility analyses, effectiveness of interventions, and the need for health care. I am a trainee lecturer and a registrar in Orthopaedics, and will be completing my Masters by the end of 2012.

Capitalizing on my special interest in orthopaedic oncology and reconstruction, I am seeking as many opportunities as possible to gain experience and knowledge to improve my services and management to orthopaedic cancer patients. I would like to thank the EORTC for awarding me the Travelling Fellowship and looking forward to share the result of my research once completed.

Mohd Ariff Sharifudin
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EORTC QLG-Workshop:

Introduction to Item Response Theory

Lonneke van de Poll-Franse, Comprehensive Cancer Center South, Eindhoven

In September 2012 the EORTC QoL group (QLG) for the first time organised a workshop before the regular group meeting. Twenty-five persons attended the workshop on Item Response Theory (IRT) given by statisticians Julie Winstanley and Morten Petersen, both active members of the QLG. Julie started by discussing the fact that most frequently used QoL questionnaires often have skewed distributed item or scale scores. Interestingly, almost all papers that report on QoL outcomes, even from research groups that develop these questionnaires, report means and SD's. This is fine if used for descriptive purposes, but not for decisions on outcomes. For example to decide whether treatment A results in a better QoL than treatment B. Furthermore, ordinal scales have the typical problem that one cannot assume equal intervals between adjoining points (in contrast to interval scaling). For example, the interval between scoring 2 ('a little') or 3 ('quite a bit') points on the item 'Did you feel depressed' might be clinically more important than the change between 3 and 4 ('Very Much').

IRT might be of help to overcome the problems of parametric testing. The most widely used approach for IRT is Rasch analysis. It makes ordinal into interval scales by taking the logit for use in parametric statistical analyses. Julie interactively took us by the hand to do a Rasch analyses of the FACT Melanoma surgery subscale, showing that the model fit of this subscale improved if a 4-point scale was being applied rather than a 5-point scale.

In the second half of the workshop, Morten gave somewhat more technical details of IRT analyses and illustrated this with the EORTC CAT (Computer Adaptive Testing) project. CAT is based on IRT, so that the response of a previous question is used to select the most informative next question. Morton also explained the advantages of IRT, (more realistic handling of missing data, better and more detailed estimation of measurement precision) and challenges and limitations of IRT (more complex to understand and apply than sum scoring, communicating results is more difficult to non-specialists, time consuming, larger sample size needed, IRT software not-user friendly yet).

During the workshop the feeling grew that questionnaire development should really include IRT analyses, at least to overcome all the assumptions that are in fact violated by most questionnaires. After this workshop I understand the basics of IRT, but for now it seems smart to consult an experienced statistician when one applies IRT analyses ■

Lonneke van de Poll-Franse



A new project to ensure data preservation and quality: **The Data Repository project**

Francesca Martinelli, Quality of Life Specialist, EORTC Quality of Life Department, Brussels



After writing in March 2011 my first contribution for this newsletter to wave goodbye after three years as a research fellow in the Quality of Life Department (QLD), I'm excited to now write a new contribution to present an important project: the Data Repository project.

How was this project born? The Scientific Advisory Committee (SAC) review, in 2010, made a number of queries about phase IV of Module Development studies which are run outside the EORTC Headquarters. After this review, two main observations were made. The first observation was, the Principal Investigator (PI) usually owns the data: what happens if the PI leaves the QLG? The second observation concerned the absence of a standard protocol template for data collection. The SAC advice was to continue running studies outside the EORTC Headquarters, but to create a dataset to store copies of all the data and to develop a standard template for data collection for phase IV studies.

Following the SAC recommendations (endorsed by the EORTC Board and the QLG Executive Committee), the Data Repository project was created. I started working on this project in May 2011, under the supervision of the Head of the QLD Andrew Bottomley and a committee composed of the former Chair of the QLG Galina Velikova and the Chair of Module Development Colin Johnson.

The aims of the Data Repository project are:

- to identify and develop generic standards for data collection in order to keep the field study process harmonized
- to promote good data preservation strategies
- to promote the sharing of data for collaborative, high-quality and ethical new research.

This project is important for many reasons. The identification and development of generic standards for data collection will harmonize and simplify the field study process. Furthermore, not only will the field study process become smoother, but harmonized data will also be an asset in the case of quality control. Data loss will be prevented by the creation of a dataset for storage of copies of all the data. Also, last but not least, data sharing will permit collaborative, high-quality and ethical new research (subject to defined rules approved by the QLG Executive Committee), making good use of the data and enhancing its long-term value.

In order to identify and develop accurate and complete standards for data collection, it is important to conduct a scrupulous review of all existing phase IV protocols. Also, in order to create a central dataset for data storage, copies of all data are needed.

For these reasons, PIs of phase IV studies conducted outside the EORTC Headquarters have been approached. Via a letter presenting the Data Repository project and explaining why we are asking them to support this project by providing copies of protocols and data. Contextually, the first draft of a document named "Data preservation and sharing initiative" which describes the project, defines rules for data preservation and sharing and specifies practical details has been prepared; at the moment of writing (December 2011) this document is under final approval by the QLG Executive Committee. The aim of this document is to illustrate, regulate and make clear and transparent the whole procedure. This project was also presented at the last QLG meeting in Innsbruck in September.

We are happy to see that PIs are being very collaborative: many protocols and data have already been sent, allowing us to start preparing the standard protocol template and to start building the central dataset. We are now looking forward to receiving the protocols and data that are still missing in order to be able to proceed with this project which is so important for data collection, preservation and quality ■



Neil Aaronson remembers valued colleague and friend

Chad M. Gundy

1952 – 2011

Chad Gundy, who has died at age 59, was a valued and respected colleague and friend who brought his deep knowledge and experience in research methods and statistics to bear on a range of studies in the fields of chronic disease, mental disorder and oncology. Chad received his bachelor's degree in psychology from the University of Florida, and his Master's degree in psychology, with a focus on statistics, methodology and psychometrics, from the University of Leiden, the Netherlands.

Starting in 1978, Chad worked for some 20 years for the Foundation for Scientific Research on Traffic Safety, where he did field research, lab studies, and scenario and simulation studies, all in the interest of making our lives on the highways and byways a little bit safer and saner. From 1998 to 2006, he worked as a methodologist and statistician in various settings, doing survey and marketing research, primary health care research, and clinical epidemiological studies. In 2006, he joined the Division of Psychosocial Research and Epidemiology at the Netherlands Cancer Institute in Amsterdam, where he advised on and participated in a range of studies on quality of life assessment in clinical research and daily clinical practice, treatment-induced cognitive deficits, and psychosocial issues in cancer genetics.

Chad loved to solve problems; the more complicated, the better. With a glint in his eye and a devilish grin, he would roll up his sleeves and delve into his collection of books, articles, and memory cells to come up with not one, but more often than not three or four potential solutions. As many of those with whom Chad worked were less experienced in the mysteries of advanced statistics, he was regularly faced with the challenge of explaining his ideas and recommendations in a way that everyone, from students to high-powered clinicians, could understand. He did this with patience, humor, and occasionally with the use of colorful metaphors.

Shortly after joining the Netherlands Cancer Institute, Chad became a member of the Quality of Life Group of the European Organisation for Research and Treatment of Cancer. He participated actively in several of the Group's scientific projects, including the Cross-Cultural Analysis Project and the QLQ-C30 Higher Order Component Project in which he took the lead. Chad continued to work on this latter project throughout his time as a patient, even preparing a cogent response to extensive peer reviewers' comments and making manuscript revisions only weeks before he succumbed to his illness. That paper, first authored by Chad, is now in press in *Quality of Life Research*.

Given his high level of professional involvement and sense of commitment, one might think that it was all work and no play with Chad. Nothing could be further from the truth. Chad was a true family man, devoted to his wife, Mirte, and their two daughters, Ellen and Mira. He had a love of classical music, was a voracious reader, grew fruit and vegetables, and even made wine from grapes grown in his own vineyard, no small feat in a damp, cool country like the Netherlands.

At work, Chad liked nothing more than to recommend a biography that he had just read, a Mozart concerto that he had heard, or to advise on the best way to preserve garden vegetables. It was that mix of professional and personal that made Chad so very likeable. His appearance reflected that mix. His typically "uniform" at work was a blue blazer, a pinstriped dress shirt (albeit slightly wrinkled), jeans, and a pair of well-worn hiking shoes. From the waist up he appeared to be all business, but he was ready to take a walk in the woods at the drop of a hat.

Chad showed remarkable courage and commitment to life – both his working life and his family life – throughout the period of his illness. He endured the trauma of surgery and the discomforts of chemotherapy with dignity, optimism, and even humor. He continued to live life to its fullest, within the constraints imposed by his physical condition, until the very end ■

Neil Aaronson, Division of Psychosocial Research and Epidemiology, The Netherlands Cancer Institute and Professor of Clinical Psychology, the University of Amsterdam



“Chad loved to solve problems; the more complicated, the better.”



EORTC QoL GROUP MEETING

Innsbruck, Austria, September 2011

The Autumn meeting 2011 of the Quality of Life Group was, for the first time in EORTC history, held in the very heart of the Alps, in the fifth largest city in Austria, Innsbruck. It was the last meeting before the 50th anniversary of the EORTC in March 2012 in Brussels. From 14th to 16th of September researchers from all over Europe and even Australia were hosted by colleagues from Innsbruck, once a central junction for cultural and trade routes between northern and southern Europe and now “the smallest, yet most beautiful world city”, as locals call it.

On the day before the meeting, an opening Workshop on Item Response Theory was held. Morten Petersen and Julie Winstanley introduced participants, statisticians and non-statisticians alike, to different methods and concepts of Item Response Theory (IRT). Both presented past IRT-experience in testing the QLQ-C30 and encouraged people to use IRT in developing questionnaires.

The first day of the meeting started with a welcome note from QLG Chair Galina Velikova, Corneel Coens from the EORTC Quality of Life Department, and from local host Bernhard Holzner. Following this introduction, various QLQ-modules were discussed in parallel sessions. The Testicular Cancer Module, the Elderly Module and the Fatigue Module have now completed Phase 3. Other modules are currently being updated, for example the Head and Neck Cancer Module and the Lung Cancer Module. Oral Health and Breast Reconstruction Module are currently in phase 3. On Friday, some aspiring projects of the Quality of Life Group were presented in plenary sessions, the Computer Adaptive Testing Project, which has completed three of the dimensions of the QLQ-C30, the CHES Project which makes the QLG30 and its modules electronically available, and the ongoing intriguing work of the Translation Committee. Thirty one new translations were finalised in the six months before the meeting, e.g. the HDC29 in Japanese, the OG25 in Farsi, the MY20 in Lithuanian and Hindi.

EORTC QLG meetings are known and valued by attendees not only for their scientific input and exchange but also for their social and cultural experiences. And this time was no exception whatsoever! On Thursday, we enjoyed a breathtaking dinner on the ski jump at the Bergisel, introduced with a glass of champagne and framed by the sunset. From the restaurant on the top of the ski jump, a few hundred metres above the city, the organisation team of Bernhard Holzner and Johannes Giesinger offered free jumps for the bravest of the group. Fortunately, no one decided to take on this offer... However, invitations from the evening's music band to dance and sing along were wholeheartedly embraced. A few of the group members demonstrated an impressive talent to entertain. The audience were swept off their feet. Less wildly celebrated but yet highly appreciated was the Friday dinner on Penz Hotel's roof top, one of the best restaurants in town. With delicious food and wine, good conversation, and much anticipation to our next meeting in Brussels we ended our meeting in Innsbruck. A big and warm “Thank you” to Bernhard and his team not only for organising the meeting and for sharing their scientific experience, but also for choosing the restaurants and taking us out for after-dinner-excursions to the nightlife of Innsbruck ■

Dirk Hofmeister

Fall meeting 2012 of the EORTC QLG

Regensburg, Germany



The fall meeting of the EORTC QLG will take place on October 4th to 5th 2012 in Regensburg Germany.

Regensburg, a city with a population of 140.000, is situated in the Free State of Bavaria, Germany, about 100 kilometers northeast of Munich. It is therefore easily accessible via airplane (an airport shuttle can be booked in advance that will take you directly to your hotel) or via Intercity Express trains. Regensburg is an interesting place, economically and scientifically as well as culturally.

Economically, it is one of the most prosperous regions in Bavaria with world class companies such as Siemens, Infineon and BMW as well as numerous successful start-up firms in biotechnology. The economic success of Regensburg is closely linked to its young university, which was established in the late sixties. The University Hospital Regensburg founded 20 years ago is the latest maximum care facility of its kind in Germany. Its scientific and clinical focus lies in transplantation, immune-oncology and functional genomics.

Historically, Regensburg looks back to a 2000-year old tradition. Located on the river Danube and unharmed by the Second World War, Regensburg is regarded as one of Germany's most beautiful mediaeval cities. In recognition of its former political importance, its role as a mediaeval trading centre and the quality of its architecture, Regensburg was added to the UNESCO World Heritage List in 2006 (quotes taken from www.regensburg.de, this website also offers more detailed information). 1200 historic buildings are to be found in the city centre around spacious plazas that offer many opportunities to enjoy a cup of coffee or a beer outside. Because of this and the large Italian influence in its architecture, for example several Patrician towers that add a Mediterranean atmosphere to the city, Regensburg is nicknamed "the most Northern City of Italy".

Well-known sights include St. Peter's Cathedral, the Old Stone Bridge and the Old Town Hall. The latter was the meeting place of the Perpetual Imperial Diet (Immerwährender Reichstag) which may be regarded as a forerunner of the European Parliament. Representatives of the Holy Roman Empire, the Estates of the realm, the clergy, the nobility and commoners met here to discuss state affairs. Famous sayings such as "to put something on the long bench" or "to decide something on the green table" have their roots from this political tradition.

The location of the congress, the Kolpinghaus (www.kolping-dev.de), is located in the city centre so that all famous sites are within walking distance. After the conference, you may consider attending the Oktoberfest in Munich, which ends on October 7th.

We are looking forward to welcoming you to Regensburg and trust that you will enjoy quality of life both from a scientific and touristic perspective ■

Michael Koller

ANNOUNCEMENT

3rd EORTC Conference on **QOL and Cancer Clinical Trials**, 17-19 October 2012, Brussels

The prominence of the Quality of Life field has become recognized as well as the valuable work we have been conducting by a major European Union grant awarded to co-fund the 3rd EORTC QOL conference; this will take place on the 17-19 October at the European Parliament.

The conference chair Dr. Bottomley stressed that *“what’s great about this event is having over 30 of the world’s leading QOL Faculty attending, from as far afield as Australia to Canada and many members of the EORTC Quality of Life Group presenting. When budgets are tighter in a recession, it becomes more difficult to meet and debate in the academic setting key issues about conducting good quality clinical trials. But for the third year running, this conference is free for researchers and health professionals to attend”*. Additionally the EORTC awards 40 Travel Fellowships to young investigators and those from developing countries, offering financial support of 400 Euros each to participate to the Conference and benefit from their contribution on the Design and Implementation of QOL in Clinical Trials.



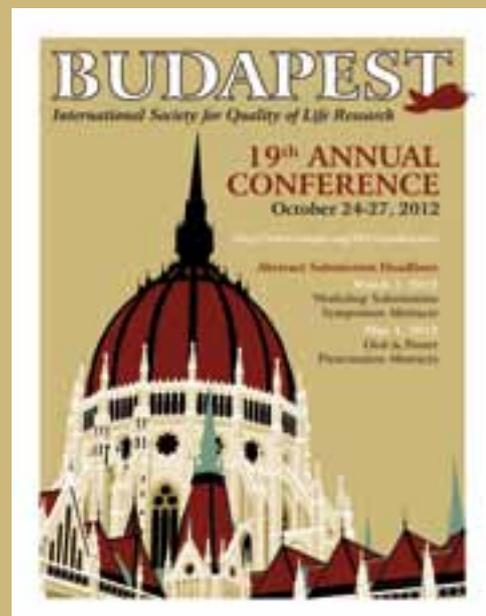
The European Parliament

An important role is played by the European Parliament and as Dr. Bottomley emphasized *“the fact that the European Parliament hosts this meeting shows that despite the economic and political challenges that we face, QOL and the cancer patients’ needs are still a key concern to our legislators”*. Meeting in the European Parliament provides a special and rare chance for an excellent dialogue between researchers and policy. Marisa Matias, MEP who will be co-chairing the patient session of the meeting, is the leading supporter of QOL and EORTC. Confirming her engagement for cancer patients’ rights, she stated *“I am very pleased to be hosting for the second time this event and we look forward to seeing what advances we have made since we last met. It is critical that the patient’s voice is being heard and taken into account in treatment decision making and we hope this conference will echo this fact with discussion and debate.”*

Further Information

If you are interested in attending it is important to register ASAP, as places are limited and on a first come first serve basis. Travel awards should be applied for before the 1 May 2012. Please visit www.eortc.be/probe to register and to find out more about applying for the Travel Fellowship program. For more information please contact qolconference@eortc.be ■

Also not to be missed



For more information on the Quality of Life Group and its activities, please visit our website:
<http://groups.eortc.be/qol>

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