



# Quality of Life Group newsletter

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EORTC Quality of Life Group meeting  
Pamplona, Spain, September 2009

*Lonneke V. van de Poll-Franse - Newsletter Editor*

**A**t our last Group meeting, hosted by Juan Arraras in Pamplona, Spain, we had two active days with almost 50 Group members attending. Once in Pamplona, all travel irritations and fatigue disappeared (no lasting late effects) because Juan had arranged a great location, a wonderful social programme and even lots of sunshine. Maria Kutz, Health Minister of Navarra, officially welcomed us to Pamplona and wished us a productive meeting. We started somewhat hesitantly with about 30 participants, but in a way, it helped to speed up a few discussions which can be very useful.

On Thursday evening, after our usual module meetings, we were invited by Maria Kutz to visit the impressive Palacio de Navarre, the seat of the Regional Government. Afterwards we all received a brochure on the Province of Navarra. We then crossed the Plaza del Castillo (where the bullring used to be, we would learn the next day) to enjoy the last sunny evenings of September on the terrace of Café Iruña. That night we had dinner at Nuevo Casino Society, where we were served several courses of Spanish and local specialties. After several glasses of Vino Blanco or Tinto, a few of us suddenly discovered that we were almost fluent in Spanish and all language barriers that had hampered conversation during the day naturally disappeared. ▶

continued from page 1

On Friday we started with our Business Meeting in which new research grants, future meetings and possibilities of collaboration with the PROMIS group were discussed. The election for Newsletter Editor appeared to be straightforward, with only myself as a candidate that fulfilled the criteria. Anyway, no-one was against it, and I am really excited to become more involved in the activities of the EORTC QoL Group.

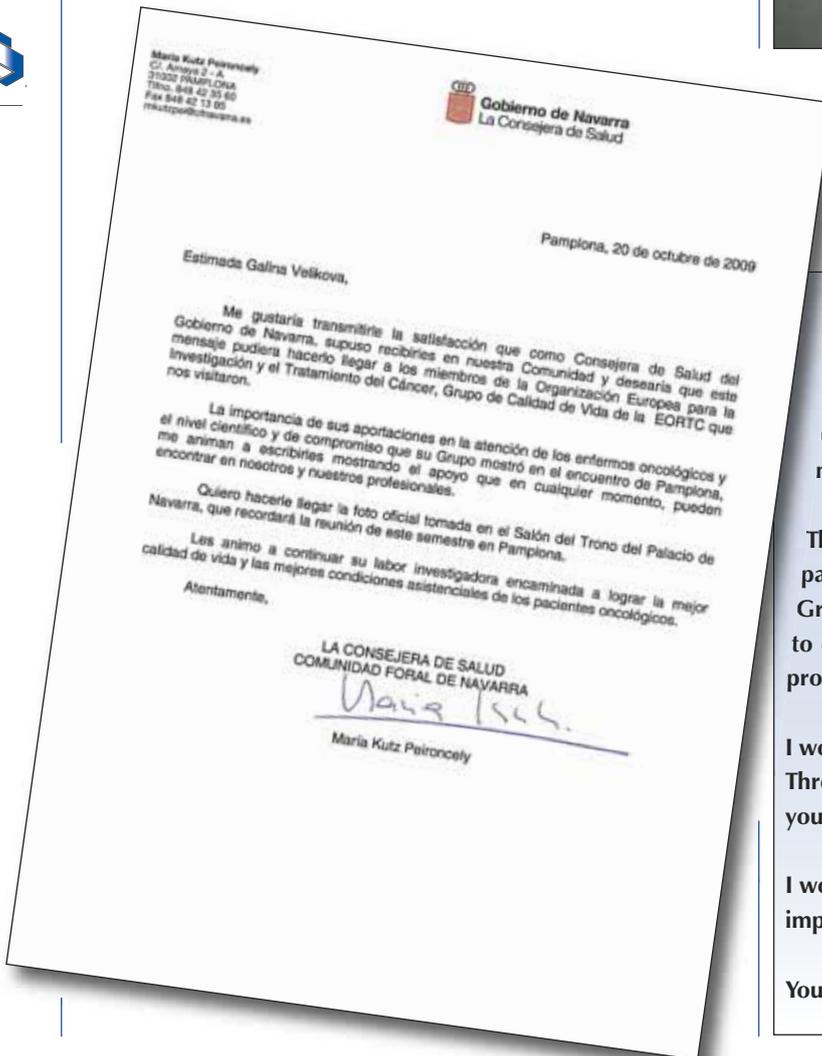
During the morning's plenary session, Sheila informed me that the newsletter evaluation showed that Group members would love to read two newsletters rather than one per year. We have not given it much thought yet, but chances are high that I will disappoint you all immediately. But I promise to continue the work that Martin Taphoorn has delivered in the past few years. Chad Gundy reported on his progress in the creation of a higher order component. In the afternoon John Brazier, a health economist, was invited to present his work on creating a health utility score out of the EORTC QLQ-C30. Juan and his colleague Jose Juan Illarramendi presented the QoL work in Navarra in recent years.

On Friday night we had the opportunity to join a guided tour of the city of Pamplona, which showed us the insights of the torro/bull fights, as well as the three cities Pamplona used to be.

We closed yet another good meeting with a nice meal, wondering whether the lung cancer incidence will decrease somewhat later in Spain compared to other European countries... ■



Lonneke V. van de Poll-Franse, PhD



*Translation of letter:*

Dear Galina,

As Minister of the Navarra Ministry of Health, I would like to express my pleasure at the visit of the members of the QLG and EORTC, which was so well received by our Community.

The significance of their contribution to the care of cancer patients and the scientific level and commitment that the Group showed during the Meeting in Pamplona inspired me to express that you can count on support from us, and our professionals, whenever needed.

I would like you to receive the official photograph taken at the Throne Room of the Palace of Navarra, which should remind you of the meeting in Pamplona during this semester.

I would like to encourage you in your continued research into improving the quality of life and conditions of cancer patients.

Yours sincerely,

# EORTC-PROBE Course on Quality of Life, Symptom Research and Patient Reported Outcomes in Cancer Clinical Trials

*Melissa Thong, PhD  
Comprehensive Cancer Center South, Eindhoven,  
The Netherlands  
Center of Research on Psychology in Somatic Diseases  
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The newly established Patient Reported Outcomes and Behavioral Evidence (PROBE) project of the EORTC Quality of Life Department organized a 3-day course from 25-27 November 2009 in Brussels.

The response for this course was overwhelming and many applicants had to be turned away. Those who attended were a large international group, which included doctors, psychologists, nurses and patient advocates.

This course promised a packed program presented by an internationally respected faculty for researchers who are working in or are interested in implementing HRQL assessment in clinical trials. The speakers did a great job in providing as much information as they could within their allotted time (usually a half hour presentation). The topics covered were indeed varied. Besides topics such as methodology/ study design and statistical analyses/ interpretation of HRQL scores, the course also covered regulatory (FDA and EMEA), ethical and translation issues involved in HRQL research. The presentations generated lively discussions from the participants, probably helped along by a reward of a box of scrumptious Belgian chocolates for the most challenging question posed!

Kudos to the PROBE team for a job well done in organising this inaugural HRQL course. It has certainly met its objectives in the range of topics touched on during the course. As such, this could be a good introductory course for someone new to or is starting



HRQL assessment. However having spoken to some other participants with more experience in this field, we hope that PROBE might also consider organising advanced courses with more in-depth coverage of selected topics. ■

## Chantal Quinten,

One of the PROBE members and part of the organizing committee, agrees with the above comment from Melissa that topics might be more specific and focused for the more experienced HRQOL specialists.

Based on feedback that the PROBE received on their evaluation forms, people show a keen interest in more advanced courses, especially on statistics (clinical trial design) and methodology (minimal important differences).

The EORTC PROBE wishes to acknowledge this in a further upcoming Symposium. Organizing a second Symposium in the near future guarantees sustainability in our training efforts to provide health care professionals with the proper statistical and methodological tools to use in their daily clinical practice and research.

Currently a recording of the Symposium from November is uploaded on the EORTC PROBE website ([www.eortc.be/probe](http://www.eortc.be/probe)) and can be consulted if you have missed the opportunity to attend this meeting.



## In this issue

- QLG meeting in Pamplona ..... p.1
- EORTC PROBE Course on Quality of Life ..... p.3
- Development of a Melanoma Module ..... p.4
- Update from Down Under ..... p.6
- News section ..... p.7
- Higher order factor models for the EORTC QLQ-C30 .... p.8
- Disease management and e-health ..... p.10
- Recent developments at EORTC HQ..... p.12
- Autumn QLG meeting - Leipzig ..... p.13
- The EORTC QLG chronic myeloid leukemia module .. p.14
- 2009 QLG Publications ..... p.17
- EORTC contact details ..... p.19

# Development of a Melanoma Module



*Associate Professor  
Julie Winstanley  
Head, Research and  
Biostatistics Group,  
Provectus Principal  
Research Fellow,  
Melanoma Institute Australia,  
University of Sydney, Australia*

## Background:

The incidence of cutaneous melanoma has increased in recent years and is still rising. In Australia, it is the commonest malignancy in the 15-39 year age group and the third most common overall. Five year survival is high (New South Wales figures: 88% male, 93% female), although the prognosis is much poorer if disease recurs or another primary appears.

The Melanoma Institute Australia (MIA) is the largest treatment centre for melanoma in Australia. It is the purpose of the MIA to be the leading centre in the world for melanoma research, clinical care and education and to minimize the impact of melanoma on society through the alignment of an exceptional group of people and resources.

The multi-disciplinary team of clinicians treats approximately 1000 new patients per year, who present with a first primary melanoma. Only about 10% of new patients who present to the MIA are Stage 3 and less than 1% are Stage 4 at first presentation and, therefore, the majority of patients, after successful treatment for their first primary melanoma, resume good physical status, but are more affected psychologically. Patients live with the possibility of the disease recurring and an expanding program of research work at the MIA now focuses on Quality of Life issues for these patients, techniques for accurate measurement and the flow-on effects for disease management.

## Measurement of QOL in melanoma:

Only two clinically validated QOL instruments have been designed specifically for use with melanoma patients; a study specific MM module developed in Sweden (Sigurdardottir 1993) and the FACT-M (Cormier 2008). A recent review reported that the content of the FACT-M was more appropriate for advanced melanomas and less suitable for the general melanoma population and that the SF36 (Ware et al 1992) was the most widely used instrument, despite its psychometric properties not being tested in melanoma populations (Cornish et al 2009). A further review by the MIA research team concurs with the findings of Cornish et al and reveals that additional melanoma specific items are required to ade-

quately measure the full range of QOL issues in this population, across a range of stages of disease.

## Overall aims of the project:

- Review the use of existing QOL instruments in a melanoma population of patients and their relatives and validate existing generic cancer questionnaires in an Australian melanoma population.
- Provide guidance of preferable QOL questionnaires to be used in melanoma research activities within Australia.
- New item generation and development of melanoma specific QOL instrument for both patients and relatives.
- Expand the MEL QOL project to an international level by collaborating with the EORTC to construct a new melanoma module with worldwide utility.

## Update since last EORTC QLG meeting in Pamplona, Spain:

Initial development of an Australian Melanoma QOL module has already begun at the MIA and activities which follow the EORTC Phase 1-2 module development guidelines are well underway. The lead investigator, Associate Professor Julie Winstanley, attended the EORTC QLG meeting last September in Pamplona, where she presented information about the project at a parallel session.

Several EORTC Quality of Life Group (QLG) members attended this



*The Poche Centre  
The Melanoma Institute Australia*

session and contributed to a lively debate about measurement of melanoma QOL and how to tease out issues which were unique to melanoma. Since then, 32 semi structured interviews have been conducted at the MIA (22 patients, 10 relatives) which involved a total interviewing time of over 17 hours. The interviews were led by an experienced researcher (Professor Dr Edward White, Osman Consulting Pty Ltd, Sydney), from which verbatim transcripts have been prepared. Content analysis will be complete by January 2010.

The core research team met for an afternoon workshop in December 2009 to plan the next phase of the project (see photo). The session was also attended by a representative of the Australian and New Zealand Melanoma Trials Group (ANZMTG), the organization which funds the present study, together with a research grant from the University of Sydney Cancer Research Fund. Funding may also support a limited number of





Workshop 16 December 2009: From left to right: Edward White, Grahame Simpson, Timothy Luckett, Julie Winstanley, Madeleine King

several collaborators to participate in Phase 1-2 activities. Clinicians from the Melanoma Institute of Australia also attended the workshop and contributed by answering a range of particular issues related to quality of life measurement during treatment.

### Activities planned for the EORTC QLG meeting in Rome, Italy:

This will be the opportunity to formally establish a working collaborative group which will expand this preliminary work, already conducted in Australia, to an international level. Members of the QLG are encouraged to contact Julie Winstanley to indicate their interest in joining the group, either to offer expertise in module development or to facilitate access to patients for data gathering activities.

Contact details: Associate Professor Dr Julie Winstanley, Melanoma Institute Australia, University of Sydney, Level 2, 1a Eden St, North Sydney, NSW 2060, Australia. Phone: +612 9911 7271; E-mail: Julie.Winstanley@melanoma.org.au.

## The incidence of cutaneous melanoma has increased in recent years and is still rising.

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### List of Principal and Associate Investigators:

- **Professor Madeleine King**, Cancer Australia Chair in Cancer Quality of Life; Director, Quality of Life Office Psycho-oncology Co-operative Research Group (PoCoG), The University of Sydney;
- **Professor John Thompson**, Director, Melanoma Institute Australia and Professor of Surgery (Melanoma and Surgical Oncology), The University of Sydney;
- **Dr Grahame Simpson**, Rehabilitation Studies Unit, The University of Sydney, and the Brain Injury Rehabilitation Unit, Liverpool Health Service;
- **Professor Rick Kefford**, Director, Westmead Institute Cancer Research and Director of Clinical Research and Medical Oncology, Melanoma Institute Australia;
- **Ms Bridget Myles**, Study Coordinator.

### List of interested collaborators and persons offering support/advice (to date October 2009)

- **Dr Anna Costantini**, Sant' Andrea Hospital Sapienza, Psycho-Oncology Unit, The University of Rome, Italy
- **Dr Anne Brecht Francken**, Isala Klinieken Zwolle, Department of Surgery, The Netherlands
- **Professor Dr Michael Koller**, Center for Clinical Studies, University Hospital Regensburg, Germany
- **Dr Agnes Czimbalmos**, EORTC Quality of Life Department, Brussels, Belgium
- **Associate Professor Dejan Nikolic**, Oncosurgeon, University Medical Center Bezanijska Kosa, Bezanijask, Serbia
- **Professor Julie Newton Bishop**, Leeds, UK
- **Dr Marc Moncrieff**, Norwich, UK
- **Dr Lonneke V. van de Poll-Franse**, Integraal Kankercentrum Zuid (IKZ), Eindhoven, The Netherlands
- **Dr Mia Bergenmar**, Karolinska University Hospital, Sweden
- **Dr Ahmed Ali-Khan**, Senior Registrar, South West, England, UK
- **Dr Philip Brackley**, North of England, UK
- **Dr Susan Gollop**, New Zealand
- **Dr Andrew Bottomley**, EORTC Quality of Life Department, Brussels, Belgium.
- **Mr Denis Bartrum**, Skin Cancer Clinic, Ipswich General Hospital, University of Queensland, Australia



# Update from Down Under: Quality of Life research activities at the Australia and New Zealand (ANZ) Psycho-Oncology Co-operative Research Group (PoCoG) (www.pocog.org.au)

*Prof. Madeleine King  
Cancer Australia Chair in Cancer  
Quality of Life (QOL) Director, QOL Office*

*Psycho-oncology Co-operative  
Research Group School of Psychology  
The University of Sydney*



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The Global Financial Crisis has squeezed research budgets around the globe, particularly for psycho-oncology and quality of life research. Australia is therefore in a very privileged position in having generous support for both provided by Cancer Australia. These include funding for the Psycho-Oncology Co-operative Research Group (PoCoG) and the Cancer Australia Chair of Cancer Quality of Life.

PoCoG was established in 2005 to develop capacity and co-ordinate collaboration for conducting large-scale, multi-centre psycho-oncology and supportive care research in Australia and New Zealand. PoCoG's specific aims are:

1. To bring together researchers, clinicians, health care professionals and consumers with an interest in psycho-oncology to foster collaboration and the exchange of ideas.
2. To develop large-scale, multi-centre psycho-oncology studies of clinical relevance and importance which would be difficult for any one team to undertake on their own.
3. To develop formal links with cancer clinical trial groups to facilitate quality of life and psychosocial sub-studies.
4. To promote psycho-oncology research and support emerging new researchers in this area.

PoCoG is located in the School of Psychology at the University of Sydney and is one of 13 ANZ Cancer Cooperative Trials Groups (CCTGs) under the auspices of the Clinical Oncological Society of Australia (COSA). Like most CCTGs, PoCoG receives infrastructure funding from the Australian federal government (via Cancer Australia), but is required to seek funding for its research activities through competitive schemes. PoCoG is currently chaired by Professor Phyllis Butow, a clinical psychologist and co-director of the Centre for Medical Psychology and Evidence-based Decision-making (CeMPED) at the University of Sydney.

PoCoG hosts a Quality of Life Office, directed by the Cancer Australia Chair of Cancer Quality of Life, Professor Madeleine King, and staffed by a full-time project manager, Dr Tim Lockett. The Chair and Office aim to build CCTG capacity to research health-related quality of life (HRQoL), promote inclusion of HRQoL sub-studies in CCTG trials wherever appropriate and promote a consistent, world-standard approach to assessment, analysis and interpretation. QOL Office resources available via the Office's web-pages include Frequently Asked Questions (e.g. choosing a measure, reasons to include HRQoL endpoints in clinical trials), links to other online HRQoL resources and suggested reading lists.

Professor King and Dr Luckett are currently involved in a number of collaborations with the EORTC QOL Group, including:

- Development of an EORTC module for melanoma, in collaboration with the ANZ Melanoma Trials Group (ANZMTG), and lead by the ANZMTG statistician, Professor Julie Winstanley;
- Contribution of recruits and data to the Phase III validation of the EORTC QLQ-TC26 for men with testicular cancer, in collaboration with the ANZ Urogenital and Prostate Trials Group (ANZUP);
- Contribution of recruits and data to the Phase III validation of items from the EORTC fatigue item bank;
- Development of multi-attribute utility instruments from the EORTC QLQ-C30 and FACT-G, in collaboration with other international and ANZ collaborators.

In addition to these, Professor King is a member of the advisory board of the EORTC's PROBE project.

Professor King is currently developing a program of research on HRQoL in gynaecological cancer with Professor Michael Friedlander, Chairman of the ANZ Gynaecology Oncology Group (ANZGOG) and ANZGOG representative in the Gynaecological Cancer Inter-Group (GCIG). So far, two projects have received funding:

- Investigation of symptom benefit in women undergoing palliative chemotherapy for recurrent ovarian cancer (in collaboration with the ANZ Gynaecological Oncology Group, ANZGOG);
- A demonstration project for the Patient Reported Outcome Measurement and Information System (PROMIS) in Australian women with gynaecological cancer.

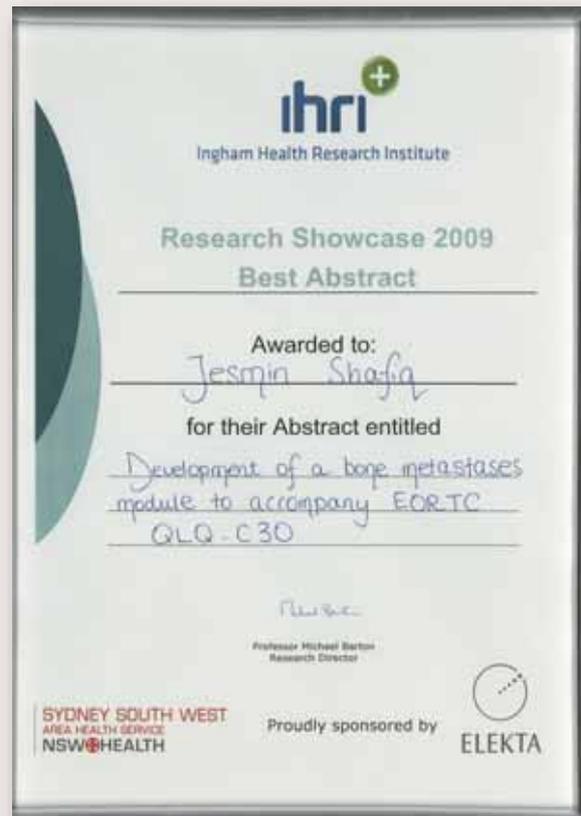
In relation to this, and in collaboration with Dr Luckett, Professors King and Friedlander have conducted a systematic review of questionnaires for assessing HRQoL in gynaecological oncology, focusing on their ability to detect clinically important differences and change. This paper is currently in press in the International Journal of Gynaecological Cancer. So things are looking up for psycho-oncology and cancer-related HRQoL research down under!

**Thanks to Dr. Tim Luckett, Project Manager of the PoCoG's QOL Office, who contributed to this article.** ■



*PoCoG is located in the School of Psychology at the University of Sydney.*

## NEWS



### Dr Jesmin Shafiq MBBS MCN MPH

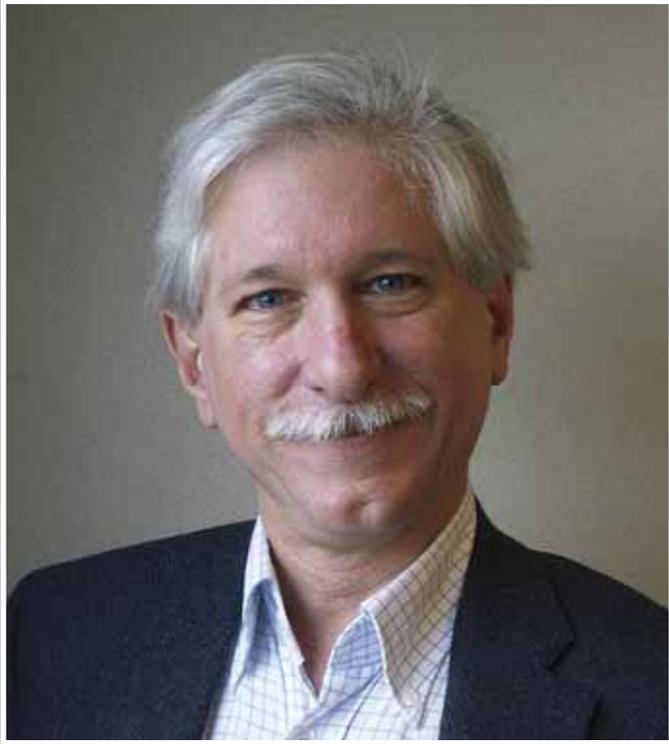


Dr Jesmin Shafiq is a medically trained epidemiologist working within the Collaboration for Cancer Outcomes Research and Evaluation (CCORE), a research unit in the comprehensive Cancer Centre in Liverpool Hospital, the biggest tertiary hospital in Sydney's South West. She is one of the main researchers involved in the quality of life (QOL) research projects being undertaken at the Centre. Jesmin is also a lecturer at the South Western Sydney Clinical School of the University of New South Wales, Sydney.

### 'Research Showcase' Event where Dr Shafiq's abstract was presented

Research Showcase is an annual event organised by the Sydney South West Area Health Research office where basic, clinical and community health researchers affiliated with the major hospitals and medical schools in the South-West of Sydney present their research work to their colleagues and researchers from other schools, university faculties and research centres. It gives them the opportunity to let others know about their work, reach out to the research community with similar interests and build research strength by collaboration.





*Chad Gundy and Neil Aaronson  
for the Higher Order Project Group: Peter Fayers,  
Mogens Groenvold, Morten Petersen, Neil Scott,  
Mirjam Sprangers, and Galina Velikova*

# Higher Order Factor Models for the EORTC QLQ-C30

*Prof. dr. Neil K. Aaronson, Division of Psychosocial Research & Epidemiology, The Netherlands Cancer Institute & Department of Clinical Psychology, The University of Amsterdam*

*Chad Gundy, Senior Statistician, Division of Psychosocial Research & Epidemiology, The Netherlands Cancer Institute, Amsterdam*

**S**ince its release in 1993, the EORTC QLQ-C30 has become one of the most widely used “core” instruments for the study of the health-related quality of life (HRQoL) of patients with cancer. It has been translated into scores of languages and dialects, and has been used in 100’s of studies. It comprises 14 single item and multi-item scales assessing physical and psychosocial functioning, key symptoms, and an overall HRQoL scale.

The major advantage of the QLQ-C30 in its basic form is that it yields a fairly detailed profile of the HRQoL of patients, particularly when combined with condition-specific questionnaires (e.g., for breast cancer, prostate cancer, etc). At the same time, interest has been expressed from both within and without the EORTC in summarizing the data generated by the QLQ-C30 into a more limited set of “summary” scores. The availability of such summary scores could reduce the complexity of analysis based on a large number of HRQoL endpoints, and also the chance of Type I errors due to multiple comparisons.

Historically, exploratory principal component analysis and factor analysis were often used to explore higher order models. However, these techniques

have a number of limitations, perhaps the most important being their sample dependency or limited generalizability. Exploratory factor analysis rarely yields the same results across samples. In contrast, more modern, confirmatory applications of latent variable theory, including confirmatory factor analysis and item response theory, provide the opportunity to explicitly test the adequacy of theoretical structures in “explaining” multi-dimensional HRQoL instruments.

To date, there has been a limited number of studies of the structure of the QLQ-C30, all of which have relied on either relatively small sample sizes (i.e.  $N < 200$ ), a subset of the QLQ-C30 items, and/or exploratory techniques.

The aim of this project is to empirically examine and compare the statistical “fit” of a number of alternative measurement models for the QLQ-C30 by means of confirmatory factor analysis in a large sample of patients. The hope is that we will be able to identify one or more higher order measurement models that, if also meeting other psychometric requirements, could be used for the computation of simpler, summary scores for this questionnaire. The results are also of interest from a theoretical perspective, and may provide insight into the HRQoL construct itself.

For use in international, collaborative studies such as those conducted by the EORTC, and for purposes of comparison of results across studies conducted in different countries, it is important that any QLQ-C30 summary scores have similar measurement and structural properties across translations and cultures, as well as across gender, disease sites, and disease stages. Thus, an important goal of this study is to investigate the stability of any higher order measurement models for the QLQ-C30 across sub-populations.

The data being used in this study were collated as part of the EORTC Cross-Cultural Analysis (CCA) Project led by Peter Fayers and Neil Scott. A major effort was made in the CCA project to obtain EORTC QLQ-C30 data from around the world, which could be used for such analyses. Briefly, relevant information from each dataset was extracted, recoded into a standard format and combined into one large project database. In addition to the responses to the 30 items of the QLQ-C30, other data collected include country, language of administration, primary disease site, stage of disease, age and gender. Whenever possible, separate EORTC QLQ-C30 assessments at three time points were extracted for each patient: baseline (pre-treatment), on-treatment and off-treatment.

A total of 124 datasets were collected: 54 from the EORTC Headquarters with permission from the relevant EORTC Group, and an additional 70 from other individuals and organizations from around the world. Data are available from 48 countries and for 33 translations of the QLQ-C30. The resulting dataset consists of 38,000 respondents, of whom more than 30,000 were classified as having available baseline (pre-treatment) assessments. After selection of only those cases in which the most recent

version of the QLQ-C30 (version 3.0) was used, 9,044 respondents remained available for analysis.

Eight factor models were compared, using confirmatory factor analysis and structural equation modeling. These models built upon a “standard” 14 dimensional QLQ-C30 model (excluding the financial difficulties scale). These models included a 1 dimensional (1D) higher order factor model, a 2D “symptom burden and function” model, two 2D “mental and physical” models, two models with “function” and a “formative” (or “causal”) formulation of “symptom burden”, and a “bi-factor” model.

The Physical-Mental model exhibits an “adequate” (albeit imperfect) fit to the data, and it appears to be the best of the approximations to the Standard model that we’ve considered here. This Physical-Mental conceptual model has also been utilized and successfully tested for other HRQoL instruments, has been considered in a large, multi-instrument study, and is consistent with the PROMIS domain mapping project and the WHO framework. It was also successfully cross-validated on a hold-out sample in the present study. For these reasons, we consider it to be the most suitable of the models considered here.

Testing measurement equivalence over sub-populations or over time, and linking them to external criteria and outcomes, as well as other instruments purporting to measure similar concepts, will be the subject of future investigations into the suitability of this model. We then hope to publish an algorithm for the computation of higher order factors. ■

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**The aim of this project is to empirically examine and compare the statistical “fit” of a number of alternative measurement models for the QLQ-C30.**

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*Prof dr Irma Verdonck-de Leeuw*

## Disease management and e-health to facilitate and innovate supportive care in cancer patients

*Irma Verdonck-de Leeuw(1,2), Remco de Bree(1), Pim Cuijpers (2), René Leemans (1)*

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*2) Department of Clinical Psychology, VU University, Amsterdam, The Netherlands*

Grassroots initiatives such as the Lance Armstrong Foundation in the United States and the Alpe d'HuZes Foundation in the Netherlands have led to broader public attention regarding living with cancer. There is convincing evidence that cancer patients have to deal with various physical and psychological side effects of cancer and cancer treatment negatively affecting health related quality of life, interfering with return to work, and leading to a higher medical care consumption. Specific stressors such as fear of death, interruption of life plans, and changes in body image and self-esteem lead to emotional distress in 25-30% of patients. Therefore, it is important to monitor quality of life in a structured manner in clinical practice and to provide adequate supportive care at an early stage. Supportive care in cancer is the prevention and management of the adverse effects of cancer and its treatment. Supportive care comes within the responsibility of several care providers: surgeons, radiation and medical oncologists, primary care physicians, and various psychosocial and allied health service providers. These care providers often have at their disposal only part of the relevant information, and communication between care

providers with regard to well-being and psychosocial functioning is limited. Because of this fragmentation of continuity of care, patients and families often complain about feelings of powerlessness and a lack of guidance.

There is growing interest in using patient-reported outcomes (PRO's) to screen for physical and psychosocial problems and the need for supportive care in routine clinical practice (Jacobsen 2007; Tuinman 2008; Valderas 2008; Snyder 2009; Luckett 2009) and several studies have shown that using PRO's in clinical practice facilitates communication about quality of life between doctors and patients (McLachlan 2001; Detmar 2002; Velikova 2002). There is less evidence that this approach may affect patient outcome or improve quality of life and it is argued that additional efforts are needed to enhance the effect of screening (Hilarius 2008; Snyder 2009). These additional efforts may include using more tumour specific (instead of generic) PRO's, improving the interpretability of feedback for both medical staff and patients, and to train patients in self-efficacy (Luckett 2009). Organising supportive care according to the chronic care model (Coleman et al., 2009) and providing evidence based supportive care options can also improve disease management in cancer patients.

Disease management refers to a system of coordinated comprehensive care along the continuum of the disease across health care delivery systems, with a special focus on self-management. In disease management programmes, health care by different professionals and in different institutions is better tuned and coordinated. A systematic review revealed that disease management programmes have a positive effect on the treatment of chronically ill patients. Other forms or definitions of supportive care delivery include integrated care, transmural care, collaborative care, and case management. Recent projects in oncological settings such as "Supporting transmural oncological care" (Van den Brink, 2006) and "Integrated care" (Ouwens 2009) revealed that supportive care coordination improves supportive care delivery in cancer patients. Also Fillion (2009) showed that the presence of a professional care navigator leads to higher patient satisfaction, shorter duration of hospitalization, fewer cancer-related problems, better emotional quality of life, and patient empowerment.

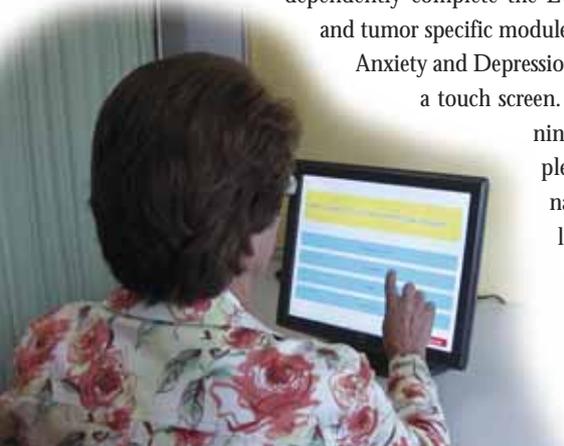
In clinical practice, many patients are not taking advantage of supportive care. Barriers may be that traditional models of the delivery of supportive care cannot meet current demand, and the often long treatment period after which cancer patients do not wish to visit other health care providers. Stepped care has the potential to improve the efficiency of cancer care. Stepped care algorithms are based on clinically proven best-practice pathways to care over a series of steps, while taking into account patient preferences (Bower 2005). The steps usually involve watchful waiting, guided self-help and other brief therapies, followed by more intensive interventions or medication. In stepped care, more intensive treatments are reserved for people who do not benefit from simpler treatments, or for those who can be accurately predicted not to benefit from such treatments.

Stepped care models have been described in relation to various issues such as smoking, back pain, alcohol treatment, migraine, anxiety, eating disorders, methadone maintenance, and depression. A crucial component in stepped care is systematic monitoring of symptoms, enabling decision making regarding changes to make ('stepping up') if current treatments are not achieving a significant health gain.

At the department of Otolaryngology / Head & Neck Surgery of VU University Medical Center in Amsterdam, The Netherlands, efficient structured monitoring of quality of life became available in 2006, by



means of a newly developed touch-screen computer-based data collection system "OncoQuest" (figure 1) that is now implemented in routine clinical practice (de Bree 2008; Verdonck-de Leeuw 2009). Patients can independently complete the EORTC QLQ-C30, and tumor specific modules, and the Hospital Anxiety and Depression Scale (HADS) on a touch screen. It takes on average nine minutes to complete the questionnaires. OncoQuest is linked to the hospital patient information system.



Data are processed in real-time and care providers can view the results by clear graphics (the well-being profile) on a computer in their consulting rooms, and if indicated, set up an individual supportive care plan. Nurses are trained as care navigators to organize the supportive care according to disease management principles. Several studies are ongoing investigating cost-effectiveness of stepped care strategies. An example is a stepped care model targeting anxiety and depression, including watchful waiting, on-line guided self-help, face to face problem solving therapy by a trained nurse, followed by more intensive psychotherapy or medication. The bottom line of these approaches is healthier patients, more satisfied care providers, and cost savings by empowering both professionals and patients.

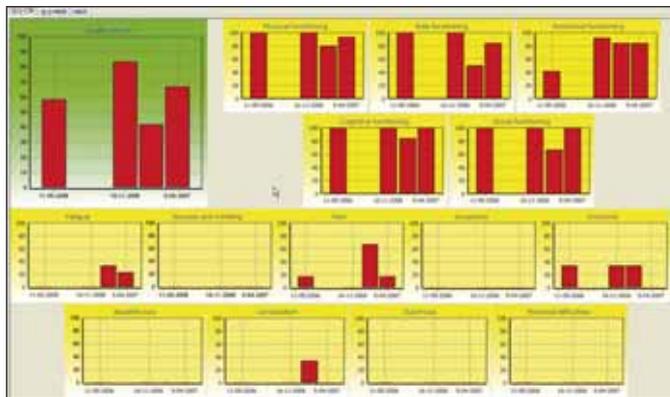


Figure 1. OncoQuest: Example of the user interface, and graphic representation of a part (EORTC QLQ-C30) of the prospective results of a patient.

The **Alpe d'HuZes Foundation** raises funds by cycling up the Alpe d'Huez in France six times in one day.

The name, Alpe d'HuZes, is a combination of the Dutch word for "six" and the name of the mountain.

Alpe d'HuZes funds research projects focussing on quality of life of cancer patients and their relatives, and has initiated a chair "Living with cancer" at VU University in Amsterdam, the Netherlands.

Prof dr Irma Verdonck-de Leeuw is holding this chair since October 1st, 2009.

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# Recent developments at EORTC Headquarters and in the Quality of Life Department

*Dr Andrew Bottomley, Assistant Director  
Head of the EORTC Quality of Life Department  
EORTC Headquarters*

Over the last 12 months, the Quality of Life Department has had yet another busy and highly productive period, publishing 14 peer reviewed papers mostly in collaboration with our clinical trial groups and delivering 18 international conference presentations. The number of new clinical trials in the EORTC HQ with QOL being included as an endpoint increased, as did the number of studies being closed and published with QOL endpoints. Large phase III trials in melanoma, and head and neck were two of the most significant ones published in journals such as the JCO.

Our collaboration with the QLG continues, with several methodological studies being published, for example, the EORTC QLG brain validation study, led by the eminent Prof. Martin Taphoorn was published in EJC, as were publications originating from the cross cultural study led by Peter Fayers and Neil Scott.

EORTC QLQ translations continue to be in demand, as researchers seek patients further across the globe. With the core questionnaire available in 85 language versions (the number still growing), a considerable part of the patients world population can take part in the research. Having finalized almost 40 new translation projects in 2009, the Department is currently working on more than 50 new language versions of QOL questionnaires. The workload increases even further with new modules being developed and needing translations.

The EORTC Headquarters is rapidly adapting, as all organizations must do in the continually changing financial and policy environment, so as to conform with the currently rapidly changing clinical trial environment. Further additional revised Standard Operating Procedures for QOL being used in EORTC clinical trials and analysis SOPs have been written, and then re-written to help keep pace with changes at the Headquarters and to standardize our work even further. The Department's staff has increased to 14 people, all very actively undertaking research in all aspects of clinical trials and the application of best practices within our clinical studies.

The staff that support QLG activities are administrators, who keep the QLG in good shape, while other Department staff are funded researchers. These researchers are regularly invited to conferences, and in 2010 for example the staff will have a presence at not only ASCO, but go as far afield as China for invited presenting at the UICC congress.

*"As I predict every year, the future is going to become even more hectic."*



As I predict every year, the future is going to become even more hectic. We shall see more RCTs with QOL endpoints, and more complex studies, and more pivotal registration studies that will demand considerable effort and insight from the QOL Department staff in their design and analysis. In 2009, we were able to organise a major QOL and clinical trial conference, with over 250 attendees from 40 countries; details are on the [www.eortc/probe](http://www.eortc/probe) web site. We plan more conferences on clinical trial design in the near future.

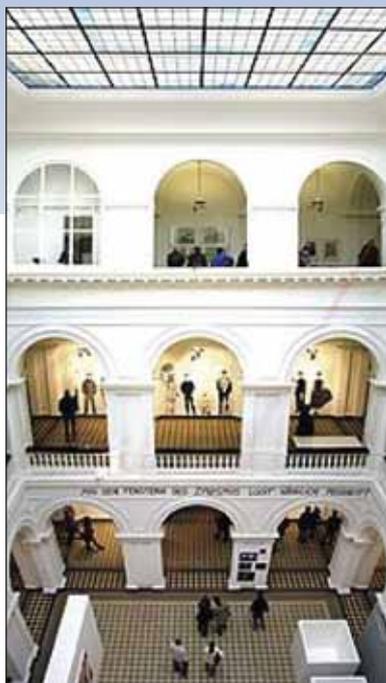
Contact us if you are interested in registering your interest. Looking into 2010 and beyond, for both the Headquarters and the Department, we can only see more studies, better quality in our trials, and greater collaboration with both national and international groups. Clearly, it is going to be another busy year. ■



# EORTC QLQ Autumn Meeting in Leipzig, Germany, 23-24 September 2010



*Dr Susanne Singer, Psychologist and Epidemiologist, Department of Medical Psychology and Medical Sociology, Leipzig University*



*Academy for Fine Arts*

If you attend our next EORTC Quality of Life Group meeting, we will be happy to show you the very birthplace of this “gentle revolution”.

Leipzig is also a city of music. Great composers such as Felix Mendelssohn, Bartholdy, Gustav Mahler, Robert Schumann, and Johann Sebastian Bach lived and worked here (although the latter did not get a lot of money from his city...). And you may have heard about the “Thomachor”, a boy choir that has been singing in Leipzig since the year 1212, with Bach being one of its most famous conductors. You can see and hear them in September, if you wish. Alternatively, you can pay a visit to the “Gewandhausorchester”, the oldest symphony orchestra in the world.

The city’s arts highlight is the Neo Rauch retrospective, opening in April 2010 at the Leipzig Museum of Fine Arts. This is a show devoted to the father of the New Leipzig School of artists. According to the New York Times, this scene “has been the toast of the contemporary art world” in the past decade. In addition there are eleven galleries in the so-called “Spinnerei”, a former cotton mill, that attract all kinds of independent artists. We will organise a tour to this place on the Saturday.

Germany’s second largest book fair is held in Leipzig every year, and even if you are not able to attend it during our meeting, you’ll see and feel the “love for books” in the city. An entire neighborhood of the city is dedicated to the graphical arts, with publishers and book makers located there. Upcoming young writers have the unique possibility of studying writing

at university level at “Deutsches Literaturinstitut”; they fill the surrounding cafés with their laptops and coffee mugs, together with the students of “Hochschule für Graphik und Buchkunst”, a school for the fine arts, famous for its New Leipzig School (see above).

You see, Leipzig is the city of music, new art, books, and of the gentle revolution. People here are a bit rebellious and independent, they have a tendency to be megalomaniac and sometimes they talk before they think. But they are also nice and welcoming, and the taxi drivers have now - 20 years after the political change – started to amend their Russian with some English...

The next EORTC Quality of Life Group meeting will take place on 23rd to 24th of September 2010 in Leipzig, Germany. We look forward to welcoming you to our beloved city! ■





*Raising the standards of quality of life research in haematology. Where do we stand in measurement quality?*

## **The EORTC QLG module on Chronic Myeloid Leukemia and the research agenda in hematology**

*Fabio Efficace, PhD*

*Chairman GIMEMA Working Party on Quality of Life*

*Head, Health Outcomes Research Unit Italian Group for Adult Hematologic Diseases (GIMEMA)*



### **Background**

***Several clinical trials in patients with solid tumors have successfully implemented patient-reported outcomes (PROs) and have provided additional robust data to better understand overall treatment effectiveness from the patients' perspective. Some of these data have also served as a basis for drug approval (or in support of) by the Food & Drug Administration (1).***

Although the impact of quality of life (QoL) for patients with solid tumors has been well studied, with several clinical trials that have included QoL as an endpoint, our understanding of this issue in patients with hematological cancers is in comparison lacking (2). Very few trials in hematological malignancies have included QoL as an endpoint. In the literature, the paucity of QoL and other types of PRO data on patients with leukemia, lymphoma, myelodysplastic syndromes, myeloma or other hematological diseases forms a stark contrast to the amount of research available for patients with solid tumors. Even though Burge and colleagues already stated in 1975 that "quality of life in leukemia is as important as its quantity," (3) several subsequent attempts to present information about QoL were based only on indirect measures, such as the number of days spent in hospital or clinician-reported observations, suggesting that the patient's perspective has historically been much less emphasized in the field of onco-hematology.

Over recent years, however, we have been witnessing major clinical achievements and the long-term prognosis for patients with hematological malignancies has greatly improved. Considerable emphasis is being increasingly placed on PRO issues in hematological research. A greater number of potentially less toxic drugs are now available and newer treatments can potentially offer many patients the option to be treated with less aggressive approaches, making patient perspective much more critical when evaluating treatments. It is not by accident that recent international recommendations for various hematologic diseases (including acute leukemia, chronic lymphocytic leukemia, immune thrombocytopenic purpura and myelodysplastic syndromes) are paying greater attention to QoL issues and are advocating more research into this area (4-8). Yet, an educational session took place for the first time at the European Hematology Association (EHA) in Berlin last year gathering a large number of clinicians and methodologists to share basic knowledge of quality of life issues in this area (9).

### **The changing scenario in hematological research: the example of Chronic Myeloid Leukemia (CML).**

CML has left more marks in the history of medicine than many other much more common diseases (10). The first drug used for these patients with consistent activity was busulfan introduced in 1959 and some 10 years later hydroxyurea was also available. However, it was only in the early 1980s that interferon (IFN-) was introduced as a treatment which provided a significant improvement in overall survival and in the achievement of complete cytogenetic response (CCyR), although in a subset of patients. At this time also, a relevant first line treatment option was

allogenic hematopoietic stem-cell transplantation (HSCT), although this was only for younger patients and for those with an available donor.

However, the treatment of CML has changed dramatically over the last decade. This rapid change in clinical practice was driven by the results of the IRIS study, which included more than 1,000 patients and compared IFN versus Imatinib (IM), which is a specific inhibitor of the bcr-abl tyrosine kinase (11). This large pivotal randomized phase III trial clearly demonstrated a number of advantages (including overall survival) for patients treated with IM. Based on this study, in 2002, the FDA approved IM as first line treatment for CML patients. More importantly, this pivotal trial also included QoL as a secondary endpoint to evaluate the impact of these two treatments from the patient's perspective. Patients randomized to IM reported major QoL benefits over patients treated with IFN, in a number of areas, including treatment-related symptoms and physical functioning (12). The effect size (1.05) found in this study was one of the largest treatment group differences ever found in QoL comparisons in clinical trial settings. In any case, IM (administered at a dose of 400 mg per day) has now become the first line treatment for newly diagnosed chronic phase CML patients. Recent data show that at 84 months (7 years), overall survival was 86% and cumulative rate of CCyR was 89% for patients who received IM (13) thus providing confidence in the long term efficacy of the drug. These revolutionary figures have hardly ever been seen in the area of solid tumors.

It is also worth noting that IM is only the first drug of the larger class of Tyrosine Kinase Inhibitors (TKIs) and more potent drugs within this area are being developed. A second generation of TKIs is now already available (e.g. Nilotinib and Dasatinib) and are also recommended as second line treatment of CML patients by international guidelines. Overall, TKIs have dramatically changed the treatment of this disease by markedly improving patient survival and by making QoL more acceptable. More importantly, the impressive survival figures obtained with this class of drugs (86% at seven years with IM) will make the evaluation of PROs (e.g. quality of life or symptom burden) even more critical when assessing the treatment effectiveness of newer drugs in the near future, or in monitoring long term QoL in CML survivors.

### **Where do we stand in quality of life measurement in hematology?**

How can the EORTC Quality of Life Group (QLG) follow this hectic research development in the area of CML? On the one hand, this is a challenging task for all our members and on the other, a great opportunity to improve standards of measurement in this area. Our Group has accepted the challenge and has recently awarded Dr. Fabio Efficace a research grant to devise a questionnaire to be used in CML patients and the work has just commenced. A systematic review on PROs in CML patients being the basis of such a development process, will be submitted soon to a major hematology journal and will include key members of the core research team.

If PROs are to fulfill their potential of allowing health-care providers to make informed decisions about the overall value and impact of a given treatment, investigators should pay careful attention to a number of methodological issues relative to the design of their studies. Among these issues, relying on a robust PRO instrument is indeed a crucial aspect. Unfortunately, it has to be noted that there is lack of specific measures to be used in hematology, and research in this area has used either generic cancer measures or very poor quality non-validated tools. Thus there is an urgent need to provide the scientific community with methodologically sound measures to foster research in this area.

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## **Over recent years, we have been witnessing major clinical achievements and the long-term prognosis for patients with hematological malignancies has greatly improved.**

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International research groups have very recently started to devise PRO tools to be used in some hematological diseases (e.g. myelofibrosis and thrombocytopenia) (14,15). However, an overview of the literature shows that no robust instrument is as yet available to be used in CML patients, also taking into account specific side effects of TKIs.

Although the EORTC QLG measurement portfolio has now gained a large visibility mainly in the area of solid tumors, the development of this CML questionnaire will bridge an important gap in the EORTC modular approach system.

### **The Team and the EORTC QLG research agenda in hematology**

#### **CML:**

The PI, Dr. Fabio Efficace, will lead the CML module development from the Health Outcomes Research Unit of GIMEMA and a research fellow: Mariagrazia Mecoli, PhD, has just been appointed to work on this challenging international initiative and act as project coordinator. The research team includes Prof. Franco Mandelli, Michele Baccarani and Massimo Breccia (Italy), Prof. Mirjam Sprangers (The Netherlands), Dr. Graeme Smith, Kim Cocks and Penny Wright (UK), Stephan Pallua (Austria), Prof. David Joske (Australia), Tobias Gedde-Dahl (Norway) and Dr. Susanne Saussele and Ute Kossak (Germany). Key members of the EORTC Leukemia Group and the European Leukemia Net (ELN) have expressed interest in joining and will also be involved. ▶



## CLL:

In addition to the CML questionnaire it has been highlighted that the EORTC Chronic lymphocytic leukemia (CLL) questionnaire will have to be revised and updated too, as this as yet has never been published. The next steps will deal with the inclusion of patients with newer treatments (e.g. Campath) and Dr. Fabio Efficace, along with the former PI of the EORTC CLL module, Dr. Shirley Croft, will lead this update.

## MDS:

The EORTC QLG is currently partially supporting a QoL study with GIMEMA in patients with high-risk myelodysplastic syndromes (MDS). This observational study is currently recruiting patients in more than 40 centers in 15 countries with the main goal of providing evidence-based data to facilitate clinical decision making in these patients and include key members of our Group such as Prof. Mirjam Sprangers and Dr. Weichu Chie.

In addition to the above mentioned efforts, and considering the important challenges to be faced over the next few years in this area, a research group within the QLG with a common interest in fostering research in hematology is being set up by Dr. Fabio Efficace and colleagues, with the main objective being to centralize project proposals and efforts by the EORTC QLG in the area of hematology. All those interested in joining ongoing projects or proposing new initiatives are more than welcome to join in the Hematology session or to contact myself, the PI (f.efficace@gimema.it).

*GIMEMA Data Center, Rome Italy*

*E-mail: f.efficace@gimema.it*

*Secretary EORTC Quality of Life Group*

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Harris K, Chow E, Zhang L. **Patients' and Health Care Professionals' Evaluation of Health – Related Quality of life issues in bone Metastases.** Eur J Cancer 45 (2009) 2510-2518

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Scott NW, Fayers PM, Aaronson NK, Bottomley A, de Graeff A, Groenvold M, Gundy C, Koller M, Petersen MA, Sprangers MAG on behalf of the EORTC Quality of Life Group and the Quality of Life Cross-Cultural Meta-Analysis Group. **A simulation study provided sample size guidance for differential item functioning (DIF) studies using short scales.** Journal of Clinical Epidemiology 2009;62:288-295

Scott NW, Fayers PM, Aaronson NK, Bottomley A, de Graeff A, Groenvold M, Gundy C, Koller M, Petersen MA, Sprangers MAG on behalf of the EORTC Quality of Life Group and the Quality of Life Cross-Cultural Meta-Analysis Group. **Differential item functioning (DIF) in the EORTC QLQ-C30: a comparison of baseline, on-treatment and off-treatment data.** Quality of Life Research 2009;18:381-388

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Singer, S., Wollbrück, D., Wolke, C., Dietz, A., Klemm, E., Oeken, J., Meister, E. F., Gudziol, H., Bindewald, J., Schwarz, R. (2009). **Validation of the EORTC QLQ-C30 and EORTC QLQ-H&N35 in Laryngeal Cancer Patients after Surgery.** Head and Neck 31, 64-76.

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Scott NW, Fayers PM, Aaronson NK, Bottomley A, de Graeff A, Groenvold M, Gundy C, Koller M, Petersen MA, Sprangers MAG on behalf of the EORTC Quality of Life Group and the Quality of Life Cross-Cultural Meta-Analysis Group. **Differential item functioning (DIF) analyses of health-related quality of life instruments using logistic regression.** Health and Quality of Life Outcomes (submitted).

Scott NW, Fayers PM, Aaronson NK, Bottomley A, de Graeff A, Groenvold M, Gundy C, Koller M, Petersen MA, Sprangers MAG on behalf of the EORTC Quality of Life Group and the Quality of Life Cross-Cultural Meta-Analysis Group. **Interpretation of differential item functioning (DIF) analyses using external review.** Expert Reviews in Pharmacoeconomics and Outcomes Research (submitted). ■



# Notes

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*Sheila Scott Sanderson  
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