

Quality of Life Group newsletter

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Visiting Professor in Japan

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During the past six months I had the pleasure to be Visiting Professor at the Hiroshima University, recognized as one of the key universities in Japan. The University comprises 11 faculties, 12 graduate schools, two research institutes, a University hospital, and 11 affiliated schools. Hiroshima University has become open to the international community and continues to develop globally. The Graduate School of Education has a long tradition of welcoming students and faculty from around the world. For more than 10 years, professors from Australia, Europe, Canada, and the United States have been invited and I was honored to be the 18th visiting professor at the Department of Learning Science. Long-lasting partnerships, scientific collaborations including student exchanges between Hiroshima University, Karl-Franzens University and Medical University Graz (Austria) exist. The Department of Learning Science at the Hiroshima University provides educational innovations through ►



*Top: Masters and PhD students of the Department of Learning Science,
Hiroshima University*

*Bottom: Members of the faculty. From left to right: Prof. Higuchi,
Prof. Hayashi (current Department Chair), Visiting Prof. Greimel,
Prof. Kodama, Prof. Oka, Prof. Inoue, Prof. Aoki, Prof. Dobashi,
Prof. Tazaki, Prof. Yamauchi, Prof. Suzuki.*

Inserted photos Prof. Kurihara, Prof. Mori



(continued from cover page)

international networking. Education is of utmost importance for any society and Japan is known for its high standard of education. Research has shown that education and socioeconomic factors are important indicators for health, well-being and quality of life. Many health-related and social problems are associated with the level of inequality of society (Wilkinson et al. 2006). When compared to 23 of the richest countries worldwide Japan has the lowest prevalence of health and social problems due to its equal society (Wilkinson et al. 2009).

The opportunity to work with excellent faculty members and highly motivated students has left lasting and positive impressions on me personally and professionally. My stay in Japan allowed me the time to reflect on various cross-cultural issues related to quality of life research. I will use this experience to develop new cross-cultural research projects that I hope to build on for years.

Serving as a Visiting Professor was an enriching and very rewarding experience. Before arriving in Japan I did some research about the culture and everyday life. I also took some Japanese lessons. However, as my Japanese was still very basic it took quite a bit of time to organize my basic daily activities. In summary, my overall quality of life in Japan was excellent, but my performance of daily activities was poor. Such activities as grocery shopping, reading nutrition labels or ordering food in a restaurant, all remained difficult even after six months. I am indebted to Prof. Higuchi, Prof. Mori and the students who introduced me not only to their scientific fields of education, but also to the culture of Japan. I have met many nice people in and outside the University who all were very helpful during my stay in Japan.

Arigato gozaimashita! ■

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Source:

Wilkinson, R. & Pickett, K. *The Spirit Level: Why greater equality makes societies stronger. New York, Bloomsbury Press, 2009*

In this issue

- Visiting Professor in Japan, Elfriede Greimel p.1

New Grants

- The Spiritual Wellbeing Module p.3
- Development of a Vulva Module p.4
- Development of a Cachexia Module p.5
- Update of EORTC's Lung Cancer Module p.6
- Update of the EORTC questionnaire for the assessment of quality of life in head and neck cancer patients p.7
- The EORTC development of a Breast Reconstruction Module p.8

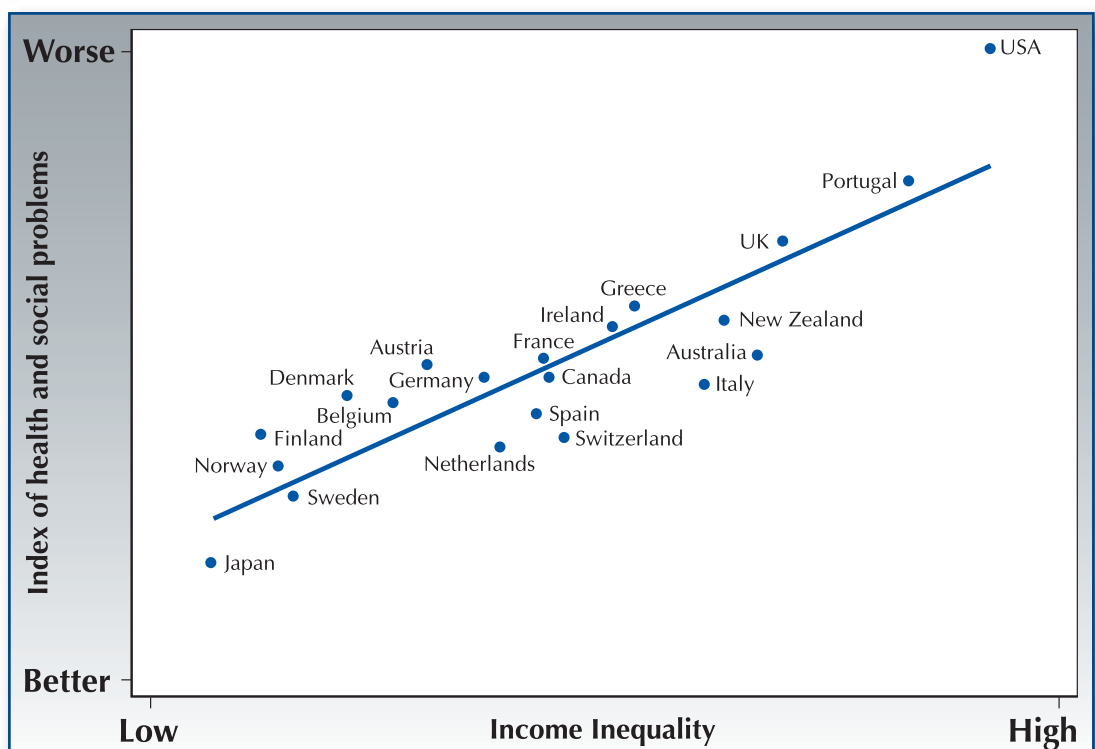
Other Group Activities

- Further development and dissemination of CHES-EORTC for electronic PRO data collection and presentation p.10
- Educational Seminar 3 June 2010 University of Athens p.12
- Normative data for the EORTC QLQ-C30 and EORTC-Sexuality items in the general Dutch population p.14

News

- An update on the PROBE project from the Quality of Life Department p.15
- EORTC QoL Group Meeting in Leipzig, Germany p.16
- EORTC QoL Group Meeting in Innsbruck, Austria p.17
- Francesca Martinelli's experience gained at EORTC p.18
- Reflections on eight years QoL Department p.19
- Recent international awards and honors p.19
- The EORTC QLQ-ELD15 Module p.20
- 2010 QLG Publications p.21
- Recent developments at the EORTC HQ p.22
- EORTC contact details p.23

Health and social problems related to level of income inequality



The Spiritual Wellbeing Module, the QLQ-SWB36

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Some people develop advanced and incurable cancer, and for these people palliative or “End of Life” care then becomes important. This should include control for pain and other symptoms and access to psychological, social and spiritual support. However, whilst validated measures exist to evaluate pain, symptoms, and some aspects of psychological and social wellbeing, evaluation of spiritual wellbeing for people at the ends of their lives is not simple. Patients may be uncertain whether it is appropriate to discuss issues around spirituality with their health care professionals. And, whilst there are existing measures in this area, not all have been developed with input from patients receiving palliative care and none have been developed simultaneously in more than one language and cultural context – a key requirement for EORTC modules.

The QLQ-SWB36 has been developed following EORTC guidelines for module development, with some modifications. The measure is functional rather than substantive. That is, it seeks to explore how a patient’s beliefs (whatever they may be) function in their daily lives, rather than exploring in detail the specific content (or substance) of those beliefs, and whether they match a pre-defined set of beliefs.

“Evaluation of spiritual wellbeing for people at the ends of their lives is not simple.”

113 papers were reviewed (1) generating 84 issues. These were shown to 22 patients and 22 health professionals in Austria, Belgium, Croatia, Iceland, Italy, the Netherlands and the UK (Phase I). 69 issues were identified as highly relevant and important and operationalised into items (Phase II). EORTC guidelines do not generally recommend discarding items in the early phases. However, because fatigue may be a concern for palliative patients near the end of their lives, criteria were identified to reduce the length of the measure, by deleting items if they were highly correlated with others, or had a high proportion of missing data. In a pre-pilot- testing phase, data from a sample of 17 patients from the UK, Italy and Iceland were analysed and 38 items identified to go forward for pilot-testing.

In the main pilot-testing, 113 patients were recruited from France, Germany, Iceland, Italy, Japan, Spain and the UK. The mean age was 64 and 69 (61%) were female. 59 were Christian, 2 Buddhist (1 Italian, 1 Japanese), 1 Hindu, and 1 Jewish. 22 had no religion (including 14/15 Japanese patients), and 17 said they had a religion but did not define it.



Teresa Young



Bella Vivat

No religious data were collected for the 11 French participants. 41 had a prognosis < 6 months, 34 6-12 months and 31 > 1 year (missing data for 7 patients). Only a few patients found any items difficult, annoying, confusing, intrusive, irrelevant or upsetting, and comments from 42 patients indicated that they appreciated the opportunity to discuss their responses afterwards, supporting the initial hypothesis/theoretical position that the measure would have both quantitative assessment and qualitative interventional properties. Items were retained if they showed a good range of response categories and had little missing data. Following consultation with the Japanese collaborator and comments from both Japanese and European patients a number of the religious items were simplified. The 36-item measure is now ready for field testing. Preliminary factor analysis suggests four domains 1) Relationship with self, 2) Relationships with others, 3) Relationship with a greater power and 4) Existential. ■

(1) Measures of spiritual issues for palliative care patients: a literature review. Pall Med 2008 22 859-68 B. Vivat

Acknowledgements:		Ph I	Ph II	Ph III
Alexander de Graeff	Netherlands	X		
Adrian Visser	Netherlands	X		
Bernhard Holzner	Austria	X		
Karin Vlastic	Croatia	X		
Bart van den Eynden	Belgium	X		
Valgerður Sigurðardóttir	Iceland	X	X	X
Gu laug Helga Ásgeirsdóttir	Iceland			X
Fabio Efficace	Italy	X	X	X
Anna Costantini	Italy		X	X
Juan Arraras	Spain			X
Anne Brédart	France			X
Kunihiko Kobayashi	Japan			X
Susanne Singer	Germany			X



The EORTC QLQ Gyne Group; development of a Vulva Module

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The Gynaecological subgroup of the EORTC Quality of Life (QOL) Group has lately completed the development and phase 4 validation of the Endometrial cancer questionnaire module. In spring 2010 the Group decided to carry on with developing a questionnaire module for patients with vulva cancer. The Group had earlier received enquiries from scientific networks running international studies on different treatment approaches for vulva cancer patients. These networks had struggled to find a suitable questionnaire to assess quality of life in their clinical studies. The Gynaecological EORTC QOL Group had discussions regarding presumed recruitment problems for the validation study due to the low incidence of this gynaecological cancer. However, there was an agreement in the Group that a QOL questionnaire was needed.

Carcinoma of the vulva primarily affects old, menopausal women with an incidence of 2-3/100.000 women. However, the incidence of vulva cancer among younger women has increased lately and today approximately 15-25% of the patients diagnosed with vulva cancer are under the age of 50. About 60-70% of the patients are diagnosed with early stage disease with a favourable 5 year disease-free survival ranging 85-95%. Patients diagnosed with locally advanced disease have a poorer prognosis, yet a 5 year survival 50-75% in stage III and 20-30% in stage IV, with number and character (extracapsular vs. intracapsular) of inguinal lymph-nodes being the most important prognostic factor.

The treatment of vulva cancer has changed dramatically since the mid-1970s: from large "en-bloc" radical vulvectomy with bilateral groin node dissection towards more individualised and conservative operative procedures. However, although modified, the treatment for vulva cancer is still considerably mutilating and may include large surgical resections in the vulva and the groin region with a need for vulvo-perineal reconstructive surgery and adjuvant chemo-irradiation towards the vulva, the groin and the pelvis. There is much knowledge regarding morbidity related to the treatment as assessed by health care professionals. However, the literature concerning the impact of the disease, treatment and treatment related morbidity on the patient's QOL is very scarce.

The Group has so far completed a thorough literature review and identified about 100 issues described as potentially relevant for vulva cancer patients. Until spring 2011 several centres in Europe will present the list of issues for patients and health care professionals. Respondents will be asked to rate the relevance of each issue and to make priorities as to which issues are the most important for their quality of life. Based on these ratings the Gynaecological EORTC QOL Group will decide which issues should be conceptualized in a future questionnaire.

At the autumn meeting 2010, it was decided to use Computer Adapted Technique (CAT) for the vulva module. The idea is to adapt the questionnaire, in real time, to the patient. Based on previously answered items, the software is able to select the best following item. After each response it is evaluated, whether enough information has been obtained or whether there is a need to include more items. The programme will select items from an "item bank" of items tested in the developmental phases to reflect all grades/aspect of the specific concept/scale. Scores are comparable across patients even if different items are completed, due to the Item Response Theory analyses used in the developmental phases.

The decision to use CAT was made to meet future demands of a high degree of flexibility of questionnaires. With the CAT software the questionnaire can be adapted to specific studies or to specific patient groups and still be comparable across studies. The instrument can be updated continuously without losing backward comparability.

So far the study has been supported with a grant from the EORTC QOL Group for phases 1 and 2. The Group will apply for a further grant to support collaborators for phases 3 and 4. The Gynaecological EORTC QOL Group welcomes all health care professionals who are in contact with vulva cancer patients to participate in the study. ■

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Development of a Cachexia Module

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Cachexia, from the Greek “kakos” and “hexis” meaning “bad condition”, is a multidimensional syndrome characterised by involuntary weight loss and physiological changes. Cancer cachexia is a multi-factorial syndrome defined by loss of skeletal muscle that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. Cancer cachexia is a continuum passing through three stages: pre-cachexia, cachexia and refractory cachexia. Cachexia can occur in any cancer type and is estimated to be the immediate cause of death in 20-40% of cancer.

The experiences and concerns of patients with cancer cachexia have been addressed in a number of qualitative studies (Fitzsimmons, George, Payne, & Johnson, 1999; Hinsley & Hughes, 2007; J. Hopkinson, Wright, & Corner, 2006; J. B. Hopkinson, Wright, & Foster, 2008). These studies highlight how the complexity of cachexia translates into a range of problems and experiences for the patient and the resulting burden of support for family and health professionals. For example, patients with cancer cachexia report an altered body image, which impacts their emotions, spirituality, relationships and social functioning. Lives are restricted and isolated, which is compounded by emotional distancing by carers and health professionals.

To our knowledge, there is currently only one instrument available for measuring QoL in cancer patients with cachexia, the Functional Assessment of Anorexia-Cachexia Treatment (FAACT). The FAACT was first published in 1993 and subsequently shortened and revalidated in 2000 (Cella, Bonomi, Leslie, VonRoenn, & Tchekmedyian, 1993; Ribaldo, et al., 2000). Despite the length of time the FAACT has been available, only a handful of studies have utilised this measure. Most studies which measure QoL in cancer patients with cachexia have used generic cancer QoL tools, e.g. the EORTC QLQ-C30, SF-36 or the WHOQOL-BREF. Generic tools are unlikely to provide an adequate framework for assessing QoL in patients with cancer cachexia because these concerns are multi-dimensional and many issues are not captured by existing cancer QoL instruments. In

a preliminary review of the literature we found 62 potential issues described by patients, caregivers and health professionals; including the altered body image and emotional distancing described above, and the majority of these issues are not contained in the QLQ-C30.

New treatments for cachexia, based on improved understanding of the pathophysiology, are being developed, specifically to reverse the biological effects of cachexia. These include anabolic steroids, and agents which interfere with the inflammatory response, which is responsible for the

catabolic breakdown of muscle tissue. Because these agents will need to be tested in clinical trials, and because cachexia has a direct and large effect on quality of life, the need for a well designed and well utilised tool for assessing QoL in patients with cancer cachexia is pressing.

Proposed Module Development

We plan a standard module development project, with collabora-

tion in several European countries involving members of the European Palliative Care Research Collaborative who have a specialist interest in cachexia. We will conduct a systematic review to address two questions: What factors impact quality of life in patients with cancer cachexia? What measures are available to record self assessment of QoL? Based on this and on responses to patient interviews we will derive a list of relevant and important issues not already covered by the core instruments (QLQ-C30 and QLQ-C15-PAL). This list will be used to develop a module to supplement the core module(s), which will then be field tested in at least six countries (UK, Norway, Italy, Switzerland, Sweden and South Africa).

This project will integrate the QoL assessment at the heart of a global cachexia assessment which will cover physical, biological and psychosocial aspects of the condition. ■

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Update of EORTC QLQ Lung Cancer Module

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EORTC's lung cancer module, the QLQ-LC13, was the first site specific questionnaire to be used in conjunction with the core questionnaire QLQ C30 and was published in 1994. As its name suggests, the QLQ-LC13 consists of 13 items. To date, the module has been translated into 62 languages and is considered as one of the standard instruments for measuring the quality of life in patients with lung cancer.

The development of the QLQ-LC13 began some 20 years ago in the absence of established module development and translation guidelines. Since then, major clinical advances have been made. New advanced imaging techniques include PET-CT (positron emission tomography), which allows refined lung cancer staging and prevents futile thoracotomies in as many as 20% of patients who would otherwise be considered for surgery. Nevertheless, surgery remains the best option for cure and is the cornerstone of a multimodal treatment for patients with resectable primary tumors. Chemotherapy may vary according to the therapeutic approach: curative, palliative, adjuvant, or neoadjuvant. Platinum-based chemotherapy is today combined with new agents, such as Docetaxel, Gemcitabine, Irinotecan, Paclitaxel, Pemetrexed, or Vinorelbine. Targeted agents constitute a new generation of cancer drugs designed to interfere with a specific molecular target that is believed to play an important role in tumor growth or progression. These drugs are expected to enable personalized therapies and, thereby, increase the efficacy of the treatment or decrease the toxicity in patients with lung cancer in the near future, or both. Last, but not least, irradiation therapy offers different modalities for different localizations: external beam radiation, stereotactic radiotherapy, and endobronchial brachytherapy.

“It is of high strategic importance for the EORTC QLQ to have a strong and updated lung cancer module in its portfolio.”

In light of these clinical developments, and in light of the fact that today a number of questionnaires for respiratory illnesses are on the market, which are frequently used in clinical studies and cited in the literature, a working group within the EORTC QLQ found it necessary to consider an update of the QLQ-LC13. The research proposal includes a full Phase I to Phase III procedure.

Phase I is aimed at compiling an extensive list of quality of life issues relevant for the patient group under investigation. The following sources will be used: (1) existing questionnaires on lung cancer and respiratory illnesses, (2) the literature, (3) investigator's brochures (IB) on new drugs, and (4) interviews with health care professionals and patients. In Phase II the issues are being converted into items that follow the EORTC format with four point response scales ranging from “not at all” to “very much”. For the sake of consistency and whenever possible, items of the existing QLQ-LC13 will be used, or items will be taken from the Item Bank which currently includes more than 6.000 items. After this stage, the procedure will be formally peer-reviewed by the EORTC QLQ Module Development Committee. After approval, the provisional list of items will be ready for Phase III. This developmental stage includes the pretest of the provisional updated lung cancer module in n = 120 patients, stratified by study region (English speaking countries including the United Kingdom and Australia; Northern Europe including Norway and Germany; Southern Europe including Italy and Spain; Asia including Japan) and clinical group (1. non-small cell lung cancer/curative approach, 2. non-small cell lung cancer/palliative approach, 3. small cell lung cancer/curative approach, and 4. small cell lung cancer/palliative approach).

The plan is to start this project in February 2011 and to finalize Phase III by January 2012. It is of high strategic importance for the EORTC QLQ to have a strong and updated lung cancer module in its portfolio. Lung cancer is the most common cancer worldwide, accounting for 1.2 million new cases annually, and is also the most deadly malignant disease which, according to recent US statistics, is responsible for 30% of all cancer deaths in men and for 26% of all cancer deaths in women. ■



Update of the EORTC QLQ questionnaire for the assessment of quality of life in head and neck cancer patients (EORTC QLQ-H&N35)

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The EORTC head and neck specific module was one of the first developed to be used in conjunction with the core questionnaire, the QLQ C30. Its first version (QLQ-H&N37) was published in 1994, and subsequently revised and validated with a transnational field study in 12 countries, comprising data of 622 head and neck tumour patients.

However, new treatment strategies are emerging and the H&N35 has been criticised for not sufficiently covering side effects related to surgery or chemo-radiation, and especially the combination of these treatment modalities in multimodal therapy concepts.

Radio-chemotherapy using a combination of several chemotherapy drugs has improved patients' survival but has also considerably increased their morbidity, e.g. severe mucositis, hair loss, neuropathy, or chronic dysphagia. In addition, biological therapies are increasingly used. The side effects are clinically known to be mainly skin rash and headaches, both of which are not included in the H&N35.

Thus, the EORTC Quality of Life Group and the EORTC Head and Neck Cancer Group were both in favour of revising the existing module. Three systematic literature searches were performed and patient and expert interviews were started in December 2009. 109 papers were found that had used the H&N35 (databases: Medline and Embase, no language restrictions). For 104 of them, the full text was available.

The H&N35 was used in 11 languages: German (28 papers), Dutch (20), Swedish (18), Norwegian (11), English (11), French (8), Mandarin (6), Danish (4), Polish (4), Cantonese (2), and Turkish (1). Reliability was investigated in 13 papers and appeared to be satisfactory overall. Insufficient internal consistency was reported on the Speech and Senses scales. Consequently, the items of the Senses scale were treated as single items in

several studies. One study found minor problems in the Pain in the Mouth scale. Some scales were considered to be difficult to differentiate psychometrically and conceptually, e.g. the Social Eating and Social Contact scale.

Compliance by patients (missing values) was generally satisfactory. Problems are sometimes reported on the Teeth and Sexuality scale, where it remains unclear whether a non-answer is due to the patient being unwilling to answer or because it is not applicable.

Compliance by researchers (number of scales used) varies. Some of the scales were skipped relatively often, especially the one-item scales. The use of the scales ranged from only 37% (Weight Gain) – which means that 63% of the studies did not use or did not report this scale – to 83% (Senses). All of the one-item scales were used/reported in less than half of the studies. Sometimes a total scale had been calculated of all head and neck scales.

14 papers were identified that investigated quality of life after chemo(radio)therapy and that met the inclusion criteria. The H&N35, like other QoL instruments, was rarely used in clinical trials. This could be due to a low interest of researchers in QoL or due to a mismatch of the H&N35 module and the research question. Additional trial specific questionnaires were used occasionally. A list of potential additional issues from the papers was extracted.

Three papers were identified investigating quality of life in biological therapies that met the inclusion criteria. There was only one study published that investigated QoL using the H&N35. No differences in the treatment arms were found. It is questionable whether this is due to a true equivalence of the treatments or to the fact that the specific side effects of biological agents are not covered by the H&N35. As only a few papers were available, potential additional issues were extracted from industry brochures.

As a result of the three reviews, a list of issues (additional to the original H&N35) was constructed and discussed at the EORTC QLQ meeting in Pamplona, resulting in a preliminary list of 92 issues ("old" module plus "new" issues) to be presented to experts and patients. 233 interviews were completed (96 expert and 137 patient interviews). According to the guidelines, only two issues were excluded from that list. Another nine issues were excluded because of duplicity.

With the aid of a grant from the EORTC Quality of Life Group, we will continue with phase III, i.e. with pilot testing the provisional questionnaire. ■



Susanne Singer



Assessing the Clinical Effectiveness of Breast Reconstruction through Patient Reported Outcome Measures (PROMS) – the EORTC QLQ development of a Breast Reconstruction Module to assess all types of breast reconstruction.

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Thirty to forty percent of the 44,000 women diagnosed annually with breast cancer in Europe will either be recommended to have a mastectomy or chose this surgery as their preferred option. This is predicted to have effects on a patient's quality of life, involving psychosocial, physical, aesthetic, body image and sexual effects. Breast reconstruction (BRR) has been recommended by the National Institute for Health and Clinical Excellence (NICE) in the UK which is reflected by 21% of women undergoing immediate BRR in the UK national mastectomy and breast reconstruction audit. A variety of types of BRR are practised and range in complexity from simple silicone implants inserted under the pectoralis muscle to various myocutaneous pedicled (back and abdomen) and free flaps from the abdomen or buttock, requiring microsurgical expertise. Patient Reported Outcome Measures (PROMs) should assess the impact of disease, treatment and surgical intervention on various aspects of a patient's outcome, as well as being clinically meaningful, scientifically sound and practical(1-2). The assessment of HRQoL can provide essential outcome information in cancer surgery and may be useful in identifying the optimal surgical procedure.

A systematic review was conducted to identify PROMs that have been developed and validated for use in cosmetic and reconstructive breast surgery patients(1-2). Only seven measures were identified, with exclusively two applicable to breast reconstruction and related to The Michigan Breast Reconstruction Outcomes Study (MBROS); one pertaining to a satisfaction questionnaire (MBROS-S) and the other to body image (MBROS-I)(1), but neither of which specifically address key issues relating to either the donor site or the reconstructed breast and were developed exclusively in the context of the expander/implant or the abdominal (TRAM) flap reconstruction. Consequently, neither has been validated across the spectrum of breast reconstructive types or in the context of European reconstructive practice. In order to understand the relative importance of many aspects of BRR and therefore to be able to best advise patients on BRR options, a tool to assess the HRQL outcomes of different types of surgical and other treatments involved in BRR is required.



Zoe Ellen Winters

We suggest that a BRR module should be developed and used in conjunction with EORTC QLQ-C30 and BR-23 in order to properly evaluate the benefits of BRR, to assess the relative benefits of the different types of BRR as well as the timing of that surgery and to provide information to better inform future patients.

The process of generating issues in keeping with EORTC guidelines on module development is shown in Figure 1(3). A final 51 issue list was taken forward to multicentre Phase 1 interviews. Fifty-eight patient interviews were carried out in three centres. Patients had undergone a range of BRR methods as well as adjuvant treatments including chemotherapy and radiotherapy. The ages of the patients as well as the durations post-operatively were clinically representative. High priority scoring by patients and Health Care Professionals and qualitative analyses of interview comments were also taken into account. As a result, 21 issues were deleted and one new issue added, resulting in 31 issues to take forward to Phase 2 (Figure 1). In Phase 2, 31 issues were then formulated into questions using the EORTC Item Bank to provide standard formatting. The



resulting 31 items were arranged into an appropriate order commencing with items that are relevant to both pre-and post-BRR and followed by items relating to the nipple and donor site being grouped together ensuring a logical progression and relevance for patient responses. A one week time frame has been adopted throughout.

“210 patients will be recruited in five European countries, with 10-15 patients per type of BRR technique.”

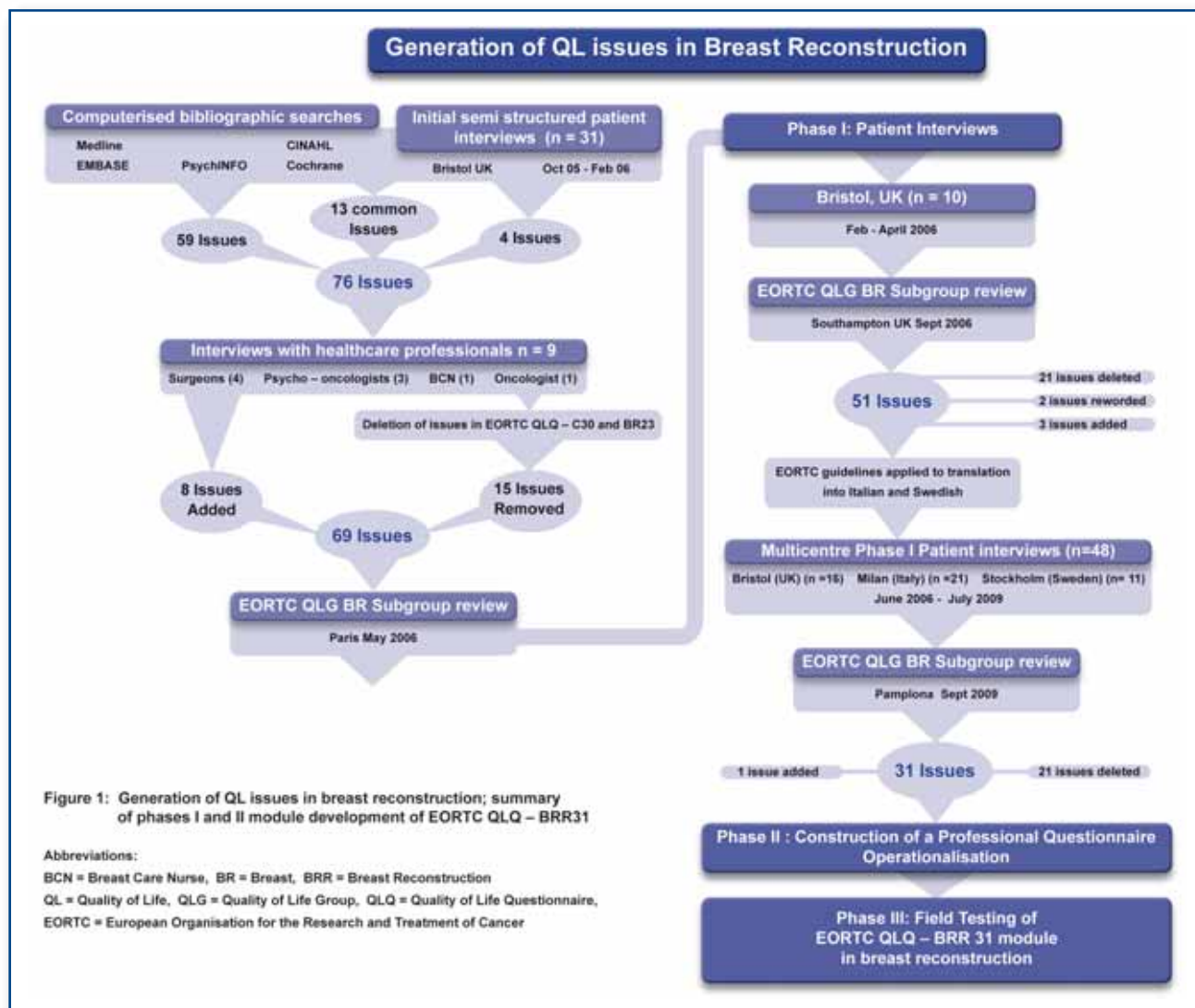
A 4-point Likert scale is used throughout providing a module layout that is easy to follow. The hypothesized scale structure (issue numbers) and (n= number of issues) of the proposed module is as follows: **Body Image:** (57, 59, 60); (n=3), **Sexuality:** (61-64); (n=4), and relating to cosmetic outcome, the **Reconstruction:** (65-71, 78, 79); (n=9), the **Donor site:** (80-84); (n=5), the **Nipple:** (72-77); (n=6), and **Disease/Treatment related symptoms:** (54-56, 58); (n=4).

The aim is to develop phase 3 of the BRR specific module to assess HRQL in women undergoing mastectomy for invasive breast cancer and ductal carcinoma in situ. 210 patients will be recruited in five European countries, with 10-15 patients per type of BRR technique predominantly

represented in current clinical practice, as well as an additional 10-15 patients having undergone radiotherapy in each group. These include implant only, vascular pedicled flaps such as Latissimus Dorsi (LD) with implant, tissue only Autologous LD (ALD), Extended autologous LD flap with implant (ALDI) and Transverse Rectus Abdominus (TRAM), either pedicled or microvascular free flaps. Finally, there is an increasing practise of microvascular free flaps including Deep Inferior Epigastric (DIEP) and lesser performed flaps such as Superior or Inferior Gluteal flaps. Recruitment will commence in 2011 for 12-18 months. ■

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Further development and dissemination of CHES-EORTC for electronic PRO data collection and presentation

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Paper and pencil-based measures of patient-reported outcomes (PROs) have been widely adopted in oncology research. By adding comprehensive longitudinal PROs to the evaluation of health status, symptom management and the detection of adverse events may be enhanced.

However, PRO monitoring requires a considerable amount of time, both for the patient by having to complete the various assessment instruments, as much as for the staff involved in the process of data entry and control. Moreover, immediate presentation of PRO results to the physician is difficult, which hampers their utilization for individualized clinical decision making.

Consequently, electronic PRO data capture (ePRO) has become an important issue over the last few years. As a matter of fact the implementation of ePRO requires software to provide data collection, storage, analysis and presentation.

Over the last six years Evaluation Software Development (ESD) has developed PC software named Computer-based Health Evaluation System (CHES) which meets such requirements. CHES is a PC-program for electronic PRO data capture allowing patients to complete questionnaires via a touch-screen (see Figure 1). In addition, it provides a database (e.g. MySQL or Oracle) for psychosocial and medical data and presents PRO results in an easily comprehensible manner (see Figure 2). In a research context ePRO enhances study logistics by reducing the need of human resources and by increasing data quality.

Already, CHES has been successfully implemented in both oncological in- and outpatient units in several hospitals in Austria, Germany and Italy. At these centres data assessment is done via tablet-PCs with screen sizes of 10 or 12 inches. Depending on screen and font size one to four questions are shown per page. In most settings, a client-server solution for data storage is in place, based on either WLAN or LAN. This is necessary in order to provide results without time loss at all working stations required. The feasibility of the use of CHES for PRO data collection has been demonstrated within several studies [1-4]. To date, almost 10.000 PRO assessments have been performed with CHES, both within clinical trials and in daily clinical routine.

In April 2010 we received a 2.5-year research grant from the EORTC Quality of Life Group to further develop this software and to provide a CHES-EORTC version to members of the Quality of Life Group. Furthermore, there is an ongoing collaboration with OncoTyrol concerning software development.

As part of the EORTC project the CHES-website (www.ches.at) was extended with an EORTC-section, providing not only the latest version of CHES-EORTC for download, but also a discussion and support forum allowing exchanges on software and implementation related issues.

A first English software version was released in November 2010, which included a comprehensive manual and an integrated up-date system allowing easy download and installation of bug-fixes and software patches.

The first weeks after the release were considered to be a test phase, allowing users to become familiar with the software before implementing it into a clinical setting. In addition, this test phase enables the collation of information on how CHES-EORTC works in different IT-environments and allows for response to possible problems, in a subsequent release.

This first release included the English EORTC QLQ-C30 to provide an example for questionnaire administration within CHES-EORTC. Further language versions and modules are available for EORTC Quality of Life Group members upon request from Bernhard Holzner (bernhard.holzner@ches.at). Whereas the software is capable of including various types of questionnaires, copyright issues might affect the integration of some questionnaires.

“CHES has been successfully implemented in both oncological in- and outpatient units in several hospitals in Austria, Germany and Italy.”

In the future, two further major CHES-EORTC releases are planned, which are going to provide important additional features such as:

- a plug-in with EORTC QLQ-C30 reference values that are automatically adjusted to specific patient characteristics;
- a web-interface to collect PROs beyond a clinical setting (e.g. for home monitoring);
- further extension of online support;
- a plug-in to enable computer-adaptive testing (CAT);
- an interface (based on the HL7-standard) to allow for data exchange between CHES-EORTC and clinical information systems;
- a multilingual CHES-EORTC version.

The web-based assessments mentioned above allow an assessment of symptoms at time points which are crucial for the patients' well being, even when she/he is not attending an in- or outpatient unit of the hospital. Especially with regard to chemotherapy, side effects and related symptom burden are known to be most severe a few days after application of





Gerhard Rumpold



Bernhard Holzner



Johannes Giesinger

cytostatic drugs. In some studies [5-6], alert systems based on home monitoring have been shown to give health care professionals the possibility to contact patients and intervene if a patient is suffering from severe symptom burden, even when he/she is not hospitalised.

With the further development of CHES-EORTC and its features we hope to promote the use of ePRO and the EORTC measurement system within research and clinical practice. ■

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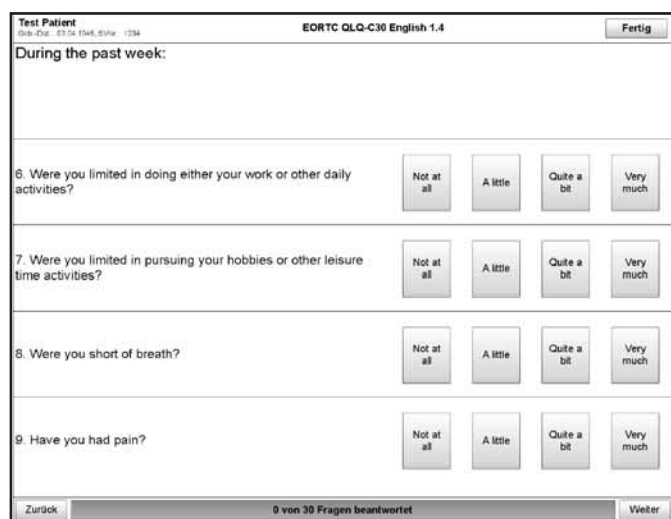


Figure 1: EORTC QLQ-C30 as administered on a tablet-PC.



Figure 2: Graphical presentation of longitudinal EORTC QLQ-C30 scores.

Educational Seminar June 3rd 2010 University of Athens

Ourania Nicolatou-Galitis
Professor & Head, Clinic of Hospital Dentistry
Dental Oncology Unit, Dental School University of Athens

The Dental Oncology Unit, Clinic of Hospital Dentistry (established in 2004), serves as a Referral Center for the prevention and treatment of oral complications in cancer patients, who receive different anti-neoplastic therapies.

Professor Ourania Nicolatou-Galitis, and colleagues / graduate students participate in the “development of the Oral Health module supplemental to the EORTC-QLQC-30 (PI Marianne J Hjermstad)”, in the update of the EORTC questionnaire for the assessment of quality of life in head and neck cancer patients, EORTC - QLQ-H & N35, (PI Susanne Singer), and in the EORTC CML QoL project (PI Dr Fabio Efficace). The colleagues from Athens are grateful to the Principal Investigators, Dr Hjermstad, Dr Singer and Dr Efficace, for this opportunity. This support of the EORTC -QoL Group is highly motivating in their work.

The discipline of Oral Supportive Oncology and the importance the Oral Health related quality of life in cancer patients was highlighted, last June 2010, in two scientific events organized by the Dental Oncology Unit, in collaboration with the Hellenic Association of Supportive Care of the Oral Cavity in Cancer-HASCOCC (established in 2005) – HASCOCC, www.oraloncology.gr.

The first event was an Educational Seminar, which took place on June 3rd 2010, at the Dental School, University of Athens, entitled: “The old, the new and the emerging oral complications in Oncology”. Professor Ourania Nicolatou-Galitis introduced the speakers and welcome the 100 dentists and other health care oncology professionals (photo 1). She gave an overall picture of the activities of the Unit, including the Educational



Photo 1



Photo 2



Seminars to the hospital and private dentists, one per semester, with the participation of health professionals from the Medical Oncology, Radiation Oncology and Haematology field. As it is well known, the oral cavity is a common site of complications of cancer therapies, with a significant negative impact on the Quality of Life of the cancer patients.

In addition to the old and well known complications, (NCI Monograph 1990, Consensus Statement) new oral complications, as the jaw bone necrosis, have been described, while other complications are emerging in the era of targeted therapies. It is apparent, that there is an increased need for information and education of the oncology health care professionals within the framework of the multidisciplinary approach.

Professor Nicolatou-Galitis mentioned that, at a minimum, oral complications are painful, diminish the quality of life and may lead to significant problems, often discouraging the patient from continuing treatment (NCI Consensus statement 1990).

At times, levels of oral morbidity may interfere with oncologic therapy, necessitating suspension of therapy until such complications resolve. Mucosal inflammation and ulceration, viral, bacterial and fungal infections, mucosal bleeding, xerostomia, osteonecrosis, fibrosis, and complications in the paediatric population, are among the well established complications.

In short, the patient is in pain, needs analgesics and opioids, may develop a dangerous infection, may bleed and may interrupt the oncology therapy. Dr Nicolatou presented cases of patients with emerging oral complications in the era of the newly introduced targeted therapies, such as gingival bleeding, associated with the administration of Sunitinib (sutent®), the lichenoid reaction and oral pain in association with Imatinib (glivec®), and other oral complications associated with cancer therapies.

Dr Mark Schubert, Professor for Oral Medicine University of Washington, Cancer Center Seattle, USA, presented the "Oral lesions and the Dentist's role in Haematopoietic Stem Cell Transplant recipients" (photo 2). He presented the Graft versus Host Disease-related oral complications, oral mucositis and oral infections with the risk of systemic dissemination.

Dr Evangelos Terpos, Assistant Professor of Haematology / Oncology,

Alexandras Hospital University of Athens, presented the "Bone metastasis and jaw bone necrosis, from the Haematology Oncology perspective". Jaw Bone Necrosis is a relatively new oral complication, first described in 2003, which is seen in patients, who receive bisphosphonates for the treatment of metastatic bone disease.

"Jaw Bone Necrosis is a relatively new oral complication, first described in 2003, which is seen in patients who receive bisphosphonates for the treatment of metastatic bone disease."

The Dental Oncology Unit, also, supported the 2nd Meeting of HASCOCC, June 12 & 13, 2010, with 300 participants from 8 countries from Dental, Maxillofacial, Radiation Oncology, Medical Oncology and Haematology Centers (Photo 3). The central theme of the Meeting was: "Oral Supportive Oncology: improving the quality of life cancer patients". The development of the Oral Health module supplemental to the EORTC-QLQ C-30 was presented by Bente Brokstad Herlosfon within the main program. ■

Email: nicolatou.galitis@lycos.com

Photo 1: June 3rd 2010. Professor Mark Shubert presents his lecture in the Amphitheatre of the Dental School. Professor Nicolatou-Galitis is also seen at the podium.

Photo 2: June 3rd 2010. Dentists and other oncology professionals attend the Seminar in the Amphitheater of the Dental School, University of Athens, Greece.

Photo 3: June 12 & 13 2010. Professor O. Nicolatou-Galitis, Head of the Dental Oncology Unit and President of HASCOCC, the Associate President of the Dental School Professor K. Tsiklakis, the Chair of the Scientific Committee, Professor D. E. Peterson, the key note lecturer, Eva Grayzel (cancer survivor, www.EnaGrayzel.com), members of the Board of HASCOCC, BB Herlosfon and other local and international participants during the 2nd HASCOCC Meeting, at the Royal Olympic Hotel, in Athens.

Photo 3



Normative data for the EORTC QLQ-C30 and EORTC-sexuality items in the general Dutch population

van de Poll-Franse LV, Mols F, Gundy CM, Creutzberg CL, Nout RA, Verdonck-de Leeuw IM, Taphoorn MJ, Aaronson NK



Lonneke van de Poll-Franse

In December 2010, Dutch EORTC-Quality of Life (QoL) Group researchers published a paper on Dutch reference data for the EORTC QLQ-C30 and for five sexuality items from the EORTC QL-Item Bank. Furthermore, they evaluated the relative impact of self-reported health problems on these outcomes and compared the Dutch normative EORTC QLQ-C30 overall QoL with available Scandinavian and German normative data.

QLQ-C30 and sexual item normative data were obtained from the Health and Health Complaints project from CentERdata. The CentERpanel is an online household panel consisting of more than 2000 Dutch households, representative of the Dutch-speaking population in the Netherlands. The questionnaire was completed by 1731 (78%) CentERpanel members.

For both men and women, functional health (except emotional functioning) decreased with age, and the symptoms pain and fatigue increased with age. Men scored statistically but never clinically significantly better on most functional scales than women. Men reported higher levels of sexual interest and activity than women. All subgroups of participants with health problems reported lower physical and role functioning and overall QoL.

Those with depression (n=79) reported functioning scores 20-30 points lower than participants without any condition. Dutch men and women reported high levels of overall QoL as compared to previously published Scandinavian and German normative data. Age, gender and other health problems are important when comparing QoL and sexuality among different cancer cohorts. Normative data on QoL and sexuality are needed to interpret QoL issues among the growing group of (long-term) cancer survivors. ■

Online, 4 Dec 2010, Eur J Cancer

Mean scores (standard deviations) of sexuality scales and items by sex and age groups (NB: scores or standard deviations ≥ 10 are rounded)

Age (years)	Men							Women							Total
	All	16-29	30-39	40-49	50-59	60-69	70-94	All	16-29	30-39	40-49	50-59	60-69	70-94	
Sexuality															
Interest	56 (28)	66	69	64	62	51	37	33 (27)	37	42	43	35	25	13	46 (30)
Active	41 (28)	48	49	49	47	37	24	29 (28)	33	38	39	29	23	8.6	36 (28)
Enjoyable	73 (24)	84	82	73	76	73	58	70 (26)	82	77	72	63	64	55	72 (25)
Men															
Erection difficult	16 (27)	2.4	4.8	6.8	10	23	41	-	-	-	-	-	-	-	16 (27)
Women															
Dry vagina	-	-	-	-	-	-	-	8.8 (18)	3.2	4.4	4.5	14	19	19	8.8 (18)
Pain at intercourse	-	-	-	-	-	-	-	5.0 (13)	7.9	5.1	1.6	6.3	6.7	9.5	5.0 (13)





An update on the PROBE project from the Quality of Life Department

Andrew Bottomley, Chantal Quinten, John Bean and the PROBE Management Team

Over the past three years the EORTC Patient Reported Outcomes and Behavioural Evidence (PROBE) program of research has been active to explore many aspects of implementing QOL in cancer clinical trials. PROBE members had a very specific mandate to focus on the practical application of QOL directly into clinical trials research. The key issues addressed in our research program are for example assessing survival prognostication in EORTC clinical trials using HRQOL data, exploring internal relationships among EORTC QLQ-C30 indicators from EORTC clinical trials and investigating Minimal Important Differences for Interpreting Health Related Quality of Life Scores from the EORTC QLQ-C30.

This international effort has resulted in several publications in scientific journals, numerous presentations, along with organizing several symposia. In August 2010, PROBE members were invited to conduct a Symposium on PROBE at the UICC 21st World Cancer Congress held in Shenzhen, China. This represented an exciting challenge for the PROBE team to reach out to such an international and influential audience. We are fortunate that UICC felt the Symposium was a success and invited EORTC PROBE to organize a future symposium to discuss pending results at the upcoming UICC meeting in Montreal, Canada in 2012. The QLG also invited the PROBE team to present at the September 2010 meeting in Leipzig.

Invitations such as these allow the PROBE team to interact, as well as to educate and train clinicians and other health care professionals on how they can improve QOL and psychosocial care of their cancer patients. Furthermore, these opportunities to speak to the EORTC Group members helps to improve the visibility of PROBE's research and simultaneously reinforce an important dialogue whereby EORTC QOL

researchers can forge new ideas for future collaborations within the EORTC Clinical Groups.

Given the success of our first EORTC PROBE Symposium held in Brussels in 2009 on QOL in cancer clinical trials, it is with pleasure that the PROBE team announces its second Symposium in September 2011. EORTC are fortunate that we have the backing of the European Parliament who will host this three day event. This collaboration will significantly increase the political focus of the event and increase awareness of the importance of psychosocial and QOL issues among the European Parliament members, the 27 EU Member States, and other non-EU Member States. Keynote speakers from the European Parliament will include Marisa Matias, Member of the European Parliament (MEP) and Chair of the Forum against Cancer Europe (FACE) as well as representatives from MEPs Against Cancer (MAC). Importantly, patient groups will be involved and make a major contribution to this event. Members of the leading news media will attend this symposium, among whom will be Dr. David McNamee, Senior Editor, The Lancet. If you are interested in attending our Symposium, we recommend you to look at our full program online, http://www.eortc.be/seminar/qol_probe_2011/proberegistrationform.aspx, and encourage you to register as soon as possible as places are limited.

The future of PROBE is promising. We are seeking additional research fellows to undertake our future work. We have several major analyses ongoing and planned, a great team at EORTC Headquarters (HQ), and a dedicated international advisory board who vigorously and unwaveringly collaborate and support the research we undertake. We are very fortunate to have the backing and support of EORTC HQ for our core work in the future. However, in order to sustain efforts and growth, PROBE plans to continue seeking grant and sponsor support. To date, several grant proposals have been submitted, and work in this regard will continue during 2011.

Over the long run we hope PROBE can play an important role in helping to facilitate the planning of new treatments and promote a better understanding of cancer care. PROBE is a means and a way to promote understanding and discussion of the values of psychosocial/HRQOL issues and their practical impact on patients with cancer. ■

For more information about PROBE, please see: www.eortc.be/probe/





QOL Group meeting, Leipzig

EORTC QoL Group Meeting, Leipzig, Germany, September 2010

Anne-Sophie Darlington PhD, University Surgical Unit, Southampton General Hospital, UK



16

The Group's 2010 autumn meeting took place in Leipzig, Germany, and was hosted by Dr Susanne Singer. The meeting was held in the beautiful Fuerstenhof hotel in the city centre, where on the first day, parallel sessions got underway after a brief introduction by the Chair Galina Velikova.

It became clear to me how extremely effective these sessions are at updating collaborators and facilitating discussions on the different studies, therefore enabling collaborators to proceed with their studies. In addition, new collaborations are easily realised because of the unique networking opportunities.

After interesting presentations during the numerous parallel sessions we were taken on a tour of the city. The guide opened our eyes to the rich history of Leipzig and showed us what a wonderful city it is. We visited the University academic building and the Dean of the School of Medicine spoke briefly and extended a warm welcome to the Group. We were also treated to a piano concert by one of Susanne Singer's former PhD students. Afterwards we continued on our city tour, which ended at the best restaurant in town, the Stadtpeiffer. During dinner we were treated to excellent entertainment by a professional singer/musician and by several of the Group members. The entertainer's contagious enthusiasm resulted in exuberant dancing and a late night!

The next day, members of the Executive Committee had to meet early in the morning for their Business meeting. The day continued with plenary sessions in the morning on spiritual well-being, electronic data collection, translations, the CAT project and minimal important differences. The afternoon was devoted to the EORTC PROBE project, an ambitious project allowing in-depth analyses on a large dataset.

Late afternoon we were picked up by coaches to take us to the canals for a boat trip. German punctuality did result in some Group members being left behind, but the coach was quickly turned around to fetch them. We had a boat trip in Leipzig's canals and saw impressive architecture and numerous stunning renovations. The day ended in a restaurant in the city centre where again we enjoyed more good food and good times.

As a first time visitor I would like to thank the organisers for a wonderful and very welcoming meeting, which I enjoyed very much. In addition, I am sure I am not the only one who will spread the word about Leipzig being a wonderful city!





EORTC QoL Group meeting, Innsbruck, Austria, September 2011

Approaching Innsbruck, no matter if travelling by plane, train, car, or bicycle, the first glimpse of “the heart of the alps” shows a small charming town squeezed between two impressive mountain chains and catching its reflection in the crystal clear river Inn. Following its stream course one passes colourful renaissance and baroque buildings along the riverside, which tell stories of former times.

Named after the bridge across the river Inn, Innsbruck has been a “bridge” for trade and culture between Germany and Italy since Roman times. During the 15th and 16th century in particular, strong connections to Italy influenced its cityscape, culture and way of life. Remaining traces can be found not only in architecture but also in a vivid music tradition resulting in numerous festivals such as the “Klangspuren” (sound traces), the “Tanzsommer” (dance summer), and the Festival of Ancient Music. These, and easy access to mountain recreation areas, have made Innsbruck attractive for students from various European countries and have turned it into a popular University and convention town, with an array of pubs and cafés.

Arriving in Innsbruck’s cosy old city centre you usually cannot miss the ‘golden roof’. Having now already visited Innsbruck’s most famous sight, you might feel free to interrupt the cultural programme for a reviving apple-strudel in one of the many traditional cafés before you continue on along historical paths. The Imperial Palace and the cathedral just round the corner from the golden roof, as well as the Wilten Basilica and Ambras Palace, are definitely worth seeing. Alternatively after an awesome cable car ride up to “Seegrube” 2000 m above sea level you can enjoy a delicious “Speckknödelsuppe” (speck dumpling soup) and the fantastic view of Tyrol’s mountain scenery. Thanks to the so-called “Föhn”, a strong and warm wind coming from the south, the view is clear most of the year. From Seegrube you can see the venue of the Olympic Winter Games which took place in 1964 and 1976. At least since then Innsbruck has become widely known as a Mecca of winter sports. To date, skiing, snowboarding, ski mountaineering, snowshoeing, and skating are among favoured activities not only for competitive athletes but in particular for visitors and residents.

Needless to say in summer also, the region offers a variety of outdoor sports such as cycling, mountain biking, paragliding, hiking and walking on the “Nordkette”, the “Patscherkofel” and in various valleys around Innsbruck. Don’t be surprised to meet an 82 year old Tyrolean running past you at 2000 m altitude, on skis or on foot, shouting a friendly “Griaß Gott” (the Tyrolean way of saying “Hello” but including God in some way).

So we would love to invite you, to not only investigate QOL but to also actively explore our hometown. ■

*Bernhard Holzner, Assoc, Prof PhD
Innsbruck Medical University
Department for Psychiatry and Psychotherapy -
University Clinic of Biological Psychiatry, Austria*





Francesca Martinelli relaxing at the UICC World Cancer Congress in China

riate data analysis techniques. I had the chance to broaden my knowledge by attending a course on multivariate data analysis techniques (Montréal, June 2008) and by spending some time at the Symptom Research Department of the MD Anderson Cancer Center (Houston, April 2009). These wonderful experiences allowed me to present my first abstract at the American Society of Clinical Oncology (ASCO) (Orlando, May 2009).

Whilst gaining more knowledge I had the opportunity to work on new projects: in October 2009 I presented, at the International Society for Quality of Life Research (ISOQOL) annual conference, a study where the possibility of creating a Symptom Index for Cancer Patients was discussed (New Orleans, October 2009). For this study I was selected for the Young Investigator Award.

In November 2009 I had the chance to participate, as faculty, in the first EORTC Course on Quality of Life, Symptom Research and Patient Reported Outcomes in Cancer Clinical Trials (Brussels, November 2009). It was a wonderful, illuminating experience, where all the participants had the possibility to broad their knowledge and exchange their ideas. One of the e-mails we received afterwards said simply, "Congratulations, it is such an inspiration". It really was, and I feel lucky I took part in such an event. The second course will take place in September 2011 and everybody is welcome to attend!

2010 was also full of surprises and experiences: a mini-symposium at the Union for International Cancer Control (UICC) World Cancer Congress (Shenzhen, August 2010); the chance to share working experience and nice evenings with Quality of Life Group (QLG) colleagues at the QLG meeting (Leipzig, September 2010); the presentation of a new study, a Cluster Analysis on Prostate Cancer Patients, at the ISOQOL annual conference (London, October 2010); and a challenging issue panel discussion on Genetics and Quality of Life at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) meeting (Prague, November 2010).

I have met so many nice people during this period that if I started naming them one by one, I would probably never end. So I would just like to sincerely thank everybody who I have had the chance to work, exchange ideas or simply sharing a glass of wine with during these three years. I hope and I'm confident that our collaboration will not end here! ■

Francesca Martinelli

Francesca Martinelli's experience gained as a Fellow at EORTC

When I started to work at the EORTC Headquarters Quality of Life Department in March 2008, I thought that it would be nice to spend one year gaining experience and studying cancer from another point of view. Three years (and a couple of rainy days) later, I'm still in Belgium and I can confirm I made the right choice.

My fellowship has been renewed twice and during these three years I have learnt a lot, had wonderful experiences, met very nice people, gained new knowledge and hopefully shared the knowledge I already had.

A brief overview of some moments I like to remember.

The first Patient Reported Outcomes and Behavioural Evidence (PROBE) meeting (Brussels, April 2008), where possible projects were proposed and discussed. It was my first international meeting, with people whose names I had only read on papers, in a language I hadn't really mastered... Do I need to add how nervous I was? Luckily, all the PROBE members turned out to be friendly and willing to help, and I went home full of enthusiasm and ready to start.

My first project was a Symptom Cluster Analysis. My experience was mainly epidemiological and I needed a wide background about multiva-



Reflections on eight years Quality of Life Department

In January 2003, I started my duty as Secretary to the Quality of Life Department, well actually it was called a Unit back then.

At first, I was a bit unsure of how the job would evolve, but under the guidance of Dr. Andrew Bottomley, I gradually grew into the job. I learnt all about quality of life, clinical trials, cancer research, etc. Step by step I also got to know the Quality of Life Group, and its activities and members. I enjoyed learning new things and getting to know new people, both in the Department and Group. I have had a lot of fun with my nice colleagues.

Of course, as with everything changes always occur. So over the years I saw colleagues leaving and new ones arriving. We have also moved offices several times and to be honest, I prefer the office we have now. But of course, the Quality of Life Department has its constant factors and people, the thriving force I would say.

Another highlight was the attendance of the Group meetings, especially the anniversary meeting in Paris. I really enjoyed that. But the meetings in Brussels were not less pleasant. It was nice to meet the members in

person because extensive contact through email is one thing, but having a personal and informal chat is another thing. I can say that I have built my own network with contacts from all over the world, which is of course a unique experience.

Unfortunately, all good things must come to an end eventually. What some people don't know is that I have to commute four hours per day to come to the office. I must admit that after eight years, I felt it was time for a new challenge, closer to home. So I'll be handing over my duties to Rossella Guzzo and I'm sure she will do a terrific job as Secretary to the Quality of Life Department.

I would also like to thank Dr. Andrew Bottomley for granting me this unique opportunity to be part of such a nice working environment. I would also like to thank my colleagues and former colleagues and all the Group members for this rich experience. I'm sure this will be valuable for my future career.

I will never forget my time at the EORTC Quality of Life Department. Thank you all and I wish you all the best. And who knows, maybe we'll meet again sometime... ■

Ken Cornelissen



Fabio Efficace

Recent international Awards and Honors

We would like to congratulate **Dr. Fabio Efficace**, joint Secretary of the EORTC Quality of Life Group, who has been elected on the **Board of Directors of the "International Society for Quality of Life Research" (ISOQOL)**. The news was announced during ISOQOL's Annual Conference held in London in October 2010.

We would also like to congratulate Dr. Fabio Efficace for his recent appointment as an **"Associate Editor"** of "Health and Quality of Life Outcomes" which is one of the leading Journals in the area of quality of life and outcome research.



Publications

The EORTC QLQ-ELD15 module: a Research Highlight in Nature Reviews Clinical Oncology

Nat Rev Clin Oncol. 2010 Oct;7(10):552.

Original publication: Johnson C, Fitzsimmons D, Gilbert J, Arrarras JI, Hammerlid E, Bredart A, Ozmen M, Dilektasli E, Coolbrandt A, Kenis C, Young T, Chow E, Venkitaraman R, Howse F, George S, O'Connor S, Yadegarfar G; EORTC Quality of Life Group.

Development of the European Organisation for Research and Treatment of Cancer quality of life questionnaire module for older people with cancer: the EORTC QLQ-ELD15. Eur. J. Cancer 46,2242–2252 (2010)



20

In the October 2010 issue of Nature Reviews Clinical Oncology, the development of the quality of life questionnaire module for older people with cancer received attention in the Research Highlights section. The module was recently published in the European Journal of Cancer.

In this Research Highlight it is described how Colin Johnson (Principal Investigator) and his collaborators conducted a literature review and were not able to find an elderly-specific tool, or a more general tool that had been validated in older people. "This discovery led to the development of the European Organisation for Research and Treatment of Cancer quality of life questionnaire module for older people with cancer (also known as the EORTC QLQ-ELD15)."

The Highlight furthermore includes the challenge the researchers had when defining 'older people' (70 years old and over) and then describes the different phases of module development: Phases 1-3 were conducted in seven countries following modified EORTC Qua-

lity of Life Group guidelines for module development. The first round included nine patients aged >70.

The second round was a comparative series of interviews with 49 patients >70 years with a range of cancer diagnoses and 40 patients aged 50-69 years matched for gender and disease site. In Phase 1, 75 issues were identified. These were reduced in Phase 2 to create a 45 item provisional list. Phase 3 testing of the provisional list led to the selection of 15 items with good ranges of response, high scores of importance and relevance in the older patients.

This resulted in the EORTC QLQ-ELD15, containing five conceptually coherent scales (functional independence, relationships with family and friends, worries about the future, autonomy and burden of illness).

The EORTC QLQ-ELD15 in combination with the EORTC QLQ-C30 is ready for large-scale validation studies, and will assess HRQOL issues of most relevance and concern for older people with cancer across a wide range of cancer sites and treatment stages. ■

"Phases 1-3 were conducted in seven countries following modified EORTC Quality of Life Group guidelines for module development."





List of publications by the QLG Group in 2010

Juan Ignacio Arraras, Eva Greimel, Orhan Sezer, Wei-Chu Chie, Mia Bergenmar, Anna Costantini, Teresa Young, Karin Kuljanic Vlastic, Galina Velikova on behalf of the European Organisation for Research and Treatment of Cancer Quality of Life Group. An international validation study of the EORTC QLQ-INFO25 questionnaire: an instrument to assess the information given to cancer patients. *Eur J Cancer*. 2010 Oct;46(15):2726-38. Epub 2010 Jul 30.

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

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

Over the last year, the Quality of Life Department has had another busy period, publishing 14 peer reviewed papers mostly in collaboration with EORTC clinical trial groups and delivering 25 international conference presentations. The number of new clinical trials in the EORTC HQ with QOL being included as an end-point has stabilized, as has the number of studies being closed and published with QOL endpoints. We were able to publish five large phase III trials with QOL studies in Head and Neck, Lung Cancer, melanoma, and gynaecological cancer.

Our collaboration with the QLQ continues to be strong, but mainly with a focus on administrative and management capacity. This means addressing the needs of users of the EORTC tools from both academic and industry interested parties. EORTC QLQ translations continue to be in demand and Department staff have been active in supporting these needs.

The Department's 14 staff have been active in all aspects of clinical trials and the application of best practices within our clinical studies. Many research activities were seen this year and staff was sent across the globe to present at numerous conferences and congress as invited speakers.

Our 2009 conference on "QOL and Cancer clinical trials" was a success and we are organising a new conference in 2011 on the same topic, but to be done now in collaboration with the European Parliament. (see web site if interested).

Looking into 2011 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.

Rossella Guzzo,
new Secretary of
the QOL Department



Andrew Bottomley



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