



## Editorial

### Jaap C. Reijneveld – Newsletter Editor

**T**his winter, I took over the position of Newsletter Editor in the Executive Committee of the Quality of Life Group from Lonneke van de Poll-Franse. She served as Newsletter Editor from 2009 till 2012, and I would like to thank her for her efforts in making such an attractive 'glossy' every year. When I first attended the group meeting in Rome in Spring 2010 it not only served as a 'who-is-who', but also as a 'who-does-what' and was really helpful!

For those who do not know me, I will introduce myself. I am a neurologist at the VU University Medical Centre and the Academic Medical Centre in Amsterdam. Amsterdam has, though the city is smaller than almost everyone thinks (only close to 800.000 inhabitants), two universities and as such two university hospitals. In both university hospitals I am part of a multi-disciplinary team, consisting of neuro-surgeons and medical and radiation oncologists, which treats patients with brain tumours. These patients often participate in clinical trials of the EORTC Brain Tumour Group, and as a member of the Steering Committee of that group, I am appointed to be liaison officer between both groups, as was Martin Taphoorn before me.

I think that maintaining QOL is pivotal during all treatment regimens for brain tumour patients, as holds true for cancer patients in general, and although QOL measurements have been incorporated in many Brain Tumour Group trials,

I still have to stand up every now and then during discussions in the Brain Tumour Group in order to stress incorporation of QOL measurements should not be forgotten in future trials. A specific problem regarding QOL assessment in the brain tumour population is that cognitive disturbances of many patients often endanger compliance of patients, and our efforts are focused on the implementation of proxy-measurements or functioning scales in order to tackle this problem.

This issue of the Newsletter, and I would especially like to thank Sheila Sanderson for her help guiding me through the process, offers a view on the spectrum of the activities of the QLG. There is a lot of information on the social aspects (as QLG we have the moral obligation to keep at least our own QOL at a high standard), such as information on the venues of Amsterdam and Canterbury, and a retrospect on our meeting in Regensburg. There is also some news on the career of some of our most esteemed (and now highly-esteemed) group members, and of course information on the activities of some of the committees of the group.

I hope that you will enjoy reading this issue, and please contact me if you have a strong wish to write a contribution for the next issue!



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# Spring Meeting EORTC Quality of Life Group

Amsterdam, 11-13 April 2013 - Irma Verdonck de Leeuw

The 2013 Spring meeting of the EORTC Quality of Life Group will be in Amsterdam, The Netherlands hosted by Irma Verdonck-de Leeuw, Neil Aaronson, and Jaap Reijneveld. Amsterdam is the nominal capital of The Netherlands, and the 2nd most attractive 2013 travel destination in the world according to Lonely Planet! Its name has been derived from 'Amstel Dam', a dam built on river Amstel. The city is popularly known as the 'Venice of the North', owing to the popularity of its historic port, the Rijksmuseum, its red-light district (de Wallen), its laissez-faire cof-

just a few kilometers from the citycentre. A Direct Rail Link connects Schiphol International Airport to Amsterdam central station and is the fastest and most convenient way to get to the city centre Airport Shuttles run by Connexion depart every 10 minutes with service to more than 100 hotels throughout the city. Tickets can be purchased inside the main arrival plaza.

The EORTC QoL Group meeting will be held at one of the famous canal houses named "Rode Hoed" (Red Hat). Rode Hoed is located in a beautiful historic building in the heart

of Amsterdam. The Great Hall is the largest and oldest remaining hidden church in the Netherlands. Both this hall and the building's five smaller halls are available for our meeting at Thursday and Friday (11-12 April).

We are looking forward meeting you in Amsterdam!

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fee shops (more than 300) and the numerous canals. Amsterdam was merely a small fishing village founded in the 12th century. The oldest area in Amsterdam is known as de Wallen and it is home to the city's famous red light district. Oude Kerk (Old Church) forms the oldest building in Amsterdam. Situated in the heart of the Wallen area, it was consecrated in 1306. Amsterdam gained importance by becoming one of the important ports during the Dutch Golden Age and transformed into a leading centre of finance and diamonds. Amsterdam Stock Exchange is the oldest stock exchange in the world. It is located in the city centre.

Amsterdam can be reached easily by air. Cheap flights from within Europe and direct flights from outside Europe are readily available, serving Amsterdam airport Schiphol located

of Amsterdam. The Great Hall is the largest and oldest remaining hidden church in the Netherlands. Both this hall and the building's five smaller halls are available for our meeting at Thursday and Friday (11-12 April).

Amsterdam owns 70 glass topped canal boats. On Thursday we will enjoy dinner on board two canal boats, while experiencing the views of Amsterdam from the water. Amsterdam has more than 150 canals and 1,200 bridges within its boundaries.

For those who will be able to stay for a little longer, on Friday we will enjoy dinner in an Italian restaurant with hosts who are also fantastic professional singers. Amsterdam is known to house the maximum number of





# EORTC Quality of Life Phase III Module

## Measuring Cancer Related Fatigue

RIGHT Joachim Weis



### EORTC QLQ-FA13

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### Introduction

**F**atigue is one of the most distressing symptoms for cancer patients affecting their quality of life in all phases of the treatment or stages of the disease.

Fatigue is described as a subjective sensation or an objective decrement of performance associated as a common symptom with various chronic diseases. Cancer related fatigue (CrF) is commonly defined as a self-recognised phenomenon that is subjective in nature and experienced as a feeling of tiredness or lack of energy that varies in degree, frequency and duration. From a patient's perspective, fatigue is described as an unusual feeling of exhaustion, weakness or a loss of activity with respect to emotional and cognitive functions (Wagner & Cella 2004), which, in general, cannot be reduced by sleep or rest.

Fatigue is the most frequent symptom occurring in cancer patients during or after medical treatment and also as a long-term late effect. Several studies concerning epidemiology reveal prevalence rates ranging from 59–100%, whereas fatigue as a long-term sequelae or late effect, is estimated to have an average prevalence rate of approximately 25%, dependent on the type of assessment and diagnostic criteria used (Henry et al 2008; NCCN 2011).

Although there has been frequent research throughout recent decades, there is limited evidence stating a comprehensive theory, which clearly explains the causes of fatigue. Numerous factors have been associated with CrF influence; these include medical conditions, both biochemical and psychological factors but in

particular mood disturbances (NCCN 2012). Among psychological factors, depression, anxiety and psychosocial distress are strongly associated with CrF (Brown & Kroenke 2009).

A literature research review shows that cancer related fatigue is mostly conceptualised as a multidimensional construct including physical, affective and cognitive dimensions (Ahlberg et al 2003). Besides the cancer specific instruments, more than 30 scales assessing CrF have been published, showing that there is a lack of consensus on the basic approach for measurement of CrF. From the cultural perspective most fatigue questionnaires are developed in one single language only and then translated into various target languages. However, cultural factors which may have an impact on daily life have not been taken into consideration, such as the way events are interpreted, including how meaning is determined (Perneger et al 1999). Therefore, the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Group (QLG) decided to develop a specific module based on a multinational approach to assessing fatigue in a more detailed way. The EORTC Fatigue module should be used in conjunction with the quality of life core questionnaire EORTC QLQ-C30 and enable the analysis of the correlation between the already existing uni-dimensional fatigue subscale with the multidimensional module. The theoretical approach is based on a multidimensional model of fatigue including physical, emotional and cognitive domains. The module is designed to be used in all areas of treatment (chemotherapy, radiation, surgery, curative and palliative

care, acute care, rehabilitation, and hospice) and to cover all tumour diagnoses in all phases and stages of cancer. The questionnaire's length should be taken into consideration; hence it should be as concise as possible with the intention that even patients with severe fatigue are able to complete the questionnaire.

### Methods

The EORTC FA13 was developed in accordance with the guidelines published by the EORTC QLG for module development (Blazeby et al 2002). These include existing fatigue instruments for cancer patients as well as expert interviews aimed at identifying a preliminary item list (phase I/II); the literature of both were comprehensively and systematically reviewed. The previous phase I/II module was developed in collaboration with 31 multi-professional specialists from eight European countries (Germany, Austria, UK, France, Italy, Spain, Norway, and The Netherlands). As the fatigue concept was already well established in the literature, patient interviews were conducted only in phase III. As a result of phase I/II, we were able to reduce the initial item list of 75 items to a preliminary list of 25 items providing two versions of the fatigue module: one with the whole item pool (FA25) to be used alone without EORTC QLQ-C30 (including the items of the fatigue subscale from the core questionnaire) and one different version (EORTC FA15)

which should be used in conjunction with the core questionnaire (not including the items of the fatigue subscale). The authors continued only with the further development of the EORTC FA15.

### Results

The initial EORTC QLQ-FA15 was pre-tested according to the EORTC Module Development Guidelines for phase III by administering the tool to 318 patients across three groups (acute treatment, rehabilitation, palliative care/hospice) in seven European countries. The estimated sample size to achieve sufficient power and coverage of different patient groups was n=300. This has been calculated to enable evaluation of the data based on multi-item response theory (IRT). For the phase III study, ethical approvals have been obtained in UK, Germany, Sweden and Norway, whereas in France, Spain and Italy this was not required due to their respective country rules.

As intended, the sample comprises a broad spectrum of tumour diagnoses with the highest percentages in haematological cancer (n=73), breast cancer (n=54) and gynaecological cancer (n=50) followed by head/neck cancer (n=29) and colorectal cancer (n=27). ECOG statuses for most patients were I (34%) and II (26.5%); only 25% were in stage 0 and 12% in stage III. In terms of tumour status, the highest percentage of the patients was in complete remission

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(39.1%) followed by progressive disease (29.0%) and incomplete remission (20.2%). In 45.9% of the patients, metastases have been proven. For treatment, most patients received surgery (56.8%), chemotherapy (completed 33.8%; ongoing 32.8%), radiotherapy (completed 27.4%; ongoing 13.9%) or hormone therapy (completed 5.4%; ongoing 10.1%). The sample covers all areas and settings of cancer care (rehabilitation centers 27.4% and palliative care/hospice 26.4%) with a highest percentage rate in acute care centres (39.9%), as we predominantly had aimed.

Descriptive analysis on the preliminary module EORTC QLQ-FA15 is shown in Table 3. Physical fatigue items were found to have the highest mean scores; these included "loss of energy" (2.45), "feeling exhausted" (2.30) or "feeling sleepy during the day" (2.16). With emotional fatigue, the highest mean score was found for the items "loss of interest in sex" (2.47) and "trouble getting things started" (2.04). Within the cognitive dimension, the item "trouble completing things" had the highest mean score (1.7) ranking on a lower level compared with the items of the other dimensions. The global item "interference of fatigue with daily activities" showed a higher mean level (2.24). The missing data rate was less than 5% for all items except the sexual interest item with an 8% figure.

**Table 1:**  
Dimensional structure  
EORTC QLQ FA 15

| Domain   | Item  | Measure | Infit |      | Corr. |
|--|---|---------|-------|------|-------|
|  |   |         | MNSQ  | ZSTD |       |
| Physical Fatigue<br>Person Reliability .79<br>Separation 1.94  | 4. Did you feel sleepy during the day?          | .50     | 1.13  | 1.6  | .83   |
|  | 3. Have you felt slowed down?                   | .22     | 1.07  | .9   | .85   |
|  | 2. Have you felt exhausted?                     | -.10    | .87   | -1.6 | .89   |
|  | 1. Have you lacked energy?                      | -.62    | .89   | -1.4 | .87   |
| Emotional Fatigue<br>Person Reliability .71<br>Separation 1.55 | 7. Did you feel frustrated?                     | .17     | .95   | -.5  | .80   |
|  | 8. Did you feel discouraged?                    | .16     | .72   | -3.5 | .82   |
|  | 9. Did you feel helpless?                       | .15     | .93   | -.8  | .81   |
|  | 10. Did you feel vulnerable?                    | -.04    | 1.17  | 1.8  | .75   |
| Cognitive Fatigue<br>Person Reliability .5<br>Separation .99   | 6. Did you have trouble getting things started? | -.43    | 1.22  | 2.4  | .76   |
|  | 13. Did you feel confused?                      | .85     | .92   | -.7  | .80   |
|  | 12. Did you have trouble thinking clearly?      | -.11    | .79   | -2.3 | .86   |
|  | 14. Did you have trouble completing things?     | -.75    | 1.28  | 2.7  | .80   |

RIGHT Pernille T. Jensen



# Update on the Vulva Cancer Module

Pernille T. Jensen, Consultant PhD, Department Of Gynaecology and Obstetrics, Odense University Hospital, Denmark.

Based on the a priori given three-dimensional structure of the scales, the uni-dimensionality of each scale was tested using the rating-scale model (Table 1). All item numbers refer to the preliminary version EORTC QLQ FA15. The global item asking for overall interference of cancer related fatigue in activities of daily living has not been taken into account for these analyses. In the emotional fatigue subscale, the items "Did you feel angry?" (Item 5) and "Have you lost interest in sex?" (Item 11) had to be removed in order to achieve sufficient homogeneity (Infit < 1.3). In the other domains, the fit of all items was sufficient (see Table 1).

## Discussion

The revision of the phase II module EORTC FA15 into phase III module EORTC FA13 has

been done on the basis of the qualitative analysis (comments of the patients), the quantitative results (descriptive statistics according to the EORTC guidelines for module development), as well as the IRT analyses. The multinational sample was wide enough, enabling data evaluation not only on the qualitative level of patients' interviews but also on a statistical level including IRT analyses. The item selection process was based on qualitative as well as on quantitative analyses of the data. Two new items were added based on patient proposals and expert discussion; one global item was included in order to assess the interference of fatigue with daily activities and work life (item 12: "Did tiredness interfere with your daily activities?"). For further details see Weis et al 2012. The revised EORTC QLQ-FA13 module (phase III) is

presented in Table 3. EORTC QLQ-FA13 is now available as a phase III module measuring cancer related fatigue in clinical trials. The module is currently available in the following languages: English, German, Italian, French, Spanish, Swedish and Norwegian. Final psychometric validation of the module will be conducted in phase IV which was started in 2011.

## Acknowledgement

Phase III has been funded by the EORTC QLG and the German Fatigue Association (Cologne, Germany). We thank all collaborators and patients helping us to develop this module.

Table 2 : Final EORTC QLQ-FA 13 Phase III Module

| Item  |
|---|
| 1. Have you lacked energy?  |
| 2. Have you felt exhausted?   |
| 3. Have you felt slowed down?   |
| 4. Did you feel sleepy during the day?  |
| 5. Did you have trouble getting things started?   |
| 6. Did you feel discouraged?  |
| 7. Did you feel helpless?   |
| 8. Did you feel frustrated?   |
| 9. Did you have trouble thinking clearly?   |
| 10. Did you feel confused?  |
| 11. Did you have trouble completing things?   |
| 12. Did tiredness interfere with your daily activities?                                   |
| 13. Did you feel that your tiredness is (was) not understood by the people close to you ? |

## References

1. Wagner LI, Cella D. Fatigue and cancer: causes, prevalence and treatment approaches. *Br J Cancer* 2004; 91: 822-828.
2. Henry DH, Viswanathan HN, Elkin EP, et al. Symptoms and treatment burden associated with cancer treatment: results from a cross-sectional survey in the U.S. *Support Care Cancer* 2008; 16: 791-801.
3. NCCN (National Comprehensive Cancer Network). Clinical practice guidelines in oncology: cancer related fatigue. Version 1.2011. [http://www.nccn.org/professionals/physician\\_gls/f\\_guidelines.asp](http://www.nccn.org/professionals/physician_gls/f_guidelines.asp).

4. Brown LF, Kroenke K. Cancer-related fatigue and its associations with depression and anxiety: a systematic review. *Psychosomatics* 2009; 50(5): 440-7.
5. Ahlberg K, Ekman T, Gaston-Johansson F, Mock, V. Assessment and management of cancer-related fatigue in adults. *Lancet* 2003; 362: 640-650.
6. Perneger T, Leplege A & Etter J. Cross-cultural adaptation of a psychometric instrument: two methods compared. *J Clin Epidemiol* 1999; 52: 1037-1046.
7. Blazeby JM, Sprangers MAG, Cull A, Groenvold M, Bottomley A on behalf of the EORTC Quality of Life Group. EORTC Quality of Life Group Guidelines for Developing

Questionnaire Modules. EORTC Quality of Life Group Publication, Brussels, 2-930064-24-2, August 2002.

8. Weis J, Arraras JL, Conroy T, Efficace F, Fleissner C, Görög A, Hammerlid E, Holzner B, Jones L, Lancelley A, Singer S, Wirtz M, Flechtner H, Bottomley A (2012) Development of an EORTC quality of life phase III module measuring cancer-related fatigue (EORTC QLQ-FA13) *Psycho-Oncology*, DOI: 10.1002/pon.3092.

The vulva module is led by two principal investigators (PI); Pernille T. Jensen and Eva Greimel. Collaborators are gynaecologists, radiologists, clinical oncologists, psychologists, and nurses related to each speciality. The gynaecological group within the EORTC Quality of Life group is well-known as a very motivated and enthusiastic group with engaged discussions at group meetings as well as between meetings.

In summary, vulva cancer is a rare disease which is often diagnosed in early stages. Hence, vulva cancer patients comprise a group with a comparatively favourable survival prognosis but due to the extensive and mutilating treatment, vulva cancer patients have a high risk of experiencing severe treatment induced negative effects on their quality of life. Studies investigating late effects and complications after vulva cancer treatment have identified significant local symptoms related to the vulva cancer itself. Furthermore severe surgery- and radiation induced morbidity has been reported. Few studies have included self-reported outcome measures although some small studies have focused on self-reported sexual morbidity. Therefore, there is a need for an instrument to comprehensively address morbidity and quality of life aspects following treatment of vulva cancer.

During phase 1 of module development it was discussed within the group whether to follow the traditional EORTC way of module development. It was discussed whether to use the Computer Adapted Technique (CAT) based on the Item Response theory to meet future demands of a high degree of flexibility of the questionnaire. Statisticians were invited to the group meeting but based on several group discussions it was

decided not to use the CAT for this module. The decision was made due to concerns regarding both recruitment of a sufficient number of patients and the considerable number of items to be completed in the developmental phase. The vulva cancer module has therefore been developed according to the traditional EORTC guidelines.

In spring 2012, a sufficient number of patients were included in phase 1. In total, 47 patients and 43 Health care professionals (HCP's) had completed the issue list emerging from a thorough literature review and comprising 104 issues to be rated regarding relevance and priority. A broad cross-country distribution of both patients and HCP's was ensured. All stages of disease were represented and the age distribution of the patients included both very elderly and very young women. Further, the sample was well balanced regarding treatment modality and was thus found to be representative for vulva cancer patients in general.

final concepts to be operationalised in phase II were decided to concern: Vulva tissue changes, vulva scarring and swelling, swelling of groins and legs, body-image, urological problems, sexual and vaginal problems.

Four members of the group met in June 2012 to further discuss the scale structure. A conceptualisation process was run for the selected issues and the final concepts were then operationalised to generate the provisional phase 3 questionnaire. The provisional module was then refined by the PIs and in autumn 2012 sent to all group members for email discussion. Suggestions by the group members have been taken into account and the PI will soon have the final provisional module ready. The English version of the module will then be sent to the EORTC translation centre for relevant translations. The final protocol and case report forms are under final preparation.

Members of the EORTC gynaecological Cancer

## Few studies have included self-reported outcome measures

Mean scores and priority ratings for patients and HCP's were presented for the EORTC QOL gynaecological group. Selection criteria from the revised guidelines were applied to select issues that met criteria of relevance scores and priority. Concepts of particular interest were discussed and related to the scores and priority ratings. It was agreed to exclude issues that were either considered to be covered by the EORTC QLQ-C30 (e.g. psychological well-being) or other modules (e.g. information needs), or which were not specific for vulva cancer (e.g. fear of recurrence). The

Group have contributed with phase 1 HCP interviews. A few members will contribute in phase III and several members have agreed to contribute with data in phase IV. In this way the group has ascertained that a sufficient number of patient data is available for final psychometric analyses.

Phase 1+2 has been supported by a grant from the EORTC Quality of Life Group. The PIs have applied for a grant to support phase 3 of module development and the Executive Committee has approved the grant.



RIGHT Marianne J. Hjermsstad



# The QLQ-OH17

## An EORTC module focusing on oral health and quality of life in cancer patients

Assessment of oral and dental problems is seldom routine in clinical oncology, despite the potentially negative impact of these problems on nutritional status, social function and quality of life (QOL). From 40 to 70% of cancer patients will experience oral side effects due to the malignancy or its treatment. While this is well-documented in patients with head and neck cancer, oral complications are often insufficiently documented in patients with cancers outside this region, with potential for inadequate management of symptoms and negative impact on QOL.

Chemotherapy may lead to painful oral mucositis, mucosal and dental infections and temporary salivary gland hypofunction and xerostomia, while other therapies may worsen complications due to anticholinergic and immunosuppressive effects. Some oral side effects are most prevalent in the acute treatment phases, and depending on the severity, may actually be dose-limiting and consequently compromise prognosis. Other adverse events such as chronic xerostomia, loose teeth and caries may manifest later. Lately, reports indicate an increasing incidence (up to 12%) of osteonecrosis of the jaw (ONJ), primarily due to treatment with bisphosphonates or targeted therapies. As 50% of cancer patients cannot be cured, but will live with their disease for shorter or longer periods of time, adequate symptom assessment and follow-up is an important part of good patient care.

The idea to develop a brief assessment tool focusing on oral health and QOL resulted from the clinical and research collaboration between oral surgeons, dentists, oncologists and nurses

at Oslo University Hospital and Faculty of Dentistry, University of Oslo, Norway about 10 years ago. Literature searches revealed that none of the widely used cancer specific QoL questionnaires such as the EORTC QLQ-C30, SF-36, FLIC or FACT include specific questions regarding oral health problems, such as oral pain and discomfort, xerostomia, problems with chewing, swallowing, and social impact etc. Other specific questionnaires focusing on oral health and problems such as the OHIP, OHRQL and the GOHAI are relatively long, not suitable for daily clinical practice and not frequently used in cancer. Therefore, it was decided to bring this under the EORTC umbrella to ensure a uniform, standardized and scientifically valid development process in an international setting.

The work towards the QLQ-OH17 started in 2008, and gained wide interest right from the start. Phase I literature searches resulted in 85 issues covering five domains; oral pain, problems and discomfort; oral/dental status and care; functional issues (dryness, chewing, speaking, swallowing); information about oral side-effects; and social function and QOL related to oral problems. Eighteen health care professionals and 133 patients from six countries were interviewed. The list of items after the conventional EORTC procedures for item deletion/retention was 41. In Phase II, the module was translated from English into Norwegian, Swedish, Greek, German, Hebrew, Italian, French and Dutch. Phase III was finalized in 2011. The provisional module and the EORTC QLQ-C30 were completed and interviews performed in 178 patients at nine centres in seven countries. Seventeen of the 41 items were retained, resulting in a 17-item module; the QLQ-OH17.

The main reason for deletion was failure to meet the sufficient number of criteria for inclusion according to the EORTC guidelines. No significant differences were found when comparing the different phases of treatment, while a higher prevalence of problems was found in patients with head and neck cancer, indicating good criterion validity. No specific language problems were detected. Phase IV has received funding from the QLG and will start at the beginning of 2013, aiming to include about 550 patients.

1 Hjermsstad MJ, Bergenmar M, Fisher SE, Montel S, Nicolatou-Galitis O, Raber-Durlacher J, Singer S, Verdonck-de Leeuw I, Weis J, Yarom N, Herlofson BB on behalf of the EORTC Quality of Life Group. The EORTC QLQ-OH17: A supplementary module to the EORTC QLQ-C30 for assessment of oral health and quality of life in cancer patients. *Eur J Cancer*, 48, 2203–2211, 2012

RIGHT Linda Dirven



# Health-Related Quality of Life: The ultimate outcome measure in patients with brain tumours?

Linda Dirven<sup>1</sup>, Jaap C. Reijneveld<sup>1,2</sup>, Martin J.B. Taphoorn<sup>1,3</sup>

**C**ancer treatment of brain tumour patients, as for patients with any other cancer, not only focuses on enhancing progression-free and overall survival, but also on the palliation of symptoms and maintenance or improvement of quality of life.

For patients who cannot be cured from their disease, as is the case for many brain tumour patients, the quality of survival is at least as important as the duration of survival. Hence, information on the patient's functioning and wellbeing has become increasingly important. Currently, there is no single gold standard tool to measure HRQOL and several valid measures of HRQOL in brain tumour patients are available. The most frequently used tool in brain tumour patients is the EORTC QLQ-C30, often used in conjunction with the brain tumour specific EORTC QLQ-BN20.

Results of these HRQOL measurements are used in clinical trials as well as in clinical practice. It thus seems important that the results of HRQOL measurements are interpreted correctly. However, interpretation of the results might be hampered by methodological issues that are not taken into account, such as selection bias, incorrect timing of the HRQOL assessments, missing data and response shift. Moreover, although HRQOL measurements provide us with subjective information on physical, psychological and social aspects as well as symptoms induced by the disease and its treatment, it does not provide us with objective information on the patient's functioning in daily life. This is even more relevant in brain tumour patients, who not only have cancer but also have a progressive brain disease, and often develop cognitive decline due to the tumour and its treatment. Therefore, one may

question if patient-reported HRQOL is the optimal and only outcome measure to determine the functioning and wellbeing of an individual brain tumour patient.

Cognitive dysfunction may hamper HRQOL measurements by the inability of the patient to correctly judge his/her own situation, leading to missing data or incorrect views. In these situations, proxy ratings might be considered. Proxies such as partners or relatives are often involved in the care of the patient, and therefore have a fairly good picture of the patients' well-being. To obtain a more complete picture on the patients' functioning and well-being, an additional measure specifically aimed at everyday functioning could also be considered. To this end, measurement of Instrumental Activities of Daily Living (IADL) might be appropriate. IADL includes the more complex activities such as food preparation, ability to handle finances, shopping, doing laundry, housekeeping, mode of transportation, responsibility for own medication or using a telephone.

An additional measure such as IADL could complement HRQOL measurements and would provide us with a more complete picture on the patient's functioning in daily life. We therefore aim to develop a new IADL questionnaire for patients with a primary brain tumour, which will be completed by the proxy. Recently, the Amsterdam IADL Questionnaire<sup>®</sup> was developed and validated to measure problems in IADL in patients with early dementia.[1] Because of good psychometric properties and the expected similarities in problems in IADL between both patients with dementia and brain tumours, we plan to adapt this existing questionnaire for use in brain tumour patients.

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2 → Department of Neurology, Academic Medical Center, Amsterdam  
3 → Department of Neurology, Medical Center Haaglanden, Den Haag, The Netherlands

## An additional measure such as IADL could complement HRQOL measurements (...)

These activities are an important aspect of the ability to function independently in society. Moreover, IADL involves higher order activities and may therefore be negatively influenced by a cognitive decline.

Although HRQOL measurements are very valuable in brain tumour research, it does not seem to be the ultimate and only outcome measure to determine functioning and wellbeing of the

# Moving the Boundaries of International Collaboration on Clinical Trials and QOL

## Experiences in oncology and legislators within the European Parliament.

Andrew Bottomley, Tony Kirby, John Bean, and Julie Walker



### Abstract

The EORTC (European Organisation for Research and Treatment of Cancer) undertook another successful event with their third annual conference addressing Quality of Life matters in cancer clinical trials. Over 40 presentations were made over a 3-day period hosted at the European Parliament on 17–20 October 2012, in Brussels. The conference managed to assemble both speakers and policy makers to debate key issues in cancer clinical trials, design and reporting, and include future policy and regulatory concerns. This meeting set the stage for future research and policy meetings to give greater visibility to Quality of Life as an outcome in clinical trials within the world of EU legislators.

### Conference report

In her conference welcome address, EORTC Director General Professor Françoise Meunier welcomed over 300 delegates from across Europe and beyond. She thanked the various conference sponsors, the European

Commission's DG SANCO, and Member of the European Parliament Ms Marisa Matias for hosting the EORTC Conference on Quality of Life for the second year running.

### *"Don't change a winning formula"*

Prof Meunier explained in her speech that the conference helped highlight a very special year for EORTC, 2012, with the organisation celebrating its 50th birthday. She told the audience that quality of life has been a central theme for EORTC for more than 30 years. Indeed, one of the first Quality of Life (QoL) questionnaires was for children with leukaemia in the 1970s. Prof Meunier emphasised that, as the years have rolled by and treatments have improved, more and more people are surviving cancer and thus quality of life issues related to survivorship and treatment have assumed higher importance.

Furthermore, she paid tribute to the 180,000+ patients across Europe who had placed their faith in EORTC and its mission by taking part in clinical trials run by the organisation.

While new treatments and the prospect of personalised medicine are revolutionising cancer care, Prof Meunier said that financial constraints and austerity across Europe were leaving many people wondering who would be able to afford these novel treatments. Prof Meunier added that the conference was taking place against a background of Euro-scepticism with commentators regularly questioning the future of the EU itself. "In these circumstances, we have to fight really hard to keep Europe on the medical research map," "We need to bring hope to the younger generation that there is a future for both health and quality of life research in Europe."

Ms Matias in her introductory remarks, said the conference was a great example of researchers, professionals, patients, and legislators

working together. "This is an opportunity to show that the European Parliament takes cancer quality of life issues seriously.". She added that while member states still played a central role in dealing with quality of life issues, the

### *"Excellent speakers, please continue to invite"*

European Parliament was a forum to provide responses to issues affecting all EU citizens. Ms Matias discussed the European Commission's Horizon 2020 research programme, which will replace the existing Framework Programmes for projects running from 2014–2020. Health is central to the societal challenges in Horizon 2020, and Ms Matias said negotiations were ongoing to make the budget of the programme as large as possible, with the largest share going to biomedical research.

Rationing of funding is becoming more important than ever before, both in terms of healthcare and health research. In Portugal we are facing questions we thought we'd never face,—which patients should we treat, because we can no longer afford to treat them all," said Ms Matias, adding that recent discussions in Portugal have covered whether or not it is economically viable to treat patients in the later stages of cancer. "Who is making these decisions?" she asked. "Issues such as this make it clear that we need more solidarity in Europe, not less."

Other key talks included the European Medicines Agency's (EMA) proposal to create a new appendix, focusing on quality of life measures, to the anti-cancer guidelines used to approve new cancer drugs and therapies. "This new guidance will be increasingly important in this new era of anti-cancer medicines. Some new therapies that lead to limited improvements in survival can cause extensive problems to a patient's quality of life. Conversely, new

### *"I am glad that I was able to participate in a conference with such a high level of scientific and organizational level. Thank you!"*

therapies can cause less toxicity than older therapies as they have become more targeted," said Dr Andrew Bottomley, Assistant Director of EORTC and Head of the organisation's Quality of Life Department.

Quality of life in the context of cancer assesses symptoms such as fatigue, nausea, sexual functioning, or psychological problems, which a patient may experience as a direct consequence of cancer treatment. These are different from the traditional clinical trial measures commonly reported such as 'overall survival' and 'progression-free survival'. Work on the new appendix is being done on behalf of EMA's Committee for Medicinal Products for Human Use by the Oncology Working Party. "During the revision of the anti-cancer guideline, it was recognized that there was enough scope to warrant a separate health-related quality of life (HRQoL) appendix so that certain issues could be considered in more depth," said Dr Daniel O'Connor, the presenter of this session who is based at the UK's Medicines and Healthcare Regulatory Authority. Dr O'Connor, who is part of EMA's working party on this guideline but who was giving his own personal views at the conference, adds: "There is increasing recognition that HRQoL is an effective and relevant measure with which to evaluate and monitor therapeutic outcomes. HRQoL measures may complement the range of traditional objective indicators such as survival which could contribute to benefit-risk decisions."

### *"Let's go up in the same direction for next year's meeting."*

Clinical trial design, HRQoL instruments, statistical methodology, clinical importance and patient-related outcome measures will be considered in the new appendix which is expected to be released for public consultation in 2013. Dr Bottomley adds: "It is excellent that EMA is making significant strides to have this separate QoL appendix added to the standard guidelines. This demonstrates to patients that their voice, wishes and needs are being taken seriously when drugs are given approval. Patients will be able to understand not only the survival benefits of the new therapies, but also the effects of new treatments on both short- and long-term QoL. I look forward to a firm release date for this guidance."

Patient-reported outcomes, essential for the next generation of cancer therapies were

another topic of this year's conference, as was charting the progress made in quality of life research for patients with breast cancer over the past three decades. However in her presentation, Professor Lesley Fallowfield, a world expert in this field, showed that huge gaps remain in terms of data needed to properly assess QoL, and that patient-reported outcomes (PROs) will be essential in future drug approvals. She also concluded that medicine must move away from its default position that PROs represent 'soft' data, whereas data reported by clinicians and other healthcare professionals is always taken much more seriously.

### *"The place was wonderful. Thank you for all, in particular to your organization staff. It was really helpful."*

She pointed out that almost all new drugs approved have an excellent safety profile until they are in the real world, where side effects, reported by patients, begin to mount. Prof Fallowfield concluded: "We really need to get away from this idea, still prevalent in medicine, that outcomes reported by the doctor or nurse are somehow more valid than those provided by the patients themselves, even though evidence shows that patients' reports are more accurate."

One of the abstracts presented unpublished data from the DietComplyf study, which aims to assess possible links between plant phytoestrogen consumption and breast cancer recurrence and survival, as well as the analysis of quality of life outcomes. The research was carried out by Dr Ruth Swann, study co-ordinator at the University of Westminster, London, UK, and colleagues. The latest analysis carried out by Dr Swann and her colleagues on nearly 3,000 breast cancer patients has produced preliminary data showing that patients with a higher QoL score had a lower body mass index (BMI) and exercised more than once a week. A higher QoL score was also associated with responsible levels of alcohol consumption and the feeling that the patient felt less alone. Furthermore, patients who perceived that they had the practical and emotional support they needed following a breast cancer diagnosis also had a higher QoL score.



*"I am very pleased by the diversity of participants that this conference attracts, including researchers and clinicians from all over the world. It truly provides a global forum to move this important field forward."*  
 (Carolyn Gotay)

presenters' speeches, and these can be found at [www.eortc.be](http://www.eortc.be).

<http://www.eortc.org/news/webcasts-3rd-eortc-qol-symptom-research-and-patient-reported-outcomes-cancer-clinical-trials-co>

On a final note, this conference was also special in being able to offer awards for best research for young investigators and also for advanced researchers (see the winners at [www.eortc.be](http://www.eortc.be)).

Clearly, QoL research in clinical trials is not suffering from a lack of results, and while we face a challenging economic environment, it is certain that QoL research is something that continues to be critical and important for society. For this reason we expect more from the EORTC in partnership with the European Parliament for the 4th Conference, tentatively planned for Spring 2014, so there is still plenty of time to prepare data ready for presentation!

Should your organisation wish to play a key role in this event, sponsorship opportunities exist and will be an excellent means of making your company visible on the world stage. Please contact Andrew Bottomley for more information.

*"Thanks a lot for the nice conference and the great atmosphere"*

In another part of the abstract session, new data were presented that showed that women undergoing breast cancer treatment are far more likely to be concerned about their reproductive health than are healthy women. The study's authors, led by Mirjam Garvelink, Leiden University Medical Centre, The Netherlands, concluded that such women should be offered counselling about interventions such as fertility preservation treatment (freezing embryos, eggs or ovarian tissue) to help improve their quality of life.

These highlights were just a few of the many excellent plenary presentations delivered at the conference. Because we don't have space to describe them all in our report, EORTC have uploaded over 20 hours of video showing the

BELOW Andrew Bottomley, Karoline Albrecht



**Acknowledgments**

Thanks to Cheryl Whittaker and Sheila Sanderson for editorial review of this article.

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*This article is an extract of an article authored by Andrew Bottomley Tony Kirby John Bean Julie Walker published in Expert Rev.Pharmcoecon. Outcomes Res.13(1)43-45 (2013)*



ABOVE © European Union - European Parliament, Audiovisual Unit.

RIGHT Andy Nordin



# EORTC Quality of Life Group Autumn Meeting 2013

September 12 & 13, International Study Centre, Canterbury Cathedral, Canterbury, Kent. UK Organiser: Andy Nordin

I am pleased to invite you to join us in Canterbury for the Autumn Meeting of the EORTC Quality of Life Group, on Thursday September 12 & Friday September 13 2013.

Canterbury is a small, beautiful medieval city in the south east of England, steeped in history. It is full of Tudor buildings, cobbled narrow streets and meandering streams. The city centre is dominated by the magnificent Canterbury Cathedral. Canterbury is the home of the Archbishop of Canterbury, the head of the Anglican Church (the Church of England), and ancient Cathedral is the greatest cathedral in the United Kingdom.

Our meeting will be held in the International Conference Centre, which is situated within the Cathedral Precincts overlooking the Cathedral. It is a magnificent venue for meetings, with a beautiful wood-panelled auditorium and a lovely hotel with bedroom views of the Cathedral to accommodate guests. Whilst there is ample hotel accommodation within walking distance of the Cathedral, ranging from deluxe to budget accommodation, rooms in the conference centre hotel are limited and will be allocated to our group members on a first-come : first-served basis.

To reserve your room (£105 per night bed & breakfast), please contact Canterbury Cathedral Lodge direct:

- Email: [stay@canterbury-cathedral.org](mailto:stay@canterbury-cathedral.org)
- Tel: + 44 (0) 1227 865350
- Fax: +44 (0) 1227 865388

During the meeting, you will have an opportunity to visit the Cathedral, informally or on a guided tour if you wish. The Cathedral Choir is famous around the world, and performs every evening during the brief Evensong choral service. My youngest son Tom is a Canterbury Cathedral Chorister, and we are invited to witness the Evensong service after the meeting closes on Thursday evening, before we enjoy pre-dinner drinks on the terrace overlooking the flood-lit Cathedral.

The county of Kent is known as The Garden of England, and the coast is dotted with delightful fishing villages and seaside towns like Whitstable, famous for its oysters. Canterbury is the perfect base for touring the area. For those able to stay on after the meeting, I have arranged dinner on Friday evening in the Goodshed Restaurant, situated in the farmers market in the centre of town. It is famous in the UK for excellent food made from fresh local produce.

I am arranging a tour of the region on Saturday morning, including a visit to the famous Leeds Castle, considered by many to be the greatest medieval castle in Britain. So if possible, delay your departure until Saturday evening or Sunday, and enjoy exploring our beautiful city and county with our friends from the group.

Canterbury is accessible by the new Highspeed rail service from London. The journey from St Pancras International to Canterbury West takes just 56 minutes.

The Eurostar service from Paris and Brussels terminate at St Pancras International, but many Eurostar trains also stop at Ebbsfleet International or Ashford International, which are closer to Canterbury on the Highspeed line. London City Airport is a short light rail journey from Stratford International station, the site of the Olympic Games, which is also on the Highspeed line to Canterbury. Regular rail services also run to Canterbury West from London Victoria, and to Canterbury East from London Charing Cross, both of which take around 90 minutes but are more convenient for Gatwick Airport. Heathrow and Stansted Airports are not particularly convenient for Canterbury, but are best served via the Highspeed line from St Pancras. Airport buses and pre-booked taxi services are available.



ABOVE Canterbury



# Regensburg 2012 a New QOL Researcher's Perspective

RIGHT Amelie Harle



Amelie Harle

On the 4th and 5th October 2012, quality of life researchers from all over Europe made their way to Regensburg in Germany to attend the Autumn 2012 EORTC Quality of Life Group meeting, hosted by Professor Koller and his team. This bi-annual meeting offers EORTC researchers the opportunity to advance the respective questionnaire module projects in a workshop format and also to be updated on wider QoL projects run by the EORTC QoL Group.



Whilst the email invitation to attend the EORTC QLG meeting in Regensburg was received with enthusiasm, the anxiety soon set in. Being a clinician who has only recently discovered QoL and symptom research in oncology, I felt apprehensive. However, I need not have been anxious. Whilst the dreaded, "stand up and introduce yourself to the group" was asked of us all on our arrival, it served to show me that I was not the only clinician, still early in my research career, to attend. In the room were clinicians, statisticians, psychologists, and many other researchers; all with experience of differing fields but all with a common interest in QoL research. Here was a truly international and multi-disciplinary research group. I instantly felt at home.

We soon broke up into working groups and attended various workshops to learn and to contribute in an informal setting to the questionnaire development process. The topics for the workshops included an update on the Elderly Module, the development of a questionnaire for Gastrointestinal Stromal Tumours (GIST), and the revision of the QLQ LC-13 lung cancer module, which has now completed the 1st phase. In total there were 18 workshops to choose from over the course of the first day, so ample opportunity to become involved in projects aligned with areas of interest and expertise. The workshops allowed me to witness for

the first time, the process I had read about in so many published articles on QoL assessment tools. I listened intently and learnt a great deal. As my confidence grew, I contributed more. Several research groups also presented specific questionnaire development projects from their respective institutions. It was clear that feedback and comments were encouraged by all. I have rarely attended such an inclusive meeting.

It was with enthusiasm therefore that I attended the conference dinner held at Haus Heuport directly opposite the cathedral. Having walked through an arch, past an internal courtyard and up a beautiful wooden staircase, I found the tables were laid in a warmly lit dining room with imposing beams. Over the course of the meal, the conversation spanned many subjects, few were work related! An exchange of cultures, languages, perspectives on living and working in different European countries served to make it a very enjoyable evening. I felt welcome.

The following day, I walked the streets of Regensburg prior to the plenary sessions. Regensburg is a beautiful medieval city in the heart of Bavaria. I was able to explore some of its hidden corners, streets and architecture. Having been given some addresses of small independent coffee shops, I set off to discover more. May I take this opportunity to recommend a pre-meeting breakfast at Café Lilal!

There, I found a relaxed atmosphere with books for customer perusal, quirky artwork, soft Jazz playing in the background and a German breakfast worthy of any hungry visitor. I idly walked around the impressive cathedral, down the cobbled streets and along the River Danube up to the Stone Bridge, so important (I later learnt) for ancient trade routes between east and west. All around me was a city that had seen Italian, Spanish, French, Czech, Bohemian and German influences among others. Regensburg truly is a European city, worthy of any EORTC meeting!

The subsequent plenary sessions provided us all with updates on important projects such as the Patient-Satisfaction International Project and the EORTC Data Repository Project. Unfortunately, I had to leave the meeting prior to the planned "Regensburg Tour" which I know included a boat ride along the Danube. Whilst I plan to return to Regensburg at a later date with my family to enjoy its historical and cultural aspects in greater depth, I left Regensburg with real excitement. I had been given the opportunity to work alongside researchers with a wealth of experience in the field of QoL research. I was encouraged along the way to participate and to contribute. I would like to thank Professor Koller and his team for their warm welcome. Their choice of venues and activities was appreciated by all who attended. I am looking forward to future EORTC QLG meetings!

# New QOL Website

Rossella Guzzo Foliaro

The celebrations for the 50th anniversary of the EORTC, combined with those of 30 years of achievements of the EORTC Quality of Life Group contributed to the visibility of our group, encouraging the QOL Group to look at future communication strategies and the role played by new technology.

The QOL website being the main interface between the Quality of Life Group and the hundreds of academics and numerous pharmaceutical industries using our measures was the basis for a renewed approach to the new media. In order to redesign the Quality of Life website (having been responsible for website maintenance in previous years), I coordinated the joint efforts of the web designer, webmasters, EORTC IT Department and the QOL Executive Committee (EC).

Before the web designer could refresh the visual identity of the QOL Group, a preliminary debate within the Executive Committee focusing on re-thinking the website's functionality was needed, to optimize the information and dissemination of EORTC tools. The delivery of a cutting-edge website required an outline of the highlights and a proper definition of the objectives of the new website. We established a hierarchy of information, giving more prominence to the Questionnaires, the Item bank, recent events and news, all of which are now displayed on the homepage.

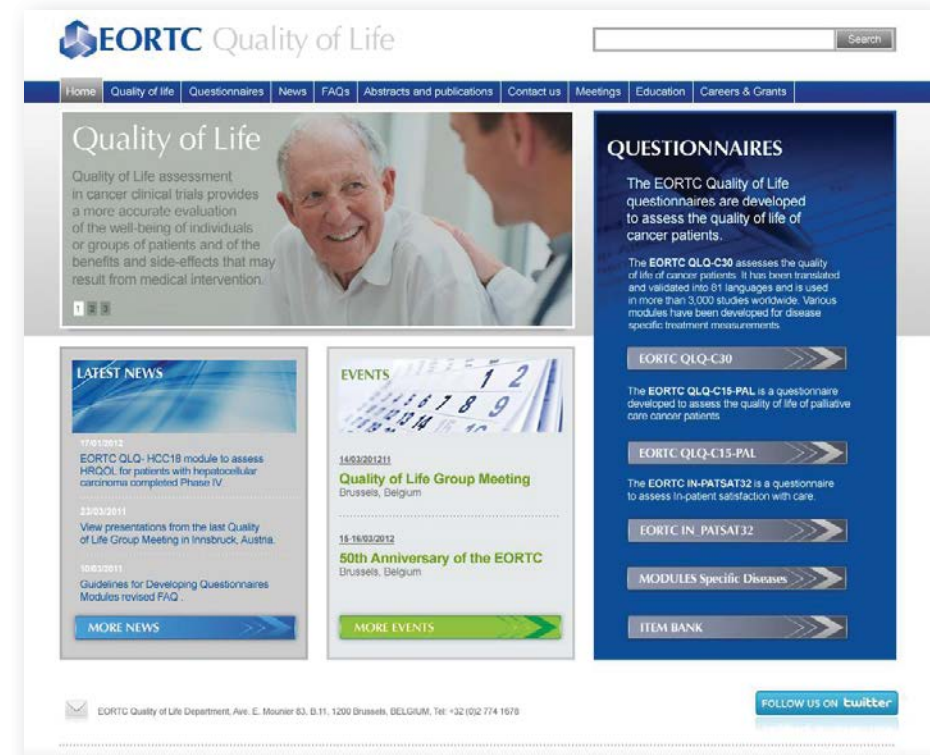
One of the aims was to make the site user-friendly - featuring a site-wide search in order to speed up information searches. A new Content Management system has been included being more intuitive, adaptable, easy to update quickly and when necessary, by different

Department personnel without intensive training being required. To address the growing interest in Quality of Life of a new generation of young researchers the website now incorporates new social media such as Twitter, to enable visitors to become EORTC "followers".

The enhancement of the website also allows the possibility of easily uploading videos, pictures, and to access documentation such as a complete and up-to-date list of publications on behalf of the Group in the "news" section.

Due to the success of the new website, as presented by Andrew Bottomley during

the 2012 Spring Group Meeting in Brussels, it was decided to continue with Phase II of the website development. As the Group is constantly growing and welcoming new members from all over the world it was thought that a restricted membership area, where confidential information could be shared, might improve efficient internal communication. The Group Meeting in Regensburg was an opportunity to obtain feedback from members and new ideas about how the proposed membership area could facilitate and simplify internal communication. The positive input received will allow us to finalize this membership area at the beginning of 2013.





RIGHT Mogens Groenvold



# News

## A new professorship in palliative care and quality of life measurement

**R**ecently Mogens Groenvold, chair of the EORTC Quality of Life Group was appointed professor at the Section for Health Services Research at the Department of Public Health, University of Copenhagen, Denmark.

The professorship is the second within palliative care and the first in quality of life (QOL) research in Denmark. It combines the two main research fields of Mogens Groenvold. It also combines a position in health services research department (where the aim is to study the health care system), with a position placed within a small unit in the health care system, i.e. at the Department of Palliative Medicine, Bispebjerg University Hospital, where he will continue as the head of the Research Unit. Finally, it combines clinical research with methodological research.

Mogens views this 'two-by-two-by-two combination' as ideal for several reasons. As palliative care deals with identifying the patients' needs and improving QOL, quality of life assessment plays a central role in clinical practice, epidemiology, and trials. Since 1998 his research unit has worked in the interface between palliative care and QOL assessment: longitudinal assessment in patients admitted to palliative care, testing and validation of instruments (leading to the development of the EORTC QLQ-C15-PAL, the Three-Levels-of-Needs-Questionnaire (3LNQ), and other instruments assessing cancer patients and their carers' needs), and use of these instruments in large national surveys.

His research group has also investigated experienced palliative care doctors' and nurses' ability to identify patient needs (this ability was surprisingly low – emphasising that systematic assessment tools are necessary) and documented poor agreement between doctors and patients about QOL assessed by the EORTC QLQ-C30, again underlining

the importance of patient self-assessment. Finally, they currently conduct a randomised controlled trial (RCT) of early palliative care, which was designed and funded before the publication of the famous Temel study and thus becomes one of the first replication studies. This study and an ongoing melatonin RCT have QOL as the primary outcome.

In all these palliative care studies the QOL methodology has been essential and challenging. Mogens Groenvold: "We need to elicit patient responses, but in palliative care complete data are never achievable – we must respect that patients are severely ill, and brief, simple instruments are important, as well as the careful analysis seeking to minimise the impact of missing data." Mogens thinks that the combination of a theoretically thinking health services research university department where the health care system is looked upon from the outside, with a research unit placed in a hospital is also fruitful. The health services researchers have a sound, sceptical point of view, and see the various specialties as 'actors' in a complex system driven by many different external and internal mechanisms. This provides an interesting contrast to the 'clinical' point of view where the well-meant focus is on specific interventions of the specific patient groups who have come into the department – often without looking at the greater picture.

The health services research approach has inspired a number of their projects. The Danish Palliative Care Database includes all patients referred to specialist palliative care in Denmark since 2010 (currently more than 20,000). The database is embedded in a national organisation, Danish Multidisciplinary Cancer Group for Palliative Care, DMCG-PAL, engaging more than 100 health care professionals in developing clinical guidelines and educational programs.

Patient completion of the EORTC QLQ-C15-PAL, which measures some of the most frequent palliative

care needs, is included in the Danish Palliative Care Database as a quality indicator, and by matching information from the national Database with data from the administrative registers, they will obtain extensive new knowledge about palliative care in Denmark: Are the 'right' patients referred? Is admission equal? Who refer which patients? What are the relationships between specialist palliative care, QL, health care use, costs, and place of death?

Finally, almost all of their projects have been characterised by the combination of being clinical and methodological, where the methodological focus is on the development, validation and analysis of QOL instruments. Morten Aagaard Petersen coordinates the large EORTC Quality of Life Group (QLG) collaborative project developing a new version of the EORTC QLQ-C30 which is based on computer-adaptive testing (CAT) (described in previous newsletters). CAT makes it possible to interactively adapt the questions to the answers given by each patient. Thereby more precise measurement with reduced floor/ceiling effect is obtained. CAT has now been developed for most of the dimensions, and the EORTC QLG has recently funded a study clinically validating the 'EORTC CAT' in ten countries. Future palliative care trials will benefit from the reduced sample size requirements resulting from CAT, thus making trials more feasible.

The EORTC QLG has been an explicit part of Mogens' work since he joined it in 1989. Much of the research he has initiated has taken place in collaboration with colleagues from the QLG: "I have learnt a lot from being part of this excellent scientific network and enjoyed it thoroughly. I therefore really appreciate that this professorship – one of the latest out of several that have been based on international collaboration involving the EORTC QLG – will give me the chance to continue research in palliative care and quality of life measurement."

RIGHT Lonneke Van De Poll



LONNEKE VAN DE POLL APPOINTED PROFESSOR OF CANCER EPIDEMIOLOGY AND SURVIVORSHIP

**O**ne of our EORTC-Quality of Life Group members, Lonneke van de Poll-Franse has been appointed Professor of Cancer Epidemiology and Survivorship at Tilburg University, The Netherlands.

The chair is sponsored by the Comprehensive Cancer Centre South, Eindhoven, the Netherlands. Lonneke van de Poll is trained as an epidemiologist and her research (CCCS) focuses on quality of care and quality of life of cancer survivors.

Since 2001 she has worked at the CCCS where she uses the Eindhoven Cancer Registry data for epidemiological analyses. In 2009 she was able to develop the PROFILES (Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship) registry with a grant from the Netherlands Organization for Scientific Research (NWO). PROFILES is an important source for her studies into the physical and psychosocial impact of cancer and its treatment.

Since 2007 Lonneke van de Poll has been an active member of the Quality of Life group and has participated in the development of the Endometrial module and Survivorship project. She is currently participating in the development of the Melanoma module and is PI in the development of the Lymphoma (NHL, HL and CLL) module. The EORTC QLQ-C30 and modules are incorporated in the different cancer survivorship studies she initiated in PROFILES. Perhaps interesting for other EORTC-QoL group members: Data from the PROFILES registry are available for non-commercial scientific research, subject to study question, privacy and confidentiality restrictions, and registration ([www.profilesregistry.nl](http://www.profilesregistry.nl)).

# News

## Susanne Singer Chairs Division of Epidemiology and Health Services Research

**S**usanne Singer, one of the secretaries of the EORTC Quality of Life Group, received a call in 2012 from the University Medical Centre Mainz, Germany, to chair the Division of Epidemiology and Health Services Research.

She started her new appointment in August 2012. The Division of Epidemiology and Health Services Research is situated at the Institute of Medical Biostatistics, Epidemiology, and Informatics (IMBEI) where the German National Child Cancer Registry and the Cancer Registry of Rhineland-Palatinate are also situated.

This will enable her to pursue quality of life research in cancer patients at a population based level. The Institute's research focus is on Cancer Epidemiology with a specialization in radiation epidemiology. Susanne will contribute her expertise in health services research, quality of life, and psychosocial oncology to the Institute's portfolio.

The IMBEI also teaches international Masters Students in Epidemiology as well as medical students. Susanne and her team are involved in this, encompassing such topics as Basic and Extended Epidemiology, Social

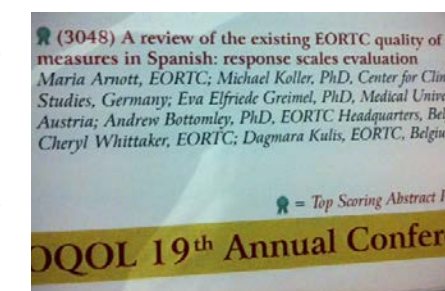
Epidemiology, Scientific Writing, Writing Grant Proposals and Evidence Based Medicine. More information can be found at: <http://www.unimedizin-mainz.de/index.php?id=17687>

## Maria Arnott's Top Scoring Abstract Poster Award

**A**t the 19th Annual ISOQOL Meeting, Ms. María Arnott received a Top Scoring Abstract Poster Award for her abstract entitled: **A review of the existing EORTC quality of life measures in Spanish: response scales evaluation.**

María's poster was recognized as the year's top poster, together with 22 other abstracts which received the highest evaluations during the review process, amongst all 280 abstracts accepted for poster presentation.

Congratulations to María and the co-authors: Michael Koller, Eva Greimel, Andrew Bottomley, Cheryl Whittaker, and Dagmara Kulis.



RIGHT Divine E. Ediebah



# News

# News

## QLG Grants Approved in 2012

|                                    |      |  |
|------------------------------------|------|--|
| Wei Chu Chie                       | 103K | HD chemo module approved pending interest from QLG members |
| Bernhard Holzner                   | 81K  | New Electronic presentation of QOL data project            |
| Eva Greimel sexual health          | 236K | Module on sexual health                                    |
| Michael Koller                     | 145K | Module on EORTC response categories                        |
| Susanne Singer                     | 99K  | module   |
| Mogens Groenvold                   | 248K | CAT  |
| Juan Ignacio Arraras               | 81K  | communication MODULE                                       |
| Colin Johnson, Vassiliou Vassilios | 77K  | Anal Cancer module   |

## New Investigator & Best Poster Awards

**D**ivine E. Ediebah, Research Fellow in the Quality of Life Department (QLD) at EORTC Headquarters, was nominated for the New Investigator Award and best poster award at the 2012 International Society for Quality of Life Research Annual Conference (ISOQOL) in Budapest.

The New Investigator Award is based on Divine's research efforts in the QLD concerning biostatistical analyses on clinical trials data in the Patient Reported Outcome and Behavioral Evidence (PROBE) projects and working in collaboration with the EORTC Lung Cancer Group.

Specifically, the award recognizes his analysis of joint modeling of longitudinal health-related quality of life (HRQoL) data and overall survival in non-small-cell lung cancer (NSCLC) patients. Divine also received the ISOQOL 2012 New Investigator/Student Scholarships to assist in the travel expenses to present his research at the ISOQOL 2012 annual conference.

In cancer clinical trials, outcomes may vary; treatment-related impairment of HRQoL may hasten death, and thus mask survival benefits of treatment. Divine analyzed data from a clinical trial comparing gemcitabine+cisplatin (arm B) and paclitaxel+gemcitabine (arm C) versus paclitaxel+cisplatin (arm A, the standard arm) in 480 advanced stage NSCLC patients. HRQoL was assessed via the global health status/QOL (GHS) scale of the EORTC QLQ-C30 questionnaire at baseline and after each chemotherapy cycle. Joint modeling was used

to assess the combined effect of treatment on HRQoL and survival.

Results of the analysis suggest that part of the survival benefit of a new treatment can be masked by the negative effect that treatment has on HRQoL. Up to 27% of the theoretical treatment efficacy was lost through impaired HRQoL affecting survival.

The results of this analysis also support the association between HRQoL and overall survival: increased attention to effective supportive care during treatment could potentially correct negative HRQoL effects and unmask survival benefits.

## EORTC Studies Cited in ASCO Annual Report of Clinical Cancer Science

**E**ach year ASCO selects top studies which they think can alter practice, 87 were selected this year. ASCO Issues Annual Report on State of Clinical Cancer Science 2012 cited three EORTC Quality of Life and PROBE studies.

One important study done under the auspices of the Probe project in the Quality of Life Department and published in JNCI (Quinten C, et al Patient self-reports of symptoms and clinician ratings as predictors of overall cancer survival. JNatl Cancer Inst 103:1851-1858,2011 is classed as a notable advance in this ASCO report. They reviewed our study and state: "Patients" self-reporting of symptoms contributes to a more accurate survival prediction. Clinicians evaluate and report patient symptoms in clinical trials using a standardized scoring system.

The scores are typically incorporated into a model for prediction of overall survival, which helps physicians select the

most appropriate treatments. Results of a retrospective study released this year suggest that adding patient-reported symptom scores to the traditional physician-based scoring system may result in a more accurate prediction of survival.

In the study, investigators analyzed pooled data on 2,279 patients who had participated in 14 different clinical trials. Physician and patient scoring on six cancer quality-of-life symptoms (pain, fatigue, vomiting, nausea, diarrhea, and constipation) had been recorded at study entry.

Researchers found notable differences between clinician- and patient-reported scores, particularly in the case of fatigue (on a scale of 1 to 4, the patient- and clinician-reported scores were 2.10 and 1.36, respectively). For each of the six symptoms, both clinician and patient scoring separately improved the accuracy of the survival prediction model.

These results suggest that patients' subjective assessment of symptom severity should be incorporated into decision making involving their care. In addition, the findings lend strong support for the Patient Centered Outcomes Research Institute (www.pcori.org), which was recently authorized by Congress to broadly develop,

**"Patients" self-reporting of symptoms contributes to a more accurate survival prediction.**

test, and implement patient-reported outcome measures across the disciplines of medicine. - Andrew Bottomley

## 20 Hours of Free On-Line HRQOL Training at the EORTC PROBE Website\*

**T**he PROBE project has completed four years of international research into understanding the burden of cancer in patients' lives.

Throughout trans-national research in HRQOL, the PROBE team managed to produce important research results and alter clinical practice, which was followed by international recognition at ASCO's Annual Report on Progress against Cancer.

The PROBE project continues its efforts to guide clinicians in their decision making for improving their patients' HRQOL and to disseminate research outcomes, by means of the 3rd EORTC QOL Conference held in the European Parliament, 17-18 October 2012. More than 20 hours of conference presentations are freely available online on the PROBE website, presenting the latest developments in HRQOL research by global key HRQOL speakers.

\* <http://groups.eortc.be/probe/>



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**BELOW** Several Members of the Quality of Life Department

