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## Quality of Life Group Executive Committee

*Jane Blazeby*  
Chair



Jane Blazeby is current chair of the EORTC Quality of life group, which she has been an active member of since 1993. Her involvement in the group started whilst developing questionnaire modules for gastro intestinal cancers. She currently holds an MRC Clinician Scientist award which splits her work between upper gastro intestinal cancer surgery and patient based outcomes research. In addition she is married to an artist and has three children.

*J.K Ramage*  
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John Ramage is a Consultant Gastro enterologist and Hepatologist, at North Hampshire Hospital Basingstoke and Kings College Hospital, London. Research interests are in Liver tumours, particularly carcinoid/neuroendocrine tumours. Chair of Wessex carcinoid group and steering committee member of UKNET work. Lead clinician in Neuroendocrine tumours for Kings College carcinoid clinic. Co-ordinator of UK national guidelines on neuroendocrine tumours. Other clinical interests include decision support in medicine and clinical information technology (national lead on case-mix in

GI diseases at NHS Information Authority). Other interests are ski-ing, mountaineering and sailing.

*Joy Ardill*  
Joint Secretary

Joy Ardill is a Consultant Clinical Scientist in the Royal Hospitals Belfast where she heads the Regional Regulatory Peptide Laboratory which provides a diagnostic service for Neuroendocrine Tumours for the northern half of the UK and Ireland. In Belfast there is a tertiary referral centre for these uncommon tumours, she works there as part of the multi-disciplinary team. In association with Queen's University Belfast she is heavily involved in research, particularly in peptic ulcer disease and neuroendocrine tumours and for the past few years she has been involved also in quality of life issues.



*Luca Incrocci*  
Joint Secretary

Luca Incrocci is a radiation oncologist and sexologist in the Department of Radiation Oncology at the Erasmus Medical Center/ Daniel den Hoed Cancer Center, Rotterdam, The Netherlands.

Dr Incrocci is a member of several scientific societies including the European Association of Urology, the American and European Societies for Therapeutic Radiology and Oncology and the European and International Societies for Sexual and Impotence Research. He is an active member in EORTC activities (QLG and GU).



Dr Incrocci is the Chief Editor of the International Society for Sexual and Impotence Research (ISSIR) Newsbulletin. He is the co-founder, Secretary/Treasurer of the International Society for Sexuality and Cancer (ISSC).

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Since 2004 he is Guest Professor lecturing in Cancer and Sexuality, at the University of Pisa, School of Andrology, Pisa, Italy.

*Galina Velikova*  
*Module Development*

Dr Galina Velikova is a Cancer Research UK Clinician Scientist working at Cancer Research UK Clinical Centre in Leeds, St Jame's Hospital, Leeds, UK. She is a Senior Lecturer at the University of Leeds and Consultant in Medical Oncology treating Breast and Head/Neck cancer patients. Her main research interest is in introducing and studying the effects of regular use of quality of life measurements in daily oncology practice. In a randomized prospective controlled study she has shown that routine use of quality of life information by physicians can contribute to doctor-patient communication and lead to improvement in cancer patients well-being.

*Neil Aaronson*  
*Liaison Officer*

Neil Aaronson is a medical sociologist working at the Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital in Amsterdam. He is also professor (chair in psychosocial oncology) in

the medical faculty of the Vrije Universiteit. He is currently pursuing two primary research lines: the development and application of health-related quality of life measures in clinical research and clinical practice, and the psychosocial impact of genetic counselling and testing for hereditary forms of cancer.

*Martin J.B. Taphoorn*  
*Newsletter Editor*

Martin Taphoorn is a clinical neurologist with a special interest in brain tumour patients. He is doing clinical research on cognitive functioning and quality of life in neuro-oncology and is an active member of the EORTC Brain Tumour Group of which he was a member of the executive committee until last year. Since 2001 he is the liaison between the Brain Tumour Group and the Quality of Life Group of the EORTC. In 2003 he was elected onto the executive committee of the QoL Group. He is currently working at the Medical Centre The Hague and doing part of his research at the University Medical Centre Utrecht.

*Andrew Bottomley*  
*Quality of Life Unit Representative*

Andrew Bottomley has been a member of the QLG Executive for just under seven years. He leads the EORTC Quality of Life Unit in Brussels helping implement QOL research in cancer clinical trials and collaborates with the QLG on instrument development. Andrew is a Board member of ISOQOL, and has written over 80 papers and book chapters on QOL in Oncology.



## Autumn Meeting

### Freiburg - location of the EORTC autumn meeting 2004

Freiburg is a flourishing University town with 212 000 inhabitants, situated in the southwest of Germany between the Black Forest and the Rhine valley, close to the area where the borders of Germany, France, and Switzerland meet. Freiburg and its surroundings are known as the warmest region of Germany (mild temperature with an average of 10.8 C° per year; compared with Lugano 11.3 C°) and with the highest average of sunshine (1900 hours per year). The height differences of the Freiburg area are of over 1000m above sea level (market place 278 m, Schauinsland 1284 m). Therefore the



climate in the lowlands and valleys is warm and dry, whereas in the region of

the Black Forest it is fresh and cool. In winter there is a lot of snow in the higher mountains where you can ski. The townscape is characterized by an old medieval centre reconstructed

after the Second World War and dominated by the old gothic cathedral Freiburg's essential symbol. The historical centre is shaped by small, narrow streets and alleys and the typical small man-made streams crossing the centre over a length of 6.3 km (called "Bächle"). Freiburg has a southern charm. For centuries Freiburg has attracted people from near and far. Many have come to Freiburg and many have remained,. Freiburg is today one of the few cities where both the population and the economy are growing.

Freiburg was founded in 1120 by Konrad of Zähringen. Around 1200 the construction of the Cathedral began

*Joachim Weis*  
*Tumour Biology Center Freiburg*

and ended with its final consecration in 1513. In 1368 Freiburg belonged to the Habsburg Dynasty. From 1677-1697 it was a French fortress. In 1806 it became part of the Grand Duchy of Baden (until 1918). In the last years of the Second World War Freiburg city was destroyed to about 70%. From 1946-1952 Freiburg was the Governing seat of the land of South Baden. Since 1952 Freiburg is the seat of the regional governing council (Regierungspräsidium).



**"...Freiburg is today one of the few cities where both the population and the economy are growing..."**

..."With its universities including all faculties and colleges Freiburg is also a city of science and education: The main university (Albrecht Ludwigs Universität) was founded in 1457 and has actually about 22 000 students. The State College of Music (547 students) attracts students from all over the world and is famous for its teachers and its department of contemporary music. Furthermore, Freiburg has a Pedagogical University, and two private Universities, for Applied Science of Social Work and Pedagogy run by the catholic and protestant churches. Social sciences in medicine are represented by a variety of departments which are collaborating in various research projects with national and international groups: department of psychology, department of medical psychology, department of psychiatry as well as the department of psychosomatic medicine. For medical care Freiburg provides seven University clinics with more than 1200 beds and four private hospitals. The Tumor Biology Center associated with the university and the University clinics are famous for cancer research and treatment. The psychosocial care of cancer patients is an integrated part in most of the clinics offering in-patient and out-patient treatment programs.

Freiburg is also famous for its many efforts to protect and preserve natural resources and the environment. In 1992, the city was awarded the title

"The German Capital for Environmental Protection ("Umwelthauptstadt Deutschlands")."

Freiburg has also a long lasting tradition of philosophy. Edmund Husserl one of the most important representatives of phenomenology taught in Freiburg until his retirement in 1928. The famous German philosopher Martin Heidegger (1889 to 1976 succeeded Husserls on his chair of philosophy and was rector of the Freiburg University from 1933 to 1934. Next to Karl Jaspers, he was the most important post 1945 representative of German philosophy in Europe. His main work "Sein and Zeit" ("Being and Time") published in 1927 remained unfinished.



Freiburg is a busy cultural city with its theatres, opera and concert hall. Every year in July the tent music festival takes place and attracts many famous musicians of jazz, pop and classical music. As museums you will find the Augustiner- museum including the city history department, museum of nature and ethnology, a museum for pre- and early history and a museum for modern art.

#### Sites worth seeing:

- the roman/gothic cathedral with a tower 116m high (Münster).
- The market place (Münstermarkt) with its daily market except Sundays and holidays of food and flowers with a focus on regional products`
- the old city (Altstadt)
- the city gates (Martinstor, Schwabentor)
- the city hall (Rathaus) with bellringing (daily at noon)
- the historic merchant house (Historisches Kaufhaus)
- many old buildings such as "Haus zum Walfisch" (House of the Whale 16th Century)
- Planetarium (near the main station).

- The old cemetery (Alter Friedhof) with picturesque tombs of the 17th and 18th century
- cable car to the Schauinsland mountain (1284 m.) (begun in 1930; the world's first two-way large cable car) 3.6 km long, height differences of 748 m
- Green areas in the town include the Colombi Park 1.3 ha, City Garden 3.0 ha close to the meeting venue, Botanical Garden 1.2 ha and the Seepark (site of the 1986 state garden show).

I am happy to host the EORTC QOL autumn 2004 Meeting and I am sure that you will have a pleasant stay in this wonderful city. Work apart I hope you will be able to enjoy the city with its culture, its many cafes, its variety of shops and boutiques and its gastronomic delights.

For further information including travel and hotel information (in English):

[www.freiburg.de](http://www.freiburg.de)

[www.baden24.de/extern/freiburg\\_online\\_e/frameset\\_b24\\_top.asp](http://www.baden24.de/extern/freiburg_online_e/frameset_b24_top.asp)

#### QLG Meetings Info

Potential new members wishing to attend these meetings should contact Joy Ardill,

[joy.ardill@bll.n-i.nhs.uk](mailto:joy.ardill@bll.n-i.nhs.uk)

**SPRING 2005 QLG MEETING**  
EORTC Groups Annual Meeting  
Brussels - Belgium

16-18 March 2005  
Followed by QOL Group Meeting  
Saturday 19th March 2005

**AUTUMN 2005 QLG MEETING**  
Copenhagen -Denmark

## Reflections on retirement

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

The first meeting of the EORTC QLG that I ever attended was in November 1992 in Brussels. This was a few months after I had run the London Marathon for the first time; the group was already into its 14th Year and I was six months pregnant. This was in the days before the QLU at the EORTC Data Center, when internet access and an e-mail address were rare, and before the opening of the Channel Tunnel. Any cheap flight involved staying away from home for at least 3 days or a Saturday night. I knew no one and wandered around in a dark basement of Institut Jules Bordet for ages looking for a meeting of the Head & Neck Module Group. We dined on Couscous at a Middle Eastern restaurant and I went back to England amazed at all these people who had done so much work and wondered whether I would ever be able to put names to all the faces. A year later I went to Edinburgh for a day (all that could be spared at home with an 8 month old son). Ann Cull had organised a party in her home and the first publication of the QLQ-C30 had just been accepted for publication in JNCI. In spring 1994 it was back to Brussels – at least this time I knew where the meeting rooms were and then off to Trondheim, Norway in November 1994. Stein Kaasa organised a party in his house one evening but the promised snow and toboggan rides never materialized, as the weather was so mild. After four days with only a few hours of sunlight I returned to Oslo and made my way up through the clouds to some sunshine at the ski lift and I pondered on how people cope with three months of darkness – not for me, thank you.

By this time Wenny Kiebert had been appointed at the QLU and a number of early modules were being field tested. The spring '95 meeting was in Warsaw courtesy of Jerzy Meyza. We took a coach everyday to the city outskirts to the Cancer Hospital past some very dismal grey high rise tower blocks. But following extensive damage in the Second World War the Old Town was restored in the 1970s and is now a beautiful UNESCO World Heritage site. The hotel bar on the top floor was actually a 'lap dancing' club. What with that and the little cards that appeared under our

doors some people's quality of life was obviously well catered for! I also recall seeing western soaps locked away as a precious commodity in the shops. By this time I was six months pregnant again, so I missed the next meeting in Copenhagen in November 1995. But I was determined to get to Pamplona in spring 1996, having been a Hemmingway fan for many years. This is the town of the "Running Bulls", part of the Sanfermines festival made famous in "A Dangerous Summer". Juan Arraras made sure we had plenty of opportunities to explore the city, the local vineyards and the nightlife, but adapting to late evening meals and early morning starts was a problem for some. By this time the 'portfolio' of EORTC QLG Blue Books was quite extensive and a new addition was the Norm Values.

### *"...Istanbul is a city of contrasts..."*

November 1997 saw us back in Brussels – by now the Channel Tunnel was open, except that a week before the meeting there was a serious fire and the Tunnel was closed, leaving us with a panic to find flights at short notice. Six months later my travel plans were thwarted again by a national rail strike in France as we tried to travel from Paris to Besançon. My 'schoolgirl' French meant that I was only able to understand that I would need to wait 24 hours for the next train to Besançon, but by chance, as I left Gare du Nord, I bumped into Darius Razavi and Sam Ahmedzai who knew that the strike only affected national trains, not international ones. The train to Switzerland, due to depart in 30 minutes was going to make an unscheduled stop at Dole, a small town in France about 50km from Besançon. We shared one stool in the buffet car for the 5 hour journey and Simon Schraub – our host for the meeting – arranged for a taxi to meet us. As was to be expected in France, we dined well and sampled the local cheeses and wines. We also visited the nearby Arc et Senans – a 17th Century Royal Salt Works, designed by a visionary architect who took his employees quality of life seriously and planned a whole community including housing, schools and a hospital around

the works – though sadly it was never completed. It was at this meeting that I first joined the Exec Committee as treasurer – though some may have questioned my organisational ability as my return journey to England was also a disaster when I tried to check in at the airport only to discover that my tickets had been issued for travel the following day and I had failed to notice the mistake.

Our next meeting was in Istanbul and we had been asked if group members could contribute to a half-day symposium at the hospital. My flight was delayed so I arrived at the hotel late only to find that as speakers at the symposium next day we were guests of honour at a dinner that night. Istanbul was a city of contrasts - it was possible to stand on many a street corner and see extremes of wealth and poverty, high tech and low tech, the old and the new all at once. Major city-wide power cuts were common making walking hazardous at night as everything was suddenly plunged into total darkness including Bengt Bergmann who fell down a large unmarked manhole. My hotel room had a magnificent view over the Sea of Marmora, from which you could watch the local fisherman casting their nets against a backdrop of slow moving supertankers. And just as some people are naturally good communicators others are good 'hagglers' – a skill I'm afraid I did not master in the Grand Bazaar – but others obviously did as they returned home with Turkish Rugs and ceramics.

### *"...London has the largest Chinese community outside Hong Kong"*

The next meeting in spring 1998 was in London and I was acting as host. Quite a challenge, to find an affordable meeting venue, accommodation and restaurants in central London. London has the largest Chinese community outside Hong Kong so we enjoyed a banquet in Chinatown at a restaurant to which we were to return in 1999 and 2002. During this dinner I was persuaded to take on the role of Group Secretary and for the first few months had to retain the job of

Treasurer as well. Back to Brussels again in autumn 1998 then in spring 1999 we returned to what many consider to be the 'home' of the EORTC QLG – Paris. (Many of the meetings between 1982 and 1992 were held there in a room overlooking Hôtel de Ville) Anne Brédart hosted the meeting at Institut Curie. Back to London in November 1999 where the launch of the Item Bank was discussed, then onto to Oslo in May 2000. This time our Norwegian host (Kristin Bjordal) got the weather prediction right, as Oslo was bathed in sunshine. We stayed in a very impressive hostel that patients can use whilst attending for radiotherapy if the distance from their home is too far for daily commuting. There were views of the nearby woods and the ski-jump whilst the city centre was only a short train ride away with its marina and expensive playboy yachts and motor launches that we could only dream of owning. We had a walking tour of the Vigeland Sculpture Park and partied in Kristin's garden having been asked to bring our 'duty free' alcohol. The following autumn saw us return to Edinburgh – hosts of autumn meetings (in this case Ann Cull) always have a harder time as the days are shorter and there is a risk of wind and rain.

**“...I would like to thank all the people who have helped me ...”**

Spring 2001 saw us in the tranquil hill-top setting of Reisenburg Castle. Germanic efficiency prevailed on the railways and on our first night, as 25 hungry quality of life researchers descended to the local bar where the landlord single handedly took all our orders, served our meals and drinks and produced 25 individualised receipts all accompanied by smiles and good wishes. Our meeting coincided with that of the EORTC GI group in nearby Ulm and Franz Porzoltz managed to organise a joint workshop and dinner in the Castle. On another night we had a moonlit walking tour of Ulm. Back to Brussels again in November and the launch of our first newsletter, then Paris and London in 2002.

And so we arrive at spring 2003 and a meeting in Graz, Austria hosted by Eve Greimel. Another beautiful city with surprises at every turn; the dancing around the Maypole outside the town hall, the bar that literally floats on the fast flowing river, the fantastic food

especially in the baroque 'Wintergarten' surrounded by trailing plants, the mountain top castle with panoramic views in all directions. (For anyone invading Austria from the east, Graz was the first place to conquer and for anyone retreating Graz was the last stronghold.) All this made something of a challenge for anyone wishing to host the autumn 2003 meeting. But Rome lived up to expectations as Fabio Efficace organised a meeting at a hotel right beside the River Tiber and close to many of Rome's most famous sites. We soon became experts at finding our way to Piazza Navonne and even as far as the Trevi fountains and Spanish Steps in the evenings.

And so we finally reach spring 2004 when my term of office as secretary came to an end. It somehow seemed very appropriate that the meeting should be in Brussels where all those years ago I had first joined the group and also that the previous Sunday I had run the London Marathon again for the second time.

You might think from reading this that our meetings are nothing but eating and sightseeing, but a lot of very productive work does get done in the parallel and plenary sessions – however my experience tells me that some of the most creative, informative and original ideas come not from these sessions but whilst chatting over dinner or admiring the beautiful cities in which many of our members live. I have certainly learnt a lot about Europe in the last 10 years and feel very privileged to have visited many of these beautiful cities with a 'local' guide. I would like to thank all the people who have helped me during the past years and I hope to visit many more European cities in the future. One of the unique features of the QLG is our ability to carry out cross-cultural research because of the diverse nationality of our members. This diversity is often stifled in the formal confines of a meeting room but it is very apparent when socialising amongst friends and colleagues. E-mails and the internet mean that we can exchange documents more easily and there is perhaps less need for face-face to meetings and hence less chances to exchange ideas and socialise. Cheap flights mean that for many it is now possible to attend just the meeting and return home the same day. I think those that do miss out on an important opportunity.

## Research Projects

# Health-related Quality of Life in glioblastoma multiforme patients is not negatively affected by Temozolomide chemotherapy: a joint EORTC/NCIC randomized clinical trial

Martin J.B. Taphoorn  
Medical Centre Haaglanden The Hague

### Introduction

Glioblastoma multiforme (GBM) is the most common type of primary malignant brain tumour. While GBM is a relatively infrequent disease, patients with these tumours cannot be cured and experience a median survival of only 9 months from diagnosis (DeAngelis 2001). Standard treatment consists of cytoreductive surgery and postoperative radiotherapy (RT). The benefit of adjuvant chemotherapy (mainly nitrosureas) following RT is debated on. In the United States adjuvant chemotherapy for high-grade glioma is part of the standard treatment, but in many European countries the limited survival benefit of adjuvant chemotherapy is not believed to outweigh treatment-related side effects which negatively affect the patient's health-related quality of life (HRQOL). A recent meta-analysis of several clinical trials concerning this issue demonstrated a median survival increase due to adjuvant chemotherapy of only 2 months and there were no reliable data on HRQOL (Stewart 2002, Efficace 2003).

Temozolomide (TMZ) is an oral alkylating agent with proven efficacy in recurrent high-grade glioma (Newlands 1997). TMZ is well tolerated by patients and has only mild side effects compared to nitrosureas. An international randomized phase III in newly diagnosed GBM patients was performed comparing standard RT following surgery to RT plus concomitant and adjuvant TMZ (Stupp 2004). The primary outcome measure, i.e., survival, significantly improved due to the combination of RT plus concomitant and adjuvant TMZ. Median survival was 12.1 months with RT alone, versus 14.6 months for the RT and TMZ arm. The 2 year survival rate was improved from 10.4 % to 26.5%.

For the HRQOL aspect of the trial it was hypothesized that despite intensification of treatment, TMZ would not have a lasting negative impact on HRQOL.

### Methods

#### Treatment

For this joint EORTC Brain Tumour Group/Radiotherapy Group (26981/22981) and Canadian NCIC Clinical Trials Group study adult patients with newly diagnosed GBM were randomized to either RT alone (60 Gy in 30 fractions) or RT with concomitant TMZ followed by 6 adjuvant cycles of TMZ every 4 weeks. Stratification took place for institution, performance status, and the type of surgery.

#### HRQOL evaluation

EORTC Quality of Life Questionnaire C30 (QLQ-C30, version 3) and the EORTC QLQ-Brain Cancer Module (QLQ-BN20) were used (Aaronson 1993, Osoba 1996). Assessments were performed at baseline, during RT, 4 weeks following the completion of RT, and every 3 months during adjuvant TMZ or follow-up until tumour progression. Changes from baseline scores in 7 preselected HRQOL domains (fatigue, global health, social functioning, emotional functioning, future uncertainty, insomnia, and communication deficit) were calculated for both groups, as well as differences on each time point between patient groups. Statistical significance and proportion of patients with improved HRQOL scores (changes of > or = 10 points) were calculated. A sensitivity analysis was done to investigate reasons for missing data.

### Results

Between June 2000 and March 2002, 573 patients from 85 institutions in 15 countries were randomized to RT alone (286 patients) or RT with TMZ (287 patients). Of these patients, 248 (RT) and 242 (RT and TMZ) had baseline HRQOL measures and were included in the final analysis. The characteristics of the patients in each treatment arm are reported in Table 1.

#### HRQOL: compliance and baseline scores

Compliance overall at baseline was 85%, dropping to 73% during RT and 78% at the first assessment after RT. Compliance percentage levels remained acceptable at the subsequent 4 assessments during the first year of follow-up. However, given the poor survival seen in GBM patients, particularly in the standard arm, there were relatively small overall patient numbers after the first year of follow-up (17 patients in the RT arm, 58 patients in the RT and TMZ arm) and it was decided to restrict the analysis to fourth follow-up.

At baseline, both groups had similar levels of HRQOL, with no significant differences on any scale at the 0.01 level. It was evident from the 7 pre-selected HRQOL domains that global HRQOL was impaired considerably in both groups at baseline. Patients suffered from considerable levels of fatigue, had sleep problems, with both impairments in emotional and social functioning. There was a marked uncertainty regarding the future. Moreover, patients reported communication deficit, motor dysfunction and leg weakness.

#### HRQOL: between group differences and changes over time

Of the 7 selected HRQOL scales, during RT, only one statistically significant difference in the social functioning scale was noted. This favoured the standard treatment. However, according to the 10 point difference criteria for clinical significance, this difference was not clinically significant. During the following assessments there were no significant differences on any of the 7 scales at any of the time points assessed.

Changes over time for these seven scales were not substantial, but nearly all indicated improvement. The only significant one was a reduction in future uncertainty for both groups.

As to the non-selected HRQOL scales

which were examined on an exploratory basis, there were statistically significant differences only during treatment for nausea/vomiting, appetite loss, and constipation between the two arms, all reflecting more difficulties in the RT and TMZ arm. However, only the difference in the constipation scale reached a clinically significant difference.

**Sensitivity analysis**

The missingness mechanism was independent of prior treatment, type of surgery, age, sex of Mini Mental State Examination at entry, but was influenced by performance status and institution.

**Discussion**

These data demonstrate that TMZ, as a concomitant and adjuvant treatment with standard RT in newly diagnosed GBM, does not negatively influence patient's HRQOL. Moreover, HRQOL did not deteriorate over time following primary treatment during the first year until recurrence of disease, and even improved in some respects. As the primary outcome (survival) of this randomized trial has been demonstrated

to be significantly enhanced by the combination treatment (RT and TMZ), this new treatment can be advocated as both an effective one but also a treatment without detrimental effect on HRQOL during the first year of treatment.

Despite these positive observations on HRQOL during and following initial treatment, the patients' baseline HRQOL scores indicated considerable impairments on many dimensions. Key areas of disturbances in both groups were high levels of fatigue, drowsiness, sleep problems, and future uncertainty. Overall HRQOL as well as physical, emotional and cognitive functioning scales indicated substantial limitations. When compared to HRQOL scores in patients with recurrent high-grade glioma, the baseline scores in our study sample this looks favourable (Osoba 2000). This is understandable given the fact that these patients had a first manifestation of their disease and not a recurrent tumour.

One of the limitations of our study could be the level of compliance. Although the percentages compliance remained fairly high following the first year of treatment

and follow-up, the actual numbers became too small to detect any reliable change in HRQOL scores. The analysis was therefore restricted to the first year of follow-up. Possible long-term complications of TMZ with a negative impact on HRQOL, like cognitive deficits due to RT, could therefore not be evaluated (Taphoorn 2004). This is, however, rather a subject for long-term surviving glioma patients, like low-grade glioma.

These data have been presented during the 29th Congress of the European Society for Medical Oncology (ESMO) Taphoorn et al 2004, Vienna, October 29–November 2 2004, and will be presented during the 9th Annual Meeting of the Society for Neuro-Oncology (SNO), Toronto, November 18 - 21 2004. As the SNO meeting co-incides with the Freiburg meeting of the EORTC QoL Group I decided to present the data in this issue of the newsletter.

| Baseline Characteristics     |            |                |               |
|------------------------------|------------|----------------|---------------|
| Variable                     | Treatment  |                | Total (N=490) |
|                              | RT (N=248) | RT+TMZ (N=242) |               |
| age                          |            |                |               |
| Medium                       | 558        | 556            | 557           |
| Range                        | 231-708    | 186-705        | 186-708       |
| N obs                        | 248        | 242            | 490           |
| mini mental state evaluation |            |                |               |
| Median                       | 290        | 290            | 290           |
| Range                        | 7.0 - 30.0 | 2.0 - 30.0     | 2.0 - 30.0    |
| N obs                        | 245        | 236            | 481           |
| sex                          |            |                |               |
| male                         | 152 (61.3) | 153 (63.2)     | 305 (62.2)    |
| female                       | 96 (38.7)  | 89 (36.8)      | 185 (37.8)    |

| Baseline Characteristics |            |                |               |
|--------------------------|------------|----------------|---------------|
| Variable                 | Treatment  |                | Total (N=490) |
|                          | RT (N=248) | RT+TMZ (N=242) |               |
| total resection          | 93 (44.5)  | 97 (47.5)      | 190 (46.0)    |

| Baseline Characteristics |            |                |               |
|--------------------------|------------|----------------|---------------|
| Variable                 | Treatment  |                | Total (N=490) |
|                          | RT (N=248) | RT+TMZ (N=242) |               |
| performance status       |            |                |               |
| 0                        | 104 (41.9) | 99 (40.9)      | 203 (41.4)    |
| 1                        | 110 (44.4) | 109 (45.0)     | 219 (44.7)    |
| 2                        | 33 (13.3)  | 34 (14.0)      | 67 (13.7)     |
| Unknown                  | 1 (0.4)    | 0 (0.0)        | 1 (0.2)       |
| corticosteroids at       |            |                |               |
| no                       | 63 (25.4)  | 78 (32.2)      | 141 (28.8)    |
| yes                      | 185 (74.6) | 164 (67.8)     | 349 (71.2)    |
| prior brain biopsy       |            |                |               |
| no                       | 179 (72.2) | 171 (70.7)     | 350 (71.4)    |
| yes                      | 69 (27.8)  | 71 (29.3)      | 140 (28.6)    |
| prior debulking surgery  |            |                |               |
| no                       | 39 (15.7)  | 38 (15.7)      | 77 (15.7)     |
| yes                      | 209 (84.3) | 204 (84.3)     | 413 (84.3)    |
| If yes:                  |            |                |               |
| partial resection        | 116 (55.5) | 107 (52.5)     | 223 (54.0)    |

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## Research Projects

### The Cross-Cultural Analysis project

Neil Scott and Peter Fayers  
Aberdeen University Medical School Scotland U.K.

The Cross-Cultural Analysis Project is a three-year project funded by the EORTC QLQ and the University of Aberdeen and carried out in conjunction with the Quality of Life Unit (QLU) in Brussels. The Project Advisory Group comprises: Neil Aaronson (Netherlands), Andrea Bezjak (Canada), Andrew Bottomley (Belgium), Alexander de Graeff (Netherlands), Peter Fayers (UK), Mogens Groenvold (Denmark), Michael Koller (Germany), Morten Petersen (Denmark) and Mirjam Sprangers (Netherlands).

**“...different cultures place emphasis on different aspects of their quality of life...”**

The project aims to determine whether there are any cultural differences in the way each item of the EORTC QLQ-C30 is answered, and also whether different cultures place emphasis on different aspects of their quality of life.

The major part of the first year of the project has involved the assembly of a large database of QLQ-C30 data. We have received data from 54 studies (trials and field studies) conducted by the EORTC, and we are grateful to the many EORTC groups that have allowed their data to be used and to Corneel Coens (QLU) for helping supply the data. In addition, data from a further 56 studies have been received from QLQ members and from a large number of individuals and organisations from around the world. We are especially grateful to everyone who has supplied their data for the project.

**“...database now contains data for over 30,000 individuals...”**

The combined project database now contains data for over 30,000 individuals, and 43 countries and 31 languages are represented. However, 80% of the data represents just seven North-

West European languages (German, Dutch, Norwegian, English, French, Danish and Swedish), thus we are now mainly looking for sources of data from Eastern Europe or countries outside Europe.

Initial analyses have been conducted for the emotional functioning (EF) scale. Differential Item Functioning (DIF) analyses have been used to determine whether or not any items in the scale function differently from other items in the EF scale, either when comparing linguistic or geographical groupings.

**“...possible translation and cultural differences...”**

If a significant DIF effect is found for a particular language it can be difficult to know whether this is a true cultural effect or due to non-equivalence of the translation to the original English. We are therefore using qualitative interviews to generate testable hypotheses. We have begun to conduct a number of structured interviews with bilingual people in which we ask about possible translation and cultural differences for each item that makes up the QLQ-C30. We have also been asking about the translation of the four response categories “not at all”, “a little”, “quite a bit” and “very much”, to explore whether the interval-scaling is expected to vary across versions. We hope eventually to interview at least two speakers of each of the most commonly-used translations. We would like to hear from anyone who is bilingual and is willing to be interviewed.

We are planning to look at all the scales that make up the QLQ-C30 as well as the site-specific modules. Future analyses will involve adjusting the results for possible confounding variables such as cancer site and stage. For many studies we have also obtained QLQ-C30 data from three timepoints (pre-treatment, on-treat-

ment and off-treatment) and plan to conduct analyses based on the change from baseline. Further analyses are also planned using structural equation modelling to determine if there are cultural differences as to the relative importance of different factors which contribute to overall quality of life.

We would be very pleased to hear from anyone who would be able to supply QLQ-C30 data for the project, particularly from Eastern Europe and non-European countries. Anyone supplying data will be fully acknowledged in all publications in which the data are used.

Please contact Neil Scott (n.w.scott@abdn.ac.uk) for further information.

## Publications

### Recent abstracts by QLG members

1. Koller M, West K, Bottomley A, Blazeby J. Translation Procedures For standardized quality of life questionnaires: The European Organisation For Research and Treatment of Cancer (EORTC) approach. Proceedings of the 10th International Society for Quality of Life Research; 2004 October; Hong Kong, Quality of Life Research, 13, 9, p.1501, 1326, Nov 2004.
2. Scott N, Fayers P, Bottomley A, Aaronson N, Bezjak A, de Graeff A, Groenvold M, Petersen M, Sprangers M, on behalf of the EORTC. Cross-cultural analysis of the EORTC QLQ-C30 Proceedings of the 10th International Society for Quality of Life Research; 2004 October; Hong Kong, Quality of Life Research, 13, 9, p. 1503, 1535, Nov 2004.
3. Efficace F, Therasse P, Piccart M, Coens C, Van Steen K, Welnicka-Jaskiewicz M, Cufer T, Lichinitser M, Shepherd L, Bottomley A. Predicting survival with health related quality of life scores in locally advanced breast cancer: results of an international randomised controlled trial. Proceedings of the 40th American Society of Clinical Oncology (ASCO) Annual meeting; 2004 Jun; New Orleans, USA. 23: p. 31, 618, Jun 2004.
4. Taphoorn M, Stupp R, Osoba D, Curschmann J, Kortmann R, van den Bent M, Mason W, Coens C, Eisenhauer E, Bottomley A, and behalf of the EORTC BTG, Radiotherapy Group and the NCIC. Quality of life from an International Phase III Randomised Controlled Trial Evaluating Health-related Quality Of Life in Glioblastoma Patients. 29th European Society for Medical Oncology Congress, October, 2004, Vienna, Annals of Oncology Supplements (in press)
5. Efficace F, Bottomley A, Osoba D, Gotay C, Sprangers MA, Flechtner H, Coens C, D,Haese S, Biganzoli L. Has the quality of health-related quality of life (HRQOL) reporting in cancer research improved over time? 29th European Society for Medical Oncology Congress, October, 2004, Vienna, Annals of Oncology Supplements (in press)
6. Bottomley A, Therasse P, Efficace F, Coens C, Gotay C, Welnicka-Jaskiewicz M, Cufer T, Dyczka J, Lichinitser M, Piccart M. Long term health-related quality of life (HRQOL) in locally advanced breast cancer (LABC) survivors: results from a EORTC-NCIC-SAKK randomized controlled trial. 29th European Society for Medical Oncology Congress, October, 2004, Vienna, Annals of Oncology Supplements (in press)

### Recent Publications by QLG members

1. JM Blazeby, T Conroy, A Bottomley, C Vickery, J Arraras, O Sezer, J Moore, M Koller, NS Turhal, R Stuart, E van Cutsem, S D'haese, C Coens, on behalf of the EORTC Gastrointestinal and Quality of Life Groups. Clinical and psychometric validation of a questionnaire module, the EORTC QLQ-STO22, to assess quality of life in patients with gastric cancer. European Journal of Cancer 2004 40: 2260-2268
2. V Kavadas, CP Barham, MD Finch-Jones, J Vickers, E Sanford, D Alderson, JM Blazeby. Assessment of satisfaction with care after in patient treatment for oesophageal and gastric cancer. British Journal of Surgery, 2004; 91: 719-723..
3. F Efficace, A Bottomley, V Vanvoorden, JM Blazeby. Methodological issues in assessing health-related quality of life of colorectal cancer patients in randomised controlled trials. European Journal of Cancer 2004; 40: 187-197.
4. JM Blazeby, J Nicklin, ST Brookes, K Winstone, D Alderson. The feasibility of quality of life assessment in patients with upper gastrointestinal tract cancer. British Journal of Cancer 2003; 89: 497-501
5. JM Blazeby, T Conroy, E Hammerlid, P Fayers, O Sezer, M Koller, J Arraras, A Bottomley, CW Vickery, PL Etienne, D Alderson, on behalf of the EORTC GI and QOL Groups. Clinical and psychometric validation of an EORTC questionnaire module, the EORTC QLQ-OES18, to assess quality of life in patients with oesophageal cancer. The European Journal of Cancer 2003 39; 1384-13948. V6.
6. Kavadas, JM Blazeby, T Conroy, O Sezer, B Holzner, M Koller, J Buckels on behalf of the EORTC Quality of Life Group. Development of an EORTC Disease-Specific Quality of Life Questionnaire for use in Patients with Liver Metastases from Colorectal Cancer. The European Journal of Cancer 2003; 39; 1259-1263.
6. CW Vickery, JM Blazeby, T Conroy, J Arraras, O Sezer, M Koller, D Rosemeyer, CD Johnson, D Alderson, on behalf of the EORTC QL Group Development of an EORTC Disease Specific Quality of Life Module for use in Patients with Gastric Cancer. European Journal of Cancer 2001; 37: 966-71.
6. JM Blazeby, JR Farndon, J Donovan, D Alderson. A prospective longitudinal study examining quality of life in patients with esophageal carcinoma. Cancer 2000; 88: 1781-1787.

## Protocols of the EORTC Quality of Life Group

### Open studies

| Study number | Coordinators                      | Brief title                                      | Study activation | Sample size | Number of patients on study September 2004 |
|--------------|-----------------------------------|--|------------------|-------------|--|
| 15011/30011* | Neil Aaronson<br>George van Andel | Field testing of prostate cancer module QLQ-PR25 | 03/2003          | 625**       | 610  |

\* This is a joint study between the Quality of Life group and the Genito-Urinary Group, it is fully managed in the Quality of Life Unit.

\*\* The initial sample size was 375. However, to obtain more balance within the geographical/linguistic categories (Southern Europe, Northern Europe, and Anglo-Saxon) and within treatment arms, the sample size was amended.  
Protocol closed as of 1st December 2004

### Closed studies

| Study number | Coordinators | Brief title  | Study activation | Sample size | Number of patients on study September 2004 |
|--------------|--------------|--|------------------|-------------|--|
| 15012        | Anne Brédart | Field testing of patient satisfaction module QLQ-SAT32 | 05/2003          | 768         | 792  |

## EGAM Meeting and Spring 2004 QOL Meeting

Brussels welcomed us on Thursday 22 April with a lovely sunny day. The weather was too good to take the tube so we sauntered through the spring sunshine to our hotel. We met up with other group members that evening at the magnificent Hotel Le Plaza theatre restaurant. The setting was splendid with beautiful gold tables lit by huge gold candlesticks laid out in the theatre. Dinner was for all the EORTC groups, so it was an excellent occasion to get to know people from other groups whom one would not normally meet. We had a fun and interesting evening chatting with members of the breast and prostate groups.

***"...from small acorns great trees can grow!..."***

The following morning we were at the Sheraton hotel for the joint meeting of all the EGAM groups. The Quality of Life Group took this opportunity to give an overview of the work of the

group, starting with a history of the group (1980's-2003) by Henning Flechtner. This demonstrated how from small acorns great trees can grow! Explanations of how the questionnaires are developed, translated and analysed followed. We were also updated on a number of the field studies. Andrea Bezak, Jane Blazeby, Galina Velikova and Neil Aaronson then gave us an insight into Quality of Life in clinical trials and clinical practice demonstrating the importance of this area of study. Mogens Groenvold and Morten Peterson completed the morning with "The future of QOL questionnaires". A demonstration of Computer Adaptive Testing, which, as a research nurse I am looking forward to using.

I have been attending the EORTC group meeting for about three years, but I still learned a lot. For my colleague, Teresa Massett, this was her first meeting, and she gained great insight into the ideals and principles of

*Joanna Nicklin Research Nurse Bristol UK*

the group and how it is organised with commitment to science based research and attention to detail.

We then lunched in the Sheraton with panoramic views over the city, followed by the business meeting for active members.

***"...Each group gave an update on their current work..."***

Valina Velikova chaired the module developers meeting in the afternoon. More people attended than had been expected which is very encouraging for the group. Each group gave an update on their current work and there was much lively discussion.

Dinner for the group was at La Quincaille Brasserie, which we were told is a favourite haunt of the European members of parliament. I did not recognise any from the UK, but maybe other members saw theirs!

The building is old with dark wood panelling which gave a wonderful atmosphere. During the evening Jane Blazeby and Peter Fayers took the opportunity to thank Teresa Young for all her hard work for the group and presented her with typical Belgian gifts of lace and chocolate. Teresa gave a humorous and witty account of

her time as group secretary, but it made us all appreciate how much work she has put in on our behalf over the past few years.

The following day the parallel sessions were held, with each group getting together to discuss their progress and future plans.

We then bid farewell to Brussels, and it was not until I got off of the plane that I realised that I had been travelling with Robin Cook, a Member of Parliament, so I did get to see a famous political face after all!

## News

**Neil Scott** has been awarded a New Investigator Scholarship from ISOQOL of 750 USD to contribute towards attending the ISOQOL meeting in Hong Kong. At the meeting he will be presenting the preliminary results of the Cross-Cultural Analysis project. The talk will focus on whether there are any translation or cultural differences in the way people answer the QLQ-C30 questionnaire.

On August 27th, 2004, during the 7th World Congress of Psycho-Oncology

held in Copenhagen, **Neil Aaronson** of the Division of Psychosocial Research and Epidemiology (Division XII) received the Bernard H. Fox Memorial Award from the International Psycho-Oncology Society. Bernard Fox was an epidemiologist and biostatistician at the U.S. National Cancer Institute (NCI), and later at the Boston University Faculty of Medicine. He was one of the founders of the field of psycho-oncology, and had a lifelong commitment to advancing the scientific quality and rigor of research in

the field. The award given in his name is in recognition of lifetime achievement in psycho-oncology research. Neil was recognized for his scientific work, in general, and in particular for his sustained contribution to the development and application of methods for assessing the quality of life of patients with cancer. The award was presented following the Bernard Fox Memorial Lecture. In his lecture, Neil focused on the application of standardized quality of life assessments in daily clinical oncology practice.

## Congratulations

We proudly announce that our former Chairman of the EORTC Quality of Life Group, Professor **Peter Fayers** from Aberdeen University Medical School, has been elected as the new Chair of ISOQOL.

We congratulate him on this prestigious position.

**Fabio Efficace** who has been working at the EORTC Quality of Life Unit as a Lady Grierson Fellow for Quality of Life Research has successfully defended his PHD thesis entitled *The Value of health related Quality of Life Assessment in Cancer Clinical Trials* at the University of Amsterdam, Department of Medical Psychology. His supervisors were Professor J.C.J.M. de Haes and Professor M.A.G. Sprangers.

**Pernille Tine Jensen** has successfully defended her Ph.D entitled *Health-related quality of life after cervical cancer*. The Ph.D. study was carried out at the Department of Gynecology, Rigshospitalet, Denmark and at the Department of Palliative Medicine, The Research Unit, Bispebjerg Hospital, Denmark and comprised five scientific papers.

## Frequently asked Questions (FAQ)

For more information on the Quality of Life Group and its activities, please visit our website:

[www.eortc.be/home/qol](http://www.eortc.be/home/qol)

Additional details on obtaining the EORTC QLQ-C30 or other EORTC modules for use in your study can be found in the questionnaires section on the website.

Academic users can download the questionnaires and the user's agreement directly from:

[www.eortc.be/home/qol/downloads/default.htm](http://www.eortc.be/home/qol/downloads/default.htm)

For industry sponsored studies you are kindly requested to contact Ms Karen West:

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