Contents:

Our Collaboration with...

EU Clinical Directive 2001/20

Cardiovascular Considerations with Antiemetic Treatment

Upcoming Events

Society News Updates

Theme: Cancer in the Elderly
Letter from the Editor

Welcome to the Spring 2004 issue of the EONS Newsletter!
The theme covered in this issue is Cancer in the Elderly. Cancer is primarily a disease of older adults. Over 50% of cancers occur in individuals older than age 65 years and this percentage is expected to continue to rise. But what do you know about cancer in the elderly? Do elderly patients with cancer have specific needs? Are older patients more vulnerable to therapeutic complications? Do they need more supportive care? Are older patients treated with respect and dignity? The Oncology Nursing Society (ONS) and the Geriatric Oncology Consortium (GOC) acknowledge the unique needs of older adults and the nature of cancer in older adults including implications for an aging society in a recently published position paper. The position paper illustrates the unique situation of this population and recommends the following changes in attitudes and policies:
- Elimination of ageism in research, education, care, and public policy as it stands against core American values of autonomy and choice;
- Education of students and practicing clinicians across health disciplines in both oncology and elder care on the unique physiologic, developmental, psychological, emotional, social, and spiritual needs of older adults with cancer and their families;
- Incorporation of measurement of age beyond chronology to include biologic, functional, and personal dimensions;
- Acknowledgement of and assessment for risks related to declining functional reserve as part of normal aging;
- Redefinition of optimal outcomes to extend beyond disease-free survival and to include comorbidity, function, and quality of life;
- Full and equal access to cancer care across the trajectory (e.g., screening, diagnosis, treatment, rehabilitation, palliative care, survivorship, wellness care);
- Interdisciplinary teams and comprehensive geriatric assessment to optimize treatment planning, access, and resulting outcomes;
- Integration of geriatric oncology care within and across care settings and delivery systems, including primary care, acute and critical care, and long-term institutional and home care and hospice;
- Increased funding for basic, clinical, and translational research in aging and cancer;
- Improved education, outreach, and incentives for older adults to participate in clinical research;
- Advocacy, policy, and legislation that recognizes the demographic implications of aging and cancer and mandates necessary research and development of appropriate health and social services.

The position paper is timely and relevant. It can be found in entirety at the ONS web site (www.ons.org). Read it, reflect over the content and start a discussion at your working place. Maybe it is time for a similar document, if not already in existence, from your national perspective!

Keep the lines of communication open! Please do not hesitate to contact members of the EONS Board or members of the Newsletter Editorial Board with comments, suggestions . . . or perhaps article contributions!

Sincerely, Karin

Upcoming Events

29-30 April 2004, Liverpool, UK. Cancer in the Elderly. European School of Oncology Advanced Course. Information: ESO, Tel.: +39 02 4335 9611, Fax +39 02 4335 9640, e-mail: teaching@esoncology.org, www.cancerworld.org

13-15 Mai 2004, Kartause Ittingen, Switzerland. 9. International Seminar: Palliative Care of the Cancer Patient. European School of Oncology, German language programme. This course will be conducted in German and has received EONS accreditation. Information: ESO Secretariat, Tel.: +41 71 243 0032, Fax: +41 71 245 6805, e-mail: eso-d@sg.zetup.ch

14-15 June 2004, Edinburgh, UK. 9th International Paediatric Haematology and Oncology Update Meeting. Information: IPHOUM 2004 Conference Secretariat, Index Communications Meetings Services, Tel: +44(0) 1794 511331/2, Fax: +44 (0) 1794 511455, e-mail: icms@indexcommunications.com, www.iphoum.com

8-12 August 2004, Sydney, Australia. 13th International Conference on Cancer Nursing. The conference is organised in partnership between ISNCC and the Cancer Nurses Society of Australia (CNSA). For further information contact: Conference Office, Tel.: +61 2 9238 3309, Fax: +61 2 9238 3308, e-mail: conference@isncc.org

18-19 September 2004, Oslo, Norway. SIOP XXXVI Congress. Leukaemia and Lymphoma: Recent progress in childhood cancers. Information: www.siop.nl
Collaborative Partnerships: EONS and The European School of Oncology

EONS has established relationships with a number of professional societies and organisations who are also involved in the fight against cancer. Although the collaboration takes on various forms and activities, EONS recognises that the development and maintenance of collaboration is of strategic importance in assisting the Society to achieve its goals. One of the Society’s oldest and most valuable alliances is with the European School of Oncology headquartered in Milan, Italy. Following is a short description of ESO.

The European School of Oncology – How it all began
ESO was founded by Umberto Veronesi and Laudomia Del Drago in 1982, with the aim of contributing to the reduction of deaths from cancer due to late diagnosis and/or inadequate treatment. ESO’S mission is reflected in its motto “Learning to Care”, which stresses the concept of studying and learning and also of caring for the patient in a global sense. By improving the skills of all health professionals dealing with cancer patients, ESO shortens the length of time needed to transfer knowledge from advanced research technology with humanism in care.

Leading oncologists from around the world have played a key role in the foundation of the School including Michael Peckham from London, Franco Cavalli from Bellinzona, Louis Denis from Antwerp and Bob Pinedo from Amsterdam. Now, after over 20 years of existence, ESO is the oldest and most structured organisation exclusively dedicated to increasing the knowledge of health professionals in all fields of cancer medicine under the auspices of an international scientific committee and advisory board.

Learning to Care
“Learning to Care” is the motto of the School. ESO has always given great importance to the learning process. Since attention is focused on the clinical aspects of the cancer problem, care is the ultimate goal of the School’s commitment to improve the oncological skills of health professionals. Care and treatment are of paramount importance because ESO believes in the holistic approach to the cancer patient. “Learning to Care” is also the name of an ambitious special three year educational programme made possible by grants provided by leading pharmaceutical companies as sustaining members of ESO.

ESO in the Next Decade
ESO has identified three main areas on which it wishes to build over the next few years: cultural, geographic and professional. The importance of advocacy and oncology nursing has been identified by ESO. In addition to a close collaboration with EONS, ESO also works with Europa Uomo and Europa Donna. Future collaborative events include educational symposia where a medical doctor, a nurse and a patient representative will speak on different areas of oncology. The Internet and palliative care are key areas that ESO is developing with the help of leading oncological institutions.

ESOs’ partners help to implement teaching programs throughout the world. In the future, particular attention will be paid to offering education in Eastern European countries. In the past, educational symposia in the Balkans and Moscow were positively evaluated and plans are underway to hold annual events in these areas. Further, the School plans to expand educational offerings in the Middle East and Latin America.

To enhance professional collaboration, ESO plans to develop closer ties with family practitioners. Further developing the oncology expertise of this group is viewed as crucially important to attain swift, accurate diagnosis of cancer for patients throughout Europe. Additionally, ESO plans to reach out to medical students to stimulate their interest in entering a career in oncology.

Further information on the European School of Oncology as well as a schedule of upcoming events can be found by visiting their website at www.cancerworld.org.
Cancer and Older People
By Mrs Candy Cooley, Head of Division Cancer and Palliative Care,
University of Central England Birmingham & Chair RCN Cancer Forum

Introduction
Demographic trends show clearly that older people living in the UK will increase in actual numbers and as a percentage of the total population in the next 20 years (Office for National Statistics, 1999). The rise will be particularly seen in the 85+ group. For the nurse working in any setting it is therefore likely that she or he will see more and more clients in the 85+ group as time goes by. Older people with cancer face a variety of problems, as they are often likely to have co-morbid conditions that may mask presenting symptoms and influence treatment options (Yip & Harper 2000). The older person may also suffer from some of the myths surrounding ‘cancer and the elderly’. For example it has been clearly identified that there is limited research into treatment options, they are under-represented within clinical trials and have adverse outcomes when compared, on a stage-to-stage comparison, with the younger patient (Balducci 1999; Fentiman et al 1990; Bailey 2001). However this does not mean that the older person should receive exactly the same treatments as the younger person but that physiological age and performance status is more important than the chronological age (Corner 1993, Yip & Harper 2000). In order to make informed clinical decisions regarding the care of older people with cancer it is imperative that nurses work from a good understanding of all aspects of the ageing process as well as a sound understanding of the needs of the individual with cancer (Cooley & Coventry 2003).

Causes & Presentation
So why does the incidence of cancer increase in the elderly? Current thinking focuses on the fact that the development of cancer takes time and that the identified patient is "a susceptible host". It is a multi-step process that can last for more than 20 years before clinical symptoms become evident (Sporn 1991). Several factors make the older person more at risk. Firstly alterations in the immune system and DNA repair-efficiency both decrease with age which may result in decreased protection (Amador & Cohen 2000) and secondly the impact of a lifetime of bombardment from potential environmental toxins may also take its toll. The signs and symptoms of cancer can be vague and non-specific in any age group, but this is even more common in the older adult when the clinical presentation may be slow to develop and masked by other physical changes. In the post-menopausal woman cancers such as breast or cervical may have very different clinical presentation and development than in the younger woman. Cervical cancer develops more rapidly in older rather than younger women. However with breast cancer, which is oestrogen-receptor positive, growth is likely to be much slower (Holmes 1989). The most important thing for the nurse is to use observation and communication in identifying whether symptoms are common to that patient eg large mole on back or whether something is new or a cause for concern. Older individuals and unfortunately health care professionals may dismiss symptoms as a sign of "old age" and late presentations are very common (Berkman et al 1994) leading to significantly higher mortality for some cancers.

A comprehensive elderly care assessment done by a multidisciplinary team which includes a specialist in elderly care is imperative for a complete understanding of the needs and risks of the patient (Balducci & Extermann 1999, Amador & Cohen 2000). Specific diagnostic techniques need to be tailored to the physical and psychosocial needs of the patient. However decisions not to fully investigate symptoms must have a sound clinical, ethical and moral basis. The belief that the older person would not tolerate the treatments for cancer is unfounded (Samet 1986 Mor et al 1994) and therefore treatment decision must be based on a full investigation and appropriate staging and prognostic indicators.

Treatment Choices
These are based on a number of factors that include the physical state of the patient as co-morbidity can have an impact on treatment tolerance. Also the psychological condition and performance status and the diagnostic and prognostic indicators as well as the wishes of the individual patient must be taken into account. Treatment decisions are based on the stage, type of cancer, sensitivity of the cells and performance status of the patient. Decision-making must be based on a multi-professional approach in which the treatment decisions are based on the best evidence. Unfortunately the older person is under-represented within clinical trials (Hutchins et al 1999), most clinical trials involve younger adults and this may not translate in decision making for the older adult (Yip & Harper 2000)

Some treatment choices are based on decisions surrounding assumptions rather than fact. Berger and Roslyn (1997) identified that cancer surgery should not be determined by chronological age and they went on to stress the importance of preparation and management of the post-operative complications of major surgery. Ampil et al (2001) demonstrated that extensive surgery for stage 3 and 4 head and neck cancer in selected elderly patients achieved long-term disease-free survival.

It has also been clearly reported that patients in their 70’s and 80’s can tolerate a full dose of radiotherapy. Olmi et al (1997) state that radiotherapy can be used in curative or palliative treatment in nearly all cases with minimal toxicity. Patients who are undergoing radiotherapy may need accommodation close to the radiotherapy unit as they will usually be having treatment everyday for up to three weeks. Older patients and their carers often find the travelling more arduous than the treatment and its side effects. Skin care is a particularly important issue due to the ageing process, which delays the healing process and lacks a defence against radiation damage.

Chemotherapy needs to be calculated on the individuals’ ability to deal with the toxicity and breakdown products of cell damage (Souhami & Tobias 1998). Chemotherapy that is cardiotoxic or nephrotoxic may need to be limited in the older person if they already have problems with their cardiac or renal systems. In the older patient hormone therapy may be the treatment of choice. The treatment does not necessarily aim to cure the patient but rather to control the growth the development of the cancer in such a way that clinical symptoms are minimised or non-existent. For the elderly patient this may be a compromise between doing nothing and potentially aggressive treatment.

One of the most important issues in deciding active treatment, for any patient, but more importantly in the elderly patient is that the

It is of little use to have a patient live for 3 extra months when 11 weeks were spent in hospital.
morbidity of the treatment should not destroy quality of life (Cooley & Coventry 2003). It is of little use to have a patient live for 3 extra months when 11 weeks were spent in hospital. Commencement and continuation of treatment must be based on the premise that it is for the benefit of the patient. A multi-professional approach to the management of the side effects of treatment will ensure that symptoms are managed well. The elderly for example, especially those over 85, are at an increased risk of poorly managed cancer pain (Maxwell 2000) even though with correct assessment and carefully calculated opioids pain can be well managed. The involvement of a pain consultant, palliative care team and the specialist in gerontology should ensure that the patient receives the best care available.

Conclusion
The importance of utilising the specialist knowledge of those caring for the older person and those caring for cancer patients, in caring for the older person with cancer is imperative in ensuring the older person with cancer gets access to the most appropriate care. As the population over 80 continues to increase so the number of patients requiring cancer care will also increase. As the older population lives a happy healthy and successful life well into their 80’s and 90’s decisions based on chronological age not only become outdated but ethically suspect. The under-representation of the older person within clinical trials needs to be addressed if the care given is to be based on sound evidence and good research.

Finally the most importance aspect of care is to include the older person in decision making, allowing choice based on sound facts and communication that recognises respect and individualism in care.

The Rights of Elderly Cancer Patients
Kathy Redmond, MSc RGN, Consultant in Oncology Nursing, Redmond Consulting

Even though most individuals diagnosed with cancer are elderly, they often receive sub-optimal cancer care. In fact there is an inverse relationship between increasing age and the likelihood of proper treatment despite evidence that otherwise healthy elderly cancer patients can benefit from treatment to the same degree as their younger counterparts. Under-treatment and sub-optimal practices mean that older patients are dying unnecessarily from cancer. In addition, elderly patients’ right to information and involvement in decision making are not always upheld in spite of the fact that a significant number of older people want to share or play an active role in decision making. Some health professionals fear that disclosing the truth about prognosis may induce unnecessary anxiety and despair and as a result, they deliberately withhold information, particularly when they lack the skills necessary to deal with patients’ emotional reactions. This approach clearly compromises a patient’s ability to make an informed choice and therefore, has no place in contemporary cancer care. The patient can, of course, make the choice not to receive any information – the key is that the patient’s preference for amount and type of information is respected. In addition, health professionals’ attitudes toward the value of particular treatment options frequently differ from those of their patients. Indeed, attitudes toward cancer treatment vary greatly between patients – some place great value on maximizing their chance of cure whereas others are more concerned about achieving a good quality of life and relief of symptoms. Evidence is emerging that many older patients are very willing to undergo intensive/aggressive treatment in order to cure or control their cancer and therefore there is a clear risk of error if the clinician makes assumptions about the older patient’s attitude towards treatment - clearly, as with information preferences, patient attitudes towards treatment should be elucidated on an individual basis. There are many barriers to optimal elderly cancer care. Ageist attitudes abound and are reinforced by the huge knowledge gap about how to care for elderly cancer patients – few health professionals have formal training in geriatric medicine and its application to cancer care. Elderly people also hold fatalistic attitudes towards cancer and its treatment that are fuelled by a life experience and results in a variety of myths and misconceptions about the benefit of and side effects of cancer treatments. Such attitudes are not counteracted easily since elderly people are less likely to have access to the Internet, more likely not to understand the language of the Internet – English – and unfortunately few educational materials are developed with the needs of elderly patients in mind. Younger family members can help elderly relatives overcome the digital divide, however, it is not unknown for some to act as powerful gatekeepers to information thereby preventing an older person accessing essential information.

In general, elderly people have difficulty in advocating for themselves and it is not surprising that when confronted with a life-threatening illness they find it difficult to demand equity of access to optimal cancer care. However, the professional community can do much to promote the rights of elderly cancer patients. Ageist and fatalistic attitudes can be challenged through public and professional education. Education and training is required to equip health professionals with the skills they need to provide optimal care for elderly patients and ensure that older patients receive treatments tailored to their physical needs and social circumstances. A concerted campaign is required to overcome the barriers elderly people face in accessing information. Finally and awareness campaign is needed to highlight the plight of elderly cancer patients and to call the well elderly to action to campaign against the inequities and discrimination confronted by elderly cancer patients.

Call for illustrations

Dear Members,

The Editorial Board of the EONS Newsletter does its utmost best to create an attractive quarterly publication for oncology Nurses in Europe. For every issue, it is a real quest to find suitable illustrations for this Newsletter. We would like to encourage every nurse to send in some nice pictures (preferable electronic) on next issue’s theme: Quality of Life.
During many years of nursing practice I have been in the fortunate situation to have worked with many good colleagues. Not only from my own profession, but from a wide range of other professions within the health care system. From these many years working clinically I have learned, that only if we work to be the best within our individual professions, and endeavour even harder to understand each other and work together, only then, are we sufficiently qualified to take care of the patients.

During the last three years I have been in the even more fortunate situation of being able to complete my education with a possible Ph. D. degree, which I do hope to achieve within the next year or so. My main subject during these last years has been related to cancer in elderly persons. I have made some observations which have been an inspiration to my work, and which I presently is incorporating in articles and more traditional academic work which now fill out my days instead of the genuine clinical work I actually miss very much.

I hope that some of these observations can be of inspiration to colleagues working with elderly cancer patients, and that I can contribute to the development of nursing and to an improved future situation for our elderly cancer patients. I have read quite a number of articles on subjects related to cancer and the elderly. I can hardly remember any (including my own first drafts) which have not set-out by explaining how many more elderly people there will be in our societies over the next decades, how a tremendous burden they will be to the health care system because they get older and older, and attract more and more diseases – specifically the age related diseases. Also arguments as: watch out for the new elderly, they are the best educated, the best organised, the best line (most often is 70 years used as a de facto deadline) are generally excluded from clinical trials. I am still analysing my own data, and I am still reading others studies, but until now I have found absolutely no proof or even justification that a specific chronological age by any standard should be the argument of excluding persons with cancer from treatment. Chronological age is of cause an indicator, but age is a process with a highly individual trajectory for each person, and an individual assessment is needed to be able to make a true evaluation of the needs and prospects of each person with cancer. This is valid not only for the physicians but for sure also for the nursing professions. This is not as some of my colleagues seem to believe an overwhelming and unrealistic resource spender. There are reasonable straightforward instruments available (such as Comprehensive Geriatric Assessment – CGA), which can be modified easily for any local clinical need. Indeed, such a systematic evaluation of the individual trajectories and needs of the patients, can generally contribute to a more targeted and more resource efficient attention to and treatment of the elderly persons with cancer in our health care system.

As a part of my doctoral studies I have systematically interviewed a large number of elderly persons with cancer and their close relatives. I am convinced that there is a need for systematic knowledge on the role and possibilities of relatives to the patients. Also for the nursing profession to be able to support these relatives in an adequate and appropriate way. This need is underlined with the shift from in-patient to out-patient based treatment. In an out-patient situation, relatively more caring is done by next of kins and/or friends to the patient. The burdens carried of these persons are then higher, and their possible need for support supposedly larger.

The development in recent years from an in-patient based treatment to an out-patient based system has also underlined the need of a more systematic evaluation of the individual trajectories and needs of the patients. In the in-patient situation there is more time to notice and observe the needs of patients. In the out-patient situation all professions in contact with the patients have limited time and to a larger extend also seems to be more focused on their own specialised observations, and to a lesser extend, on the overall situation and needs of the elderly person with cancer.

In working with issues like Quality of Life and the symptoms complaints of the patients offered some kind of cancer treatment, I am among other matters looking at how the patients perceive their situation and what are the possible drivers for an overall better situation for the elderly person with cancer. I do of cause hope to find, that we nurses (as a minimum) are capable of relieving some of the unpleasant symptoms related to the treatment offered to the cancer patients. We nurses would probably have to think carefully about our work focus and the development of our research if we are not even capable of improving our patients’ most obvious problems with dyspnoea, fatigue, insomnia, insomnia and the like.

I am somewhat worried over the tendency that the nursing profession and its development seems to be so close linked to the development of the individual diagnose related disciplines of the physicians. Especially in a situation where the clients of the health care systems show indications of difficulties in understanding and overviewing the system, and feel somewhat alienated and treated as a diagnose and not as an actual human being. The nursing profession could be one of the few professions with the possibility to re-establish a concern for the human being as such, and the profession which could secure a truly multi-disciplinary approach to cancer patients. The specialisation of the treatments needs to go hand-in-hand with a true multidisciplinary and holistic approach to the individual patient. The nursing profession could spearhead such a development towards a new kind of “personification” to the health care system’s general approach to its clients. This would be specifically relevant in relation to elderly persons with cancer.

Correspondence to: bente.appel.esbensen@inet.uni2.dk
Cancer in the Elderly: A Task for Oncology Nurses

On Friday, November 21, 2003 a special nursing symposium took place in Rome during the conference of the International Society of Geriatric Oncology (SIOG). EONS was invited to organise, in collaboration with ONS, a symposium entitled “Cancer in the Elderly - impact for nursing”. Giel Vaessen (EONS) and Julie Meyer (ONS) succeeded in bringing together an excellent panel of expert lecturers. Topics covered at the symposium included: Cancer in the elderly: an aging dilemma (Nora Kearny, UK); The rights of elderly cancer patients (Kathy Redmond, I); Establishing an oncology nursing research agenda for the elderly (Deborah Boyle, USA); The 3 D’s: Delirium, Depression and Dementia in elderly cancer patients: implications for nursing care (Koen Milissen, B); The silent syndrome of acute onset, poses a common (prevalence rates reported from 8% to 12% depending on the stage of cancer disease) and multifactorial complication in elderly oncology patients (Lawlor et al., 2000; Ljubisavljevic et al., 2003). Delirium is manifested in patients by a reduced ability to focus, sustain, or shift attention; a change in cognition such as memory loss, disorientation, or language disturbance; or the development of a perceptual disturbance, that develop over a short period of time (usually hours to days), and tends to fluctuate over the course of the day (APA, 1994). It is a highly distressing experience not only for patients, but also for spouses/caregivers and nurses caring for these patients. Delirium impedes communication with family members and caregivers at a time when it is often most desired (Breitbart et al., 2002; Lawlor et al., 2000; Ljubisavljevic et al., 2003). Further, it has been demonstrated that delirium contributes to poor clinical outcome (increased morbidity and mortality) and interference with pain and other symptom assessment and control (Bruera et al., 1992; Francis & Kapoor, 1992; Lawlor et al., 2000).

Because of its clinical impact and potential reversibility (Lawlor et al., 2000 and Ljubisavljevic et al., 2003 report 50% to 85% of episodes in oncology inpatients are reversible, respectively), efforts for prevention or prompt treatment are essential, starting with early recognition and correct diagnosis of the syndrome. However, delirium is frequently underdiagnosed by nurses and medical doctors and transient changes in cognition frequently are attributed incorrectly to dementia or depression (Farrell & Ganzini, 1995; Pompei et al., 1995).

Dementia, like delirium, can have prominent memory and cognitive deficits, but typically has an insidious onset, a chronic, progressive course, and is relatively stable over short periods of time (Milisen et al., 1998). Individuals with dementia usually do not demonstrate a reduced level of alertness until the terminal stage. Since an individual’s alertness and attention tend not to be affected, many are able to participate in therapies that are appropriate for their level of impairment. Complicating the differential diagnosis of delirium and dementia is the superimposition of delirium upon dementia. In this instance, the clinical feature of each condition will coexist. It is the sudden and fluctuating deterioration of cognitive or functional ability that is suggestive of delirium superimposed upon dementia (Rummans et al., 1995).

Depression and delirium, especially the hypoactive variant, have very similar presentations: withdrawal, slowed speech, sleep disturbances, abnormally slowed psychomotor activity, apathy, and fatigue (Milisen et al., 1998). Depression, however, differs from delirium in that the impairments in attention and cognition are not pronounced, onset is more gradual, perceptual disturbances are uncommon, and the patient is alert (Farrell & Ganzini, 1995).

Thinking in a depressed individual tends to be intact, although the person may verbalize hopelessness or helplessness. Dementia and depression should be included in the differential diagnostic workup of the symptoms presenting as delirium in elderly oncology patients. However, nurses and medical doctors often inaccurately and incompletely evaluate the changes in a patient’s cognitive functioning (Milisen et al., 2002). Yet, failure to diagnose delirium limits attempts for prevention or early intervention, thus contributing to the risk of the aforementioned distress experienced by patient and family and poor clinical outcomes associated with delirium.

Therefore, use of standardized assessment instruments for the routine and systematic assessment of changes in overall cognitive functioning [e.g. Mini-Mental State Examination (Folstein et al., 1975) and 5-item Geriatric Depression Scale (Rinaldi et al., 2003)] and detection of delirium [e.g. Delirium Observation Scale (Schuurmans et al., 2003) and the Confusion Assessment Method (Inouye et al., 1990)] could guide the prompt and accurate diagnosis of delirium.

Finally, health care workers need to recognize both the multifactorial nature and reversibility of delirium. Although in some cases the presence of delirium can signal impending demise, in other cases delirium can be reversed by treatment of underlying reversible causes (e.g. opioid toxicity, dehydration, infection, medications, metabolic disturbances). This may result in precious time spent with family members (Lawlor & Bruera, 2002).
EONS News - Spring 2004

Susan G. Komen Breast Cancer Foundation supports Spring Convention
The Susan G. Komen Breast Cancer Foundation is pleased to announce the awarding of a grant in the amount of $10,500 to EONS to provide 10 travel scholarships to the 4th EONS Spring Convention. For more than 20 years, the Susan G. Komen Breast Cancer Foundation has been a global leader in the fight against breast cancer through its support of innovative research and community-based outreach programs. Working through a network of U.S. and International Affiliates and events such as the Komen Race for the Cure®, the Komen Foundation is fighting to eradicate breast cancer as a life-threatening disease by funding research grants and supporting education, screening and treatment projects in communities around the world. EONS extends appreciation to the Komen Foundation for the generous grant which supports the educational activities of the Society.

Aliza Yaffe Recipient of ONS International Award
The 2004 ONS International Award for Contributions to Cancer Care has been awarded to EONS member Aliza Yaffe. The award recognises Aliza’s outstanding contributions to the improvement of cancer care in the State of Israel. EONS congratulates Aliza on her receipt of this prestigious award and wishes her continued success in her efforts to advance cancer nursing in her homeland, in Europe and at the international level.

FECS Multidisciplinary Newsletter
The Federation of European Cancer Societies (FECS) has launched a multidisciplinary scientific newsletter aimed at the 18,000 members of societies represented under the FECS umbrella. This newsletter has been under discussion for some time and the first one is planned to be launched in April 2004. The intention is that the newsletter will act as a brief ‘news-flash’ to spread information on recent developments and achievements between all disciplines involved in the fight against cancer. To ensure the newsletter is relevant, FECS has solicited the input of nominated experts from each of its 17 member societies. These experts have volunteered to give their time to liaise with FECS to provide news and information regarding new developments in their field of activity. The FECS representatives on the FECS newsletter experts group are Jan Foubert and Karin Ahlberg. If you have any suggestions for articles for the FECS newsletter please contact the EONS Secretariat. The newsletter will be published on a quarterly basis and available as a PDF document which can be downloaded from the FECS website or the websites of the societies that FECS represent.

FECS to Launch Newsletter directed at Patients
In keeping with its mission to disseminate information on cancer, FECS has decided to develop a patient-focused newsletter which will be written in layman’s language and distributed to cancer patients, cancer leagues as well as lobbyists and politicians working in health care capacities. The idea for the newsletter stems from the knowledge that patients are keen to receive information about cancer and that FECS has a responsibility to supply reliable and accurate information to interested individuals. This exciting and timely initiative is in the developmental stages. EONS will keep its members informed on the newsletter’s progress.

Membership Update
Did you know? EONS now boasts an individual membership of 260! Additionally, 26 national cancer nursing societies from 23 countries are members in EONS. A hearty welcome is extended to the Lithuania national cancer nursing groups which recently joined EONS as a full member. Fourteen organisations and institutions are Associated Members of the Society. The oncology nursing section of the Slovak Association of Nurses and Midwives will join EONS ranks in April 2004. A request has been received by the SIOP Nurses Group to become an EONS members. Recent efforts to attract corporate members have been successful: to date there are 5 Sustaining Members including Amgen, Astra-Zeneca, Novartis, Nutricia, and Roche.

If you are not an individual member of EONS, think about becoming one – the benefits will surely enhance your professional career.

Contact the EONS Secretariat for membership information.

Accreditation Update
The EONS project, TITAN (Training Initiative in Thrombocytopenia, Anemia and Neutropenia) has been awarded EONS Accreditation. The course, supported by an unrestricted grant from Amgen, is aimed at improving the prevention, detection and management of haematological toxicities in patients with cancer through education and exchange of best practice. The first pilot testing of this multi-centre project (a full description of the initiative was provided in the Winter 2003 issue of the EONS Newsletter) was conducted in Dublin in March 2004. The TITAN programme includes pre-course work, attendance at a short course, and a follow-up dissemination project. In addition to Ireland, pilot testing will be conducted in France and The Netherlands.

Jan Foubert will officially launch the project during a presentation to be held on Saturday, April 17th at the EONS 4th Spring Convention.

Attention EONS Advisory Council Members
Please be advised that an Advisory Council meeting will take place on Saturday, 4 September until Sunday 5 September 2004 in Brussels. Materials for the meeting will be mailed in due time. The Secretariat requests that Advisory Council Members reserve the date in their calendars.

ECCO 13: 30 October - 3 November 2005
Preparations are ongoing for the next ECCO conference to be held in Paris. Nursing Programme Chair, Jan Foubert, has been busy selecting topics for plenary sessions as well as contacting qualified and dynamic speakers to disseminate their expert knowledge as invited speakers. Important dates and updates on the planning progress can be found at www.cancerworld/eons.

PREVIEW: 5th EONS Spring Convention
It’s never too early to mark your calendars for the 5th EONS Spring Convention to be held from 20-22 April 2006 in the historic city of Dresden, Germany. The theme for the conference will be “Cancer in the Elderly: New Developments, Changes, and Implications for Nursing”. Yvonne Wengström, Chairperson, Organising Committee, stresses that the conference will concentrate on the newest developments and issues which impact on the management of care for this steadily growing number of patients.

Watch www.cancerworld/eons for further information on the conference.
Challenges of the Clinical Trial Directive

By K. Vandendael, Director of FECS

Background
The EU Clinical Directive 2001/20/EC aims at ensuring a high level of protection for patients enrolled in clinical trial as well as simplifying and facilitating the implementation of regulatory provisions governing such trials across the EU. Accordingly, specific obligations are imposed by the Directive and implementing guidelines on the parties involved, especially the Sponsor, the Manufacturer, the Investigator, the Competent Authorities and the Ethics Committees. Many if not all of the measures ensuring the protection of the clinical trial participants were previously in effect through Good Clinical Practice Guidelines (e.g. the ICH guidelines). However, such guidelines had not full legal power.

Although the Clinical Directive briefly consider ‘Non-Commercial Clinical Trials’ to allow some simplification of the labeling procedure for investigational medicinal products (IMP), it generally makes no distinction between clinical trials conducted by commercial or non-commercial sponsors (e.g. academic centers or network, investigator-sponsored trials). More importantly, it thereby fails to distinguish clinical trials investigating new medicinal products (most often sponsored by commercial entities) from clinical trials investigating best medical practices with available therapies (most often sponsored by academic networks). A distinction would have been appropriate as the purpose, incentives, means, and the benefits and risks for the clinical trial subjects clearly differ depending on the nature of clinical trials. Only ‘non-interventional trials’ are out of the scope of the directive (i.e. epidemiologic, observational trials).

Although the practice of Good Clinical Practice were standard in all Member States, only a minority of Member States had previously codified the obligations of the different parties and the involvement of the competent authorities as now imposed by the Directive. National implementation is therefore a matter of current debate, with possibly divergent views between Member States. Whatever the outcome of these discussions, it is beyond doubt that in most, if not all, Member States the administrative and other obligations associated with the conduct of clinical trials will increase considerably, may be especially for academic and investigator-sponsored trials that used to function under different operational structures than commercial trials. As economic impact analysis was done for this Directive (this was not common practice at this time), the exact consequences on academic research are not well evaluated. It is clear however that the adaptations will be very costly, which will necessarily result in a reduction of non commercial trials and/or more dependence of clinical research to commercial sponsors. This was certainly not the intention of the authorities.

Practical challenges for non commercial research
All the consequences of the Directive for non commercial research have not yet been identified, especially as uncertainties remain with regard to National implementation and no practical experience exists under the new system. Therefore, the following list does not intend to be exhaustive but rather identifies the main categories of concern.

1. Administrative aspects
The Directive and implementing guidelines imposes many administrative requirements that did not exist, or were not similarly developed in the Member States. This includes an obligatory new Database (EUDRACT) with a lot of administrative information prior to initiation of the Clinical Trial Authorization process; an authorization request to the competent authorities, which includes a Clinical Trial Application (CTA, i.e. an extensive dossier) as well as an Investigational Medicinal Product Dossier (IMPD) for each IMP used in the study; an other (closely linked) dossier for the Ethics Committee(s); annual reports for clinical trials; adverse reaction reports; final study reports; etc.

2. Scope
Investigational trials, sponsor, investigational medicinal products, etc...are defined very broadly in the Directive, therefore extending obligations and liabilities sometimes beyond necessity. As discussed above, there is no distinction between a trial investigating a new medicinal product for which little human experience exists or a trial comparing two therapeutic regimens with commonly prescribed and recommended marketed products. The sponsor is defined as an individual, company, institution or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial. Apparently only one sponsor is foreseen for any clinical trial, which is not reflecting the realities of international academic research usually working through networks of local sponsors /institutions. Given the liabilities of the sponsors under the Directive, this raise many important practical and structural questions (see below). The Investigational Medicinal Product (IMP) is defined largely, including the products (or placebo) used as reference as well as already authorized products 'when used to gain further information about the authorized form'. A restricted interpretation of this wording, unnecessary but currently considered by some competent authorities, could be a considerable impediment to academic research for improving medical practices with approved drugs.

3. Liabilities
Given the legal nature of the Directive and its transposition into local law, liabilities of the involved parties are reinforced. This, of course, is at least partly intended to better guarantee the protection of clinical trial subjects. However this will raise new challenges for non-commercial research given the structures and legal entities under which investigators usually work, as opposed to commercial companies.

As examples:
- Non-commercial multi-center international academic trials usually works based on a network of academic institutions, each assuming the local obligations of the sponsor for patients enrolled in their institution. None would currently be in a situation to endorse the liabilities of the sponsor for other institutions. Contrary to commercial sponsors, there is generally no legal entity that could act as a global sponsor in such cases, and setting up such an organization would be costly and challenging for many reasons. Only few permanently established organizations have the adequate legal structures, usually as "non-profit organizations", to possibly serve as the legal umbrella to selected multicenter trials conducted by academic networks.

- Investigator-sponsored trials are often small trials sponsored by a single investigator, sometimes for compassionate reasons: in this case, the investigator may obtain a Medicinal Product not yet authorized in his country from a commercial entity, in order to try it in special patients, usually as a last recourse. It seems that the Directive will introduce additional dependence to the commercial sponsor: the investigator will not only need to obtain the IMP but also the administrative information related to it to comply with the regulatory obligations, some of this information possibly perceived as confidential by the commercial entity. The commercial entity may not wish to be seen as taking any sponsor responsibility in this case, e.g. by ‘financing the trial’ because it would provide the IMP free of charge. In conclusion neither the investigator nor the commercial entity will be in a situation to facilitate such trials due to the burden or risks associated with the possible legal interpretations from the Directive. The disparition of many such investigator-sponsored trials could therefore be a dramatic consequence of the implementation of the Directive.
4. Dependence from Commercial companies

The obligations and administrative information related to the IMPD, especially if the definition of the IMP is interpreted broadly (see above), will necessitate the support of the manufacturer, possibly even for marketed products. When this is the case, it implies that academic research could be impeded by a lack of support from the manufacturers. Some Member States apparently intend to reduce the IMPD requirements for marketed products used in clinical trials without additional manufacturing steps (such as blinding), but specific restrictions and conditions differ between Member States. As discussed above, the fear of commercial companies to take sponsor responsibilities under the new law by supporting an investigator trial is expected to reduce considerably the opportunities for such trials by independent investigators. Sponsors are normally expected to provide the IMP free of charge (although the Directive allows for specific National provisions in this regard). Because of the broad definition of IMP, academic research comparing drug regimens with commercialized products could be under the obligation to provide all these products free of charge, even when such products would have been standard therapy for the trial subjects. This could be a major financial impediment to academic research involving often therapeutic regimens with multiple drugs, such as in oncology.

Finally, all costs associated with the adaptation to the new requirements (administrative and structural costs, costs of IMP, possible additional fees for the Competent Authorities and for Ethics Committees, cost of additional Good Manufacturing Practices, stricter documentation of GCP and possible inspections, etc...) will reduce the possible investments in independent research, in the absence of alternative financing (currently not foreseen). Research will therefore be more dependent of commercial support, limiting research that would benefit public health but without direct commercial interest.

Proposals

FECS acknowledges that the Clinical Trial Directive was well-intended and includes valuable provisions to ensure legally the protection of clinical trial subjects and to start some harmonization across the EU. However this is being implemented at the cost of an increased bureaucratic rigidity without clear benefit for non-commercial research, but with a risk of raising new barriers to independent clinical trials. In this context and given the current timelines, FECS has proposed to the competent authorities and all the relevant interlocutors a two step approach, has requested to be involved in the discussions related to academic research and has requested further support for non-commercial research.

1. Short term: smoothing the implementation of the Directive
- Clarifying definitions of IMP and Sponsor to facilitate research on therapeutic strategies with commercialized products and network of sponsors for multi-center academic research.
- Ensure reasonable, transparent, and coherent implementation measures within Member States, preferably with transitional measures, to reduce the barriers for academic research. Some Member States have already agreed to use the clauses of the Directives to exempt the sponsor to pay for the IMP under some conditions; to simplify the requirements for the IMPD and labeling provisions for marketed products. However the conditions differ, and may be so restrictive that it will not cover the scope of Pan European non commercial research as of today. Adequate European guidance aiming at facilitating such exemptions could be more effective, and would avoid further divergent approaches between Member States.
- Make funds available at EU and/or MS levels to support organizational measures and regulatory assistance to initiate non-commercial trials and compensate for additional costs of conducting clinical trials by independent investigators and non-commercial organizations, including flexible (trial-specific) networks of academic institutions across Member States.

2. Longer-term:
- amend the Directive and/or provide adequate exemptions to protect independent research. There are clear opportunities to improve the situation for non-commercial trials, without discrimination between sponsors, with some amendments to the current legal text. For example, in the US, the FDA recognized the special character of many oncologic trials, as well as their importance for improving patient care. Accordingly, the FDA has defined "exemptions" to the obligations to submit an "IND" (clinical trial application to the authority) under well described conditions, and without prejudice to the patients. For Europe to keep some leadership in the development of best oncologic therapeutic regimes, such solutions should be urgently considered for improving the current legislation and/or its implementation rules.
Cardiovascular Considerations with Antiemetic Treatment

Major changes in cardiovascular (CV) physiology commonly occur with aging, predisposing elderly patients to developing CV disease.1 With the majority of cancer patients being over the age of 65 years,2 the incidence of pre-existing CV conditions is high. For example, in one study of 698 elderly patients with non-small cell lung cancer, 60.3% had some form of CV comorbidity.3 To set these figures in context, respiratory and/or digestive disorders each occurred in about one-third of these patients (Table 1).

CV risk is a concern in cancer patients

Healthcare professionals with responsibility for selecting cancer or supportive care treatments for patients at high risk of CV disease, including the elderly, need to bear in mind several factors:

- many cytotoxic agents (e.g. anthracyclines, mitoxantrone, taxanes) are cardiotoxic;
- radiotherapy to certain sites - particularly the chest and breast - may also be cardiotoxic;
- CV risk increases with multiple cardiac insults (e.g. consumption of several medications with known CV risk).

Particular care should therefore be taken when choosing which antiemetic to prescribe for cancer patients, ensuring that the agent selected does not have CV warnings.

Why does the choice of antiemetic matter?

Recent publications have highlighted concerns regarding the CV risk to patients receiving some of the 5-HT3-receptor antagonist antiemetics, particularly with respect to electrocardiogram (ECG) findings.4-7 The QT interval is often normalized into a heart rate-independent 'corrected' value known as the QTc interval. Prolongation of the cardiac QTc interval is a risk factor for sudden cardiac death and the potentially fatal condition, torsades de pointes.6 In a recent report that reviewed CV safety of the 5-HT3-receptor antagonists, it was suggested that ECG alteration is a class effect.8 Some other recently published reports, however, demonstrate important CV safety differences between the agents. Both dolasetron and ondansetron have been shown to increase the QTc interval in cancer patients undergoing highly emetogenic chemotherapy and in healthy volunteers.9 Granisetron has no warnings for CV safety. Dolasetron, tropisetron and palonosetron all have cardiac warnings in their prescribing information; ondansetron, despite some observed CV effects, does not. Given that the 5-HT3-receptor antagonists are often administered as part of a polypharmacy regimen, where patients may already be receiving drugs which affect cardiac function, the possibility that some 5-HT3-receptor antagonists may precipitate further QTc interval prolongation is a real concern. In addition, a recent analysis of the FDA combined Spontaneous Reporting System/Adverse Event Reporting System database revealed a potential 'signal' for ventricular arrhythmia and cardiac arrest with dolasetron but not granisetron.10 Furthermore, recent data in cancer patients have revealed that granisetron does not significantly affect ECG intervals when administered at high doses (up to 160 mcg/kg)11,12 or as a rapid 1-second injection.13 Granisetron is considered to have less effect on ECG intervals than either ondansetron or dolasetron.6

Conclusions

Thus, CV safety – including additive complications – should be an important consideration when choosing antiemetic therapy for elderly cancer patients. Given a choice, it seems prudent to use a 5-HT3-receptor antagonist, such as granisetron, that has no warnings or precautions concerning CV safety.

The Accreditation Council of Oncology in Europe (ACOE)

Since the start of its activities in 1999, the Accreditation Council of Oncology in Europe (ACOE) has accredited more than 200 events in oncology, ranging from workshops to large congresses, everywhere in Europe. The multidisciplinary nature of ACOE, which is composed of experts from the full range of oncology disciplines, makes it unique in the European Union. Aware of this specificity, event organisers are increasingly eager to obtain CME accreditation from ACOE. About 38 events were accredited in 2003 and already 22 events taking place in 2004 have been reviewed by the Accreditation Council. The ACOE label confers the guarantee of an unbiased, quality scientific programme with a high educational value.

The Council works in close partnership with the European Union of Medical Specialists (UEMS) who, through its network, can ensure the acknowledgement of ACOE accreditation by the national CME authorities participating in the European Accreditation Council on CME (EACCME). For the time being, with the exception of Italy and to a certain extent Belgium, ACOE CME credits, once endorsed by the EACCME, are recognised as valid CME credits in all European countries and in the United States through a mutual agreement between the UEMS and the American Medical Association. Besides the accreditation of life events, ACOE, in response to the growing development of other means of continuing medical education, has devised a plan to set up a European Accreditation system for distance learning materials for CME in oncology. Following pre-selection by the European Commission, a full application for funding has now been submitted under the Leonardo da Vinci programme. The project consists of a survey on the views and initiatives of relevant decision-makers in charge of CME in all current EU and acceding countries and the consecutive development of a European model of accreditation for distance learning CME material.

ACOE also keeps up-to-date with the activities and developments of other European and national professional accrediting bodies through regular meetings, on the grounds that each can learn from the other in an environment made difficult by the major disparities between the national CME systems and regulations.

Until recently, information on ACOE was only available from the FECS website. Because of its growing activities and enhanced profile among the scientific community and the authorities, the Accreditation Council in Oncology in Europe felt the need to become more visible by itself and launched its own website in January 2004. All information regarding its structure, activities, guidelines for accreditation, application procedure and useful links are now available from www.acoe.be.
Roche Grant 2004 Recipients

Each year, Roche, in partnership with EONS, issues a call for applications for an unrestricted grant for the financial support of projects related to education, research and/or practice in cancer care. The 3 recipients of the 2004 EONS-Roche Research Grant will be honoured at the 4th EONS Spring Convention on Thursday evening, April 15th. As part of the ceremony, the recipients will be given the opportunity to present an overview of their projects.

Karin Bergkvist, RN, BSN, Clinical Nurse Specialist, Dept. of Oncology, Karolinska Hospital, Sweden.

**Subjective experiences of nausea and vomiting following chemotherapy**

Several studies indicate that nausea and vomiting are common problems for patients with cancer. Nausea and emesis has also been described as one of the most difficult problems during chemotherapy by the patients themselves. It is a well known fact in today’s highly specialised health care that there is an increased need to investigate factors that may contribute to patients perceived lack of care when treated for cancer. Increased knowledge of how patients perceive nausea and emesis can contribute to show resources or lack of resources for patients treated with chemotherapy. The aim for this study is to explore patients experiences of nausea and emesis during chemotherapy. Study methods are qualitative and hypothesis generating. A qualitative approach using semi structured interviews will be used to collect data. Questions addressing the patients subjective experience of nausea and emesis, what is expressed during this experience and the significance of what is expressed will be covered. The results of this study can contribute to a foundation for identification and development of nursing care for patients treated with chemotherapy. The study will provide a knowledgebase for development of preventive support measures that are of value for the patient.

Alexander Molassiotis, RGN, MSc, PhD, Reader in Cancer and Supportive Care, School of Nursing, University of Manchester.

**The management of cancer related fatigue using two alternative therapies: pilot study of the effect of acupuncture and acupressure.**

During the last decade we have seen a tremendous amount or research directed towards the distressing symptom of cancer-related fatigue (CRF) which often affects the patient’s quality of life. However, little work has gone into ways of alleviating this distressing symptom, with evidence existing only about the role of exercise and self-care. This study will be utilising acupuncture and acupressure using for a first time 2 points that traditionally are associated with the ‘source of energy’ in the body. This pilot study will randomise 36 cancer patients experiencing CRF into those receiving acupuncture at points ST36 (below knee) and LI4 (hand) bilaterally given every other day for 2 weeks, pressure/massaging at the same points given every day for 2 weeks or sham acupressure (ie. pressure in 2 points that are unrelated to ‘energy’). Patients will be stratified in the groups according to their site of cancer. Assessment using the Fatigue Symptom Inventory (MFI) will be carried out before the treatment, end of 2-week treatment and 1 month later.

This study could provide indications of simple and cost-effective techniques that may be utilised by nurses in the management of CRF during cancer therapies.

Theresa Wiseman, RN, BSc, PhD and Rebecca Verity, RGN, BSc, MSc, Lecturer in Cancer and Palliative Care, Florence Nightingale School of Nursing and Midwifery, Kings College, London.

**Exploring the work of Nurses who administer Chemotherapy**

This study will explore nurses’ attitudes and beliefs concerning the chemotherapy administration process and what they say and do in practice. There will be two elements to the study: Element one is a questionnaire which will be given to all nurses working in the London Cancer Networks; Element two will be an ethnographic study of 2 outpatient chemotherapy clinics. An overall expectation of this study is that the factors which facilitate and impinge upon the current practice of chemotherapy administration will be identified. An understanding of these factors is needed to ensure that nurses have the educational, emotional and instrumental support to deliver safe chemotherapy administration practice.

This study will provide a holistic exploration of the care of patients during chemotherapy, by gathering data in a number of different ways (participant observation, questionnaires and interviews), framed within an ethnographic approach. Data yielded will provide a clear description of nurses’ attitudes, feelings and beliefs re: chemotherapy administration and how these impact on their practice. The data will also highlight any discrepancy between attitudes and practice and be valuable in understanding why these occur. The ethnographic approach will provide insight into how individual and collective culture influences practice. In addition, data from element 1 of the study (a pan-London survey) will situate the findings within the wider context of cancer care.