when secondary to cancer, it can also be a daily reminder of their cancer diagnosis.
Patients have reported experiencing difficulty in accessing local lymphoedema clinics, and getting advice and treatment for their condition. Lymphoedema Specialists working in the South East London Cancer Network (SELCN) wished to develop local services to better meet patients' needs, and to do this, it was proposed that a project be undertaken that would identify what patients consider to be important, and to use this information as the core of the development plan.
Material and Methods: Snap Survey's (a Research and Data Processing service) were commissioned to assist with the last stage of the design of an OutPatient Questionnaire; to conduct the survey and to produce a report outlining the findings.
A pilot study was conducted in a lymphoedema service outside of SELCN. The Patient Questionnaire consisted of a single mailing; there was an overall response rate of 50% – N = 868. The sampling method used was a census and no incentive was offered.
Results: Figures in the report were calculated as a proportion of respondents who answered each question.
All factors included in the analysis achieved a satisfaction level of above 90%. However, it was evident that there were areas that the services should consider focusing on, these included:
1. Location of the clinic
2. Phone access to lymphoedema therapists
3. Understanding patients needs

The results of the Patient Questionnaire will be used to prioritise areas for service improvement.

3622 POSTER

The effectiveness of continuing professional development (CPD) for clinical oncologists

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Background: The purpose of this study was to see how Clinical Oncologists learn and change practice and to see how Continuing Professional Development (CPD) influences this.
Materials and Methods: A focus Group and individual semi-structured interviews were undertaken with 9 Clinical Oncologists in a Cancer Centre in the UK. The sessions were taped and transcribed and the data was analysed qualitatively using a grounded theory approach.
Results: The themes that emefged form the focus group were (1) The importance of colleagues in learning and changing practice, (2) The challenge of change in practice and (3) the motivations and barriers to involvement in CPD. In the semi-structured interviews these themes also emerged as well as a a fourth (4) a sense of realism about what could CPD achieve in it's current form. It appeared that Consultants valued informal interactions with colleagues when faced with a gap in their knowledge. Colleagues provided reassurance about practice. There was a desire to change practice and improve patient outcome but there was also some degree of conflict between wanting to change and needing to feel comfortable with change. Having colleague support and experience of the change in practice in a controlled setting was very important in facilitating change in practice. The main motivation for involvement in CPD was the percieved relevence to ones practice.
Conclusions: Consultant Clinical Oncologists were involved in many forms of CPD which lead to a change in practice. Some of this CPD was recognised by the RCR but much of it was informal. Many of the findings in the study were consistent with much of the CME/CPD literature. This however is a small qualitative study from a large cancer centre and the findings may not relate to Clinical Oncologists as a group. A study like a questionnaire with a larger sample size would be required to see if these findings are generalisable to Clinical Oncologists in the UK.

3623 POSTER

Phase 0 trials: ethical and regulatory issues

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In 2003, the European Agency for the Evaluation of Medicinal Products published a concept note followed by a Position Paper on the nonclinical safety studies needed to support human clinical trials with a single dose of a pharmacologically active compound using microdose techniques. In April 2004, also the American FDA published a draft guidance regulating early human screening studies, and in January 2006 new industry guidelines for early exploratory drug studies (i.e. Phase 0 studies) in humans have been issued. According to both guidelines, the shift away from the use of nonspecific cytotoxic chemotherapeutic agents in cancer therapy to more specific, molecularly targeted agents has necessitated a re-evaluation of the cancer-drug development process. After the publication of the US FDA guidelines, the National Cancer Institute started in 2006 the NCI Phase 0 program and the first Phase 0 pharmacokinetic and pharmacodynamic study of ABT-888, an inhibitor of poly(ADP-ribose) polymerase, in patients with refractory solid tumors and lymphoid malignancies, was performed. Phase 0 trials are unique in declaring for the first time their lack of therapeutic intent. The participant in the trial is not anymore a 'patient', but only a 'subject'. Compared to the "traditional" kinds of clinical trials, in Phase 0 studies the interests of the society play a greater role than the interests of the participants, as society represents "the others", ie the future patients that will receive the benefits of the research. Some scholars have suggested that the long-standing principle expressed in the Helsinki Declaration, namely that the interests of human subjects should always take precedence over the interests of society, is being challenged. Is it true? And if it is, does it follow that interests of human subjects cannot ever be overridden in a clinical trial? It is time to reflect upon the nature of statements such as the Helsinki Declaration. Have they become "articles of faith", dogmas as there are in religions, as British bioethicist John Harris argues? Or are they the results of a diplomatic and political decision? In this latter case, they would remain very important principles nonetheless, but such that could be overridden in very specific cases, given that the autonomy of the patient is respected. Due to the most recent development of Phase 0 trials, there are only few empirical data available on which to evaluate the ethical concerns they raise, but a comparative analysis with the ethical issues of phase 1 cancer trials is possible and interesting.

Cancer in the older individuals

Oral presentations (Tue, 22 Sep, 09:00–10:30)
Cancer in the older individuals

4000 ORAL

Frailty in elderly patients: winograd and vulnerable elders survey-13 criteria applied to INRCA comprehensive geriatric assessment database

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Background and Aims: Frail patients are at high risk of adverse events and disability. INRCA has developed, validated and implemented a Comprehensive Geriatric Assessment (CGA) for patients aged $\geqslant$70 years. Aim of our study was to analyze the ability of Winograd and VES-13 criteria to recognize frail patients.
Materials and Methods: 6746 patients aged $\geqslant$70 years consecutively admitted to INRCA hospital, from January 2005 to May 2007, evaluated with CGA, including: Comorbidity Index Rating Scale (CIRS), Mini Mental State Examination (MMSE), Geriatric Depression Scale (GDS-15), Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL), Informal Social Support (Lubben Social Network Scale), Health-Related Quality of Life (SF12), as well as socio-economic and environmental information.
Winograd and VES-13 criteria were applied to recognize frail patients. Multidimensional Prognostic Index (MPI) for 1-year mortality was also calculated.
Results: Out of 6746 patients 46.3% were male (n = 3122), 53.7% were female (n = 6624). The mean age was 79.39$\pm$5.8 yrs, range 70–103 yrs. A significant difference in mean age was observed between male and female (M 78.8$\pm$5.6 vs. F 80.0$\pm$6.1 yrs; $p < 0.01$).
70% of pts had $\geqslant$3 diseases, 28.7% were incontinent, 30.2% MMSE $\leqslant$ 20, 9% GDS $\geqslant$ 10, 15.6% ADL $\leqslant$ 2 and 20.2% 0 $\leqslant$ IADL $\geqslant$ 2.
20.1% presented poor social support (Lubben scale <19) and 39.3% poor quality of life (SF12 PCS $\leqslant$ 35.7 and MCS $\leqslant$ 40.7).
VES-13 criteria were applied to 5328 patients: healthy (0–2) 25.3% (n = 1350), vulnerable (3–6) 22.5% (n = 1198) and frail ($\geqslant$7) 52.2% (n = 2780).
According to these criteria healthy cancer and non cancer patients resulted respectively 34.95% and 24.9% and frail patients 39.5% and 52.8%, showing a statistically meaningful difference, instead of Wingrad criteria which evaluated 6746 pts, 4188 frail and 2558 not frail pts, without showing significative difference between cancer and not cancer patients.

Then we have applied Multidimensional Prognostic Index (MPI), developed on mortality risk, finding that cancer patients have a lower risk in comparison to non cancer patients.
Conclusion: VES-13 criteria and Multidimensional Prognostic Index are shown sensitive to recognize and to discriminate frail patients with or without cancer. We have found that comorbidity and functional status are independent in cancer patients. Cancer patients are less frail showing best scores, with a statistically significant lower mortality risk than non cancer patients.

4001 ORAL

The role of family caregivers of elderly cancer patients in the choice of non disclosure – a GIOGer study

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Background: To investigate the caregiver's role in the choice of non disclosure and in the patient-physician communication.
Materials and Methods: 622 elderly cancer patients and 194 family caregivers of partially Informed (PI) or not-Informed (NI) patients were interviewed. PI patients received only approximate information, aimed at reassurance, NI patients had no access to information. Family caregiver was identified by the patient as the primary source of emotional and social support.
Results: Out of 622 patients, 210 (33.8%) received limited information, 136 patients (64.8%) were partially informed (PI) and 74 (35.2%) not informed (NI). Out of 210 caregivers, 16 refused study participation and 194 were interviewed.
Patients living with their spouse were better informed than patients living with their children. The decision to not inform the patients arose into the family (77% of PI, 86% of NI) due to the psychological frailty of the patient (52.8% NI, 32.8% PI) and considering the direct patient-physician communication at risk of destabilizing emotional strain (66.7% NI, 67.25 PI). PI patients' caregiver consider more destabilizing the information on prognosis (48.4%), while NI patients' caregiver on diagnosis (44.4%). Interviewed caregivers were afraid of increased risk of anxiety and depression in their relatives (55.7%).
Conclusion: The choice of non disclosure was independent from an explicit request of the patient and driven by caregiver's fear and needs. Caregiver preferred to preliminarily define the contents of clinical communication and discuss with the physician social and family contest of the patient. They were not aware that adequate information provides a better opportunity to share anxieties.
Early intervention tailored on caregiver's needs and skills, are needed to avoid the risk of distress of the caregiver and to help medical staff to manage the various aspects of clinical communication.

4002 ORAL

Surgical treatment of colorectal malignancies in patients aged 80 and older: does age make a difference?

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Background: In the elderly with cancer, clinical decision making is often complicated by the effects of aging. However as life expectancy continues to rise, more people aged 80 and older will present with gastro-intestinal malignancy and may need major surgery. We evaluated our results in colorectal surgery, especially regarding the perioperative mortality, in this oncogeriatric population.
Materials and Methods: Data of 121 patients aged 70−75 and 132 patients aged 80 and older operated upon for colorectal malignancies between 2000 and 2008 were prospectively registered. The registered parameters included: gender, age, tumor location and stage, type of surgery performed, American Society of Anaesthesiologists (ASA)-score, duration of hospitalisation, follow-up, mortality and neoadjuvant treatment. The data were compared between the two age groups and a risk factor analysis for perioperative mortality was performed, stratifying for both age groups.
Results: The perioperative mortality was significantly higher in the 80+ group (n = 18 (13.6%) vs n = 1 (0.8%) in the 70−75 group (P < 0.001). Mean follow up was significantly longer in the 70−75 group 30±23 months versus 18±18 months in the 80+ group (P < 0.001).
In the 80+ group significantly higher tumor stages were found (P = 0.031). More patients in the 70−75 group received radiotherapy (14.0% vs 3.8%, P = 0.008). Type of surgery also differed between groups: more Hartman and derivative procedures in the octogenarian group and more anterior and rectosigmoid resections in the 70−75 group (P = 0.027). In addition, risk factor analysis showed an ASA-score of 4, and higher tumor stage to increase the perioperative mortality in the 80+ group (P = 0.020 and P = 0.043 respectively), whereas these risk factors were not significant in the 70−75 group.
Conclusions: In octogenarians, high ASA-score and high tumor stage contribute to perioperative mortality when operated upon for colorectal cancer. In these specific patients other therapeutical options should be considered. In case of lower ASA-scores (⩽3) and tumor stage surgical treatment should not be denied to octogenerians. We found that our 80+ population seems to be underdiagnosed and undertreated based upon the shorter follow up and more advanced tumor stage at presentation in this group.
To offer the optimal oncological treatment in this geriatric population more extensive preoperative screening is needed.

4003 ORAL

ICE Study: A prospective, multi-centre, controlled, open-label, randomized phase III trial of ibandronate (I) with or without capecitabine (X) in elderly patients (pts) with early breast cancer (GBG 32)

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Background: Data on elderly pts with breast cancer are limited. The CALGB reported data comparing EC or CMF combination therapy versus X monotherapy, suggesting that hormone receptor (HR)-negative pts particularly benefit from polychemotherapy. The ICE study compared X monotherapy plus bisphosphonate versus bisphosphonate alone in elderly pts at increased risk of relapse.
Methods: Pts received either I alone for 2 years (50 mg p.o. daily or 6 mg i.v. every 4 weeks according to pt preference) or the same dose of I for 2 years + X 1000 mg/m^2 bid on days 1−14 q21 days for 6 cycles. Pts with HR positive disease received endocrine therapy according to local/institution guidelines. The primary objective is to compare disease-free survival (DFS) with either I alone or I + X as adjuvant treatment for primary breast cancer in pts ⩾65 years. Secondary objectives are to compare overall survival between the two arms and to assess compliance, toxicity, bone-related events, preference for oral or i.v. I, quality of life, and prognostic and predictive factors. Main inclusion criteria are: female ⩾65 years with histologically confirmed breast cancer that is either node-positive or high-risk node-negative (tumour size ⩾2 cm, grade > I, and/or ER- and PR-negative); no prior chemotherapy, adequate organ function and a Charlson score ⩽2.
A total of 1,394 pts (697 per arm) with 497 events are needed to show an improvement in 5-year DFS from 65% to 71.5% with X, assuming a drop-out rate of 5%. A clinically relevant difference between the treatment arms is detectable at $\alpha = 0.05$ (two-sided) with 80% power.
Results: Between 06/2004 and 08/2008 1409 pts were recruited in 172 German centers; 703 pts received X+I, 706 pts received I only. The median age was 71 years (range 64−88). 570 pts (80.7%) were HR positive and 133 (19.3%) were HR negative. Lymph nodes were positive in 335 (48.2%) pts and negative in 368 (51.8%) pts. A safety analysis of the first 100 pts treated with X+I demonstrated that >75% of pts received the full dose and cycles of chemotherapy. During the entire recruitment period, no safety-related amendment to the study protocol was required. 305 SAEs were reported, the majority due to gastrointestinal (45), skin (38) and cardiac (43) disorders.
Conclusion: This is the largest adjuvant study in the elderly population and the only one involving a non-chemotherapy arm. So far, there are no safety concerns. First safety data from the entire population will be presented.