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.