handicapped. These populations are suspected to have worse prognosis. According to one report, on the other hand, patients with Medicaid were more likely to receive chemotherapy than patients with NHI despite the uniform health insurance coverage within the two types of health cost financing. Owing to these conflicting findings, we investigated the relationship between health insurance type and prognosis.
Materials and Methods: Patients are stage IV advanced gastric cancer patients who received palliative chemotherapy. Medical records were reviewed from January 2006 to November 2008 in Seoul Medical Center (municipal teaching hospital).
Results: Total 37 patients were found. Median age was 61 years (range 31−85) and male constituted 75.7%. Platinum (cisplatin or oxaliplatin) combined with 5-FU was the most frequently used regimen (78.4%). Twelve patients (32.4%) were recipients of Medicaid. Median PFS and OS of NHI group were 6.9 (95% CI, 1.7−12.0) and 7.8 (95% CI, 3.4−12.1). And that of Medicaid were 5.6 (95% CI, 2.6−8.6) and 7.8 (95% CI, 3.4−12.2) months. The difference from two groups were not statistically different ($p = 0.739$ for PFS and 0.466 for OS). When patients were divided into longer or shorter survivors according to mean OS (14.1±2.6 months), NHI recipients had more probability for survival (odds ratio 0.72, 95% CI 0.56−0.92).
Conclusions: The question is raised whether recipients of Medicaid have poorer prognosis than patients with NHI in metastatic gastric cancer in South Korea. Although it seems that NHI recipients has better prognosis, still we cannot sure. It should be cleared in large scale cohort study whether this is related to low socio-economic status or other uncontrolled confounder.

3617 POSTER

Significance of postoperative follow-up for colorectal cancer from economic viewpoint

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Background: Recently importance of the long-term follow-up adds to the cancer therapy as well as initial treatment. The aim of the study is to verify the postoperative follow-up for colorectal cancer from the viewpoint of cancer economics.
Material and Methods: According to a Markov model, we developed systems model to compare medical cost of the postoperative follow-up of colorectal cancer and incremental benefit (gain of the economic productivity after recovery). We used data registered in two study groups (Sugihara K, et al.) following the patients for more than 5 years in Japan for the systems model and performed a cost-benefit analysis.
Results: Registered cases of colon and rectal cancer are 5,599 in group A and 5,230 in group B. Recurrence rates in colon and rectum cancer are 2.5% and 7.3% respectively in Stage ? of group A. Those are 13.4% and 22.8% in Stage II, and 25.0% and 39.6% in Stage III. The cost-benefit ratios in colon and rectum cancer in group A are 0.14 and 0.46 in Stage ?, 0.86 and 1.34 in Stage II, and 1.27 and 2.15 in Stage III respectively. With respect of group B, those are 0.20 and 0.29 in Stage ?, 0.86 and 1.05 in Stage II, and 1.23 and 2.43 in Stage III respectively. Almost the same tendency is observed in two groups.
Conclusion: It can be said that postoperative follow-up has the definite economic effect in Stage II rectal cancer, and Stage III colon and rectal cancer. Meanwhile, postoperative follow-up has little economic effect in Stage ? colon and rectal cancer, and Stage II colon cancer, since the cumulative costs of follow-up exceed the incremental benefits.

3619 POSTER

Oral cancer treatments and adherence: medication event monitoring system assessment for capecitabine

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Background: Oncological treatments are traditionally administered via intravenous injection by qualified personnel. Oral formulas which are developing rapidly are preferred by patients and facilitate administration however they may increase non-adherence. In this study 4 common oral chemotherapeutics are given to 50 patients, who are still in the process of inclusion, divided into 4 groups. The aim is to evaluate adherence and offer these patients interdisciplinary support with the joint help of doctors and pharmacists. We present here the results for capecitabine.
Materials and Methods: The final goal is to evaluate adhesion in 50 patients split into 4 groups according to oral treatments (letrozole/exemestane, imatinib/sunitinib, capecitabine and temozolomide) using persistence and quality of execution as parameters. These parameters are evaluated using a medication event monitoring system (MEMS®) in addition to routine oncological visits and semi-structured interviews. Patients were monitored for the entire duration of treatment up to a maximum of 1 year. Patient satisfaction was assessed at the end of the monitoring period using a standardized questionary.
Results: Capecitabine group included 2 women and 8 men with a median age of 55 years (range: 36−77 years) monitored for an average duration of 100 days (range: 5–210 days). Persistence was 98% and quality of execution 95%. 5 patients underwent cyclic treatment (2 out of 3 weeks) and 5 patients continuous treatment. Toxicities higher than grade 1 were grade 2−3 hand-foot syndrome in 1 patient and grade 3 acute coronary syndrome in 1 patient both without impact on adherence. Patients were satisfied with the interviews undergone during the study (57% useful, 28% very useful, 15% useless) and successfully integrated the MEMS® in their daily lives (57% very easily, 43% easily) according to the results obtained by questionary at the end of the monitoring period.
Conclusion: Persistence and quality of execution observed in our Capecitabine group of patients were excellent and better than expected compared to previously published studies. The interdisciplinary approach allowed us to better identify and help patients with toxicities to maintain adherence. Overall patients were satisfied with the global interdisciplinary follow-up. With longer follow up better evaluation of our method and its impact will be possible. Interpretation of the results of patients in the other groups of this ongoing trial will provide us information for a more detailed analysis.

3620 POSTER

Of money and healthcare

P. Fava[1], T. Vuong[1]. [1]*McGill University Health Centre, Radiation Oncology, Montréal, Canada*

Introduction: Certain factors must be considered when a department needs to replace a treatment unit. With the escalating cost of healthcare and the need to manage a waiting list of patients, striking a balance between cost and efficiency of a treatment machine is of utmost importance. The choice is vast; linear accelerators, TomoTherapy® units, CyberKnife® System units, are all possibilities. This study investigates the impact a cyberknife would have on the workload of a radiotherapy department, when acquired as a replacement unit. We focused on prostate patients as they are the most numerous on our waiting list.
Methods: Ten centers in the United States and five in Europe with a cyberknife in operation for at least 1 year were contacted by phone. They were asked: Daily number of patients treated and patient selection on cyberknife and whether the cyberknife replaced an old accelerator or if it was an add on.
Results: The number of patients treated daily on cyberknife ranges from 4 to 8, for an average of 6. All centers treat primarily brain and lung tumors. The US centers treat few prostate patients as insurance companies won't cover costs. All confirmed the cyberknife was an addition, not a replacement unit.
On the outgoing accelerator we treat 32 prostate patients daily over an 8 week period (208 per year). Literature reveals phase II studies for prostate patients treated with cyberknife are presently using 5 fractions over 1 week. Assuming 2 of 6 slots on cyberknife are allocated to those patients willing to participate in a hypofractionation study, the number of prostate patients treated annually with the cyberknife would be approximately 104 or 50% of the present number. Although the patients treated on cyberknife would liberate a number of slots on the conventional accelerators, the feasibility of absorbing about an extra 100 patients could be problematic. Furthermore, treatment planning for the cyberknife is done by a physicist not a dosimetrist. This must be taken into consideration in the department planning budget. Presently the start up costs of a CyberKnife® System is about $4M (US).
Conclusion: We concluded that if the cyberknife is acquired as a replacement unit, the workload on the other accelerators must increase in order to maintain the present waiting list in check. Extending the working hours is an added cost to the department. Purchasing the cyberknife as a replacement unit would neither be an efficient nor financially savvy choice.

3621 POSTER

Development of patient centred lymphoedema services

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Background: Lymphoedema is a chronic, progressive condition that requires timely and appropriate interventions, if patients' physical and psychological needs are to be met. Patients have reported that living with lymphoedema can have a negative impact on their quality of life, and

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.