oncology and public health

RISK OF MAJOR BLEEDING IN CANCER PATIENTS RECEIVING CHEMOTHERAPY

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Cancer patients receiving chemotherapy are at increased risk of venous thromboembolism (VTE). The presence of cancer and anticoagulant use are risk factors for bleeding, yet data on bleeding risk are limited in these patients. This analysis evaluated the risk of major bleeding in cancer patients receiving chemotherapy using a US claims database. This retrospective cohort study used the MarketScan® databases, a nationwide database containing data from about 100 payers and covering >30 million patients annually. Adult cancer patients receiving chemotherapy within 6 months of cancer diagnosis between January 2004 and December 2010 were included. Cancers of interest were: lung, colon/rectum, pancreas, bladder, stomach, and ovary. The index date was the first date of chemotherapy. Patients were followed until the earliest of: 1) first diagnosis of major bleeding; 2) termination of enrolment in the health plan; 3) end of study. The primary outcome was the first occurrence of major bleeding, based on selected ICD-9-CM/CPT codes, following chemotherapy initiation. Of 74,575 patients identified, exclusion of those with prior history of bleeding at baseline (~5%) resulted in 70,822 patients included in the analysis. Mean age was 62 years, 37% were ≥65 years, and 52% were male. Average time of follow up and chemotherapy were 14.3 and 8.6 months, respectively; 6% had a history of VTE within 6 months prior to the index date. Major bleeding occurred in 5.8% of patients and the incidence rate for all cancers combined was 4.9 per 100 person-year (PY) and 10.5, 9.3, 6.2, 4.3, 3.6, and 3.3/100 PY for pancreatic, stomach, lung, bladder, colon/rectum, and ovarian cancer, respectively. Approximately 14% of patients (N = 10,456) developed VTE after chemotherapy initiation (>half in the first 3 months of chemotherapy treatment). Of these, 7.8% experienced major bleeding with incidence rates ranging from 5.9-17.7/100 PY after VTE. Major bleeding incidence in cancer patients receiving chemotherapy varies by cancer type with the highest rates in patients with upper gastrointestinal cancer. Compared to the overall cohort, major bleeding risk was higher in cancer patients who developed VTE.


Table: 1370P

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Cancer Type</th>
<th>PFS in RCT (months)</th>
<th>PFS in Clinical Practice Oncology (months)</th>
<th>Ex-factory (euro /1mg)</th>
<th>Effectiveness Adjusted Price (euro /1mg)</th>
<th>Difference in price (Discount proposal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorafenib</td>
<td>Kidney</td>
<td>5.5</td>
<td>3.2</td>
<td>0.16</td>
<td>0.09</td>
<td>44%</td>
</tr>
<tr>
<td>Sorafenib</td>
<td>Liver</td>
<td>5.5</td>
<td>3.0</td>
<td>0.16</td>
<td>0.09</td>
<td>44%</td>
</tr>
<tr>
<td>Erlotinib</td>
<td>NSCLC</td>
<td>2.2</td>
<td>2.0</td>
<td>0.48</td>
<td>0.44</td>
<td>8%</td>
</tr>
<tr>
<td>Sunitinib</td>
<td>Kidney</td>
<td>11.0</td>
<td>7.0</td>
<td>3.87</td>
<td>2.46</td>
<td>36%</td>
</tr>
<tr>
<td>Cetuximab</td>
<td>Colorectal</td>
<td>4.1</td>
<td>3.0</td>
<td>2.08</td>
<td>1.52</td>
<td>27%</td>
</tr>
<tr>
<td>Pemetrexed</td>
<td>Lung adenocarcinoma</td>
<td>2.9</td>
<td>1.8</td>
<td>3.02</td>
<td>1.87</td>
<td>38%</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>Colorectal</td>
<td>10.6</td>
<td>6.3</td>
<td>3.36</td>
<td>2.00</td>
<td>40%</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>Breast</td>
<td>11.8</td>
<td>7.9</td>
<td>3.36</td>
<td>2.25</td>
<td>33%</td>
</tr>
<tr>
<td>Panitumumab</td>
<td>Colorectal</td>
<td>2.0</td>
<td>1.9</td>
<td>4.22</td>
<td>4.01</td>
<td>5%</td>
</tr>
</tbody>
</table>

HEALTH RESOURCE UTILISATION (HRU) IN EUROPE ASSOCIATED WITH SKELETAL-RELATED EVENTS (SRES): RESULTS FROM A RETROSPECTIVE STUDY

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In Europe pricing of new drugs is assessed directly by member countries contracting with pharmaceutical companies. Health technology evaluation is based on efficacy/safety results in approval RCTs and scarce resource allocation. Since clinical outcomes in wider population are more variable and conditions less selected, the clinical outcomes may result changed. The real cost benefit value should be revised once effectiveness data from clinical practice is available. The clinical data were collected from web-based national oncology registry Onco-AIFA, as part of mandatory surveillance. The observational study was performed on 724 advanced cancer patients treated with high novel oncology drugs. The median follow up was 67 months from May 2006 to December 2011. Approval RCTs of seven selected drugs were reviewed. The comparison was performed between survival outcomes achieved from RCT and those from our setting (see table). Progression free survival is a valuable indicator for efficacy/effectiveness assessment.

Based on the difference in benefit in PBS, a new price adjusted for effectiveness was proposed. The post-marketing evaluation showed that in all analysed drugs the PFS from clinical practice was shorter in comparison to RCTs outcomes. As a result the real price value should be revised taking into account the difference of clinical response. The calculated effectiveness adjusted price is ex-factory price, expressed in euro per 1 mg, proportional to the difference of PFS form RCTs and that from clinical practice.

The post marketing study allows for assessment of response outcomes in real life practice in order to verify both effectiveness and safety in general population testing external validity of the randomized trials. This kind of assessment lacks in approval RCTs, further emphasizing the importance of observational investigations in clinical practice. The price should be based on net clinical benefits achieved in real life practice as more appropriate in evaluating cost-benefit balance.

Disclosure: All authors have declared no conflicts of interest.

Objective: To evaluate European HRU associated with SREs (radiation to bone [RB], surgery to bone [SB], pathologic fracture [PF], spinal cord compression [SCC]).

Methods: Eligible patients (bone metastases from breast/lung/prostate cancer or multiple myeloma, with an index SRE [defined as an SRE preceded by an SRE-free period of at least 6.5 months] between July 2004 and July 2009) were enrolled from Hospital, Athens, GREECE, Comprehensive Cancer Department, University Hospital, Pizen, CZECH REPUBLIC, Centre for Observational Research, Amgen Ltd., Uxbridge, UNITED KINGDOM, 2Health Economics, Amgen (Europe) GmbH, Zug, SWITZERLAND, 3Biostatistics, Contractor Amgen Ltd., Cambridge, UNITED KINGDOM, 4Medicina Oncologico Veneto IOV-IRCCS, Padova, ITALY, 5Medical Oncology II, Istituto Oncologico Veneto IRCCS, Padova, ITALY

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Austria, Czech Republic, Finland, Greece, Poland, Portugal, Sweden and Switzerland (Study:20090146). HRU data were gathered from baseline (pre-index SRE period: 3-month period, beginning 3.5 months pre-index SRE) and post-index SRE period (14-day diagnosis period pre-index SRE to 3 months post-SRE). We present mean (bootstrapped 95% confidence interval [CI]) change in HRU from baseline per index SRE for pooled country data.

**Results:** The Table presents the mean change from baseline in HRU per index SRE for the pooled data from the 8 European countries included in this study. An increase was observed in all HRU types following the index SRE. Change in overall HRU was predominantly driven by increases in the duration of inpatient stays, with a mean increase of between 7.81 and 22.21 days depending on SRE type. Substantial increases were also seen in the number of procedures and the number of outpatient visits, with mean increases from 5.85 to 9.58 and from 2.58 to 4.24, respectively. Of the index SREs, SCC was associated with the greatest increase in HRU burden for the following HRU types: duration of inpatient stays, emergency room (ER) visits, and procedures.

**Conclusions:** Overall, SREs are associated with substantial HRU burden. The largest increases in HRU burden were seen following SCC.

Mean (95% CI) change from baseline in HRU according to index SRE type (full analysis set).

<table>
<thead>
<tr>
<th>HRU type</th>
<th>RB n = 482</th>
<th>SB n = 99</th>
<th>PF – long bone n = 118</th>
<th>PF – other n = 241</th>
<th>SCC n = 82</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient stays</td>
<td>0.52 (0.41, 0.62)</td>
<td>1.48 (1.24, 1.72)</td>
<td>1.23 (1.02, 1.44)</td>
<td>0.80 (0.65, 0.95)</td>
<td>1.33 (1.01, 1.65)</td>
</tr>
<tr>
<td>Duration of inpatient stays</td>
<td>7.81 (6.53, 9.09)</td>
<td>18.81 (15.31, 20.92)</td>
<td>12.27 (9.71, 14.81)</td>
<td>22.21 (18.98, 25.49)</td>
<td>27.54 (24.91, 30.27)</td>
</tr>
<tr>
<td>Outpatient visits</td>
<td>4.24 (3.67, 4.80)</td>
<td>2.65 (1.52, 3.78)</td>
<td>2.58 (1.70, 3.46)</td>
<td>3.96 (3.22, 4.71)</td>
<td>4.06 (3.25, 4.74)</td>
</tr>
<tr>
<td>ER visits</td>
<td>0.10 (0.03, 0.17)</td>
<td>0.18 (0.03, 0.33)</td>
<td>0.30 (0.17, 0.42)</td>
<td>0.32 (0.12, 0.37)</td>
<td>0.64 (0.37, 0.91)</td>
</tr>
<tr>
<td>Procedures</td>
<td>8.51 (7.84, 9.18)</td>
<td>6.36 (4.83, 7.90)</td>
<td>6.10 (4.80, 7.40)</td>
<td>5.03 (4.67, 5.36)</td>
<td>9.58 (8.21, 11.35)</td>
</tr>
</tbody>
</table>


**1375P**

**ECONOMIC BURDEN OF COSTLY CANCER DRUGS IN A HEALTHCARE SERVICE**


**Background:** The equitable access to medical treatment according to individual needs is an important issue to discuss taking into account that resources are limited. In this study we describe the incidence of costly cancer drugs in a healthcare service with 200000 affiliates from Buenos Aires city, from January 2010 to December 2011 and compare both years. We also calculate the total annual cost of expensive drug treatment and identify the highest cost drugs used.

**Material and methods:** Retrospective study Source: clinical history and files from patients on anticancer treatment from January 2010 to December 2011 and drug costs information from the accounting department.

**Results:** During the year 2010, 3% of the total cancer patients (906) received costly cancer treatment. The most used therapies were: Trastuzumab (39.2%), Trastuzumab (25%), Bevacizumab (10%). The total annual cost was $710000 which is 42% higher than the mean annual cost per patient was $20113. During the year 2010, 3% of the total cancer patients (906) received costly cancer treatment. The most used therapies were: Trastuzumab (39.2%), Trastuzumab (25%), Bevacizumab (10%). The total annual cost was $710000 which is 42% higher than the mean annual cost per patient was $20113.

**Conclusion:** The results of this analysis provide useful information to health care providers and decision makers in understanding the economic burden of cancer.

Additionally, this cost information will greatly assist in determining the cost-effectiveness of new technologies and early detection systems. In order to warrant adequate access to these expensive treatments we need to generate a model of health coverage enhancing participation of all parts.

**Disclosure:** All authors have declared no conflicts of interest.

**1376P**

**ADVANCING CLINICAL ONCOLOGY PRACTICE IN DEVELOPING COUNTRIES: INTEGRATING RESEARCH INFORMATICS FOR CONTINUOUS PROCESS IMPROVEMENT**

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In developing countries, Clinical Research is considered a luxury interest with lower priority. Ongoing studies show considerable gap in response between developed countries where most research is conducted and developing countries where most of needy population is located. We demonstrate a case where practice was improved in a multi-disciplinary cancer center through setting the institution vision and objectives to be patient centered, research focused and outcome oriented. Since the development of the Protocol Monitoring unit and the Research Department, a monitoring process has been established which identified violations and deviations from the developed clinical protocols with a continuous feedback to the attending treatment and research teams i.e treating each treatment regimen as a research protocol. This process proved effective and necessitated developing tools for providing more comprehensive treatment roadmaps and tracking patients’ treatment milestones. Another advantage of applying the system is the improvement of medical team conduct knowing that their performance is being reviewed in what’s known as Hawthorne Effect. With the establishment of first research informatics unit in the region Monitoring process became live web-based activity where performance and survival can be monitored instantaneously. The customized treatment protocols were developed through identifying key evidence-based practices, integrating it with research questions and local clinical expertise. Cooperation with international centers like St. Jude Children’s Research hospital and Dana Farber Cancer Institute as well as Children’s Hospital-Boston has supported our transition into an international center through benchmarking and training.

**Conclusion:** Within five years we’ve developed a model example for developing countries to improve clinical practice through integrating research methods and informatics. Dealing with all treatment regimens as research protocol with the integration of audit and feedback approach in the treatment process definitely improves treatment outcome most specifically at poorly established settings.

**Disclosure:** All authors have declared no conflicts of interest.

**1377P**

**CANCER AWARENESS PROGRAMMES IN URBAN AND SEMI-URBAN POPULATIONS OF WEST BENGAL, INDIA**

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**Background:** Of the current world estimate of 9 million new cancer cases diagnosed each year, India contributes 7.2% of new cases every year with an overall count of 20 lakhs. Of these, 2.3 lakhs cancer (33%) are obesity and life style related.

**Objectives:** Our non-government cancer control program aims to educate the urban and semi-urban population in and around the outskirts of the city of Kolkata about the perils of cancer and its symptoms. Ultimately it aspires to create public awareness regarding the inter-relation between obesity, cancer and lifestyle modification, thus informing them about the benefits of minor lifestyle changes in preventing cancer.

**Methods:** A 5 year (Jan’06–Dec’11), bi-monthly awareness program was conducted by NCRI in Kolkata and its immediate outskirts targeting the urban and semi-urban population. Main concerns were oral, breast and cervical cancers detected by oral examination, self breast inspection, Pap Smear test followed by collecting patient history and lifestyle factors including dietary fat-caloric & tobacco intake, alcohol consumption, and weight of the subject which might act as a pre-determinant disease markers. Positive screening results stage-specific planning of treatment and/or palliative care at our institute.

**Results:** Enthusiastic public participation (approx.85%) including women was observed. Out of 46,000 screened individuals, cancer was detected in 3840 (8%) cases, of which

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*Note: The above text is a sample of how the document could be represented in plain text format.*
58% were female and 42% were male. Incidence of breast cancer in female were predominant (29.99%), followed by cervical carcinoma (23.99%). Tobacco habits predominated among 40% of males and 20% of females. Hence oral cancer was the most common (35.98%) amongst men, followed by lung cancer (29.98%).

Conclusion: The results showed a strong association of overweight and obesity with cancer in this group primarily due to life style, dietary and smoking habits. Hence some minor lifestyle choices which encompasses dietary restriction of calorie/fat intake and avoiding animal protein especially red meat, cessation of tobacco and alcohol intake, exercising and maintaining an ideal body mass index, healthy body weight and composition through a diet rich in fruits and green vegetables reduces the risk of cancer.

Disclosure: All authors have declared no conflicts of interest.

<table>
<thead>
<tr>
<th>HRU</th>
<th>US (n = 354)*</th>
<th>EU (n = 893)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Stays (IS) Proportion of SREs with IS Number/SRE</td>
<td>14.7%</td>
<td>29.5%</td>
</tr>
<tr>
<td>Mean</td>
<td>0.18</td>
<td>0.32</td>
</tr>
<tr>
<td>Median Length of Stay (days)</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Mean</td>
<td>10.6</td>
<td>19.9</td>
</tr>
<tr>
<td>Median</td>
<td>7.0</td>
<td>17.0</td>
</tr>
<tr>
<td>Outpatient Visits (OV) Proportion of SREs with OV Number/SRE</td>
<td>88.1%</td>
<td>74.1%</td>
</tr>
<tr>
<td>Mean</td>
<td>9.1</td>
<td>4.8</td>
</tr>
<tr>
<td>Median</td>
<td>9.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Emergency Room Visits (ERV) Proportion of SREs with ERV Number/SRE</td>
<td>4.0%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Mean</td>
<td>0.05</td>
<td>0.04</td>
</tr>
<tr>
<td>Median</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Inpatient/Outpatient Procedures (P) Proportion of SREs with P Number/SRE</td>
<td>95.5%</td>
<td>96.4%</td>
</tr>
<tr>
<td>Mean</td>
<td>11.3</td>
<td>6.9</td>
</tr>
<tr>
<td>Median</td>
<td>12.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Bisphosphate (BP) Use Proportion of pts receiving oral or IV BP at or before enrollment</td>
<td>70.0%</td>
<td>63.0%</td>
</tr>
</tbody>
</table>

* n = number of SREs; **Kaplan-Meier estimate

Disclosure: I. Duran: Advisory Board Member, Amgen. A. Bahl: Advisory Board member Amgen, Novartis. G. Hechmati: Employee of Amgen and owns Amgen stock. R. Wee: Employee of Amgen and owns Amgen stock. C. Atchison: Employee of Amgen and owns Amgen stock. All other authors have declared no conflicts of interest.

Background: Cancer registry is a systematic data collection about cancer incidents. They are either population based or hospital based (also known as center based) cancer registries. Population-based cancer registries can help in building hypotheses about cancer shared risk factors in contrast with hospital-based registries which focus more on improving quality of therapy. Standardizing documentation and communication methods fosters collaboration between different regional institutes for building a national cancer registry. In our study we aim at demonstrating how recent Web 3.0 technologies can help cancer registries.

Material and methods: We started by studying the available information technology resources by qualified researchers who work on analyzing clinical research needs. We’ve developed a system analysis after studying paper and computer-based cancer registries. Starting from this set of recommendations we started to match needs and available technologies. Development took place in adherence to international standards of modernization and communication. Implementation and Evaluation phases were conducted with assistance of other clinical researchers, research nurses and cancer registrars.

Results: The analysis phase stated that cancer registries can be improved using interoperability, semantic and visual data entry, client & server side-validation, usability and artificial intelligence technologies that are offered by current Internet era.

, Delivery for mobile phones with intelligent validation and interpretation facilitated the portability of the system. Integration with knowledge bases added a decision support property to cancer registry with providing real-time reports and diagrams plotted over demographic maps. Usability was enhanced by providing user-friendly interfaces.

Conclusions: Cancer registries have potential stunning future by gaining benefit from the recent web technologies. Research on improving cancer information systems should go hand in hand with continuous internet revolution.

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Background: The STARS study was a prospective, multicenter, international, observational study designed to measure the burden of SREs (radiation or surgery to bone, pathologic fracture, or spinal cord compression) in pts with advanced cancer and bone metastases. Here we report results in pts with solid tumors by geographical region for US vs EU (Germany, United Kingdom, Spain, and Italy).

Methods: This analysis included pts with bone metastases secondary to breast, prostate, or lung cancer and ≥ 1 SRE in the 97 days before enrollment (05/08 – 05/10).

1. Data on SREs and health resource utilization (HRU), including inpatient stays, outpatient visits, emergency room visits, nursing home/long-term care facility stays, home health visits, procedures, and certain medications, were collected retrospectively for the 97 days before enrollment and prospectively for up to 21 months. Investigators were responsible for attributing HRU to each SRE.

Results: US = 190 pts with 354 SREs; EU = 478 pts with 893 SREs. Baseline demographics and disease characteristics were similar for US and EU. Inpatient stays were more frequent especially in EU compared with US, and the length of stay was longer in EU (table). Outpatient visits were more frequent in US vs EU, while emergency room visits were similar between regions. Nearly every SRE was associated with a procedure in both regions; however, the number of procedures per SRE was higher in EU, which was in part due to a much greater number of external beam radiation procedures per SRE in US likely reflecting standard use of multi-fraction radiation. Slightly more pts were receiving bisphosphonates at/or before enrollment in US compared with EU, and pts in US received IV bisphosphonates sooner than in EU.

Conclusion: The HRU burden of SREs was substantial in both US and EU. Some regional differences were observed, particularly with respect to hospitalization, length of stay, and time to receipt of IV bisphosphonates.

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Strengths of this observational study include the large sample size of sites and patients contributing to the study. Each site is trained to capture the appropriate data and all data is extracted to a central database. Weaknesses include the lack of randomization and the lack of control for confounding variables. This study demonstrates the potential for using Web 3.0 technologies to improve cancer registries. Future work should focus on more rigorous evaluation of the impact of these technologies on the registries.

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were every 6 weeks (wk) (S1), every 8 wk (S2), and 4, 8, 12 and every 8 wk thereafter (S3), sample size was 250 patients in each group. S3 is the same schedule plan as in the TAS-102 PII trial (2011 ECCO, #6005).

Results: The following table shows the simulation results assumed that a probability of unscheduled progression is 0%. Simulated mPFSs were similar between the schedules in each treatment group of L1 and L2, but not in the control group of L3. Simulated hazard ratios (HRs) were almost the same regardless of the schedules in all lines. The difference of mPFSs between schedules in the control group of L3 depended on the timing of first evaluation. The simulated mPFSs in L3S2 were similar to results of the above three PII trials, and those in L3S3 were similar to results of TAS-102 PII trial. The simulation results assumed the proportion of unscheduled progression of 20% were similar to that of 0%.

<table>
<thead>
<tr>
<th>Setting</th>
<th>True Parameters</th>
<th>Simulation Results</th>
<th>Mean of mPFS (mo)</th>
<th>Mean of HR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mTTP, MST (mo)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L3S1</td>
<td>2, 6</td>
<td>1, 4, 5</td>
<td>1.9 [1.5, 2.6]</td>
<td>1.4 [1.4, 1.4]</td>
</tr>
<tr>
<td></td>
<td>0.58 [0.49, 0.67]</td>
<td></td>
<td></td>
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<tr>
<td>L3S2</td>
<td>1.9 [1.9, 2.0]</td>
<td>1.8 [1.8, 1.9]</td>
<td>0.59 [0.50, 0.69]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.57 [0.48, 0.65]</td>
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<td></td>
</tr>
<tr>
<td>L3S3</td>
<td>1.9 [1.8, 1.9]</td>
<td>1.0 [1.0, 1.1]</td>
<td>0.57 [0.48, 0.65]</td>
<td></td>
</tr>
</tbody>
</table>

TTP: Time To Progression, E: Experimental Group, C: Control Group. [ ]: 2.5 and 97.5% percentiles.

Conclusion: The HR in PFS is a more important indicator than mPFS regardless of the timing of the first evaluation of tumor response in patients with mCRC in the later line. These idea might be applicable for mCRC as well as other cancers.

Disclosure: T. Taneja: Employed by, and own stock in, Taibo Pharmaceutical. C. Hamada: Taibo pharmaceutical. H. Fujii: Chugai Pharmaceutical, Bristol-Myers Squibb, Sanofi-Aventis, Novartis Pharma, GlaxoSmithKline, Eisai, Yakult Honsha, Takeda Pharmaceutical, Shionogi, Taibo Pharmaceutical, Ono Pharmaceutical, Takeda Bio Development Center, N. Nakayama: merck serono, Takeda pharmaceutical. T. Denda: Taibo Pharmaceutical, Pfizer, Yakult Honsha, Daichi Sankyo. T. Yoshino: Consulting fee from Takeda; honoraria from Chugai, Takeda, Yakult, Bristol-Myers Squibb, and MerkSerono; research funding from Daichi Sankyo, Taibo, Bayer, and IncIone. A. Ohbue: Employment position in Bayer, and consulting fee from Takeda, Daichi Sankyo, Novartis, Chugai, and Taibo; honoraria from Takeda, Daichi Sankyo, Taibo, GlaxoSmithKline, Pfizer, Yakult, MerkSerono, and Bristol-Myers Squibb. All other authors have declared no conflicts of interest.

1379P MOLECULAR THERAPEUTICS IN HEAD AND NECK SQUAMOUS CELL CARCINOMA: A SYSTEMATIC REVIEW OF COST-EFFECTIVENESS ANALYSES

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Background: The focus of locally advanced (LA) and recurrent and/or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN) therapy has recently shifted to the molecular level. Although the clinical effectiveness of novel therapeutics has been discussed extensively, the experience with cost-effectiveness analyses (CEAs) of targeted agents is limited. The objective of this study was to systematically review CEAs of molecular therapeutics in LA and R/M SCCHN.

Methods: A systematic literature review was performed focusing on CEAs of molecularly targeted therapeutics in LA and R/M SCCHN using MEDLINE, EMBASE, NHS Economic Database (NHS EED) and the Tufts CE Registry. Studies were screened according to a priori eligibility criteria. Two independent reviewers appraised the studies using published criteria by Philips et al. to assess the quality and methodology of decision analytic models.

Results: A total of four studies and eight CEAs met the inclusion criteria. All CEAs were conducted from the perspective of the health care sector. Country-specific costs were applied. Efficacy data for LA and R/M patients were obtained by the Bonner (Bonner et al.) and the EXTREME (Vermorken et al.) trials, respectively. Lifetime horizon and discounting were considered. The incremental cost-effectiveness ratios of combination therapy with cetuximab ranged from likely to be cost-effective in LA patients ($8,135-$36,691/quality-adjusted life year (QALY) gained) to unlikely to be cost-effective in R/M patients ($158,060/QALY gained). The most influential variable was the cost of cetuximab. Critical assessment of the CEAs revealed that decision analytic models varied in quality and methodology. Type of sensitivity analysis justification of preferred methods, transparency and credibility were key areas in which differences were evident.

Conclusions: Well-performed CEAs suggest that cetuximab may provide good value for money in LA SCCHN patients. Critical review of existing CEAs helps to improve the quality of forthcoming studies. Future research in LA and R/M SCCHN should explore the optimal role of molecularly targeted agents in daily practice.

Disclosure: All authors have declared no conflicts of interest.

1380P THE QUALITY OF SAMPLE SIZE CALCULATION (SSC) REPORTING IN CANCER CLINICAL TRIALS

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Background: SSC is a pivotal step in clinical trial concept and design. It determines the chance of detecting a significant result, ensures appropriate power, and helps sponsors to allocate adequate resources into trials. Here we describe the frequency with which randomized cancer clinical trials (RCT) report the data required for SSC.

Methods: We systematically searched for phase III RCT published in top clinical oncology journals which were accompanied by editorials from Jan 2008 to Oct 2011. We assumed that RCT discussed by editorialists were clinically important. Two blinded investigators extracted data on SSC. Table 1 describes the information required for SSC according to variable type used for primary endpoint.

Results: 140 out of 150 RCT were eligible. Median sample size was 596 subjects (50-40,000) per RCT. In 65.7% of RCT, the number of enrolled subjects was at least 90% of the planned sample size. The primary endpoint was a categorical variable in 19.0%, continuous in 27.9%, and time-to-event in 62.1%. In general, 80.7% reported a planned sample size. 57.9% described their null hypothesis (H0), with 20.7% giving a scientific rationale for H0. 57.9% informed their alternative hypothesis (H1). Alpha (α) and beta (β) errors were explicit in 92.9% and 90.7%, respectively. Expected difference between arms was reported in 88.6%. Only 2.9% of RCT provided all information for proper SSC (required and optional, Table). Excluding "optional information", SSC could be reproducible in 18.6% of RCT.

Conclusion: Regardless of the CONSORT 2010 statement, the quality of SSC reporting in phase III cancer RCT seems inadequate. This may compromise future study designs, pooling of data and interpretation of results. Lack of transparency in SSC reporting may also have ethical implications.

Disclosure: G.M. Bariani: Travel expenses covered: Novartis, Roche. A.C.R.C. Ferrari: Travel expenses covered: Roche. R.P. Riechelmann: Honoraria (Roche, Merk Serono, Novartis and Bayer). Consultancy (Novartis and Merck Serono). Travel to scientific meetings (Roche, Merk Serono, Novartis e Bayer). All other authors have declared no conflicts of interest.

1381P PERCEPTIONS OF CLINICAL TRIALS IN ASIAN CANCER PATIENTS: A COMPREHENSIVE SURVEY IN A KOREAN TERTIARY HOSPITAL

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Background: In the past few years, the number of clinical trials has increased rapidly in East Asia, especially for cancer types such as gastric and hepatobiliary cancer that...
are prevalent in Asian populations. However, the actual degree of understanding or perceptions of clinical trials by cancer patients in East Asian countries have seldom been studied.

Methods: Between July 1st 2011 and November 30th 2011, we conducted a prospective study to survey cancer patients regarding their awareness of, and willingness to participate in, a clinical trial. The questionnaire consisted of 21 questions based on an Index of Clinical Trial Understanding. Patients with gastrointestinal/hepatobiliary cancer who visited the Hematology-Oncology outpatient clinic at Samsung Medical Center (SMC) and who signed an informed consent form were enrolled. The survey was conducted by a well-trained research nurse and the data were statistically analyzed at the biostatistics core at SMC.

Results: In this survey study, 1,000 patients were asked to participate and 675 patients consented to participate (67.5%). The awareness of clinical trials was substantially higher in patients who had a higher level of education (p = 0.001), were married (p = 0.004), and had a higher economic status (p = 0.001). Willingness to participate in a clinical trial was not significantly increased by higher level of education (p = 0.286), marital status (p = 0.685), or economic status (p = 0.310). The most common source for acquisition of clinical trial knowledge was attending physicians (52.0%) followed by mass media (36.6%), other patients (6.39%), the internet (5.3%), and other sources (1.5%). The most influential factors for patient’s willingness to participate were physician’s opinion (N = 181, 26.8%), limited treatment options (N = 178, 26.4%), and expectations of effectiveness of new anti-cancer drugs (N = 142, 21.0%). Patients were likely to refuse to participate in a clinical trial due to unverified treatment morbidity (N = 320, 47.4%) and negativity toward clinical research (N = 191, 28.6%).

Conclusions: We surveyed a large patient cohort to specifically inquire about willingness to participate in, and awareness of, clinical trials in patients with Asian-prevalent cancer types. Further correlative analyses with diverse variables will be presented at the meeting.

Disclosure: All authors have declared no conflicts of interest.

1382P

AWARENESS AND UNDERSTANDING OF STRATIFIED/PERSONALIZED MEDICINE IN PATIENTS TREATED FOR CANCER: A MULTINATIONAL SURVEY

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Background: The identification of biomarkers predictive for the efficacy of targeted anticancer agents allows for the tailoring of treatment to maximize patient (pt) benefit and outcomes. It is important that information about the potential for personalized anticancer therapy is available to pts so that they are fully informed about treatment and biomarker screening options. The current survey assessed pt awareness and understanding of these issues.

Methods: Pts with a diagnosis of late-stage breast cancer (BC), stage III/IV non-small cell lung cancer (NSCLC) or metastatic colorectal cancer (mCRC) within the previous 5 years were eligible. Participating physicians or pt organizations in seven countries (Argentina, China, France, Germany, Italy, Spain and the UK) identified potentially suitable pts and invited them to take part. Written informed consent was obtained from all pts, with those confirmed as eligible then completing a telephone-based questionnaire.

Results: Questionnaires were completed by 811 pts: 164 previously diagnosed with BC, 157 with NSCLC and 490 with mCRC. Of those interviewed 260/811 pts (32%) thought that there was no method of testing to determine which cancer treatments might work (or work better) in certain people, while 430/811 pts (53%) thought that such testing might be possible (62% of pts with BC, 48% with NSCLC and 52% with mCRC). Most pts (532/811, 66%) were willing to delay treatment if that helped select the most effective drug, 286/532 (54%) of those, by more than two weeks, and most (557/811, 69%) were willing to undergo a tumor re-biopsy as part of any such treatment selection process. Almost all pts (737/811, 91%) would allow a hospital to retain a tumor sample for future research. The internet was cited as a useful source of information regarding disease and treatment options by 192/811 pts (24%).

Conclusions: Pts are generally willing to participate in biomarker test procedures to facilitate the personalization of their treatment. There is considerable scope for physicians and support groups to better inform pts that not all cancers are the same and that new tests may be able to identify which pts will benefit most effectively for them.

Disclosure: S. Tejpar: The author declares research and speakers’ bureau funding from Merck Serono. T. Teague: The author is an employee of Merck KGaA. J.

1383P

WHEN DOES PERSONALIZED CANCER THERAPY RESEARCH PROVIDE POSITIVE RETURN ON INVESTMENT IN EUROPE?

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Background: Personalized cancer therapies targeting pre-specified genetic mutations currently benefit only subsets of patients. Developing the technologies and supporting the research to identify new targets and treatments requires a significant monetary outlay. How much money should the European public invest in such research?

Methods: Since current investment should be less than or equal to the net present-value (NPV) of the future health gains achieved, the marginal benefit gained from a new drug can be estimated by calculating the difference between the incremental cost-effectiveness ratio (ICER) and the willingness-to-pay (WTP) for the incremental health by society. We calculated the NPV of the future development for new drugs with similar characteristics to crizotinib, a prototypic personalized cancer therapy. Sensitivity analyses were performed to assess the influence of WTP thresholds, time horizon of return, and size of treatable population. Systematic reviews of PubMed and EMBASE were employed to determine the current range of ICERs for approved small-molecule inhibitors and monoclonal antibodies, and WTP thresholds. European cancer statistics were used to estimate the size of population who may benefit.

Results: Of 1576 titles, 104 abstracts and manuscripts were included in the final analysis. The median ICER for targeted therapies was €45,000 (range, €10,000–€163,000), and median WTP was €50,000 (range, €2,000–€512,000). With a development time horizon of 8 years, €840 million in research funding provides positive societal returns for new pharmaceuticals bought at a marginal value of greater than €5,000. Doubling the time horizon reduces the NPV of current research by €230 million. If current-generation personalized therapies are dominated by newer technologies earlier than predicted, halving their market-life as an example, only €500 million in public investment would be worthwhile. The NPV of research was highly sensitive to changes in the estimated size of the treatable population. Focusing on drug development for breast, lung, and colon cancer only, may yield a NPV for research of €1.34 billion.

Conclusion: Regional differences in cancer incidence and WTP for new therapeutics should be formally incorporated into research funding decisions to ensure optimal resource allocation.

Disclosure: All authors have declared no conflicts of interest.

1384P

ARE THERE DIFFERENCES IN PATIENT CHARACTERISTICS AND TREATMENT PATTERNS BY TREATMENT SETTING?

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Background: Few studies have examined whether differences in treatment and outcomes exist among cancer patients by the setting where care is delivered. This study investigates differences in demographics, treatment patterns and health care resource use among non-Hodgkin’s lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL) patients receiving rituximab (R) or R+ chemotherapy based on site of care: office/practice (OC) vs. hospital outpatient (HO).

Methods: Patients ≥18 years with evidence of NHL or CLL diagnoses code at least 30 days apart and received ≥2 R claims from Jan 2007 to Mar 2011 were identified from a large US commercial insurance claims database. Patients were required to be enrolled in the health plan for at least 6 months before and after the index date (date of first R claim). The follow-up period was the date of the first infusion to 30 days after the last infusion prior to a gap of ≥7 months. Patients with evidence of multiple cancers or receipt of R at both sites of care were excluded. Cohorts were created based on site of care where R was administered. Multivariate analyses examined differences in number of infusions, ER visits and inpatient stays by cohort.

Results: There were 2,594 OC and 286 HO patients with a mean follow-up of 242 days and 289 days, respectively. Compared to the HO cohort, the OC patients were significantly younger (71yrs vs. 63 yrs), had a lower mean baseline Charlson comorbidity index (3.88 vs. 3.40) and a lower percentage were Medicare
Advantage enrollees (83% vs. 25%) [each p < 0.01]. The mean R infusion count was 7.4 (OC) vs. 5.4 (HO) with a monthly mean of 1.19 (OC) vs. 1.00 (HO) [each p < 0.01]. In adjusted analyses, R infusion counts were also lower for HO compared to the OC cohort (IRR 0.80, CI 0.75-0.86) and HO patients had higher number of inpatient stays (IRR 1.40, CI 1.07-1.84) though ER visits were not different between cohorts.

Conclusions: Patients treated in the OC setting compared to the HO setting had different treatment patterns and fewer inpatient days. These results warrant further investigation to assess whether clinical outcomes differ by site of care.

Disclosure: C. Reyes: Has Roche stock and employment at Genentech/Roche. S. Dacosta Byfield: Employed at OptumInsight, the entity that was paid by Genentech to conduct the study. A. Small: Has Roche stock and employment at Genentech/Roche.

1386P ABBREVIATED COMPREHENSIVE GERIATRIC ASSESSMENT (CGA) IN ELDERLY CANCER PATIENTS: PRELIMINARY RESULTS OF AN OBSERVATIONAL PILOT STUDY

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Background: In Western countries elderly people constitute the fastest growing segment of the population and currently in our Institute patients aged ≥70 are about 43% of all cancer patients. CGA is a key component of the treatment approach for this population, but it is time-consuming.

Methods: This is an observational pilot study on consecutive therapy-naive elderly cancer patients (aged ≥70 years). The main aims were to verify the feasibility of an abbreviated CGA (aCGA) in an outpatient setting, the acceptability by patients, physicians, and nurses as well as the ability of this tool to discriminate the three prognostic classes of older cancer patients: fit, vulnerable, frail. Patients underwent aCGA (which consisted in filling in some short questionnaires, instead of the standard ones) with a medical oncologist (medical history, clinical examination, ECOG-performance status. Cumulative Illness Rating Scale-CIRS) and with a nurse (Activities Daily Living-ADL, Instrumental ADL, Mini Nutritional Assessment-MNA, cognitive Short Blessed Test, Geriatric Depression Scale-GDS, Quality of Life Health Survey-SF-12, motor status).

Results: From January 2010 to November 2011, 151 patients were enrolled. Median age was 77 (70-91) years, and 47% were males. Patients, doctors and nurses evaluated the information obtained by aCGA as, respectively: very useful in 47, 66, 42% and quite useful in 47, 28, 52%. The time required for the compilation of the questionnaires with nurses was <30 minutes in 40% of cases, 31-60 min in 43%, and >60 min in 17%. Physicians considered to have had no difficulty (83%) or little difficulty (10%) in compiling the form,. For nurses these figures were 40% and 43%.

PREDICTORS OF NONCOMPLETION OF CANCER TREATMENTS IN ELDERLY PATIENTS: THE ELDERLY CANCER PATIENTS (ELCAPA) COHORT STUDY

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Background: The objective was to assess 1) prevalence and the predictors of non-completion of cancer treatments in elderly and 2) prognosis value of non-completion of cancer treatments.

Methods: Between 2007-2010, 421 consecutive patients aged 70 years and older with solid tumors and indication of surgery, chemotherapy (CT), hormonal therapy (HT) or radiotherapy (RT) were included. Comprehensive Geriatric Assessment was performed at baseline. Patients were followed up for completion of surgery, first line CT (observed/expected number of cycles < 1), RT and HT (observed/expected dose < 1) and one year overall survival. Multivariate logistic regression and Cox -Proportional Hazard Model were used to estimate predictors of noncompletion treatments and survival.

Results: Mean age was 79.2 years (±5.4) years and 224 patients (53.2%) were women.190 (45.1%) had gastrointestinal, 109 (25.9%) gynaecologic and 97 (23%) genitourinary primary tumors.192 (45.6%) had metastatic disease. 76 (33.3%) received platinum-based therapy, 10 of noncompletion was 39.1% for CT versus 65.5 %, 3.5 % and 2.4 % for HT, surgery and RT respectively. In multivariate analysis, predictors of noncompletion of CT were: poor performance status (PS ≥ 2), living alone (HR = 2.1, 95 %CI, [1.06-4.17], p = 0.03, (or Activity of Daily Living (ADL): OR i point decrease ≥ 1.5, [1.1-2.0], p < 0.024), decreased renal function: OR1 ml/min decrease Cockcroft clearance = 1.02, [1.03-1.03], p< 0.009 and living alone :OR = 1.9, [1-3.6], p = 0.05. One year rate of mortality was 26.2 %. Independent prognostic factors for survival were noncompletion of CT: HR = 3.6, [2.2-6], p < 0.0001, a poor functional status (ADL HR i point decrease ≥1.5, [1.3-1.9], p< 0.0001, metastatic disease.HR = 3.3, [1.7-6.3], p <0.0001 and malnutrition: HR = 2.6, [1.6-4.4], p < 0.0001.

Conclusion: In the elderly with solid tumors, noncompletion of CT was common whereas HT, RT and surgery were not. Predictors of noncompletion of CT are poor functional status, decreased renal function and living alone. Noncompletion of CT is an independent prognostic factor for survival.

Disclosure: All authors have declared no conflicts of interest.

WILL ‘FIT’ OLDER CANCER PATIENTS AS ASSESSED BY FRAILTY SCREENING TOOLS TOLERATE THE FIRST CYCLE OF RADIOTHERAPY CHEMOTHERAPY WITHOUT SERIOUS ADVERSE EVENTS?

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Background: There is a need for tools to effectively select elderly cancer patients for therapies with significant potential toxicity such as chemotherapy. The Comprehensive Geriatric Assessment (CGA) is recommended by several guidelines to guide the oncologist in treatment decision making. However, because CGA is time and man-power consuming a two-step approach with screening has been recommended. This pilot study was undertaken to evaluate the predictive validity of 2 frailty screening tools in relation to the tolerability of chemotherapy in ‘fit’ older patients.

Methods: Patients over 65 years with various types and stages of cancer were screened for CGA before start of treatment with the Groningen Frailty Indicator (GFI) and the G8 screening tool. ‘Fit’ patients were defined as having a normal screening test. A G8 score of ≤14 corresponds with an abnormal screening test. For the GFI we evaluated 2 cut-off values. Serious adverse events (SAE) were recorded during the first cycle of treatment.

Results: From October 2009 to December 2011, 85 patients (44 women) were included in the study. The median age was 76 years old (range: 66-88 years). The treatment intent was curative in 39 patients (46%) and palliative in 46 patients (54%). In total, 15 patients (18%) had a SAE of which 3 resulted in death. According to the GFI 60% were ‘fit’ whereas the G8 identified 30% as ‘fit’ prior to treatment. The probability to complete the 1st cycle of chemotherapy without a SAE for ‘fit’ patients was according to the G8 and the GFI (cut-off ≥ 4) respectively 77% (95%CI: 63-89%) and 78% (95%CI: 73-86%). The alternative cut-off ≥ 3 for the GFI resulted in probability of 85% (95%CI: 79-94%) to tolerate treatment.

Conclusion: Patients with a normal screening test for CGA are considered to be able to tolerate proposed treatments comparable to younger patients. However, no data exist concerning this assumption. In this study, we attempted to address this in a heterogeneous sample of older cancer patients for 2 screening tools. Further research is needed to compare standard of care with this CGA-based approach with screening.

Disclosure: All authors have declared no conflicts of interest.

COMPLEMENTARY AND ALTERNATIVE MEDICINES (CAM) – A CURSE TO BREAST CANCERS OF THE INDIAN SUBCONTINENT

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Purpose: In India, CAM practitioners give a major share of the first visits by patients with breast lumps, leading to inadvertent delays in their management. This multi-institutional prospective study conducted in IPGMER, MCH & RG Kar, Kolkata, aims to quantify the exact percentage prevalence of CAM usage,
USE OF INTEGRATIVE THERAPIES IN BREAST CANCER PATIENTS, HEALTH SERVICE RESEARCH IN A NETWORK OF INTEGRATIVE ONCOLOGY

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Background: Diagnosis of breast cancer induces high emotional distress. Integrative oncology (IO) responds to patients needs by offering a variety of non-pharmacotherapeutic interventions (NPI) and Viscum album extracts (VA). VA enhances health-related quality of life and reduces adverse effects caused by conventional strategies, whereas NPI activate patients’ resources. In the present study we evaluated the use of IO therapies in breast cancer patients from a clinical registry.

Methods: We analyzed 3289 female patients collected by the Network Oncology, a conjoint clinical registry of German hospitals and out-patient practitioners. We used non-parametric Fisher exact test (F) to compare observed frequencies, Wilcoxon rank sum (W), Kruskal-Wallis test (KW) for differences between groups. We fitted a conjoint clinical registry of German hospitals and out-patient practitioners. We used

Mean age was 54.5 ± 11.7 and frequencies of UICC stages were 0: 71%, I: 29.5%, II: 15%, III: 15% and IV: 7.6%. 93% of the patients got VA and were in median three years younger than non-VA patients (medVA = 52, W = 0.002). Median length of VA was 4.11 years (1stQ 0.13, 3rdQ 7.42) and was neither influenced by UICC nor obvious reasons, none biopsied, valuable 9.3 months lost & 56% presenting upstaged, the anticipated prognostic losses are unacceptable large.

Conclusion: With more than 1/3 of breast cancer patients still opting for CAM for obvious reasons, none biopsied, valuable 9.3 months lost & 56% presenting upstaged, the anticipated prognostic losses are unacceptable large.

Disclosure: All authors have declared no conflicts of interest.
Methods: We retrospectively reviewed hepatitis B and C serology in 746 consecutive early breast cancer patients treated at National Institute for Cancer Research between January 2009 and March 2011. All patients were screened for hepatitis B antigen (HBsAg), HBc antibodies (HBcAb), HBs antibodies (HBsAb) and HC (HCV) antibodies. Data collected included patients and tumour characteristics, treatment received, changes in aminotransferases and impact on systemic treatment (delay or discontinuation). A comparison between patients with positive serology (cases) and patients with negative serology or vaccinated for HBV (controls) was performed.

Results: 371 patients were excluded because serology was not available. Among 375 evaluable patients we identified 312 controls (83.2%) and 63 patients (16.8%) with positive serology defined as cases: 16 patients (4.2%) with HBV infection, 8 (2.1%) with occult HBV (HBsAg negative, HBsAb Ab negative, HBCAg Ab positive), 36 (9.6%) with cleared HBV (HBsAg negative, HBsAb Ab positive, HBCAg Ab positive) and 4 (1%) with chronic HBV (HBsAg positive, HBsAb Ab negative, HBCAg Ab positive). Because of the lack of serum HBV DNA and HCV RNA evaluation, we adopted only a clinical definition of hepatitis, i.e. at least threefold increase in serum ALT level. Hepatitis, according to this definition, during systemic treatments occurred in 9 (20.4%) of 44 evaluable cases and in 14 (5.9%) of the 234 evaluable controls. The increase in transaminases resulted in discontinuation of systemic treatment in 3 patients (6.8%) among cases and in 2 patients (0.85%) in the control group.

Conclusion: Nearly 16% of newly diagnosed breast cancer patients have positive serology for viral hepatitis and about 20% of them may develop hepatitis during systemic treatment. Pretreatment serum detection of viral hepatitis B and C antigen and antibodies may be useful for adequate monitoring of liver function during anti-cancer therapy.

Disclosure: All authors have declared no conflicts of interest.
Results: The mean serum 25(OH)D concentration of 197 cases with lung cancer in China was 10.63 ± 7.04ng/mL; the proportion of vitamin D deficiency was 173/197 (87.7%). Among them, 24.4% were female (vs. 16% in 2000; p < .0001). There was no significant difference between male and female NSCLC patients regarding age (65.7± 10.9 vs. 64.9± 13.0, p = 0.03). Regarding smoking status, between 2000 and 2010, women remained more frequently former smoker (21.3% vs. 46.8%) and showed lower consumption (37.2 ± 13.5 vs. 64.9± 13.0, p = 0.03). Regarding tumor characteristics, between 2000 and 2010, the percentage of adenocarcinomas significantly increased in both women (53.4% in 2000 vs. 65.9% in 2010; p < .0001) and men (32.4% vs. 49.4%; p < .0001). However, in 2010, tumors remained more frequently adenocarcinomas in women than in men (65.9% vs.49.4%; p < .0001). In addition, in 2010, when explored (48.5% in women vs. 32.4% in men; p < .0001), an EGFR mutation was more frequently found in women than men (20.6% vs. 5.2%; p < .0001), stage IV tumor more frequent in women than men (62.4% vs. 56.9%; p = 0.0008), and regarding first-line treatment, 64.5% of women vs. 61.0% of men (p = 0.01) received chemotherapy and 13.4% of women vs. 5.7% of men (p < .0001) targeted therapy. In 2010, tumors, non-smokers among men, and adenocarcinomas in both men and women increased. However, differences between women and men in baseline and tumor characteristics persist.

Conclusion: Breast cancer in young women (<35 years) is uncommon and accounts for 1-2 % of all breast cancer cases in the West. There is a paucity of data on young breast cancer from India. The aim of our study was to assess clinical, pathological parameters and outcome of breast cancer in young breast cancer patients.

Methods: This analysis was carried out in 250 patients aged 35 years or less, who were registered in our clinic between 2000-2011 at I.R.C.H., A.I.M.S. This constituted about 7.5% of all cases. Patients’ records were analyzed from computer database using ICD code (C-50).

Results: The median age was 31 years (range 18-35). The median duration of symptoms was 10 (range 0.25-60). Breast lump was the commonest (93%) presenting symptom (left >right side). Ninety percent of patients were married and median age at first child birth was 23 years. Positive family history was elicited in 10 patients. Five patients presented with synchronous malignancy. The TNM (7th edition) stage distribution was stage I - 2.5 %, stage II - 30%, stage III - 46.5%, and stage IV - 22%. The median clinical tumor size was 5.0 cm. Modified radical mastectomy was the commonest surgical procedure and this was done in 83 % of cases. The histopathological analysis showed 94% had infiltrating ductal carcinoma. Thirty percent of tumors were high grade and 70% had pathological node-positive disease. ER/PR and Her2neu positivity was 33% and 29%, respectively. Triple-negative breast cancer (TNBC) constituted 31%. A combination of anthracyclines and taxanes were used in the majority of patients and trastuzumab was used only in 3 % of cases. With a median follow up of 28 months (non-metastatic group), 3-year disease-free survival (DFS) and overall survival (OS) was 50% and 60%. Higher- Nodal stage, tumor size (>5 cm), negative hormonal status (triple negative) and visceral metastasis as baseline predicted poor outcome.

Conclusion: Young women constituted 7.5 % of breast cancer cases. The proportion of triple negative (nearly one third) was also higher than the Western population. Higher stage and triple negative status results in poorer outcome.

Disclosure: All authors have declared no conflicts of interest.
cancer tumors 12%, Germ cell tumor 8%, Brain tumor 4% and other 12%. During preliminary diagnosis of these patients prior to beginning of therapy, an initial anthropometry was done in all the cases that included measurements of Weight for age (WFA), Height for age (HFA), Mid arm circumference (MAC), Biceps Skin Fold Thickness (BSFT). The values of these variables were compared with the ICNR recommended standards provided by percentile curve of the growth chart for that age and sex. BSFT lies between 3.8cm and 6.5cm but during malnutrition it falls below 3.8cm. We pursued initial diagnosis based on biochemical parameters, chiefly, serum total protein and serum albumin levels. The albumin level was considered normal if the value was equal to or more than 3g. It was seen that 190 (38%) children were malnourished on diagnosis. The patients with malnutrition had poor outcome (45%) as compared to well-nourished children (80%). Malnourished children also showed significantly higher toxicity level (<.0001). Hence we concluded that malnutrition was an important determinant factor for outcome of pediatric cancer patients. Next we would like to focus on assessment of nutritional status in children starting cancer chemotherapy, radiology and surgery.

Disclosure: All authors have declared no conflicts of interest.

IATRIGGER PROJECT: DEVELOPMENT AND VALIDATION OF A TOOL TO EVALUATE ADVERSE DRUGS EVENTS IN ONCOLOGY PATIENTS

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Objective: Adverse events related to drugs occur frequently and many of them are preventable. Despite cancer treatment is known to involve hazardous drugs, there are few practical methods to identify adverse drug events (ADEs) and measure harm to the patient. The purpose of this work was to develop a tool for adverse event detection in oncology patients.

Methods: The Trigger Tool approach has been developed and tested in oncology. First, 27 triggers were identified and dichotomous were constructed, based on international, national or local recommendations. Second, 11 clinical experts have validated the content of each trigger on three criteria: the criticality of the adverse event, the educational value of feedback, and the clinical relevance of the analysis. For each trigger, severity has been graded according to the NCI CTCAE 4.03. Third, the feasibility of the analysis based on a random sample of 130 patient records has been assessed through the time of analysis for each patient record, and the number of trigger and ADE observed.

Results: Experts evaluated the criticality of the 27 triggers from 5.1 to 10.9/25 and their educational value from 4.5 to 7.7/10. Regarding the feasibility analysis, 1157 patients were included in the study and 1359 ADEs were identified, 88 of which are adverse events and 46 were drug related (ADE). The study counted 0.6 ADE/patient, including 1 grade 3 or more ADE for 11.8 patients. The most frequently observed ADE were constipation (7 ADE), fall (5 ADE), hypo/hyperglycemia (4 ADE), hypo/hyperkaliemia (3 ADE). The average time of analysis was established at 26min35s by patient record. Based on these results, 22 triggers have been preserved, composing the Itrigger tool.

Conclusion: ADE detection is an important priority in patient safety research. The use of a ADE detection method requires some resource commitments. However, a validated tool like the Itrigger tool can be applied in different hospital settings, allowing a precise follow-up of this particularly frail population.

Disclosure: All authors have declared no conflicts of interest.

ESSOR STUDY: ORAL CHEMOTHERAPIES FOR ONCOLOGY PRACTICES: A RETROSPECTIVE ANALYSIS IN THE COMMUNITY SETTING FOR SELECTED DRUGS

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Background: Use of oral chemotherapies is still increasing: currently it represents about 10% of anti-cancer drugs. In 2015, it might be between 25-30%. Oral drugs take part in the increased survival and improvement of patient’s quality of life. The Observatory of Cancer Bretagne – Pays de la Loire and the French Regional Health Insurance System had made an observational study of oral cancer drug use in its area (10% of French Population).

Methods: French Regional Health Insurance System has made an extract in its database for patients treated with oral cancer drugs (erlotinib, everolimus, gefitinib, sorafenib, sunitinib) between september 2009 and the end of 2010 (projected three-year follow-up) : prescriber (competence in oncology or not), patient care reimbursed by the health insurance system, gender, age, death, cancer location, type of drug have been collected.

Results: 1313 patients (846 men and 437 women) were analysed: 630 patients from Brittany and 683 from Pays de la Loire. According to the National health system, 13.5% of patients did not have optimal reimbursement for care. 30% of patients were under 59 years old, 35% between 60 and 69 and 35% over 70. The more significant cancer location was lung (53%), kidney (26%), digestive tract (19%) and breast (2%). Indeed oral cancer drugs have greatly improved the management of patients with non small cell lung cancer (erlotinib, gefitinib) or kidney cancer (sunitinib, sorafenib, everolimus). More than half of patients were died between 2010 and the end of April 2011. 74% of patients have taken oral drugs for the first time in 2010. 82% of prescriptions have been done according to oral chemotherapy label (10% for another cancer; 8% insufficient data). 5% of patient have received more than a first line oral drug during the follow-up (mainly for kidney cancer).

Conclusions: Few data have been published about successive oral chemotherapies and their impact on clinical response, overall survival, toxicities and quality of life. That’s why we wanted to complete these data via two dedicated studies about kidney cancer (IVOIRE) and lung cancer (EPINIB). Moreover, compliance of patients treated for a kidney cancer, toxicity of treatment and drugs interaction will be evaluated via a pharmacoeconomic approach through face to face interview (IPTATCOS).

Disclosure: All authors have declared no conflicts of interest.

DRUG INTERACTIONS IN CANCER PATIENTS TREATED WITH ORAL ANTI-CANCER DRUGS

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Background: Drug–drug interactions (DDIs) in patients with cancer are common, and most DDIs can cause considerable adverse reactions. At present, epidemiological data regarding DDIs in oral anti-cancer therapy is totally absent in the literature. Therefore, we assessed the prevalence of DDIs among ambulatory cancer patients on oral anti-cancer treatment.

Methods: A search was conducted in a computer based medication prescription system for dispensing oral anti-cancer drugs to out-patients. DDIs were identified using electronic (Drug Interaction Fact software) and manual screening methods (peer-reviewed reports). DDIs were classified by the level of severity and the level of scientific evidence. Descriptive statistics and binary logistic regression analyses were performed to analyze the data.

Findings: In the 898 patients included in the study, 1359 DDIs were identified in 426 patients [46%, 95% confidence interval [CI] = 42% to 50%]. In 143 patients (16%) a major DDI was identified. The drug classes most frequently involved in a major DDI were coumarins and anti-infective drugs. The majority of cases concerned central nervous system interactions (73%) DDIs that can cause gastrointestinal toxicity or prolongation of QT intervals were also seen frequently. In multivariate analysis, concomitant use of more drugs [odds ratio [OR] = 1.66, 95% [CI] = 1.54-1.78, P <.0001] and genito-urinary cancer [OR = 0.25, 95% [CI] = 0.12-0.52, P <.0001] were identified as risk factors for DDIs.

Interpretation: DDIs are very common among cancer patients on oral cancer therapy. To identify and avoid DDIs a computer-based patient record is needed. Funding: This study was supported by the Maastricht University Medical Center.

Disclosure: All authors have declared no conflicts of interest.

The International Collaborative Project to Evaluate the Availability and Accessibility of Opioids for the Management of Cancer Pain: Survey Result

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Introduction: The International Collaborative Project to Evaluate the Availability and Accessibility of Opioids for the Management of Cancer Pain was coordinated by ESMO, EAPC, UICC, PPSG + WHO with the collaboration of regional and international palliative care and oncology societies.
To develop a comprehensive database on the availability and accessibility of opioid medication for the management of cancer pain in: Africa, Asia, Latin America and the Caribbean and Middle East. The adequacy of formulary availability is evaluated relative to the International Association of Hospice and Palliative Allie list of Essential Medicines for Palliative Care. Overregulation is evaluated according to descriptors identified by the World Health Organization and the International Narcotics Control Board.

Results: Between 12/2010-7/2012, 156 reports were submitted from identified reporters in 76 countries and 19 Indian states (58% countries, 83% population). Very few countries provide all 7 opioids on the essential drug list of the IAHPC (codeine, immediate and slow release oral morphine, oral IR oxycodone and transdermal fentanyl) and in many countries less than 3/7 drugs are available. Furthermore, in most of the countries opioids are either not or are weakly subsidised by govt. and availability is often limited. Many countries have highly restrictive regulations that limit entitlement of cancer patients to receive prescriptions, limit prescriber privileges, impose restrictive limits on duration of prescriptions, restrict dispensing, and increase bureaucratic burden of the prescribing and dispensing process.

Conclusions: In many places across Africa, Asia, ME and L.+C America governments are failing cancer patients in delivery of adequate pain relief. There is a need for increased availability of affordable opioids for the management of cancer pain. A priority action is examination of drug control policies and repeal of excessive restrictions which impede this most fundamental aspect of cancer care.
ONCOMOVIES: CANCER IN CINEMA

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Aim: To describe how movies portray cancer, and the experience of illness, through an analysis of movies throughout more than 70 years of cinema.

Materials and methods: Cross-sectional descriptive study. In order to retrieve the relevant literature, we searched the Medline database using different keywords. A sample of convenience of films was analysed in which cancer had “prominent”, “relevant”, or ‘plot’ character. Movies yearbook and databases (allmovie, IMDb, Movierplay, Mymovies) were consulted. Each film was viewed by two observers who recorded patients variables (age, gender, marital status, etc), the cancer process (type, symptoms, therapy, and evolution), and the health care environment, among others.

Results: 376 papers have been retrieved, but only a small percentage has been considered as relevant to the study. 75 films produced by 13 countries (years 1939-2012) were analysed. 40 patients were women, 35 men, and 64% belonged to the upper and upper/middle social class. The most common cancers were lymphoma, CNS tumours, and leukemia. In 21 films the type of cancer was not mentioned. Symptoms were considered in 72% of the movies, while diagnostic tests were mentioned in 65%. The most frequent treatment mentioned in the movies was chemotherapy followed by antilag therapy. Death occurred 46 times (63% of all movies). Doctors and nurses turned up in 58 films (77%).

Conclusions: there is a trend of cancer narrative in movies, especially in the last few years. Cancer experiences described in the films are quite different from the truth: movies prefer younger patients, higher social class; the prevalence of cancer does not match the epidemiological data (e.g. breast cancer only in 5 movies). However, symptoms, diagnostic tests, and treatments tend to be based on real life, particularly in the production of the last twenty years. Usually, cancer patients die at the end of the movie. Some of the films evaluated may be a first hand resource for training health professionals, while some others could be a valuable example of malpractice.

Disclosure: All authors have declared no conflicts of interest.

NEOPLASTIC DISEASE AND CHRONIC KIDNEY DISEASE: DOES THE ASSOCIATION WORSEN PROGNOSIS?

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Neoplastic diseases (ND) and chronic kidney disease (CKD) are strongly related. Side effects of neoplastic treatments can cause CKD and the latter can be a risk factor for ND. Even in early stages of CKD, the risk of developing ND increases, the latter being drastically increased in patients (pts) treated with hemodialysis.

Objectives: Compare, within a population of cancer pts with and without CKD, demographic characteristics, length of hospital stay, and prognosis.

Methods: Observational prospective study with all consecutively admitted pts in an Internal Medicine department of a CentralHospital between November 2010 and October 2011. Collection of data using a previously normalized questionnaire, completed on admission and date of release, finalized with a posterior telephonic contact. The following characteristics of pts with ND and CKD (GFR CKD < 60 mL/min/1.73m2) - GROUP A (GA) and with ND but without CKD - GROUP B (GB) were compared: demographics, in-hospital evolution, hospital stay and post-release mortality.

Results: We evaluated 104 pts with ND with an average follow-up of 162 days. GA= 40 pts (38.5%) 78.9 ± 10.6 years, 52.5% women, GFR =39.6 ± 12 mL/min/1.73m2, stages III = 77.5%, IV = 22.5% GFR =64 pts (61.5%), 72.9 ± 12.6 years, 46.9% women, GFR = 72.9 ± 14.5 mL/min/1.73m2. Hospital stay length: GA 9,3 ± 5 vs GB 9.9 ± 9.3 days. Hospital stay mortality: GA: 27.9% VS GB: 11.5%.

Conclusions: CKD correlates with hospital-stay mortality: (χ² = 13,371; p = 0.000 N = 104); Significant differences were found between both groups pertaining to average survival during follow-up: (U = 53,2; Z = 3,437; p = 0.001); The average length of hospital-stay and the number of readmissions are not related to the existence of CKD: (χ² = 0,399; p = 0,53 N = 90)

Conclusion: More than 1/3 of ND pts had CKD, the majority within stage III. ND pts with CKD were older. CKD contributed to hospital stay mortality and shorter survival rate on follow-up of pts with ND but did not contribute to an increase of hospital stay length.

Disclosure: All authors have declared no conflicts of interest.
CANCER AND LUNG TRANSPLANTATION

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All authors have declared no conflicts of interest.

Introduction: Malignancies rank fourth on the leading causes of death in recipients of solid organ transplants. High-dose immunosuppression, infections with oncogenic viruses and the pre-transplant risk, mainly due to tobacco, make these patients more susceptible for developing cancer. In the present study we reviewed a collective of 50 patients with lung transplantation (LT) and cancer.

Patients and methods: Retrospective study of 503 lung transplant patients, performed at the Hospital Universitario Puerta de Hierro Majadahonda, Madrid, SPAIN, Pulmonology, Hospital Universitario Puerta de Hierro Majadahonda, Madrid, SPAIN, Medical Oncology, Hospital Universitario Puerta de Hierro Majadahonda, Majadahonda, SPAIN.

Results: The 503 included transplant patients developed a total of 55 post-transplant malignancies in 50 patients. Four patients presented tumors already previous to the transplantation. The main underlying pathologies of the patient collective are idiopathic pulmonary fibrosis (50%), emblysma (30%) and cystic fibrosis (14%). The histology of the 55 post-transplant tumors was distributed as follows: 18 skin cancer, 12 lung cancer, 8 gastrointestinal cancer, 6 Non-Hodgkin’s Lymphoma, 2 bladder cancer, 2 myelodysplastic syndrome, 2 sarcomas and 5 others. The mean age of diagnosis of malignancies is at 59 years (18-68). The mean time from transplantation to tumor diagnosis amounts 4 years (1-15). Of the 21 patients (42%) that have died until data collection, cancer was death cause in 15 (30%).

Conclusion: Relying on our data, the majority of malignancies are skin and lung cancer and lymphoproliferative syndromes, attributing complications that should be considered in lung transplantation.

Disclosure: All authors have declared no conflicts of interest.

A REINFORCEMENT LEARNING APPROACH FOR OPTIMIZATION OF CHEMOTHERAPY AND ITS APPLICATION IN OPTIMAL CONTROL

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The diagnosis and treatment of the cancer has been the subject of discussion in different scientific fields in the recent years. In this paper, an optimal control strategy for the nonlinear systems is presented for application in chemotherapy of the cancer. The tumour growth model can be represented by a system of equations from population dynamics based on the competition between normal cells and tumour cells. The effect of the immune system on cancer is also included in the model. Reinforcement learning technique is proposed to eradicate in a very short time with a small amount of drug using proposed optimal method of the therapy.

Disclosure: All authors have declared no conflicts of interest.

ALLOCATION OF PHYSIOLOGIC RESERVE FOLLOWING CHEMOTHERAPY AS A MARKER OF FRAILTY IN ELDERLY CANCER PATIENTS


Introduction: The aim of this study is to identify the presence of frailty in elderly patients with cancer by comparing their functional reserves before and after treatment with chemotherapy.

Materials and methods: This study is a prospective cohort study of cancer patients over 70 years of age who were consecutively evaluated between January 2010 and December 2011 in the Cancer Consultation in the Elderly program, Medical Oncology Section, Virgen de la Luz General Hospital in Cuenca. Group A comprised patients treated with chemotherapy, and group B comprised untreated patients. For each group, we collected demographic data, data concerning the cancer and data describing the physiologic reserve relating to each individual (muscle mass evaluation [MME], walking speed, peak-flow, grip strength, creatinine clearance, and Pfeiffer score). The parameters of each patient’s functional reserve were determined at baseline (the day of the patient’s first visit) and 4 months later. Analyses of the data were conducted to identify whether there were significant differences between the groups for each of the variables under study pre- and post-chemotherapy (Student’s t-test and Fisher’s exact test for independent groups).

Results: We analyzed data from 131 patients treated with chemotherapy (group A) and 68 patients who were not treated with cytostatic drugs (group B). The mean age of the patients was 78.68 +/- 4.90 years. There were 38 cases with metastatic tumors (28.8%). In our study there were no significant differences in walking speed (p = 0.333), handgrip strength (p = 0.182), expiratory flow (peak flow) (p = 0.954), cognitive status (Pfeiffer score) (p = 0.074), or creatinine clearance (p = 0.425). However, in patients treated with chemotherapy, there was an increase in the MME (0.618 kg/m2, 95% CE: 0.020 to 1.215, p = 0.043).

Discussion: Physiologic reserve in the elderly, measured by walking speed, handgrip strength, creatinine clearance, the Pfeiffer questionnaire and peak-flow, does not change as a result of chemotherapy. Strikingly, the only parameter to undergo significant changes after the use of cytostatic medications is skeletal muscle mass. This work was funded by the ‘Young Investigator Grant SEOM 2008-2010’.

Disclosure: All authors have declared no conflicts of interest.

QUALITY OF LIFE INCriminating SYMPTOMS IN CANCER PATIENTS AND THEIR WEIGHT IN THE DOCTOR-PATIENT-TALK: A SURVEY OF THE “QUALITY OF LIFE” WORKING GROUP OF THE “ARBEITSGEMEINSCHAFT INTERNISTISCHE ONKOLOGIE” (AIO): A PRELIMINARY ANALYSIS

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Introduction: Most cancer specific Quality of life (QoL) questioners (including the EORTCQLQ-C30) are based on the assumption that fatigue, pain, nausea & vomiting are the most important symptoms with impact on QoL of cancer patients. During the last 20 years, progress in supportive care has been made and the weight of symptoms may have changed. Using a standardized questioner, we investigated which symptoms incriminate cancer patients (pts) most.

Methods: Pts were asked to provide confidential information on the following items: patient characteristics, underlying malignant disease and treatment, performance status (PS), incrimination of the QoL by various symptoms (19 items) and their weight in the patient-to-doctor talk. Data were collected and analyzed using standard statistical methods.

Results: 1,300 pts participated so far. The median age was 63 years (18-93). 51.7% of pts were female and 72.7% had an ECOG PS of 0-2. Most frequent malignancies were breast cancer (211), colorectal cancer (153), lymphomas (98) and lung cancer (88). Most pts received chemo- or radiotherapy (67%), 16% were in follow-up or surveillance and 17% had other forms of therapy or did not state at all. The most incriminating problems were weakness, tiredness & poor concentration, the question “what is going to happen?” and alopecia. Sexual life, social trouble, depression, anxiety & sorrows than other pts.

Conclusion: Overall pts reported fatigue, alopecia and insomnia as the QoL most incriminating symptoms. Pain & nausea & vomiting were less incriminating, possibly due to improved supportive care. Sexual life, social trouble, depression, anxiety & sorrows, and insomnia receive inadequate attention in the doctor-patient-talk.

Disclosure: All authors have declared no conflicts of interest.
IMPLEMENTATION OF CANCER REGISTRY IN GEORGIA

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Background: Georgian Population-based Cancer Registry was set up in 2000. In 2009 most of medical facilities in Georgia became private. Currently private clinics are not instructed by law to submit data to central registry and nearly 30% of data are lost from the population registry.

Objectives: The aim of the project was to: 1. Implement Modern Cancer Registration System in Georgia. 2. Ensure compliance of reporting standards. 3. Create registry that will meet international data standards.

Methods: In 2011 as a result of active work with Ministry of Health Care (MOH) • Cancer Registry program was included in NCCP • Government has funded a “State Program of Modern Cancer Registry Implementation”. By the end of the project Cancer Registry will be linked to EMR notification system that itself will be linked to public and death registry and data on every cancer patient will automatically appear in the cancer registry database

Results: According to the schedule 1 stage of the program has been completed successfully. • New model of cancer registry has been developed • ICD-O third edition has been translated • Committee of Healthcare at Parliament of Georgia prepared legislation proposal for consideration. By the end of 2012 development of software, training of registrars and piloting of cancer reporting is planned.

Conclusion: Developed model of Cancer Registry will serve as a basis for clinical, epidemiologic, and health care services research and for the assessment of their efficacy in Georgia.

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PROGRESS AND TRENDS FOR CANCER DRUG APPROVAL – AN ANALYSIS OF FDA ADVISORY COMMITTEE

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Objectives: To evaluate the progress and trends for cancer drug approval over the last decade.

Methods: From 2001 to 2011, applications from (Oncologic Drug Advisory committees) ODAC session were reviewed.

Results: Of 46 applications, 34 (74%) involved solid and 12 (26%) hematologic tumors. These drugs were for leukemia (n = 8, 17%), lymphoma (n = 8, 17%), breast (n = 5, 11%), prostate (n = 5, 11%), and others (n = 20, 44%). 30 (65%) were phase III and 16 (35%) were phase II trials. 67% (n = 31) were full applications and 33% (n = 15) were for accelerated approval. 22 (48%) drugs were not approved with most common concerns being missing or inadequate data (65%), excessive toxicity (55%) and inappropriate study endpoints (45%). 19 applications used hazard ratios (HR), (median = 0.67) and 18 used response rates (RR) (median = 0.42). In a predictive model combining efficacy and toxicity, drugs with lower HR or higher RR with lower toxicity were more likely to be approved vs. other drugs (89% vs. 46%; p = 0.025). We then divided applications into 3 periods with their corresponding approval rates: 2001-2004 (n = 11; 55%), 2005-2008 (n = 12; 50%), and 2009-2011 (n = 23; 53%). Over time, there was a significant increase in the proportion of applications using progression-free survival as an endpoint (0% to 50% to 70%; p = 0.011).

Conclusion: In this analysis of oncology drug applications, our model employing hazard ratio and toxicity correlates with a high rate of approval. The most common concerns of the rejected applications involved missing or inadequate data, excessive toxicity, and inappropriate study endpoints. Clinical researchers need to consider these FDA recommendations in the future design of clinical trials.

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NICE TECHNOLOGY APPRAISALS AND THE UPTAKE OF BREAST CANCER DRUGS IN THE UK

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Background: Health technology appraisal (HTA) recommendations from the UK National Institute of Health and Clinical Excellence (NICE) are intended to standardise health care throughout the NHS, and to hasten the uptake of new, more effective medicines that are cost-effective. Although it is compulsory for the NHS to fund drugs recommended by NICE, it is not clear how well NICE guidance is implemented. A number of studies have investigated whether NICE guidance influences UK drug uptake as intended. Most have used sales data, however, this approach has significant limitations. Sales data do not reveal which indication, line of therapy, nor patient sub-group a drug has been used to treat. Many drugs are licensed for multiple indications, and many HTAs only recommend the use of drugs in defined sub-groups, often subsets of the licensed indication. To avoid the limitations of sales data-based analyses, this study used IMS Health’s Oncology AnalyzerTM as the primary data source. Oncology AnalyzerTM contains detailed records for a representative sample of patients, allowing analyses to be focused on the particular indication and treatment criteria specified in NICE HTAs.

Methods: HTAs for breast cancer drugs appraised by NICE from 2005 to 2008 were analysed. For each HTA, the proportion of the eligible patient sub-group that received the recommended (or not recommended) drugs from Q1 2005 to Q1 2009 was determined. Changes in uptake of the drugs in the relevant patient populations were assessed for the UK, and were also compared to uptake in similar European countries.

Results: NICE produced 6 HTAs for breast cancer, encompassing 8 drugs, during the period assessed. In 5 out of 6 cases, the proportion of patients recommended by the HTA was lower than uptake of the similar drugs in the EU.

Conclusion: Our study suggests that, despite international comparisons, NICE appears to have understated the need for new drugs in the UK. This study recommends that a future analysis looks at the impact of NICE HTAs on drug uptake for cancer indications.

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SCREENING TOOL FOR UNFITNESS IN GERIATRIC ONCOLOGY: WHAT DOES IT TELL US IN DAILY PRACTICE?

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Background: We are facing a growing number of cancer patients (pts) aged ≥70 years. However, cancer treatment decision-making appears a difficult task in such heterogeneous population as solid recommendations are still lacking. The G8 scale was designed to help discriminate older cancer patients needing a geriatrician’s opinion before cancer treatment decision-making. This 8-item tool can be completed in <5 minutes and scores range from 0 to 17 (best). The ONCODAGE study confirmed that G8 scores <15 selected pts needed a geriatrician’s opinion. With this cut-off, G8 sensitivity and specificity were respectively 68% and 74%.

Objectives: We have decided to implement the G8 scale in daily practice at our Comprehensive Cancer Centre to study the feasibility of such a tool in outpatient clinics and to evaluate the proportion of elderly pts requiring geriatric resources. Study design: An auxiliary nurse administered G8 to pts ≥70 years with newly diagnosed cancer or relapse at their first attendance in our oncology clinics.

Results: From January to April 2012, 101 pts completed the G8 scale. They were mainly men (64); mean age was 81 years (70-98). Main primary tumor sites were lung (16), prostate (14), hematologic malignancies (14), head & neck (13), breast (12), digestive tract (12), and sarcoma (6). Only a quarter of pts had an advanced-stage disease and half of them had a localized tumor. Around two thirds (68 out of 101) of the pts obtained a G8 score <15. Most frequently impaired items were item H (number of medications) with 65 pts indicating that they took >3 drugs, and items A and B on nutritional aspects telling respectively that 30 pts had mild to severe anorexia and 35 pts had lost ≥1 kg in the last 3 months.

Discussion: G8 appears easy to implement in daily practice in the outpatient setting. However, our results, as well as those of the ONCODAGE study, indicate that around 7 out 10 pts should be referred to a geriatric team before cancer treatment decision-making. This approach is clearly not realistic in daily practice due to the lack of geriatric resources. Alternatively, we are considering another process including a second step of screening in order to select more accurately older pts candidate to geriatric evaluation.

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