01-001
Missed Consults At A Supportive Care Outpatient Clinic In A Comprehensive Cancer Center
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Objectives: Missed appointments cause problems to both patients and clinic operations. Several factors have been reported as related to lower clinic attendance in different populations, but the attendance of cancer patients to supportive care outpatient clinics (SCC) is poorly studied. Our purpose was to determine the frequency of missed consults (MC) and patients’ and appointments’ characteristics associated with MC.

Methods: Review of 783 consecutive charts of cancer patients referred to a SCC to identify the first 200 MC. Data were collected for them and the first 200 patients who kept their consults (KC) regarding demographic and clinical characteristics. Consults’ day, time, and number of days since booking were registered. Temperatures and rainfall data were obtained for the consult days. Distance from the patients’ residence to the center was also obtained.

Results: 200/783 (26%) patients missed their consults. Median age (Interquartile range, IR) was 62 (55-70) and 59 (49-69) years for KC and MC respectively (p<0.01). Gender, ethnicity, marital status, and insurance status were not different between groups. Patients with gastrointestinal cancers missed consults more frequently (54/90 (60%) versus 146/310 (47%), p<0.05), as patients with no evidence of disease (18/24 (75%) versus 182/376 (48%), p<0.05). Patients referred to the SCC because of end of life issues (EOL) missed more frequently (16/22 (73%) versus 184/378 (27%), p<0.05). Median(IR) average temperature in the day of consult was 28 (26-29) degrees Celsius for KC versus 23 (19-27) degrees Celsius for MC, p<0.0001. Median number of days between appointment date and death was 75 (30-184) for MC versus 110 (56-224) for KC, p<0.01. Day of the week, scheduled time, distance from the hospital, number of days between booking and appointment, and rainfall were not associated with MC.

Conclusions: The frequency of MC at our SCC was 26%. MC were associated with younger age, diagnosis of gastrointestinal malignancies, referral for EOL, shorter survival, and lower average temperatures in the consult day.

01-002
An Empowerment For Supportive Care On Cancer Patient And Family
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1Nursing Department, Faculty of Medicine Siriraj Hospital Mahidol University, BKK, Thailand

Objectives: to describe and explain empowerment in cancer patient and family.

Methods: A Phenomenological study used purposive-selection ( one- cancer- patient, family’s 3- members, community’s 3- men of and 2 NGO - staff ). Semi-structure and observation tool was used. Data were obtained by in –depth interviews, participant observations and field notes from 19 Aug. 08- 31 Jan. 09 and analyzed by content analysis.

Results: The empowerment, participation, and motivation were emergence for each other. There were all inclusion, capacity building, democratic participation, ownership perception and they had same goal setting, deliberation on their resources as well as future plan together. The outcome elicited innovation called as Moon-rise Over Bed for supporting and no admission during 6 months. Factors promoting the empowering were 1 .hope to have a quality of life, 2. need to live longer, 3. democratic participation with action learning, 4.having nurse’s support and trust, 5. lack of some resource but could make up their minds.

Conclusions: There was the empowerment in cancer patient and family elicited a learning organization by action learning. The empowerment composed of all for supporting each other.

01-003
Characteristics Of 1635 Acute Care Palliative Medicine Unit (Acpmu) Admissions: Impact On Post Acute Care (Pac) Service Utilization
Declan Walsh, Ruth Powazki, Wael Lasheen, Susan LeGrand, Mellar Davis, Ruth Lagman
Cleveland Clinic, Taussig Cancer Institute, The Harry R Horvitz Center For Palliative Medicine and Supportive Care, Cleveland, USA

Objectives: We report: 1) Demographic characteristics of patients admitted to ACPMU. 2) Post Acute Care (PAC) service utilization 3) Factors which influenced discharge planning.

Methods: We analyzed 2006 and 2007 electronic databases.
Results: Patient Characteristics: 1635 admissions: Median age 62 (20-99); female 52%; Married 56%, single 19%, widowed 15%, divorced 10%. Ethnicity: African-American 27% and White 70%. Admit source: outpatient clinic 62%, emergency room 21%, outside hospital transfer 17%. Of those, 44% were referrals from other inpatient services (ex. Oncology service). Payer: Commercial 38%, Government Funded Insurance (GFI) 56%, others 6%. Top 4 Diagnostic Related Groups: Respiratory/Nervous System/ Digestive Malignancy, Pathological Fractures. 22% readmitted within 30 days. Respiratory/Nervous System/ Digestive Malignancy, 56%, others 6%. Top 4 Diagnostic Related Groups: Respiratory/Nervous System/ Digestive Malignancy, Pathological Fractures. 22% readmitted within 30 days.

PAC service utilization: 1028 patients received one/or more PAC service: 46% one service; 35% two; 17% three; 1% four; and 0% five. We provided in total 1803 PAC: Home or Inpatient Hospice 34%; Homecare 14%; Skilled/Unskilled Nursing Facility 9%. Additional PAC: Transportation 18%, Pain Pump 15%, Durable Medical Equipment 3%, Durable Medical Respiratory 2%, Home Intravenous Antibiotics 2%, Others 3%. Impact on Discharge Planning: Readmission was predicted by younger age, and fewer PAC on initial discharge. Longer LOS predicted by higher Case Mix Index (CMI) were referred from other inpatient services, or GFI. More PAC predicted by longer LOS, readmission, GFI, referral from other hospital services, younger age. Discharge home without services was predicted by shorter LOS, lower CMI, younger age. Death correlated with referral from other inpatient services. PAC referral was more likely if unmarried or a readmission.

Conclusions: An electronic database appraises and identifies patterns which influence discharge planning and PAC utilization. This could improve discharge processes, hospital throughput, and enhance the operational viability of inpatient palliative medicine units.

02-005
Aprepitant Prevents Chemotherapy-Induced Nausea And Vomiting Associated With Non-Anthraclyine/Cyclophosphamide-Based, Moderately Emetogenic Chemotherapies: A Randomized, Double-Blind Study
Judith Boice1, Carole Brown2, Arlene Taylor2, James Hardwick2, Alexandra Carides2
1Merck Research Laboratories, Rahway, USA, 2Merck Research Laboratories, North Wales, USA

Objectives: Aprepitant was shown previously to be effective in preventing chemotherapy-induced nausea and vomiting (CINV) with moderately emetogenic chemotherapy (MEC) in breast cancer patients receiving an anthracycline and cyclophosphamide (AC). This study assessed aprepitant in patients with a variety of tumors receiving a broad range of MEC regimens.

Methods: This Phase III, randomized, gender-stratified, double-blind trial enrolled patients ≥18y old with confirmed malignancies naïve to MEC or highly
emetogenic chemotherapy who were scheduled to receive a single dose of at least one MEC agent. Patients received an aprepitant triple-therapy regimen (aprepitant 125mg, ondansetron 8mg b.i.d., and dexamethasone 12mg on Day 1 of chemotherapy, aprepitant 80mg q.d. on Days 2-3) or a control regimen (ondansetron 8mg b.i.d. and dexamethasone 20mg on Day 1, and ondansetron 8mg q12h on Days 2-3) administered orally. Episodes of vomiting, nausea, and rescue medication use were recorded in a patient diary. Tolerability was assessed by physical and lab examinations, and adverse event reporting. Primary and key secondary efficacy endpoints were proportions of patients with No Vomiting and Complete Response (no vomiting/no rescue medication use), respectively, during the 120 hours post-chemotherapy. Overall, treatment group comparisons were based on a logistic regression model with terms for treatment, region, and gender. The displayed subgroup proportions (n/m) were calculated but not included in the treatment group comparison model.

**Results:** Among 832 patients analyzed, 52% received non-AC-based antineoplastic therapy. Significantly more patients in the aprepitant subgroups achieved No Vomiting and Complete Response (no vomiting/no rescue medication use), regardless of whether they received AC or non-AC regimens. Overall, the incidences of adverse events were generally similar in the aprepitant (61.9%) and control groups (66.5%).

<table>
<thead>
<tr>
<th>Overall Phase, (0-120 hours post-chemotherapy)</th>
<th>Aprepitant Regimen, n/m (%)</th>
<th>Control Regimen, n/m (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Vomiting (all regimens)</td>
<td>324/425 (76.2)</td>
<td>252/406 (62.1)</td>
</tr>
<tr>
<td>AC regimen</td>
<td>136/199 (68.3)</td>
<td>108/204 (52.9)</td>
</tr>
<tr>
<td>Non-AC regimen</td>
<td>188/226 (83.2)</td>
<td>144/202 (71.3)</td>
</tr>
<tr>
<td>Complete Response (all regimens)</td>
<td>292/425 (68.7)</td>
<td>229/407 (56.3)</td>
</tr>
<tr>
<td>AC regimen</td>
<td>125/199 (62.8)</td>
<td>96/204 (47.1)</td>
</tr>
<tr>
<td>Non-AC regimen</td>
<td>167/226 (73.9)</td>
<td>133/203 (65.5)</td>
</tr>
<tr>
<td>n/m = patients with favorable response/patients included in subgroup</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Conclusions:** The aprepitant regimen provided superior efficacy over the control regimen in the prevention of CINV in patients receiving either AC or non-AC MEC. Aprepitant was generally well tolerated. Supported by Merck & Co., Inc.

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02-006

**Phase Iii Study Of Granisetron + Dexamethasone +/- Aprepitant In Patients With Germ Cell Tumors Undergoing 5 Day Courses Of Cisplatin Based Combination Chemotherapy: A Hoosier Oncology Group (H.O.G.) Study.**

Mary Brames^1, Erica Johnston^1, Craig Nichols^3, Joel Picus^4, Angela White^3, Lawrence Einhorn^1,2

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**Objectives:** Aprepitant is approved for chemotherapy induced nausea and vomiting with single day cisplatin. There are no data with multiple day cisplatin regimens. A phase III double blind placebo controlled study was undertaken by the H.O.G. to assess safety and efficacy.

**Methods:** Germ cell tumor patients receiving 2 consecutive courses of any 5 day cisplatin regimen were eligible. Patients must have had no nausea or vomiting for 24 hours prior to study entry or antiemetics for previous 72 hours. Stratification was chemo-naïve versus prior chemotherapy. Patients received granisetron or ondansetron days 1-5 plus dexamethasone 20 mg days 1 and 2. Subjects were randomized to aprepitant (125 mg day 3 and 80 mg days 4-7) versus placebo with their first course of chemotherapy with crossover to opposite arm with second cycle. Dexamethasone was given 8 mg p.o. bid days 6-7 for the placebo cycle and 4 mg bid days 6-7 for the aprepitant cycle and 4 mg bid day 8 both cycles. Primary objective was percentage of patients with complete response (no emesis or rescue medications). Endpoints also included nausea and emesis control based on visual analogue scales, number of emetic episodes, and presence of symptoms measured by the M.D. Anderson Symptom Inventory. A correlative study to explore prevalence of polymorphisms of genes that encode for drug metabolizing enzymes, receptors and drug transporters was appended. After 2 cycles, patients stated their preferred cycle. Total sample size of 71 patients will be enrolled.

**Results:** 28 patients have been entered. Median age is 35 (range 16 to 53). Chemotherapy regimens were bleomycin + etoposide + cisplatin (BEP) or EP. There were no safety concerns.

**Conclusions:** This is the first study of aprepitant for patients receiving 5 day courses of cisplatin. Updated results will be presented at the time of the meeting.
Using Two Meta-Analysis Methods To Determine Whether Common Dose Differences Affect Efficacy With The Serotonin Antagonist (5-HT3) Palonosetron: An Individual Patient Data (IPD) Meta-Analysis And An Abstracted Data (AD) Meta-Analysis Of The 1947 Patients Entered Into The 8 Double-Blinded Randomized Clinical Trials (RCTs).

Emilio Bria¹, Martin Lesser², Harambolos Raftopoulos³, Richard Gralla³, Barbara Napolitano³, Diana Giannarelli¹
¹Regina Elena National Cancer Institute, Rome, Italy, ²Feinstein Institute for Medical Research, Manhasset, USA, ³North Shore – LIJ Health System, Lake Success, USA

Objectives: 5-HT3 antiemetic agents are among the most frequently used drugs in oncology and are considered key agents in guideline-recommended combination regimens. Double-blinded RCTs have demonstrated advantages for palonosetron when compared with other 5-HT3 agents in single agent trials and in a recent combination trial with dexamethasone (Saito, Lancet Oncology 2009). Controversy continues whether efficacy differs between palonosetron doses (0.25 mg or 0.75 mg). Meta-analyses were conducted to address this issue employing the two most frequently used meta-analysis methods, IPD and AD.

Methods: A literature search and colleague inquiry identified double-blinded RCTs with palonosetron 0.25mg and 0.75mg treatment arms. Primary endpoints were Complete Response (CR – no vomiting and no rescue) over days 1-5 after chemotherapy; secondary endpoints were Complete Control (CC - no vomiting, days 1-5), acute CR (day 1), delayed CR (days 2–5), and grade 3-4 toxicities. Sensitivity analyses by setting (highly or moderately emetic chemotherapy - HEC or MEC), and a meta-regression analysis for predictive factors were undertaken. Odds Ratios and Relative Risks with 95% confidence intervals were derived for IPD and AD analyses, respectively. Interaction and Cochrane Q-Heterogeneity tests were performed.

Results: 8 double-blinded RCTs were identified (HEC/MEC: 4/4; IV/PO: 6/2). Individual patient data were obtained for the 1947 subjects. No significant heterogeneity was found for CR or CC. Remarkably similar emetic outcomes were found for all endpoints at both doses. No significant differences were found between palonosetron doses, regardless of: 1) meta-analysis approach (IPD or AD) and for either CR or CC; 2) acute or delayed emesis; and 3) HEC or MEC. Results are seen in the table below. No significant toxicity differences were found.

<table>
<thead>
<tr>
<th>Palonosetron doses: 0.25 mg versus 0.75 mg</th>
<th>IPD: Odds Ratio (95% Confidence Interval)</th>
<th>AD: Relative Risk (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete Response (no vomiting or rescue, days 1 - 5)</td>
<td>1.00 (0.83 – 1.20)</td>
<td>0.998 (0.909 – 1.097)</td>
</tr>
</tbody>
</table>

Conclusions: Both palonosetron doses provide very similar efficacy for all end-points, for both HEC and MEC. These findings can help in guideline considerations and in practice settings for all chemotherapy groups studied.
with patient receiving Palonosetron and were 500 INR (>100 US$) of with Ondansetron. Even in the least favorable clinical scenario, palonosetron was a preferred antiemetic strategy.

**Conclusions:** Palonosetron exerts efficacy against CINV acute and in the delayed phase, with a comparable safety profiles in the setting of single and multiple-day chemotherapy and Cost Effective which is an important issue in treating cancer in resource constraint countries.

**02-009**
**Prevention Of Nausea And Vomiting Induced By Chemotherapy Followed By Combined Chemo/Radiotherapy In Head And Neck Cancer Patients**
Jelena Dimitrijevic, Snezana Bosnjak, Natasa Medic-Milijic
_Institute for Oncology and Radiology of Serbia, Belgrade, Serbia_

**Objectives:** Optimal prevention of chemotherapy (CINV) and radiotherapy induced nausea and vomiting (N/V) is an important supportive care issue in head and neck (H/N) cancer patients.

**Methods:** H/N cancer patients (n = 18) were treated with 3 cycles of CDDP-based neoadjuvant chemotherapy followed by combined chemo/radiotherapy. The antiemetic regimen was: dexamethasone (20 mg i.v, o.d) plus palonosetron (0.25 mg i.v, o.d) for acute N/V and dexamethasone (8 mg i.v, o.d) for delayed N/V. Patients completed diaries were used to monitor incidence of acute and delayed N/V (D1-D4) and need for rescue antiemetics. Complete response (CR: no vomiting or use of rescue medication) and satisfaction with antiemetics used (0-100% rating scale) were final efficacy endpoints.

**Results:** For acute CINV, CR was achieved in 15/18 (83.33%, cycle 1), 13/18 (72.22%, cycle 2) and 15/18 (83.33%, cycle 3) of patients receiving CDDP-based neoadjuvant chemotherapy. For delayed CINV, CR was achieved in 15/18 (83.33%, cycle 1), 17/18 (94.44%, cycle 2) and 16/18 (88.88%, cycle 3) of patients. In the first cycle of combined chemo/radiotherapy control of N/V was as follows: CR in 16/18 (88.88%, acute N/V) and 16/18 (88.88%, delayed N/V). Percentage of patient satisfied with antiemetic regimen was more than 70% (D1), more than 80% (D2, D3) and more than 85% (D4) for all 3 cycles of chemotherapy. With combined chemo-radiotherapy 100% of patients were satisfied with antiemetic control (D1-D4).

**Conclusions:** The effectiveness of investigated antiemetic regimen was particularly high in prevention of delayed vomiting induced by CDDP-based neoadjuvant chemotherapy followed by combined chemo/radiotherapy. Patient satisfaction had a growing tendency from D1 to D4 in all tree cycles of chemotherapy, and it was particularly high with combined chemo-radiotherapy.

**02-010**
**Cardiac Safety Data For Casopitant, An Nk-1 Receptor Antagonist, Given With Anthracycline**
Michael Ewer¹, Steven Grunberg², Sulabha Ranganathan³, Stephen Lane³, Mark Russo³
¹University of Texas M. D. Anderson Cancer Center, Department of Cardiology, Houston, USA, ²Vermont Cancer Center, University of Vermont, Department of Medicine/Pharmacology, Burlington, USA, ³GlaxoSmithKline, Oncology MDC, Collegeville, USA

**Objectives:** The NK-1 receptor antagonist casopitant is a promising agent for the prevention of chemotherapy-related and postoperative nausea and vomiting. However, findings suggestive of cardiac damage were noted in animal studies of long-term administration of casopitant at supratherapeutic doses. Evaluation of the concomitant use of casopitant with anthracyclines was therefore of particular interest.

**Methods:** Patients receiving anthracyclines as part of a phase III moderately emetogenic chemotherapy study regimen were randomized to receive ondansetron and dexamethasone plus one of the following casopitant regimens: single-dose 150-mg oral casopitant (ORAL1); 3-day IV/oral casopitant (90 mg IV/50 mg oral/50 mg oral) (IV/ORAL); 3-day oral casopitant (150/50/50 mg) (ORAL3); or placebo. Serial cardiac troponin (cTnI) levels were measured using the Beckman assay. Although this assay is generally considered reliable within the range of 0.04-0.5 ng/mL, levels below the limit of quantitation (LOQ) (<0.04 ng/mL) were also measured in an attempt to identify patterns of subclinical change.

**Results:** In total, 611 patients were evaluated: 155 ORAL1, 145 IV/ORAL, 159 ORAL3, and 152 placebo. Three patients (0.5%) had median cTnI >0.12 ng/mL (1 each IV/ORAL, ORAL3, and placebo); 59 patients (9.7%) had median cTnI 0.04-0.12 ng/mL. Of the remaining patients with cTnI below LOQ, median baseline levels across groups were similar (ORAL1 and IV/ORAL 0.008 ng/mL; ORAL3 0.01 ng/mL; placebo 0.009 ng/mL). After 4 cycles of anthracycline, median cTnI increased to 0.02 ng/mL in all groups, with no difference noted between casopitant and placebo groups.

**Conclusions:** Subclinical elevations in cTnI occurred in patients receiving anthracyclines but were not deemed related to or accentuated by simultaneous administration of casopitant. Use of appropriate cardiac biomarkers in
ranges below those commonly used to detect infarction may be valuable to detect or exclude subclinical toxicity of potentially cardiotoxic agents used in combination. Supported by GlaxoSmithKline.

**02-011**

*Prevention Of Nausea And Vomiting Following Highly Emetogenic Chemotherapy With Single-Dose Oral Nk-1 Receptor Antagonist Casopitant In Combination With Other Antiemetics*

Steven Grunberg1, Mark Russo2, Simon Thorn3
1Vermont Cancer Center, University of Vermont, Department of Medicine/Pharmacology, Burlington, USA, 2GlaxoSmithKline, Oncology MDC, Collegeville, USA, 3GlaxoSmithKline, Oncology MDC, Harlow, United Kingdom

**Objectives:** Data from phase II and phase III randomized, placebo-controlled, double-blind studies have shown that casopitant, a novel neurokinin (NK)-1 receptor antagonist, prevents chemotherapy-induced nausea and vomiting (CINV) in patients receiving highly emetogenic chemotherapy (HEC) regimens that include cisplatin. Data from these 2 trials were pooled to better evaluate the safety and efficacy of single-dose oral casopitant, added to a regimen of ondansetron and dexamethasone, for the prevention of cisplatin-induced CINV.

**Methods:** All patients received ondansetron and dexamethasone. In both the phase II and phase III studies, patients included in this pooled analysis also received 150 mg single-dose oral casopitant or placebo control. Antiemetic efficacy was determined by the proportion of patients having a complete response (CR, defined as no vomiting/retching or use of rescue medication for 120 hours after initiation of HEC), evaluated across both studies. Adverse events (AEs) were reported for all cycles (maximum 4-6) and were graded according to NCI CTCAE.

**Results:** In the pooled analysis, patients who received single-dose oral casopitant as part of their antiemetic regimen (n=353) had a CR rate of 82% compared with 64% in the control arm (n=353), consistent with the results of individual studies. Of the patients taking single-dose oral casopitant (n=349), 75% experienced at least one AE (27% neutropenia of any grade), compared with 72% (28% neutropenia) of those taking placebo (n=348).

**Conclusions:** An antiemetic regimen including single-dose oral casopitant is effective for prevention of CINV over the 120 hours following cisplatin-containing HEC. Reduced exposure with single-dose versus 3-day dosing of NK-1 antagonist regimens may offer reduced potential for drug interactions and improved convenience for patients. Supported by GlaxoSmithKline.

**02-012**

*Correlation Between Neurotransmitter Levels And Current Antiemetic Practice Guidelines*

Gerald Higa1,2, Miklos Auber1,3, Gerry Hobbs4
1Mary Babb Randolph Cancer Center, Clinical, Morgantown, USA, 2WVU School of Pharmacy, Pharmacy Practice, Morgantown, USA, 3School of Medicine, Hematology/Oncology, Morgantown, USA, 4School of Medicine, Community Medicine, Morgantown, USA

**Objectives:** The efficacy of 5-HT3 and NK1 receptor antagonists suggests that serotonin and substance P (SP) are involved in chemotherapy-induced vomiting (CIV). As such, all major oncology organizations have incorporated these agents into their antiemetic guidelines. We provide correlative evidence based on laboratory data to support this practice.

**Methods:** The major serotonin metabolite, 5-HIAA, and SP were assayed in each of five urine and blood samples obtained from 23 patients over a 72 h period. All patients were treated with cisplatin-containing regimens with dosages ranging between 30 mg/m² – 120 mg/m². Prior to chemotherapy, a 5-HT3 antagonist/glucocorticoid combination was administered to all patients; 19 patients also received an NK1 antagonist. Data were normalized, expressed as percentage (%) change from baseline, and analyzed by repeated measures ANOVA.

**Results:** Data were analyzed by: 1) phase of emesis, with two time points during the acute phase and collectively during the delayed phase; and 2) cisplatin dose based on the Hesketh classification. First, the mean change in 5-HIAA at 4 h, 24 h, and >24 h was +43%, +2%, and +8.8%. The corresponding change in mean SP was +5.7%, +10.1%, and +31.1%, respectively. Second, increases in 5-HIAA excretion during the acute phase occurred almost exclusively among patients receiving >50 mg/m² of cisplatin. While modest changes of SP were observed at 4 h, the levels were substantially higher at >24 h. Increased levels during the delayed phase were observed primarily with higher cisplatin dosages.

**Conclusions:** These data: 1) endorse the current antiemetic practice guidelines; 2) support the recommendation that prolonged blockade of the 5-HT3 receptor may be clinically beneficial, and 3) suggest that delayed CIV may be mediated by both neurotransmitters.
Evaluate The Effects Of Implementing The Multinational Association Of Supportive Care In Cancer (Mascc) Antiemetic Guideline On The Incidence Of Chemotherapy-Induced Nausea And Vomiting (Cinv) Following Platinum Chemotherapy.

Alan O'Kane

**Objectives:** To determine the significance of implementing the MASCC antiemetic guideline on the rate of CINV following cisplatin, carboplatin and oxaliplatin chemotherapy.

**Methods:** A 2 phase cohort study based at the outpatient and 5-day chemotherapy area within the oncology unit at Ninewells Hospital. Outcome measure is complete response, defined as no nausea, no vomiting and no use of rescue therapy. The incidence of CINV and the adherence to evidence-based practice was determined retrospectively during phase 1. The common toxicity grade was used to determine the severity of CINV. The dose, duration and route of aprepitant, ondansetron or granisetron and dexamethasone were collated from electronic prescriptions. Data collected was compared to the MASCC antiemetic guideline and annotated if adherence occurred. Initial results were presented to all 8 oncology consultants and consent gained to amend protocols as appropriate. After amending 80 protocols, practice was then re-audited prospectively to determine the effect of implementing MASCC recommendations.

**Results:** 20 patients receiving carboplatin and oxaliplatin and 60 patients receiving cisplatin as part of their chemotherapy regimens were assessed before and after implementation of the guideline. Table 1 highlights the results found.

<table>
<thead>
<tr>
<th></th>
<th>Oxaliplatin</th>
<th>Carboplatin</th>
<th>Cisplatin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre</td>
<td>50%</td>
<td>39%</td>
<td>73%</td>
</tr>
<tr>
<td>Post</td>
<td>100%</td>
<td>100%</td>
<td>58%</td>
</tr>
</tbody>
</table>

Conclusions: Adhering to MASCC antiemetic guidelines reduces CINV with cisplatin and oxaliplatin. Carboplatin patients did not show any improvement. The majority of patients at baseline were free from CINV therefore the benefit of additional antiemetic cover is reduced. The study is ongoing and stratification work is not complete. Stratification will incorporate gender, dose of chemotherapy, concurrent chemotherapy, alcohol intake, age and number of cycles. Clear conclusions cannot be made at the time of writing. Issues such as compliance to prescribed medicines and diagnosing anticipatory nausea and vomiting were highlighted.

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Emesis Prophylaxis For Chemotherapy In Clinical Practice; The Experience At The S. Giovanni Bosco Hospital

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¹ASL TO 2, Hospital Pharmacy, Torino, Italy, ²ASL TO 2, Oncology, Torino, Italy

**Objectives:** To investigate how likely oncologists are to apply antiemetic guidelines in daily practice, and the economic impact of the appropriate use of antiemetic prophylaxis. To standardize emetic prophylaxis protocols with the Oncologists’ collaboration. Appropriate prevention of emesis can improve the quality of life of cancer patients as well as their compliance to cancer treatment.

**Methods:** Chemotherapy and antiemetic prescriptions issued in June 2007 by the unit of Oncology, S. Giovanni Bosco Hospital were analyzed by the Pharmacists with respect to both the choice of the prescribed drug and the dose. These prescriptions were then compared with AIOM 2006, NCCN 2007 and ASCO 2006 guidelines.

**Results:** In June 2007, 161 chemotherapy regimens were prescribed, but 45% of the antiemetic prophylaxis varied from the guidelines with respect to either the choice of the prescribed drug (75% of non aligned antiemetic therapies) or dose (25% non aligned antiemetic therapies, 65% of which were prescribed at a lower dose). The guidelines regarding antiemetic therapy were not followed in low and minimal emetogenic chemotherapy regimens (80%), while patients undergoing either high emetogenic chemotherapy regimens (87%) or moderate ones (70%) were administered appropriate antiemetic prophylaxis. In addition, if Aprepitant had only been prescribed to patients with severe emesis, a 13% saving could have been obtained by following the guidelines appropriately.

**Conclusions:** This retrospective study of antiemetic prescribing practices highlights in which cases antiemetic therapies vary from the guidelines with regards to chemotherapy protocols. This is due to the fact that our Oncologists tend to over-protect their patients from emetogenic risks. In addition, Aprepitant has a strong financial impact on antiemetic prescriptions. Close collaboration between Oncologists and Pharmacists will optimize antiemetic prophylaxis in clinical practice, leading to the appropriate use of antiemetic therapies, decreasing drug costs, and improving the quality of patient care.
02-015
A Pooled Analysis Of The Efficacy Of The Nk₁ Receptor Antagonists Aprepitant And Casopitant.
Kelly Pendergrass¹, James Street²
¹Kansas City Cancer Center, Kansas City, USA, ²Reagent (contractor to Merck & Co), New York, USA

Objectives: Combination of NK₁ and 5HT₃ receptor antagonists (NK₁RA and 5HT₃RA) with dexamethasone has substantially reduced the incidence of CINV, and is now considered standard-of-care for patients receiving HEC (highly emetogenic chemotherapy). Aprepitant has been available since 2003, but with the forthcoming introduction of casopitant, oncologists will for the first time face a choice of NK₁RA. This analysis compares the efficacy of aprepitant and casopitant.

Methods: Studies for inclusion were identified using PubMed and through systematic searches of abstracts of key oncology conferences. Studies included compared a NK₁RA-containing regimen to an active-control regimen comprising dexamethasone and a 5HT₃RA. For aprepitant, only studies at approved doses were included; for casopitant all studied doses and regimens were included. The ratio of incidence rates (NK₁RA regimen:active control) for complete response (no emesis and no rescue) was calculated for the overall, acute and delayed phase across all studies. Analysis included trial as a stratification variable (HEC/MEC; moderately emetogenic chemotherapy), as well as pivotal/non-pivotal.

Results: Six study arms containing aprepitant (n=1,489) and 14 containing casopitant (n=2,895) were included. The table shows the incidence rate ratio for complete response (no emesis and no rescue) for the NK₁RA compared to active control. Similar trends were seen for the nausea and emesis endpoints.

<table>
<thead>
<tr>
<th>Ratio of incidence rates</th>
<th>Aprepitant (n=1,489)</th>
<th>Casopitant (n=2,895)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All studies (0-120 h; n=4,384)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall (0-120 h)</td>
<td>1.31</td>
<td>1.23</td>
</tr>
<tr>
<td>Acute (0-24 h)</td>
<td>1.14</td>
<td>1.04</td>
</tr>
<tr>
<td>Delayed (24-120 h)</td>
<td>1.29</td>
<td>1.23</td>
</tr>
<tr>
<td>Pivotal MEC (0-120 h; n=1,874)</td>
<td>1.21 (n=433)</td>
<td>1.24 (n=1,441)</td>
</tr>
<tr>
<td>Pivotal HEC (0-120 h; n=1,382)</td>
<td>1.42 (n=520)</td>
<td>1.25 (n=535)</td>
</tr>
</tbody>
</table>

Conclusions: Aprepitant and casopitant both provide improvements in complete response rates compared to active control, with little difference observed in most strata measured. However, aprepitant did appear to have a greater incidence rate ratio for complete response in the first 24 h following chemotherapy. Similar trends were seen when only pivotal trials of aprepitant and casopitant were considered. The safety, efficacy, and clinical experience with aprepitant are well established, and in the absence of a head-to-head clinical trial there is no suggestion that the new NK₁RA casopitant offers any therapeutic advantage to aprepitant.

02-016
Prevention Of Nausea And Vomiting Following Moderately Emetogenic Chemotherapy With Single-Dose Oral Nk-1 Receptor Antagonist Casopitant In Combination With Other Antiemetics
Fausto Roila¹, Jeremey Levin¹, Simon Thorn¹
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Objectives: Data from a phase II and a phase III randomized, placebo-controlled, double-blind study have shown that casopitant, a novel neurokinin (NK)-1 receptor antagonist, prevents chemotherapy-induced nausea and vomiting (CINV) in patients receiving moderately emetogenic chemotherapy (MEC). Data from these 2 trials were pooled to better evaluate the safety and efficacy of single-dose oral casopitant, added to a regimen of ondansetron and dexamethasone, for the prevention of CINV.

Methods: Patients included in this pooled analysis received 150 mg single-dose oral casopitant or placebo control. All patients in both the phase II and phase III studies also received ondansetron and dexamethasone. Antiemetic efficacy, evaluated across both studies, was determined by the proportion of patients having a complete response (CR, defined as no vomiting/retching or use of rescue medication for 120 hours after initiation of MEC). Adverse events (AEs) were reported for all cycles (maximum 4-6 cycles) and were graded according to NCI CTCAE.

Results: In the pooled analysis, patients who received single-dose oral casopitant as part of their antiemetic regimen (n=603) had a CR rate of 74% compared with 61% in the control arm (n=604) in cycle 1, consistent with the results of individual studies. Of the patients taking single-dose oral casopitant (n=598), 81% experienced at least one AE (38% neutropenia of any grade), compared with 82% (36% neutropenia) of those taking placebo (n=598).

Conclusions: An antiemetic regimen including single-dose oral casopitant is effective for prevention of CINV.
over the 120 hours following administration of MEC. Reduced exposure with single-dose vs 3-day dosing of NK-1 antagonist regimens may offer reduced potential for drug interactions and improved convenience for patients. Supported by GlaxoSmithKline.

02-017
Risk Factors Of Chemotherapy-Induced Nausea And Vomiting (CINV): Integrated Analysis From One Phase Iii And Two Phase Ii Studies Of Palonosetron In Japan - Palo Japanese Cooperative Study Group
Ikuo Sekine1, Yoshihiko Segawa2, Kaoru Kubota3, Mamoru Tsukuda4, Toshiaki Saeki5, Yutaka Ariyoshi6
1National Cancer Center Hospital, Tokyo, Japan, 2National Hospital Organization Shikoku Cancer Center, Matsuyama, Japan, 3National Cancer Center Hospital East, Kashiwa, Japan, 4Yokohama City University, Yokohama, Japan, 5Saitama International Medical Center, Hidaka, Japan, 6Aichi Cancer Center Aichi Hospital, Okazaki, Japan

Objectives: Nausea and vomiting are one of the most problematic adverse events of cancer chemotherapy. Severity of the CINV was reported to be influenced by gender, age and alcohol consumption. Palonosetron, a second-generation 5-HT3 receptor antagonist (RA), showed non-inferior efficacy on acute (0-24 hrs) and superior efficacy on delayed (24-120 hrs) CINV compared to a first-generation 5-HT3 RA granisetron [Lancet Oncol 2009; 10: 115–24]. We sought to identify CINV risk factors in patients enrolled in palonosetron trials.

Methods: This integrated analysis was performed using pooled data from two phase II dose-ranging trials and a phase III comparative trial of palonosetron in patients receiving highly or moderately emetogenic chemotherapy in Japan (HEC or MEC respectively). Palonosetron or granisetron was administered before chemotherapy in Japan (HEC or MEC respectively). Palonosetron on day 1 was expected to reduce risk of delayed CINV. Supported by Taiho pharmaceutical.

Results: A total of 1549 patients were evaluated; 721 (47%) were male and 828 (53%) were female; 870 (56%) and 555 (36%) received cisplatin and combination of anthracycline and cyclophosphamide, respectively; 990 (64%) and 559 (36%) received palonosetron and granisetron, respectively. Risk factors (p<0.05) of acute CINV were female gender, younger age, cisplatin treatment, poor performance status, no history of smoking and little alcohol consumption, whereas only female gender and cisplatin treatment were associated with delayed CINV. The poor control of the acute CINV was an additional risk factor for the delayed phase. Patients receiving palonosetron experienced delayed CINV less frequently than patients receiving granisetron (Table 1).

Conclusions: This analysis identified the study population risk factors of acute and delayed CINV respectively. Palonosetron on day 1 was expected to reduce risk of delayed CINV. Supported by Taiho pharmaceutical.

02-018
Nausea And Emesis In Radiotherapy Patients- Is This Still A Problem? A Prospective Evaluation Of The Daily Praxis
Maria Steingraeber1, Petra Feyer2, Luise Bischoff3
1Praxis for Radiotherapy and Radiooncology Berlin-Hellersdorf, Berlin, Germany, 2Clinic for Radiooncology and Radiotherapy Berlin-Neukölln, Vivantes Clinics, Berlin, Germany

Objectives: Radiotherapy can be a risk factor for nausea and emesis. Often the risk is underestimated and a prophylaxis is not performed. We evaluated the use of an antiemetic prophylaxis versus rescue medication in
Methods: During 01.06.2008-30.07.2008 all patients of two radiotherapy departments with only radiotherapy or radiochemotherapy with 5FU were prospectively evaluated. They were classified into risk groups according to the antiemetic guidelines. All patients with moderate emetogenic radiotherapy were informed about the higher risk of nausea and emesis. A prophylaxis with MCP or 5HT3-antagonists was recommended. The patients could decide for a prophylaxis or a rescue medication, this is a widely accepted procedure in the daily radiotherapy praxis. The patients could also decide if they like a prophylaxis with guttae, a tablet or a sublingual tablet.

Results: All 212 patients were evaluated for nausea and emesis. Nausea and emesis were a problem in patients with radiotherapy of the lower thorax or abdomen. (Risk for nausea 66%, for acute emesis 38% and delayed emesis 21%). All patients with moderate risk don’t suggested a prophylaxis, all patients got a rescue medication. The rescue medication was taken to late-as a sign of underestimation of the symptom. The rescue medication with 5HT3 antagonists showed a good and safe effect, MCP was effective but at a lower level. 2/3 of our patients were satisfied with the rescue procedure, 1/3 would decide for an effective antiemetic prophylaxis in next time.

Conclusions: Patients with radiotherapy of the lower thorax or abdomen are at moderate risk for nausea and emesis. These patients should be treated prophylactically with antiemetics. In contrast to this most of our patients preferred a rescue medication. If the rescue medication is equally effective as an antiemetic prophylaxis we will investigate in our ongoing study.

Can Prognostic Factors Identify Women Receiving Anthracycline Plus Cyclophosphamide-Based Chemotherapy (Mec) Who Do Not Require An Nk1 Receptor Antagonist?

David Warr1, James Street2, Carides Alexandra3
1Princess Margaret Hospital, Medical Oncology and Hematology, Toronto, Canada, 2Reagent, New York, USA, 3Merck Research Laboratories, West Point, USA

Objectives: Age, alcohol use and history of sickness associated with pregnancy or motion have been identified as risk factors for chemotherapy-induced emesis. Can these prognostic factors identify a low risk group for whom ondansetron (OND) plus dexamethasone [D] alone provide a high level of protection (≥80% no emesis), and does the NK1 receptor antagonist aprepitant improve antiemetic outcome regardless of emetic risk?

Methods: The analysis was based upon outcomes in patients with breast cancer enrolled in a Phase III double-blind, placebo-controlled trial randomized to Day 1 OND 8 mg and D 20 mg before chemotherapy and OND 8 hours later and OND 8 mg bid Days 2-3 vs. Day 1 aprepitant 125 mg PO, OND 8 mg, and D 12 mg before chemotherapy and OND 8 mg 8 hours later and aprepitant 80 mg PO qd Days 2-3. Multivariate logistic regression models were used to assess the impact on emesis of the regimen with aprepitant, and previously reported risk factors, including age (<55 and ≥55 years), ethanol use (0-4 or ≥5 drinks/week), history of pregnancy-related morning sickness, and history of motion sickness.

Results: 856 patients were assessed. Treatment with aprepitant (P<0.0001), older age (P=0.006), ethanol use (P=0.0048), and no history of motion sickness (P=0.0007) were all significantly associated with reduced likelihood of emesis; motion sickness was not a risk factor. The table below shows the probability of no emesis associated with the presence of 0, 1, 2, or all of these factors in the aprepitant and active control arms.

<table>
<thead>
<tr>
<th>No. of risk factors</th>
<th>Aprepitant (n=432)</th>
<th>Active control (n=424)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>94.1% (16/17)</td>
<td>87.5% (7/8)</td>
</tr>
<tr>
<td>1</td>
<td>82.8% (96/116)</td>
<td>66.4% (75/113)</td>
</tr>
<tr>
<td>2</td>
<td>73.2% (156/213)</td>
<td>63.4% (128/202)</td>
</tr>
<tr>
<td>3</td>
<td>70.2% (59/84)</td>
<td>38.6% (39/101)</td>
</tr>
<tr>
<td>Overall</td>
<td>75.7% (327/432)</td>
<td>58.7% (249/424)</td>
</tr>
</tbody>
</table>

Conclusions: 1) The low-risk group identified by this analysis is of questionable utility because it comprised less than 3% of patients; 2) We could not confirm that motion sickness was a significant risk factor; 3) Aprepitant improved the control of emesis irrespective of the number of risk factors for emesis. Supported by Merck Research Laboratories

Effect Of Cisplatin On The Hypothalamic Glutamate Release And Emetic Response In Suncus Murinus (House Musk Shrew)

Kouichi YAMAMOTO1, John RUDD2, Sze Wa Chan2, Keiko ASANO1, Atsushi YAMATODANI1
1Osaka University, Department of Medical Science and Technology, Division of Health Sciences, Suita, Osaka, Japan, 2 The Chinese University of Hong Kong, Emesis Research Group, Department of Pharmacology, Faculty of Medicine, New Territories, Hong Kong

Objectives: Emesis is frequently observed in patients receiving cancer chemotherapy. Serotonin 5-HT3 receptor antagonists have been used extensively for the...
prophylaxis and treatment. However, the symptom still persists in patients receiving the highly emetogenic chemotherapeutic agent, cisplatin. It is known that autonomic symptoms such as anorexia, hypotension, tachycardia, salivation and secretion of vasopressin are accompanied with emesis and the glutamatergic system is involved in the development of these symptoms. To investigate the role of glutamatergic system for the cisplatin-induced emesis, we investigated the effect of cisplatin on glutamate release in the hypothalamus of Suncus murinus (house musk shrew) measured by in vivo brain microdialysis.

Methods: Female Suncus murinus were placed in a stereotaxic apparatus. A guide cannula was implanted into the hypothalamus using the following coordinates (AP: +4.7mm, ML: +0.7mm, DV: -3.7mm from lambda) and the cannula was fixed with dental cement. On the day of the experiment, a microdialysis probe was inserted into the hypothalamus through the guide cannula and the probe was perfused with artificial cerebrospinal fluid at a rate of 1.0 µL/min. Following a 1 h equilibration period, animal were injected with cisplatin (30 mg/kg, i.p.) with the animals also being observed for the development of emesis. Dialysis samples were collected every 20 min for 1 h before and 3 h after the administration and subjected to HPLC assay of glutamic acid.

Results: Cisplatin caused a significant 150 % increase in extracellular glutamate levels within 1 h after the administration (P<0.01) and the increase was closely associated with the temporal occurrence of emesis. Pretreatment with the 5-HT3 receptor antagonist, ondansetron (2 mg/kg, i.p.), completely inhibited both the increase in hypothalamic glutamate release and the emetic response.

Conclusions: These results suggest that the hypothalamic glutamatergic system may be involved in cisplatin-induced emesis in Suncus murinus.

03-021
Oral Conditions On Patients Taking Intravenous Bisphophonates In Public Hospital From Brazil
Ana Mello1,3, Luiz henrique gebrin2,3, Marise laza-creti-castro1
1unifesp, endocrinology, sao paulo, Brazil, 2unifesp, mastology, sao paulo, Brazil, 3Hospital Pérola Bygton, Mastology, sao paulo, Brazil

Objectives: Osteonecrosis in the jaws (ONJ) associated with Bisphosphonates (Bph) use has been described since 2003. The reason of this pathology is not clear. Studies suggest many risk factors include oral healthy .The aim of this study was to assess the oral conditions from patients a public hospital on use of intravenous Bph, identify cases of ONJ and test the knowledge from these patients about the ONJ.

Methods: Between March 2007 and February 2009, all patients who have metastatic breast cancer and received at least one dose of Bph were including on the study. Patients were submitted to an oral clinical exam and a panoramic Rx. And after this point all patients received instructions about side effects of the treatment and ONJ. Symptom check-list, and questionnaire about oral care and treatment, healthy stage was performed and data from their chart were collected.

Results: The data were collected, tabulated and analyzed. 179 patients were identified. 88 died before or during the study.91 patients were submitted to the study. One patient had the ONJ diagnosis. 35, 3% from the group have at least 1 tooth, and from these 85 % need some dental treatment. 52 % have some kind of proteses and 30 % from these the proteses have bad conditions and hurt themselves. 38, 2% went to a dental service at least once in the last year, and 21% had teeth extraction. In 35% were taking BPh when extraction were performed. One patient had osseointegrated implants. None patient shows knowledge about ONJ.

Conclusions: Currently no intervention exists that is completely successful to treat ONJ, and prevention should be the best approach. Our study showed that no one patient knows about ONJ which suggest that a specific protocol to prevent ONJ and instructions to the dental public team are needed. As a recent pathology more studies are needed.

03-022
Findings And Interventions In Cancer Patients Referred To A Cachexia Clinic (Cc)
Zohra Nooruddin, David Hui, Shalini Dalal, Eduardo Bruera, Egidio Del Fabbro
MD Anderson Cancer Center, Palliative Care and Rehabilitation Medicine, Houston, USA

Objectives: Anorexia-cachexia syndrome (ACS) is defined as hypercatabolic state which results in the context of a chronic aberrant inflammatory response and neurohormonal dysfunction. Cancer related ACS is highly prevalent in advanced cancer patients. It can determine the response to treatment and thus overall prognostication. Secondary causes that contribute to diminished nutrient intake include dysgeusia, early satiety, nausea, vomiting, constipation and mood alterations. The objective of this study was to determine the frequency of secondary cachexia symptoms and its management in a specialized cachexia clinic (CC) at a Comprehensive Cancer Center.
**Methods:** We conducted a retrospective chart review of 159 consecutive patients who underwent structured assessment at the CC from November 1, 2005 to September 30, 2008. Demographics, cancer diagnosis, weight loss, secondary causes and specific treatments were assessed.

**Results:** The patients had the following characteristics: median age 59, 61% were males, 39% had GI malignancies, 22% pulmonary malignancies, median body mass index 20.3, hypoalbuminemia 105 (76%) and median weight loss over the preceding 3 months 7%. At consultation, 102 (64%) were on chemotherapy/radiation and 13 (8%) were on enteral or parenteral nutrition. Appetite stimulants prior to consult included megestrol (n=36, 22%), corticosteroids (n=21, 13%) and dronabinol (n=10, 6%). 22 (14%), 105 (66%) and 32 (20%) patients had 0-1, 2-4 and 5-8 secondary cachexia causes, respectively. The median number of secondary causes was 3 (Q1-Q3 2-4), with a median number of 2 (Q1-Q3 1-3) interventions per patient. Table 1 lists the significant findings and corresponding interventions. After CC consultation, 52 (33%) were enrolled onto clinical trials for primary cachexia.

**Conclusions:** Three or more inadequately treated secondary causes of cachexia were identified in the majority of patients. Low cost, effective interventions were available for the most common causes of secondary cachexia.

**Table 1. Clinical Findings and Treatments in 159 cancer patients referred to a cachexia centre.**

<table>
<thead>
<tr>
<th>Secondary Cachexia Causes</th>
<th>Corresponding Interventions</th>
<th>Number of Patients, %</th>
<th>Number of Treatment Interventions, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI malignancies</td>
<td>Megestrol</td>
<td>66 (41.3%)</td>
<td>44 (73.6%)</td>
</tr>
<tr>
<td>GI malignancies</td>
<td>Corticosteroids</td>
<td>39 (24.4%)</td>
<td>26 (42.6%)</td>
</tr>
<tr>
<td>GI malignancies</td>
<td>Dronabinol</td>
<td>33 (20.8%)</td>
<td>33 (54.7%)</td>
</tr>
<tr>
<td>GI malignancies</td>
<td>Other Nutritional Interventions</td>
<td>13 (8.1%)</td>
<td>13 (21.3%)</td>
</tr>
<tr>
<td>GI malignancies</td>
<td>Other Interventions</td>
<td>16 (10.1%)</td>
<td>16 (26.3%)</td>
</tr>
</tbody>
</table>

**Methods:** One hundred-seventy-five patients were evaluated during 2004-2008. Diagnoses at presentation were multiple myeloma (58.3%), breast cancer (28%), prostate cancer (4%) and other malignancies. Patients were receiving zoledronic acid (69.8%), and other bisphosphonates, with an average administration of 3 years. Sixty-seven patients presented with osteonecrosis. Tooth extraction had preceded osteonecrosis in 80.3% of the cases. Three or more inadequately treated secondary causes of osteonecrosis were identified in the majority of patients. Low cost, effective interventions were available for the most common causes of secondary cachexia. After CC consultation, 52 (33%) were enrolled onto clinical trials for primary cachexia.

**Objectives:** To present our 3-year experience in the treatment and prevention of bisphosphonate-related jaw osteonecrosis.

**Methods:** One hundred-seventy-five patients were evaluated during 2004-2008. Diagnoses at presentation were multiple myeloma (58.3%), breast cancer (28%), prostate cancer (4%) and other malignancies. Patients were receiving zoledronic acid (69.8%), and other bisphosphonates, with an average administration of 3 years. Sixty-seven patients presented with osteonecrosis. Tooth extraction had preceded osteonecrosis in 80.3% of the cases. Three or more inadequately treated secondary causes of osteonecrosis were identified in the majority of patients. Low cost, effective interventions were available for the most common causes of secondary cachexia. After CC consultation, 52 (33%) were enrolled onto clinical trials for primary cachexia.

**Conclusions:** Conservative antibiotic treatment resulted in healing or stability of osteonecrosis, while using a prevention protocol, with oral hygiene measures and education, the incidence of the lesion was diminished in patients with compliance.

**Treatment And Prevention Of Bisphosphonate-Associated Osteonecrosis Of The Jaws**

Erofili Papadopoulou, Ourania Nicolatou-Galitis, Aikaterini Karagianni, Marie-Christine Kyrtsonis, Panagiotis Repoussis, Vasilios Barmounis

School of Dentistry, Clinic of Hospital Dentistry, Athens, Greece, School of Dentistry, Clinic of Oral Diagnosis and Radiology, Athens, Greece, 1st Department of Propaedeutic Clinic of Internal Medicine, Athens, Greece, "Metaxa" Cancer Hospital, Clinic of Hematology, Piraeus, Greece, Agios Savvas Cancer Hospital, 2nd Department of Medical Oncology, Athens, Greece

**Objectives:** To present our 3-year experience in the treatment and prevention of bisphosphonate-related jaw osteonecrosis.

**Methods:** One hundred-seventy-five patients were evaluated during 2004-2008. Diagnoses at presentation were multiple myeloma (58.3%), breast cancer (28%), prostate cancer (4%) and other malignancies. Patients were receiving zoledronic acid (69.8%), and other bisphosphonates, with an average administration of 3 years. Sixty-seven patients presented with osteonecrosis. Tooth extraction had preceded osteonecrosis in 80.3% of the cases. Three or more inadequately treated secondary causes of osteonecrosis were identified in the majority of patients. Low cost, effective interventions were available for the most common causes of secondary cachexia. After CC consultation, 52 (33%) were enrolled onto clinical trials for primary cachexia.

**Conclusions:** Conservative antibiotic treatment resulted in healing or stability of osteonecrosis, while using a prevention protocol, with oral hygiene measures and education, the incidence of the lesion was diminished in patients with compliance.

**The Pathologic Fracture As A Complication Of The Bone Metastases At The Unknown Original Tumor**

Oxana Pihut

National Oncologic Institute of Moldova, Chisinau, Moldova

**Objectives:** To present our 3-year experience in the treatment and prevention of bisphosphonate-related jaw osteonecrosis.

**Methods:** One hundred-seventy-five patients were evaluated during 2004-2008. Diagnoses at presentation were multiple myeloma (58.3%), breast cancer (28%), prostate cancer (4%) and other malignancies. Patients were receiving zoledronic acid (69.8%), and other bisphosphonates, with an average administration of 3 years. Sixty-seven patients presented with osteonecrosis. Tooth extraction had preceded osteonecrosis in 80.3% of the cases. Three or more inadequately treated secondary causes of osteonecrosis were identified in the majority of patients. Low cost, effective interventions were available for the most common causes of secondary cachexia. After CC consultation, 52 (33%) were enrolled onto clinical trials for primary cachexia.

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**Conclusions:** Conservative antibiotic treatment resulted in healing or stability of osteonecrosis, while using a prevention protocol, with oral hygiene measures and education, the incidence of the lesion was diminished in patients with compliance.
Methods: A group of patients was selected by the diagnosis "cancer with metastases and unknown original tumor" for the period of the years 2001-2006. 40 patients got the solitary pathology at their bones, and 107 patients got the pathologies at their bones and internal organs. 65 patients (44.2%) got the pathologic fracture (vertebrae: 30 patients; bones of limbs: 35 patients).

Results: The original tumor was unveiled for 83 patients (56.5%). The most frequent localizations of it were: lungs, prostate, kidney, and also myeloma. The patients got a standard surgical, chemotherapeutic, and radiologic treatment depending of the histological structure of the tumor.

Conclusions: In 10-25% of cases, the first manifestation of the malignant process is the bone metastasis, and 20-45% of cases of the bone metastases lead to the pathologic fracture. The original tumor remains unknown in 20-30% of cases with the pathologic fracture. The most frequent tumors metastasized in bones are: breast cancer, prostate cancer, thyroid cancer, kidney cancer, and lung cancer. The pathologic fracture is a frequent complication at the metastases of cancer with the unknown original tumor. This complicates the search and the histological verification of the original tumor, especially at the spinal fracture, but does not contraindicates to the complex therapy. The standard treatment improves the quality of life of these patients.

03-025
Bisphosphonate Related Osteonecrosis Of The Jaws: Outcome Of Conservative Treatment
Noam Yarom¹,², Towy Lazarovic³, Sharon Elad³, Shlomo Taicher³, Rony Weitzen³, Ran Yahalom¹
¹Sheba Medical Center, Department of Oral and Maxillofacial Surgery, Tel Hashomer, Israel, ²Tel Aviv University, Department of Oral Pathology and Oral Medicine, School of Dental Medicine, Tel Aviv, Israel, ³Hebrew University-Hadassah School of Dental Medicine, Department of Oral Medicine, Jerusalem, Israel, ⁴Sheba Medical Center, Division of Oncology, Tel Hashomer, Israel

Objectives: To evaluate conservative treatment (e.g., long-term antibiotics and superficial surgery) outcome of patients following bisphosphonate (BP)-related osteonecrosis of the jaw (ONJ).

Methods: Files of all patients with ONJ followed at our oral medicine clinic between October 2003 – October 2008 were retrieved. Only patients with a follow-up of ≥6 months were included for analysis. Patients with incomplete data on the duration and dosage of BP use were excluded. The study group was divided into those who took intravenous (IV) and those who took oral bisphosphonate. Response to treatment was classified as complete, partial (exposed bone with mild or no symptoms) and negligible/none.

Results: Of a total of 129 files, 102 patients (71 females, 31 males) met study entry criteria. Eighty-four patients received IV BPs and 18 received oral BPs. The IV group had taken zoledronate or pamidronate for a mean of 40.1 months. The oral group had taken mainly alendronate for a mean of 64.3 months. Twenty-four (28.6%) IV patients and 10 (55.6%) oral patients had complete response to treatment, while 41 (48.8%) IV patients had only partial response compared with 8 (44.4%) oral patients, and 19 (22.6%) IV patients had negligible/no response. No oral patients had negligible/no healing. The differences between the treatment outcomes in the two subgroups were significant (P<0.05). The response to treatment correlated with the patients' age. No correlation was found between the response to treatment and other evaluated parameters, such as gender, co-morbidities, smoking and clinical presentation.

Conclusions: The overall response of ONJ to treatment is relatively poor. Patients with oral BP-related ONJ respond better to conservative treatment than those with IV BP-related ONJ. Younger patients respond better to treatment than older patients.

04-026
Deaths In An Irish Tertiary Referral Centre - An Audit Of Referral Practices To Palliative Medicine And Documentation Of Resuscitation Orders
sharon beatty, peter lawlor, rory wilkinson, cathriona corcoran, morna o hanlon
st james hospital, palliative medicine, dublin, Ireland

Objectives: Optimising end of life care in an acute hospital setting requires early recognition of the needs of the patient with a life-limiting illness. Historically, referral to palliative medicine and resuscitation decisions are made on a reactive basis in response to an acute clinical deterioration. Decisions on DNR orders have been associated with patient preferences and short-term prognoses, but practitioners avoid such discussions and vary with prognostication. Active treatment and interventions may continue until death is imminent. To facilitate a proactive approach to end-of-life care planning in St James hospital, we examined timing of referral to the palliative care team and timing of documentation of resuscitation.

Objectives:
• To identify timing of referral to palliative medicine services.
• To identify timing of DNR documentation.
• Identify if Oncology specialists are more likely to instigate an early referral to palliative medicine.
• Identify if oncology specialists are more likely to
address resuscitation preferences at an earlier date.

**Methods:** Retrospective chart review of 208 patients who died in St James Hospital while under review by palliative medicine services.

**Results:** In 2008 the Palliative Medicine Consultation Service reviewed 834 patients representing 26% (208/800) of total deaths in St James in 2008. 77.4% were malignant and 22.6% non-malignant.

Time DNR to death median 7 days range 0-171 days
Time pall care initial review to death median 7 days range 0-187 days
Time from admission to pall care review median 11 days range 0-291 days
Kruskal wallis test:
Significant difference time to referral in relation to specialty P<0.001
Hematology/oncology referring earlier.
Significant difference between time from pall care referral and death. P=0.01. Shortest for medical and surgical specialties.
Time from resus to death p=0.02 shortest for surgery.

**Conclusions:** Significant variations in referral practices and DNR documentation within specialties. HemOnc specialists referring earlier and documenting earlier than medical or surgical specialties.

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**04-027**

**Legal Practice Of Euthanasia In Belgium. Analysis And Interpretation Of The Last Three Years Registration Documents And The Experience Of A Supportive Care Unit.**

Dominique Lossignol, Marc Englert, Isabelle Libert, Bénédicte Michel, Julie Meunier, Myriam Obiols

**Institut Jules Bordet, Supportive care, Brussels, Belgium, **

**Commission de contrôle et d'évaluation, Brussels, Belgium, **

**Institut Jules Bordet, Psycho oncology, Brussels, Belgium**

**Objectives:** The Belgian law relative to euthanasia prescribes that a physician performing an euthanasia has to complete a registration document and to send it within 4 days to the Federal commission for control and evaluation of euthanasia. The present paper analyses 924 reports from January 2006 and December 2007.

**Methods:** Analyses from national reports

**Results:** The most frequently reported diagnosis remains cancer in 81% of cases and neuromuscular illness in 9%, in 80% of cases, the age of the patients is between 40 and 79 and the place where euthanasia was performed is: 49% at home (by a general practitioner: 45%) and 50% in a hospital. The method used in more than 90% of cases is an intravenous injection (mostly barbiturate) inducing unconsciousness followed, if needed, by an intravenous injection of a neuromuscular relaxant. Euthanasia requests were mostly related to severe dyspnea, GI occlusion, lost of hope, fear of intractable pain, lost of dignity. The important and recurrent difference in the number of registration documents written in French (14%) and those written in Flemish (86%) will be analysed and discussed.

In our supportive care unit, 25 requests for euthanasia were followed (3 in 2006, 6 in 2007, 16 in 2008 (end September)). Among them 13 led to euthanasia according to the Belgian law (10 performed at hospital and 3 at home). We met the same clinical and symptomatic conditions as the rest of the country. Furthermore, there were no suicidal ideation and no “intractable depression”. Each patient was seen by our psycho oncology team and all symptoms received adequate treatment with an optimal relief. More specific data (Age, tumors, symptoms evaluation, etc.) will be presented.

**Conclusions:** Our experience confirms that Belgian law meets medical expectations in terms of end-of-life decisions and euthanasia.

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**04-028**

**Which Variables Are Related To Residents ’Ability to Detect Patients’ Distress?**

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**Objectives:** Although detection of distress has been considered as a core clinical skill for residents, there are not enough empirical evidence currently available about variables which may be related to residents’ ability to detect patients’ distress accurately. The objective of this study is to test the value of a model designed to determine variables related to residents’ ability to detect patients’ distress.

**Methods:** Potential variables included in the model - assessed during a highly emotional simulated patient interview - are the following: residents’ sociodemographic, professional and psychological characteristics (assessed by questionnaires); residents’ communication skills (assessed by a utterance by utterance analysis); residents’ psychological arousal (assessed by the STAI); and physiological arousal (assessed by monitoring heart rate and blood pressure). A mean detection accuracy score was calculated for each physician by comparing residents’ rating of patients’ distress (assessed on a 10-point VAS) with patients’ distress (assessed with the HADS) during a half-day clinical round.
Results: Ninety-four residents and 442 inpatients were included in the study. Thirty percent of the variance in residents’ detection of patients’ distress was explained by the following residents’ variables of the model: self-reported anxiety level before the interview ($r=-.21; p=.040$), mean arterial blood pressure level before the interview ($r=-.26; p=.019$), use of empathy during the interview ($r=.23; p=.027$) and the evolution in mean arterial blood pressure between the pre-interview rest and the post-interview period ($r=-.27; p=.012$).

Conclusions: This study shows that several variables are partly related to residents’ ability to detect patients’ distress. Residents’ psychological and physiological arousal before and during a highly simulated interview are key variables - beside their empathic skills - which must be considered in models designed to determine their ability to detect patients’ distress. Future interventions designed to improve residents’ detection should therefore focus on these variables.

04-029
Internet Use Of Cancer Patients In Germany: An Online Survey Of The Sophia Working Group
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Objectives: The internet has become an important information source for all questions of daily life. This can be also seen in medicine, especially in serious and chronic illnesses. But often, patients can not distinguish between reliable medical information and misleading websites. We conducted a survey about the internet use of cancer patients in 3 hospitals in Germany and the way patients use information and assess the validity of data.

Methods: In the participating centers, cancer patients received a printed leaflet at their appointment. They were asked if they used the internet as a source of information. If they responded positively, they were asked to participate in this anonymous online survey. Questions included why, how and how often the internet was used, what kind of web sites were visited for information, if they used search engines, what were key reasons for the search and how patients assessed and used the displayed information. The online questionnaire is available in German at www. http://pomme-med.de/umfrage/index.php?lang=1

Results: In the pilot phase from February to June 2008, 217 cancer patients with different malignancies filled in the printed leaflet. 94 patients (43.3%) answered that they used the internet as a source of health information and 34 (36.2%) patients took part in the subsequent online survey. 88.2% of patients were looking for information on diagnostics and treatment. But only 38.2% were aware of quality certificates for health web sites, most patients relied on their own judgement (67.6%). 64.7% considered an internet presence reliable when the operators of the website and 79.4% when the authors of the medical texts were stated.

Conclusions: Patients need guidance how to use medical data from the net. This should be included into routine cancer patient education and this concept will be incorporated in the German National Cancer Plan.

04-030
Communicating About Chemotherapy-Induced Nausea And Vomiting: A Comparison Of Patient And Provider Perspectives
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Objectives: Despite recent progress, chemotherapy-induced nausea and vomiting (CINV), especially delayed CINV, continues to be a problem. Grunberg et al. (2004) reported that delayed CINV is underestimated and perceived differently by providers and patients. Understanding communication about CINV between providers and patients may help improve outcomes. The purpose of this study is to identify patients’ and providers’ perceptions of communication, management, and barriers to quality CINV care, and to explore solutions to these barriers.

Methods: Provider and patient versions of a Nausea and Vomiting Management Barriers Questionnaire (NVMBQ) were developed to address potential barriers (e.g., desire to limit medications, lack of provider-initiated communication, and desire to be a “good” patient). Providers and patients were given opportunities to add detail in open-ended questions. Data collection is ongoing. 150 provider and 300 patient surveys will be collected via the internet. Providers are being recruited through the National Comprehensive Cancer Network and Oncology Nursing Society mailing lists. Patients who received at least 2 cycles of chemotherapy and experienced CINV are being recruited through a consortium of advocacy groups.
Results: To date, 76 providers (72% oncology nurses, 28% oncologists) and 165 cancer patients (30% Breast, 45% Colon, 12% Lung, and 13% Leukemia/Lymphoma) have completed the survey. A comparison of NVMBQ items revealed that providers (39%) and patients (47%) agreed medication side effects were a concern but more patients (70%) than providers (32%) tried to limit the number of medications taken. Many providers (69%) spontaneously reported financial (cost, drug access, insurance coverage) and patient-related barriers (noncompliance, underreporting) to managing CINV. Few patients (9%) reported cost as a barrier, but 40% endorsed the desire “to be strong by not complaining.”

Conclusions: Barriers to communication and quality care of CINV differ between caregivers and patients. Establishment of mutually consistent goals will lead to more effective overall care.

04-031
Oncology Consultations With Patients From Culturally And Linguistically Diverse (Cald)

Backgrounds: The Interpreter Perspective
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Objectives: Migration is increasing world-wide. In our research into the unmet needs of cancer patients and carers from culturally and linguistically diverse (CALD) backgrounds, interpreter accuracy, professionalism, and continuity emerged as key concerns. Our audiotape studies show that the presence of an interpreter clearly affects information provision and consultation dynamics. Little is known about the experiences of the interpreter. The aim of this study was to understand the experiences, challenges and needs of interpreters.

Methods: 30 interpreters (Greek n=7, Chinese n=11, and Arabic n=12) were recruited through two Sydney Health Care Interpreter Services, and an organisation responsible for the provision of interpreters for major Melbourne hospitals. Participants took part in focus groups which were audio-taped, transcribed, and analysed for themes using content analysis.

Results: Four broad themes emerged from the data: a) interpreter perceptions of their role and responsibilities: some saw themselves as merely a conduit of information, while others saw their role in broader terms, encompassing cultural brokerage, patient advocacy and provision of emotional support; b) challenges experienced by interpreters: these included difficulty balancing professional obligations with their own emotional responses, feeling caught between two conflicting value systems, and systemic difficulties; c) need for training and support in areas such as medical terminology, field placements, communication skills and debriefing; and d) advice to oncologists included checking on interpreter/patient’s language or dialect compatibility; using lay language in short sentences and speak in first person.

Conclusions: Resolving potential conflicts between information provision and advocacy is an important area of research and guideline development in cross-cultural communication. Further training and support should be provided to facilitate interpreters’ efficacy in a culturally appropriate manner and enhancing their competence in managing delicate situations from a professional, cultural and psychological perspective. Doctors should be trained in how to collaborate with interpreters to enable culturally competent communication.

04-032
End-Of-Life Decision Making For Cancer Patients In Different Clinical Settings
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Objectives: Differences in the general focus of care between hospitals, nursing homes and home may affect the adequacy of end-of-life decision-making for the dying. We studied end-of-life decision-making practices for cancer patients who died in either of these settings, and assessed the impact of the Liverpool Care for the Dying Pathway (LCP), a template for care in the dying phase.

Methods: Physicians and relatives of 311 deceased cancer patients filled in questionnaires. The LCP was introduced halfway the study period.

Results: During the last three months of life, patients who died in hospital more than patients in both other settings received anti-cancer therapy and medication to relieve symptoms. During the last three days of life, patients who died in the hospital or nursing home received more medication as compared to patients who died at home. The LCP had no clear impact on the use of medication during the last days of life, except that the extent to which physicians thought that medication might have hastened death was reduced after introduction of the LCP. Relatives of patients who died in the hospital tended to be least positive about the
methods, and individualizing care. Cultural and systems problems can be addressed through public and professional education, alternative models of care, and changing the attitude of the society to cancer and the death phenomena.

04-034
Effectiveness Of An Educational Intervention Program (EIP) In Neutropenia Management In The Community Oncology Practice Setting
Kevin Weeks, Dennis Kim, May Mo, Thomas Jones

Objectives: Integrating emerging oncology data and literature updates represents a challenge for practicing physicians. When available, clinical-practice guidelines organize such data into a medical evidence hierarchy that provides valuable clinical decision-making guidance. We hypothesized that an educational intervention program (EIP) summarizing clinical studies according to evidence level could improve cancer care quality for febrile neutropenia (FN) and associated complications.

Methods: This cluster-randomized, controlled, multicenter study involved cross-sectional chart reviews in community-based oncology practices in the United States. Sites were randomized 1:1 to receive EIP or no-EIP. Analyses were based on data from 2 retrospective abstractions: pre-EIP and post-EIP. The primary endpoint was post-EIP incidence of clinically significant chemotherapy-induced neutropenia (CSCIN) ([ANC <1.0x10^9/L with temperature ≥38.0°C], FN-associated hospitalization, neutropenia-related chemotherapy dose reduction or dose delay ≥7 days).

Results: Forty-five sites without written neutropenia guidelines or pathways participated in the study (21 EIP and 24 no-EIP), and 1518 sequential patients’ charts meeting criteria for specified malignancy and chemotherapy (>20% FN risk) were abstracted (767 pre-EIP; 751 post-EIP). CSCIN incidence during the first 4 cycles of treatment was similar for both the EIP and no-EIP groups; pre-EIP (6.3% and 7.7%, respectively) and post-EIP (9.0% and 8.2%, respectively; p = 0.715).

Conclusions: CSCIN incidence both pre- and post-EIP indicates a higher than expected rate of neutropenia-related events relative to historic data where growth factor prophylaxis has been consistently utilized (Vogel et al, JCO 2005;23:1178). The EIP did not significantly affect CSCIN incidence. Coincidentally, ASCO published updated guidelines on myeloid growth factors after this study started, recommending growth factor prophylaxis in chemotherapy regimens with an FN risk threshold of
≥20%, which may have confounded the EIP effect. Although this study was not designed to evaluate the impact of EIP versus ASCO guidelines, follow-up chart abstractions could be valuable in assessing their relative impact on reducing CSCIN incidence. Supported by Amgen.

**05-035**

**Family Strategies For Managing Childhood Cancer: Using Complementary And Alternative Medicine In Jordan**

Ahmad AL Khatieb¹, Mohamad Al-Quidemat², Ne’meh Farhan

**Objectives:** Using Complementary-Alternative Medicine CAM has become an international phenomenon especially in oncology field. It has been gaining acceptance in the developed countries as well as in developing countries. Health care professionals are becoming increasingly aware that patients use CAM either covertly or overtly. In many occasions, CAMs are discussed by some physicians or herbalist in unsystematic methodology and isolated form the oncology consideration insisted of creating a trend toward an evidence based regulations and CAM usage. We aim through this study to evaluate the prevalence of CAM usage among Jordanian pediatric oncology patients.

**Methods:** Descriptive-cross sectional design was used; Proxy-assessment has been made to obtain information regarding CAM usage among children with cancer in Jordan. Descriptive questionnaires were distributed to parents of children with cancer after complete interview and informing consent.

**Results:** 59 pediatric cancer parents who were attending one of the four out-patient services (leukemia, lymphoma, solid tumors and neuro-ocular tumors) at King Hussein Cancer Center in Amman, Jordan had filled the questionnaire. 64.4% reported using at least one type of CAM (61.5% Leukemia, 66.6% Lymphoma, 66.7% Solid tumors and 71.4% for Neuro-ocular tumors patients). The most commonly used therapies includes; praying, special diets and herbs.

**Conclusions:** Parents were motivated to use CAM either for support their children’s medical treatment, or in case to use all possible methods to cure their kids. The reason for parents not using CAM included not being aware of CAM. Most of the patients have not discussed the issue of using CAM with the medical staff.

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**05-036**

**Complementary And Alternative Medicine (Cam) Usage In Singaporean Breast Cancer Patients: A Cross Sectional Study**

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**Objectives:** To determine the prevalence of CAM utilization among Singaporean breast cancer patients; to list the factors influencing consumption of CAM; to determine the attitudes of breast cancer patients towards CAM.

**Methods:** This was a single-centre, cross-sectional, interviewer-administered survey-study. Patient inclusion criteria include: 21 years and above, diagnosed with any type of cancer, undergoing treatment at NCC, conversable in English or Mandarin, and willing to undertake this study. Written consent was obtained prior to the start of the survey. Statistical analysis was performed by SPSS, and Chi-Square test was utilized to detect the association of demographics and CAM consumption.

**Results:** One hundred and forty six patients were included in this analysis. Over half (58.9%) of the patients consumed CAM while receiving chemotherapy. Vitamins (53.5%) were the most widely consumed form of CAM, followed by Organic Vegetables and Fruits (52.3%). The top three reasons for using oral CAM were to boost immunity (53.5%), for general health purposes (21.0%) and to reduce side effects of chemotherapy (10.0%). Most oncologists allow their patients to continue using oral CAM (69.6%), while 4.3% were against it. These patients continued using oral CAM at their own risk. Statistical analysis revealed that consuming CAM before cancer diagnosis is associated with CAM consumption during chemotherapy treatment (p<0.05).

**Conclusions:** A substantial number of breast cancer patients consume CAM concurrently with chemotherapy. Healthcare professionals should take a proactive approach to counsel these patients regarding CAM use during chemotherapy. Follow up studies should evaluate whether CAM can affect treatment outcomes of these patients.
Objectives: Venous thrombosis is the second leading cause of death in breast cancer patients. Malignant tumors and cancer treatment cause an elevated tendency towards blood coagulability and thrombogenesis. The aim of the present study was to define the preventive effect of Phallus impudicus on the platelet pathologic aggregation in breast cancer patients undergoing chemotherapy and hormonal treatment.

Methods: During the period of 1991-2008, 1252 patients with newly diagnosed breast cancer were followed for 1 to 12 months to assess the levels of platelet aggregation, spontaneous intravascular platelet aggregation, antiaggregative and anticoagulative activity of the vascular wall. The standart juice from Phallus impudicus fresh fruiting bodies was used by all patients in the dose of 10 grams three times daily and as a topical cream for lower limbs two times daily.

Results: The results showed that patients undergoing chemotherapy and adjuvant hormonal therapy with tamoxifen and aromatase inhibitors were at increased risk of venous thrombosis: platelet aggregation enhanced by 58% with 2,3-fold increase in functional platelet activity. Antiaggregative activity of the vascular wall was decreased by 25% and anticoagulative activity decreased by 39%. Minimum of 20 days of Phallus impudicus consumption excluded the steep rise in platelet aggregation, prevented a drop in antiaggregative and to a lesser degree anticoagulative activity. The insurance against spontaneous intravascular aggregation of platelets was doubled.

Conclusions: Breast cancer patients with recurrent venous thromboembolic disease are usually maintained on anticoagulants for their lifetime. New prophylactic agents may be needed for adequate prevention in patients. Phallus Impudicus has been a folk remedy for patients with advanced breast cancer since antiquity. Now It is possible to speculate that Phallus impudicus longterm consumption can prevent thromboembolic complications without side effects in breast cancer patients as a remedy of supportive preventive nutrition and skin care.

Objectives: The incidence of non–AIDS-defining cancer (anal, vaginal, Hodgkin’s lymphoma, liver, lung, melanoma, oropharyngeal, leukemia, colorectal and renal) is significantly higher in HIV-infected than in the general population. In contrast, breast and prostate cancer risk is significantly reduced in the HIV-infected population. The molecular mechanisms underlying the phenomenon of suppression of breast and prostate cancer in the HIV-infected population may serve as a basis for development of a new platform for prevention and treatment of breast and prostate cancer.

Methods: (i) Comparison of informational properties of HIV-1 gp120 and VIP by the informational spectrum method; (ii) screening of HIV-positive and HIV-negative sera for natural anti-VIP/NTM reactive antibodies by the NTM-based ELISA immunoassay; (iii) digital data mining and literature survey.

Results: It was shown that HIV-1 envelope glycoprotein gp120 facilitates viral replication by binding to the vasoactive intestinal peptide (VIP) receptor type 1 (VPAC1). A longitudinal study of disease progression in HIV-infected patients showed that natural antibodies recognizing VIP and the gp120-derived peptide NTM are significantly more prevalent during the asymptomatic stage of the disease than in overt AIDS [Veljkovic et al. J Clin. Virol. 2004; 31: 39], and in long term non-progressors than in normal progressors [Djordjevic et al. Curr. HIV Res. 2007; 5; 443]. These results indicate that natural autoantibodies, which suppress VIP-like activity of HIV-1 gp120, significantly contribute to the control of HIV disease progression. Here we suggest that natural anti-VIP/NTM antibodies contribute to a decrease of breast and prostate cancer in HIV-infected population by suppression of VIP, which might play a pro/oncogenic function.

Conclusions: The immunotherapy based on natural anti-VIP/NTM antibodies could serve as an effective adjunctive therapeutic approach for the treatment of breast and prostate cancers. Similarly, aerobic exercise, which efficiently stimulates production of natural anti-VIP/NTM antibodies, should be considered as an inexpensive and safe preventive and supportive therapy.
**06-039**

**Reduced Fatigue Through A Six Week Structured Group Exercise Intervention In Cancer In Patients Undergoing Chemotherapy - A Randomized Clinical Controlled Trial.**
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**Objectives:** Fatigue is a very frequent symptom in cancer patients, who are being treated with chemotherapy and is associated with physical inactivity, lower functional level, and lack of energy, impacting negatively on the patient's QOL. Fatigue may be a long-lasting, devastating symptom and may persist years after termination of the treatment. The objective of this study was to examine the effect of a group exercise intervention on fatigue in cancer patients undergoing adjuvant chemotherapy or treatment for advanced disease.

**Methods:** The study was designed as a prospective randomised controlled trial. Participants were randomly assigned to the intervention (n=135) or control (n= 134). The Intervention was supervised exercise comprising: high-intensity cardiovascular- and heavy resistance training; relaxation- and body-awareness training, massage, 9 hours weekly for 6 weeks. Participants completed Functional Assessment of Cancer Therapy - Anaemia (FACT - An) at baseline and after 6 weeks.

**Results:** The sample included 73 males, 196 females, representing 21 diagnosis and with a mean age of 47 years. The intervention group significantly reduced their level of fatigue compared to the control group (P=0.0145). The intervention group reduced the FACT-An score with an estimated effect size of 5.4064 points (95% confidence interval 1.09 to 9.73) compared to the control group. The results were adjusted for baseline score, relative change in B-haemoglobin, and disease- and demographic covariates.

**Conclusions:** The findings indicate that exercise intervention reduces fatigue in cancer patients of both genders and with a variety of cancer diagnoses. More studies are needed in order to conclude on the causality of the documented effect bearing in mind that fatigue is a multifactorial symptom with an as yet unestablished aetiology.

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**06-040**

**Defining Cancer Related Fatigue: A Conundrum**
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**Objectives:** The prerequisite for delivering optimal supportive care is to have a clear case definition of cancer-related fatigue (CF). To date there is no universally accepted case definition of CF, which is estimated to affect between 18% and 96% of cancer patients. This study is a meta-synthesis of CF definitions to present the evolution of the dimensions included in CF definitions over time, across countries and disciplines.

**Methods:** A systematic search identified 75 articles published between 1996 and 2007 that attempted to define, measure, explain, or review CF. Search terms included fatigue, tiredness, lassitude, weakness, or asthenia. Each article was independently reviewed to extract and examine the definition and encompassing concepts, the context for the definition retrieved, and the source used to establish the definition.

**Results:** This research yielded 47 distinct CF definitions supported by findings from literature reviews (n = 30), expert opinion/panels (n = 5), qualitative research (n = 4) and adaptations of the National Comprehensive Cancer Network CF definition and guidelines (n=8). There has been an exponential increase in publication of CF definitions over time. The majority of definitions (87%) define CF as multi-dimensional. While there is considerable agreement among CF definitions regarding concepts (e.g., 87% associated it with interference with usual functioning; 51% reported it as persistent), no single concept is mentioned in all definitions nor are all concepts included in any multidimensional concept.

**Conclusions:** The analysis of dimensions identified in each definition demonstrates the inconsistency and variability of concepts across definitions. There is no conclusive consensus in the definition, associated concepts or dimensionality of CF, making it difficult to formulate optimal treatment decisions or manage patients and design treatment efficacy or safety assessments. Supported by J&J Pharmaceutical Services, Merck & Co, Inc., Novartis Pharmaceuticals Corporation, sanofi aventis, and Boehringer Ingelheim GmbH.
06-041
The Evaluation Of Valeriana Officinalis To Enhance Sleep And Fatigue In Cancer Survivors: Ncctg Trial N01C5
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Objectives: Sleep/wake disturbance is an under-reported symptom in cancer survivors, potentially contributing to physiologic dysregulation that is involved in the etiology of several other symptoms, including fatigue and mood. The purpose of this trial was to evaluate the ability of valeriana officinalis to improve sleep, fatigue and anxiety in cancer survivors receiving treatment for their disease.

Methods: 202 patients receiving cancer treatment who reported sleep difficulties (>3 on a 0 to 10 scale) were randomized to 450 mg valerian or placebo at bedtime for 8 weeks. Exclusion criteria included primary insomnia from other causes, including sleep apnea. Other pharmacologic sleep aids were not allowed. The primary outcome was measured with the Pittsburgh Sleep Quality Index (PSQI), with secondary outcome measures including the Brief Fatigue Inventory (BFI), the Functional Outcomes of Sleep Questionnaire (FOSQ), Profile of Mood States (POMS), and numeric analogue scale (NAS) single item questions. Area under the curve and change from baseline were compared between valerian and placebo treatment groups using Wilcoxon rank sum and t-test where appropriate.

Results: The PSQI did not reveal any statistically significant differences. There was also no positive effect on anxiety or the FOSQ. However, several secondary endpoints were significant and favored valerian (table below). There were no significant differences in toxicity reporting between arms.

<table>
<thead>
<tr>
<th>Measure - Mean change from baseline at week 8 (higher is better)</th>
<th>Valerian</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BFI-fatigue now</td>
<td>22.1</td>
<td>10.5</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>BFI - usual fatigue</td>
<td>19.4</td>
<td>10.0</td>
<td>.05</td>
</tr>
<tr>
<td>BFI - worst fatigue</td>
<td>14.8</td>
<td>12.4</td>
<td>.65</td>
</tr>
<tr>
<td>POMS fatigue/inertia</td>
<td>17.5</td>
<td>9.2</td>
<td>.02</td>
</tr>
<tr>
<td>POMS tension/anxiety</td>
<td>9.2</td>
<td>8.9</td>
<td>.54</td>
</tr>
<tr>
<td>NAS - Drowsiness</td>
<td>24.3</td>
<td>13.8</td>
<td>.04</td>
</tr>
<tr>
<td>NAS- sleep affects QOL</td>
<td>24.4</td>
<td>13.4</td>
<td>.03</td>
</tr>
</tbody>
</table>

Conclusions: Although the primary sleep measures did not detect significant differences, there is preliminary evidence for some potential benefit from valerian for some related secondary endpoints. As valerian was very well tolerated, further studies examining dose response and more sensitive outcome measures are warranted.

06-042
Cancer-Related Fatigue: Experiences From The Experienced
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Objectives: To explore the multidimensional experience of cancer-related fatigue and its repercussions on quality of life across curative, supportive and palliative phases of care.

Methods: Purposeful sampling methods were undertaken to recruit fatigued individuals across the cancer trajectory. A qualitative design was employed to gain an insight into this highly subjective symptom, following the principles of grounded theory throughout data analysis.

Results: 26 participants with varied diagnoses and staging were recruited into the study. The main themes that emerged detailed the side effects of treatment, including the physical, mental and emotional nature of fatigue and its negative ability to dramatically transform individuals’ lifestyles. Identified within these findings was the need for strategies to be put in place for the overall management of fatigue, which should include the provision of support and educational services and be open to patients across all phases of care. Differences in results were observed within trajectory subgroups.

Conclusions: Findings from this study provide an insight into the journey undertaken by patients following a diagnosis of cancer. It is evident that fatigue remains a symptom that is underestimated and undermanaged by oncology healthcare professionals. The emerging themes have demonstrated the need for ongoing research in this area and continued progress until an evidenced based framework for fatigue management is developed, proven feasible and implemented. Only then can the burden of this debilitating and prevalent symptom be alleviated and optimum patient management and satisfaction achieved.
**06-043**
Symptom Management - Let’s Do It Evidence Based
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**Objectives:** Patients with cancer disease are troubled by a multitude of symptoms related to both the disease and its treatment. Numerous studies have shown the positive effects of providing patients with the requisite information of what they can expect in relation to their situation. Research results show that patients feel emotionally better and can deal more effectively with their daily life if they are well informed about their condition. Results from a cross-sectional investigation performed in 2007 at the Department of Oncology, showed that fatigue (cancer-related fatigue) was the most frequently reported symptom (n=214), followed by pain (n=126). Based on these research results, a change in work routine began in which a special clinic group of nurses (‘Evidence group’) was formed from all of the departments.

**Methods:** The Evidence group has met on a regular basis since the beginning of December 2007. The aim was to establish broad clinical guidelines. Evidence for the management of each symptom is acquired through the systematic evaluation of the literature.

**Results:** Fatigue was evaluated, treated and systematically followed-up in line with the guidelines. It was the responsibility of each nurse to perform an assessment of the patients’ experienced fatigue, the possible factors triggering and the effects on everyday life. The investigation was conducted by routinely asking four questions about experience of fatigue. The rating of patients’ experience of fatigue was done on a four-point scale. Based on the patients’ ratings and narratives, the nurses could identify the causes of fatigue, as well as give the patients oral and written information about fatigue according to the guidelines. Follow-up and evaluation will place continuously during the patients’ next visit to the clinic.

**Conclusions:** The Evidence group will continue to work regarding symptom management. This project increases the continuation for safe, secure and standardized care. Patients’ participation in dealing with their symptoms becomes noticeably improved.

**06-044**
Fatigue In Advanced Cancer - A Master Without Mercy Or A Refuge
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**Objectives:** Fatigue is known to be a prevalent symptom in patients with advanced cancer and can be more distressing and disruptive to daily activities than the pain associated with the disease. Many studies are focused on assessment and management of cancer related fatigue but there is also a need for a better understanding of the meaning of fatigue at the end of life. This study aims to elucidate the essential meaning of fatigue as narrated by patients with advanced cancer.

**Methods:** A purposive sample of 10 patients with advanced cancer at a palliative care facility cared for at home were interviewed. Data were analyzed using phenomenological method.

**Results:** The descriptive structure emerging from the analysis contained four closely interrelated constituents; ‘a overwhelming burden on body and soul’, ‘a rescue from pain and distress’, ‘provider of new solutions in daily life’ and ‘a creator of new meaning in life’ These constituents formed the essence of fatigue in the patients' lifeworld: ‘A mark of illness, restricting daily life without mercy but providing a shelter from the unbearable and creating a new meaning into life at the edge of death’.

**Conclusions:** Cancer related fatigue is understood as a merciless intruder, restricting daily life but might also provide a rescue from the unbearable. This knowledge might help health care providers and persons close to the patient to better understand the meaning of fatigue in the end of life.

**06-045**
Fatigue And Quality Of Life Of Egyptian Cancer Patients Receiving Chemotherapy
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**Objectives:** Evaluate patient’s experience of fatigue and its impact on the quality of life during chemotherapy treatment.
Methods: 150 cancer patients with different diagnoses and receiving chemotherapy, patients were recruited from medical oncology department, National Cancer Institute, Cairo, Egypt. Data were collected through patient structured interview, reviewing medical and nursing records, and facit- fatigue scale (version 4). Patients were assessed before, and after chemotherapy.

Results: Results revealed significant correlation between fatigue and quality of life. Also patients who received radiotherapy showed higher scores of fatigue. Physical and psychosocial domains were significantly affected while the spiritual domain was kept within normal.

Conclusions: Quality of life of patients is affected by fatigue, screening of fatigue as well as quality of life should be performed on admission and frequently during treatment to identify patients at risk in an earlier stage. Nurses should include fatigue screening in their routines, and orient patients to different coping measures before commencing treatment.

06-046
Patient Apathy And Increased Symptom Burden:
Initial Experiences In A Cancer-Related Fatigue (Crf) Clinic
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Objectives: Background/Objectives Apathy, or lack of motivation, has been little studied in cancer patients. Because interventions for CRF often include behavioral change and involve commitment to treatment, patient apathy may be detrimental to outcome success. We conducted a pilot study in our CRF Clinic and report on the first 30 patients evaluated for apathy during assessment. Our objectives were to investigate associations between apathy and fatigue-related symptoms and determine if apathetic patients differed from non-apathetic patients in symptom burden.

Methods: New CRF patients were evaluated for apathy, using the Apathy Evaluation Scale, Clinician Version (AES-C) as the primary outcome measure. The AES-C provides a score from 18-72. To explore apathy and symptom associations, AES-C scores were correlated with four symptoms commonly experienced by CRF patients (fatigue, pain, depression, and anxiety). AES-C scores can also be used to categorize patients as apathetic or non-apathetic, with scores of ≥ 38 considered clinically significant apathy. Level of symptom burden by apathy vs. non-apathy was compared across groups.

Results: 30 new CRF patients were evaluated for apathy. The median age was 63 years (range 36-84 years); 57% (n=17) were female, 87% (n=26) white, and 70% (n=21) married. The most frequent groups were breast (30%, n=9) and leukemia/lymphoma/myeloma (20%, n=6). Apathy scores ranged from 18-61 (median=25.5), with nearly one quarter (23%, n=7) clinically apathetic. The self-reported symptom burden of apathetic patients was significantly greater than of non-apathetic patients for fatigue, depression, and anxiety; apathetic patient pain burden was also observably greater than non-apathetic pain, though not statistically significantly (p=.118).

Conclusions: Summary There is a statistically significant positive correlation between apathy and fatigue, depression, and anxiety. Thus, apathy may undermine their CRF treatment objectives. Future investigations include determining factors involved in development of patient apathy and identifying methods to reduce or eliminate apathy.

06-047
Fatigue In Low Risk Febrile Neutropenia (Fn) Treated As Outpatients (Ops)
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Objectives: Background: OP management of FN in low risk cancer patients is the standard of care at our institution. Frequently these patients complain of fatigue. The objective of this study is to describe these patients and determine whether fatigue improves as patients are treated for FN as OPs.

Methods: Methods: Low risk cancer patients with FN enrolled in our OP FN pathway were eligible for the study if they had ≥4 on the Brief Fatigue Inventory (BFI) question #3 at their Emergency Center (EC) visit. Patients were enrolled in the study on d#2 of the pathway and completed the BFI on d#2, d#3 and d#7 of the pathway. Demographic and diagnostic information was collected.

Results: 19 patients were enrolled. 12 (63%) were females with mean age 48 years (range 18-72). Most had...
Cancer-Related-Fatigue In Paediatric Oncology - A New Physiotherapeut Approach To Reduce Crf
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Objectives: The author translated the PedsQL 3.0 Multidimensional Fatigue Scale into German and made a prestudy with 66 Children. Our subjective impression of CRF in paediatric oncology was confirmed by the following data: Low values in the dimensions “general fatigue” and “fatigue related to sleep/rest” and a significant correlation (0.028) between “age” and “fatigue related to sleep/rest” and close to significant correlation (0.053) between “age” and “general fatigue” observed in the answers of 49 children aged 5 to 18 years. After we made sure, that this most bothersome side effect of oncological disease is present in children, we were searching for a strategy to reduce CRF. According to the efforts made with adults, we developed a training program to reduce CRF. In cooperation with the Institute for Sports medicine in Frankfurt, we decided to use home trainer in the patient’s room.

Methods: Interviews and questionnaires seem to be the common way to evaluate fatigue, but additional to this, we want to demonstrate the increase of physical strength. Therefore we evaluate handcraft once a week, doing a lactate-measurement and examine the Quality of Life with a questionnaire. We created an information-flyer in order to introduce the topic to parents and children about the specifics of CRF and introduce adequate measures to reduce this problem. This flyer was hand out before the transplantation, so everyone was informed, what kind of rehabilitation concept is standard in our hospital. To avoid muscular atrophy and immobility the Physiotherapy and Sports therapy cooperate in different situations with the care-givers.
**Results:** All children with bone-narrow- or stem-cell transplantation in our hospital are included in this study. We strated in 12/2008 and our first results will be presented.

**Conclusions:** This is the first investigation in Germany, which tries to reduce CRF with Physio- and Sports-Therapy.

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**06-050**

**Sources Of Apathy Information: Clinician Versus Self Reporting On The Apathy Of Cancer-Related Fatigue (Crf) Patients**

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**Objectives:** Interventions for CRF, often incorporating lifestyle change, require patient commitment. Apathy, i.e., lack of motivation, may diminish prospects for successful outcomes. To date, few studies have addressed apathy in cancer patients. We conducted a pilot study in our CRF Clinic and report on the initial 30 patients evaluated for apathy. Our objective was to determine apathy information source (clinician vs. patient) most associated with fatigue-related symptoms.

**Methods:** New CRF patients were evaluated for apathy, using the Apathy Evaluation Scale (AES); scores range from 18-72 and classify patients as apathetic or non-apathetic (≥38=clinically significant apathy). Two AES versions were employed: Clinician (AES-C) and Patient Self-Report (AES-S). Score distributions were compared, and scores correlated (Spearman) with 4 symptoms commonly experienced by CRF patients (fatigue, pain, depression, anxiety). Symptom burden of apathetic vs. non-apathetic was compared per apathy measure (Mann-Whitney U test), and agreement on apathy classification assessed.

**Results:** 30 new CRF patients were evaluated for apathy by clinician and self report. Median age was 63 years (range 36-84); 57% (n=17) were female, 87% (n=26) white, and 70% (n=21) married. Breast (30%, n=9) and leukemia/lymphoma/myeloma (20%, n=6) were the leading cancer diagnoses. AES-C median score was 25.5 (range 18-61); 23% (n=7) were clinically apathetic. AES-S’s median score was higher (30.0), its range restricted (18-52); more patients (27%, n=8) were clinically apathetic. AES-C and symptom score correlations (.33-.60) were all statistically significant (p<.10); AES-S correlations (.25-.45) were significant for fatigue, depression. AES-C classified apathetic patients had significantly greater (p<.10) fatigue, depression, and anxiety burden than non-apathetic; AES-S classified apathetic patients had significantly greater depression burden than non-apathetic. Classification discordance was 10%.

**Conclusions:** Clinician-reported patient apathy exhibited stronger symptom correlations and greater discrimination of apathetic vs. non-apathetic symptom burden. Initial evidence suggests patient apathy reported by clinicians may have greater clinical and research usefulness.

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**06-051**

**Fatigue Aggravated By Pain In Breast Cancer Patients**

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**Objectives:** The correlation and comorbidity between fatigue and pain in women with breast cancer is practically unknown. This study aimed to analyse the comorbidity between pain and fatigue in women with breast cancer.

**Methods:** A cross-sectional study was developed with a non-probabilistic sample composed of 182 women with breast cancer under ambulatory care, in any treatment or disease phase (means: age = 52.8y; years of school = 12.4y). Data were collected from July 2006 to March 2007. Fatigue was assessed by Revised Piper Fatigue Scale (0 to 10) and pain intensity by Numeric Scale (0-10). Fatigue and pain scores were classified in 0.1 to 4.9 = mild, and 5.0 to 10.0 = moderate or severe. Zero was not considered in the correlations. Statistical analyses were performed by Student's t-test, Pearson's correlation coefficient, and differences were considered significant when P<0.05.

**Results:** Fatigue was reported by 94 women (51.6%), from which 44 (24.1%) had moderate to severe fatigue (total score ≥ 5). Pain was reported by 86 women (47.2%), from which 50 (27.4%) had moderate to severe pain (total score ≥ 5). The comorbidity fatigue and pain happened in 20.8% of the sample and the correlation between fatigue and pain was 0.379 (P=0.003). The presence of pain increased fatigue (P=0.012), but the presence of fatigue did not influence pain (P=0.644).

**Conclusions:** Fatigue and pain occurred in frequent comorbidity in women with breast cancer, and pain aggravated fatigue. Further studies should be done to analyse pain treatment effects on fatigue relief.

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06-052
Randomised Phase Iii Clinical Trial To Evaluate The Efficacy And Safety Of An Integrated Treatment (Diet, Pharmaco-Nutrional And Pharmacological) In Cancer Patients With Cancer-Related Anorexia/Cachexia And Oxidative Stress: Focus On Fatigue Symptom.
Giovanni Mantovani, Antonio Maccio

Objectives: Cancer-related anorexia/ cachexia syndrome (CACS) is multifactorial and is characterized by tissue wasting, loss of lean body mass (LBM), metabolic alterations, fatigue and anorexia. One of the main symptom of cachexia is fatigue.

Methods: In April 2005 we started a phase III randomised study to establish the most effective and safest treatment of CACS addressing as primary endpoints: LBM, resting energy expenditure (REE), total daily physical activity, IL-6, TNF-α and fatigue. Fatigue has been evaluated by the Multidimensional Fatigue Symptom Inventory - Short Form. The sample size was 475 patients. All patients enrolled received as basic oral treatment: poliphenols + alpha lipoic acid + carbocysteine + Vitamins ACE. Patients were then randomised to one of the following 5 arms: 1) Medroxyprogesterone Acetate (MPA)/ Megestrol Acetate (MA); 2) Pharmaco-nutritional support containing EPA; 3) L-carnitine; 4) Thalidomide; 5) MPA/MA + Pharmaco-nutritional support + L-carnitine + Thalidomide. Treatment duration 4 months. Interim analyses were planned after every 100 randomized patients.

Results: At January 2009, 332 patients were randomized and 287 were evaluable: M/F 168/119, mean age 62 yrs (range 30-84), 96% stage IV. A first interim analysis demonstrated that arm 2 was by far less effective as for LBM, REE and MFSI-SF and therefore it was withdrawn from the study. A second interim analysis showed that arm 1 was significantly less effective than the others for primary efficacy endpoints: therefore it was withdrawn from the study. Statistical analysis at January 2009 showed a significant improvement of LBM, REE, fatigue and IL-6 in arm 5. As for fatigue a significant improvement in arm 5 has been observed. The treatment was well tolerated overall and patient compliance was good.

Conclusions: The results so far seem to suggest that the most effective treatment for cancer patients with CACS should be a combination regimen. As for fatigue, the combination regimen seems to be the most effective one.

06-053
A Hidden Problem? Sleep Disorders And Fatigue In Cancer Patients
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Objectives: Fatigue is the most common and often most distressing symptom experienced by cancer patients. At our institution a Cancer-Related Fatigue (CRF) Clinic, established in 1998, is dedicated to evaluating and treating cancer patients suffering from fatigue. There are potentially many causes for CRF; we investigated whether sleep disorders were a significant etiology of fatigue.

Methods: We performed a retrospective study of patients evaluated in our CRF Clinic between 9/1/06 and 5/31/08. We identified patients referred by our clinic for a sleep consult to our institution’s sleep center and reviewed their demographic, clinical, and symptom status data (e.g., fatigue, pain, sleep disorder, depression, anxiety). We determined whether patients had a sleep evaluation performed and reviewed results of sleep studies completed.

Results: Of 130 patients referred for a CRF consult, 25% (n=32) were subsequently referred for a sleep evaluation. The median age of these 32 patients was 55 (ranging from 37-81 years), 66% (n=21) were female, 69% (n=22) white, and 66% (n=21) married. Median BMI was 30.1 (ranging from 20.0-58.1). The two most frequent cancer diagnoses were breast (47%, n=15) and leukemia/lymphoma/myeloma (16%, n=5). Most had good Zubrod performance scores (78%, n=25) and exhibited no present evidence of cancer (75%, n=24). Their median fatigue score (BFI) was 6.2, ranging from 1.8-9.2, while their median sleep disorder score (BSDS) was 28.5, ranging from 5-40. 63% (n=20) had a sleep study; the two most common diagnoses were obstructive sleep apnea (80%, n=16) and periodic limb movement disorder (20%, n=4).

Conclusions: Sleep disorders such as obstructive sleep apnea may be under-recognized in CRF patients. Approximately one-quarter of our patients were determined appropriate for a sleep assessment. Therefore, when evaluating patients with CRF, sleep disorders should be considered. Future work includes studying the impact of sleep dysfunction on CRF, especially as interventions are made.
Characterstics Of Fatigue In Patients With Advanced Prostate Cancer
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Objectives: Patients with advanced prostate cancer experience significant fatigue related to the disease and treatment. There are limited studies characterizing fatigue in this patient population. This retrospective study aimed to identify the incidence, severity, factors associated with fatigue and predictors of fatigue improvement in patients with advanced prostate cancer.

Methods: Electronic records of 55 consecutive patients with advanced prostate cancer referred to a supportive care center in a tertiary cancer center with a complete ESAS scores from an initial and subsequent visit were included. Information regarding demographics, ESAS score, delirium (MDAS) scores, ECOG performance status, CAGE (alcoholism), hemoglobin, testosterone and medication changes during the initial visit were analyzed.

Results: Baseline characteristics included median age of 67 yrs, 73% caucausian, median time between the visits was 15 days, 69% had ECOG performance status ≤2, median fatigue was 6/10. 78% of the patients had fatigue score of ≥4/10. Factors associated with fatigue include ↓weight (0.01), nausea (0.013), and appetite (p=0.02). There was no association between fatigue and depression, anxiety or sleep disturbances. 22 (40%) had an improvement of ≥2/10 in ESAS fatigue score. The use of Methylphenidate (24%) (p=0.003) was positively associated with improvement of fatigue. Use of opioids or cortosteroids during the initial visit was not associated with improvement.

Conclusions: Fatigue is common and severe in patients with advanced prostate cancer. Nausea, anorexia and weight loss are most closely associated with fatigue. Methylphenidate use at the initial visit was associated with improvement in the symptom. Further studies are needed.

The Influence Of Polarity Therapy And Massage On Cytokine And Neuroendocrine Dysregulation, Fatigue And Quality Of Life In Breast Cancer (Bc) Patients During Radiation Therapy
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Objectives: Cancer and its treatments produce cytokine and neuroendocrine dysregulation, cause cancer-related fatigue (CRF) and impair quality of life (QOL). Polarity therapy (PTH) and massage (MAS) elicit a relaxation response that may improve inflammatory cytokine expression and cortisol (CORT) rhythm, as well as CRF and QOL. PTH is an integrative medical therapy that uses light touch without tissue manipulation, whereas MAS involves tissue manipulation.

Methods: This 3-arm pilot study compared the influence of PTH, MAS and standard care on cytokines, CORT, CRF and QOL at baseline and week (wk) 1, 2, and 3. Randomly assigned BC patients (N=45; mean age=52) received standard radiation plus 3 weekly treatments of PTH or MAS (75 minutes/session) or no additional treatments (control).

Results: ANOVAs comparing change scores revealed significant differences in sTNFr1 at wks 1 and 3 (all p<0.05) and a trend at wk 2 (p=0.16), with sTNFr1 increasing in the PTH group, but not in the MAS or control groups. TNFα decreased in the PTH (mean change=-0.96 wk 1; -3.32 wk 2; -0.49 wk 3, ns) and MAS (mean change=-1.33 wk 1; -0.96 wk 2; -7.07 wk 3, ns) groups across all 3 wks, but not in the control group (mean change=-0.55 wk 1; -0.55 wk 2; 4.83 wk 3; ns). Significant differences in CRF and QOL were found at wk 2 (all p<0.05), with CRF and QOL improving in the PTH group, but not in the MAS or control groups. Mixed modeling revealed a significant difference in diurnal CORT rhythm profiles, with a smaller area under the curve at wk 2 among the PTH and MAS groups compared to the control group (p<0.05).

Conclusions: Results of this pilot study suggest that PTH and MAS may be promising for improving inflammatory cytokine expression, diurnal CORT rhythm, CRF and QOL among BC patients receiving radiation. Funding: NCCAM 5R21AT2531.

Measuring Fatigue By Assessing Adaptive Capacity
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Objectives: The objective of this study was to develop an instrument, subsequently called the Adaptive Capacity Index (ACI), that could distinguish among individuals who were tired, fatigued, or exhausted.
**Methods:** Following the development of items drawn from 5 qualitative studies, items were submitted to 18 expert judges for review and pilot tested with 48 advanced cancer patients. Supported items were administered to 228 advanced cancer patients in 6 settings, and data were analyzed using factor analysis. The internal consistency of each resulting factor was analyzed using Cronbach’s alpha. and standardized factor scores were compared to other fatigue measures.

**Results:** Four factors (Central Adaptive Mechanisms, Peripheral Adaptive Mechanisms, Social Adaptive Mechanisms, and Sleep Quality Adaptive Mechanisms) were identified. The correlations among the factor scores was modest ($r=0.19$ to $-0.48$), indicating that the factors measured different constructs, and the internal consistency of the factors was acceptable (Cronbach’s alpha 0.69 to 0.89). Hypotheses regarding participants’ mean scores on other fatigue measures (Eastern Cooperative Oncology Group performance status; Edmonton Symptom Assessment System; Functional Assessment of Cancer Treatment-Fatigue; Profile of Mood States Vigor subscale) were supported. All but two of the correlations among factor scores and these four measures were statistically significant. When the sample was stratified into three groups based on the ESAS Tiredness score, the ACI Central Adaptive Mechanisms score distinguished Exhausted individuals from those who were Fatigued or Tired, and the ACI Peripheral Adaptive Mechanisms score distinguished among all three groups. The ACI Social Adaptive Mechanism score did not distinguish among any of the three groups, but the ACI Sleep Quality Adaptive Mechanism score distinguished individuals who were Tired from those who were Fatigued or Exhausted.

**Conclusions:** This study provides some support for the hypothesized distinctions between tiredness, fatigue, and exhaustion and suggests that changes in sleep quality may be the earliest indicator of impending fatigue.

**06-057**
Identification Of Subgroups Of Oncology Patients And Family Caregivers Based On Their Distinct Trajectories Of Fatigue
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**Objectives:** Recent evidence suggests that a significant proportion of both oncology patients and their FCs experience moderate to severe fatigue. However, less is known about how fatigue changes over time or which individuals may be at greater risk for worse fatigue trajectories. The purposes of this study were to determine if subgroups of patients and FCs who differed on fatigue scores over a period of six months could be identified and whether these subgroups differed on demographic and symptom characteristics, as well as quality of life (QOL) outcomes.

**Methods:** Participants (168 patients, 85 FCs) completed a demographic questionnaire and the Lee Fatigue Scale (LFS), as well as valid and reliable measures of depression, anxiety, sleep disturbance, and QOL. No differences were found in baseline or mean LFS scores between patients and FCs. Therefore, their longitudinal data were combined in the growth mixture model (GMM) analyses.

**Results:** GMM analyses identified four distinct classes (Class 1 (14.3%) with low LFS scores, Class 2 (25.4%) with medium LFS scores; Class 3 (11.1%) with high fatigue scores; and Class 5 (49.2%) with very high fatigue scores over six months). No differences were found in the percentage of patients and FCs in each of the four classes. No differences were found among the classes in any demographic characteristics except age and gender. Participants in Class 4 were more likely to be younger and female. In addition participants in Classes 3 and 4 were significantly more likely to report higher levels of anxiety, depression, and sleep disturbance at the time of the patient’s simulation visit for RT and poorer QOL outcomes.

**Conclusions:** Use of GMM is an important analytic tool to identify subgroups or patients and FCs with different symptom experiences for fatigue. This type of analysis may lead to the identification of individuals who require different interventions for fatigue.

**06-058**
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**Objectives:** Cancer-Related Fatigue (CRF) is the most common and distressing symptom experienced by cancer patients worldwide. In the USA, the National Comprehensive Cancer Network (NCCN) has developed guidelines for CRF assessment and management. Few studies have investigated the knowledge, barriers, and resources needed to translate/implement these guidelines clinically in the USA, and none have assessed these
guideline requirements and their translation/implementation internationally. The primary study purpose is to survey the Fatigue Study Group and MASCC/ISOO membership about knowledge of existing CRF Guidelines, barriers and resources needed for translation/implementation within their countries and practice settings. A secondary purpose is to identify the Study Group’s role in this significant supportive care arena internationally. The Barriers Intervention Model tested in a 5-year NCI-funded study to reduce barriers to the clinical translation/implementation of the NCCN CRF Guidelines guides this study.

Methods: Design: Exploratory, descriptive, correlational, international survey. Sample: Fatigue Study Group Members (n=134) and MASCC/ISOO Membership at large (n=800). Instrument: Investigator-developed survey created using MASCC/ISOO’s online survey vendor that addresses demographics, knowledge about NCCN and other existing CRF Guidelines, guideline translation/implementation within specific countries/practice settings, existing barriers and resources needed to translate/implement the guidelines, and the role the Study Group should play in this significant international supportive care arena. Procedures: Following IRB approval, the Study Group will pilot-test the survey via MASCC/ISOO’s online survey vendor. Once the pilot phase is completed and the survey revised if needed, all MASCC/ISOO members will be asked to complete the online survey. Notices for both study phases will be distributed via Study Group and MASCC/ISOO Listservs, websites, and newsletters. Data Analysis: All data will be downloaded into an SPSS file for data analysis using descriptive, correlational and inferential statistics.

Results: Findings will be available May, 2009.

Conclusions: Study findings will generate new knowledge about CRF Guideline translation/implementation internationally. A future study will be planned based on these findings.

06-059
Evidence Of Genetic Association Between A Polymorphism In The Il6 Gene And Evening Fatigue In Oncology Patients And Their Family Caregivers (Fcs)
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Objectives: Recent evidence suggests that a significant proportion of both oncology patients and their FCs experience moderate to severe fatigue. However, little is known about the biological mechanisms that underlie the development of fatigue. The purpose of this study was to identify whether genetic variations in IL-6 could impact levels of evening fatigue in oncology patients and their FCS.

Methods: DNA was recovered from plasma archived from 253 patients and FCSs who participated in a descriptive longitudinal study of symptoms. The IL-6 (rs4719714) genotypes were collected by TaqMan Allelic Discrimination and the distribution of the polymorphism met Hardy-Weinberg expectations. Evening fatigue was measured using the Lee Fatigue Scale. Differences in severity of symptoms between the two genotype groups were evaluated using Independent Student’s t-tests. Because of the exploratory nature of these analyses, p-values of 0.10 were considered statistically significant.

Results: Mean age of the sample was 61.4 years; 46% were male, and 75% were Caucasian. IL-6 genotype frequencies were 63.9% common allele homozygotes (TT), 4.1% rare allele homozygotes (AA), and 32.0% heterozygotes (AT). No sex differences were found in genotype distribution. Common allele homozygotes for IL-6 reported significantly higher evening fatigue scores at the initiation of radiation therapy (4.4 ± 1.9) than carriers of the rare allele (i.e., AT+AA, 3.9 ± 2.2; p=.08). In addition, the common allele homozygotes reported higher mean evening fatigue scores (4.8 ± 2.0) than the carriers of the rare allele (4.0 ± 2.3, p=.004).

Conclusions: These results provide preliminary evidence of a genetic association between a prominent cytokine and levels of evening fatigue in a sample of oncology patients and their FCSs. Carriers of the IL-6 minor allele appear to have less evening fatigue In the future, patients and FCSs may undergo genotyping for symptom-related genetic polymorphisms to identify high risk groups who warrant more targeted symptom management interventions.

06-060
Factors Associated With Fatigue And Predictors Of Improvement Of Fatigue In Patients With Advanced Cancer
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Objectives: Fatigue is the most distressing symptom in patients with advanced cancer. However, there are limited studies regarding the associated factors and predictors of improvement. The aim of the study is to determine factors associated with severity of fatigue and predictors of improvement of fatigue in patients with advanced cancer with cancer related fatigue.
Methods: Consecutive patients with advanced cancer presenting in the Supportive care clinic in a comprehensive cancer center with a complete Edmonton symptom assessment scale (ESAS) at initial and subsequent visit were analyzed. All patients received interdisciplinary care by specialist supportive care team (IDT). A logistic regression model was created to determine if baseline demographics, primary cancer type, ESAS, Memorial Delirium assessment scale (MDAS), hemoglobin, albumin, and CAGE (screening for alcoholism), were related to improvement in fatigue.

Results: A total of 1778 evaluable patients were analyzed (median age 59 years; males 52%). The most common primary cancer types were H&N and Lung (27%). The median time between visits was 15 days. Mean (SD) fatigue score was 6(2.39). 80% of these patients reported moderate or severe fatigue (n=1489). The hierarchical model showed that fatigue did improve over time (b = -0.009, p = 0.0009). All ESAS factors were found to be positively related to fatigue. Pain (b = 0.12, p <0.0001) and appetite (b = 0.18, p <0.0001) had the strongest association with fatigue. Among patients with severe fatigue, lower levels of symptom distress score (SDS) (OR=0.32, p=0.0005), genitourinary cancer (GU) (OR=2.83, p=0.04), and lower intensity of shortness of breath (OR=0.88, P=0.007) were associated with improvement of fatigue.

Conclusions: A Supportive care clinic is effective in reducing fatigue. Low levels of symptom distress score (SDS) and GU cancers are predictive of successful improvement of fatigue.

06-061
Scenar In Cancer-Related Fatigue (Crf): Are Cytokines Involved?
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Objectives: SCENAR-technology as multipurpose approach in supportive care was presented earlier (e.g., Zaidiner & al., 2001). The aim of this study was to determine whether SCENAR impact on CRF corresponds with changes in the serum levels of some cytokines.

Methods: In the preliminary study 26 patients with various forms of malignancy were observed, all these patients have fatigue which was rated on a 0 – 10 numerical rating scale (NRS). After signing the informed consent every patient 15 SCENAR-procedures were performed in addition to conventional supportive care. Serum levels of TNF-α, IL-1β and IL-6 were measured using standard enzyme-linked immunosorbent assay.

Results: Positive results were achieved in 16 of 26 patients: their NRS values dropped more then 5 points (in the mild-to-moderate disorders the values could come to zero), IL-1β and TNF-α levels were significantly decreased (mean 3.6 pg/ml with p<0.01 and 2.8 pg/ml with p<0.05). In 6 patients reasonable results were noted: their NRS values lowered between 2 and 5 points without significant cytokine decrease. 4 patients hadn’t any improvement.

Conclusions: These results confirm the suggestion that in patients with CRF the action of SCENAR is mediated, at least partly, with pro-inflammatory cytokines. Further research needs to establish the exact position of this technology in comprehensive management of CRF.

07-062
Sexuality Issues In Palliative Care Pooly Explored
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Objectives: Sexual needs and problems of patients living with life limiting illnesses receive little attention if any, and coping mechanisms are seldom discussed. During weekly audit of patient care at the Hospice, it was noted with great concern that in very rare occasions do the clinical staff explore patients’ sexuality needs during an assessment. This prompted a need for a survey.

Methods: A retrospective survey was carried out by reviewing 200 patients’ clinical notes seen between March-December 2008. The aim was to assess whether the 8 clinical staff ever explored sexuality issues during patient assessment, the factors that may have influenced the exploration or omission and to chart a way forward.

Results: 37% of staff attempted to explore sexuality issues in 18 patients when there was an entry point especially when patient or the accompanying spouse initiated the discussion. When cancer is related to reproductive organs, 50% of the staff explored sexuality issues in 41 patients. When a patient is accompanied by a parent, or a child, sexuality issues are never explored. When patient is HIV infected, 34% of the staff interviewed 33 patients. More female patients were concerned of their spouses’ unexpressed and unmet sexuality needs as opposed to male patients.

Conclusions: There is a strong need to effectively explore and encourage patients to express their fears and concerns, surrounding sexuality. To provide true holistic care to patients and families facing life limiting illnesses, it is imperative that a holistic approach must be adopted. Lack of comprehensive and appropriate assessment tool,
poor communication skills, cultural inhibitions, social stigma in HIV patients are some of the factors that hinder effective exploration of the sexuality issues. Good communication skills, appropriate assessment tool, demystifying cultural connotations and inhibitions will give good impact. This will not only enhance the patients self esteem, but also add quality life into their days.

07-063
Optimising Sexuality Outcomes For Women Following Breast And Gynaecological Cancer: The Partner’s Experience.
Natalie D’Abrew

Objectives: Sexuality, relationship and psychological concerns have a significant impact on the quality of life for couples who have had a diagnosis of breast or gynaecological cancer. The impact of cancer treatment on a women’s sexual functioning can be both profound and irreversible, leading to physical problems such as low sexual desire, pain, and infertility. This can result in changes in intimacy and frequency of sexual intercourse, leading to additional concerns about the couple’s relationship and an increase in psychological distress. This paper will focus on data with partners that have been collected as part of a larger program of research undertaken on sexuality and cancer.

Methods: Male partners of women who have been diagnosed with breast or gynaecological cancer in Australia were recruited to participate in individual or focus group interviews.

Results: Long term survival was the main focus for the partner, with a reluctance to focus on issues such as sexuality and sexual function. A major barrier identified was limited access to information, with most information obtained via the women. Uncertainty in how to address concerns, limited access to members of the health care team, privacy, fear of being judged, and the need to “do it right” were identified. The men identified feeling helpless, feeling the need to help but not knowing how.

Conclusions: Interventions that could be implemented by clinicians to improve psychosocial outcomes for both women and their partners have been identified. Partners have unique information needs for supporting women with cancer. Access to tailored information for partners and women with cancer, recognition of the role partner’s play in recovery, practical strategies to address physical concerns, early referral to counseling services are vital. Health care teams are important in proactively addressing psychosocial concerns, providing information and addressing sensitive topics such as sexuality and intimacy for both women and their partners.

07-064
Dyspareunia After Radiation Treatment For Anal Carcinoma - An Under Reported Complication.
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Objectives: Anal carcinoma can be cured with timely anal sphincter conserving chemo-radiotherapy in a high percentage of cases. Many patients resume a full lifestyle after treatment. Female survivors however may have radiation vaginal toxicity that impacts greatly on their ability to maintain sexual activity.

Methods: The host institution has an established clinic for all cancer patients with radiation late effects. Patients are assessed and managed by a dedicated team using quality of life questionnaires and consult with physical examination. The characteristics of patients being referred with dyspareunia over an eight year period have been analyzed.

Results: Fifteen patients with prior chemoradiotherapy for anal carcinoma have been seen with dyspareunia. This accounts for 52% of all vaginal dysfunction referrals. The median age at referral was 55. All patients had been treated with radical intent with concurrent chemoradiation with median dose of 63Gy. Median time from completion of therapy to onset of symptoms was 4 months (range 0-85) and median duration of symptoms when referred was 8 months (1 – 104). The reason for dyspareunia was multifactorial. Eight patients had grade 2 EORTC CTCv3.0 vaginal stenosis and one had a grade 3 stenosis. Six had dyspareunia of other causes.

Conclusions: Dyspareunia is a real and pertinent issue for many sexually active survivors of anal cancer. At a specialised clinic, this group outnumbered those treated for other pelvic malignancies suggesting an under reporting of cases in literature to date. Symptoms often start within weeks of chemoradiation completion indicating patient education and preventative interventions should be considered during anal cancer therapy.

07-065
Sexuality And Rehabilitation Needs During Chemotherapy
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Objectives: Sexuality is an important aspect of quality of life (QOL) and is affected by cancer and its treatment.
The aim of the study was to assess QOL and rehabilitation needs (RN) of cancer patients receiving chemotherapy at three time points. The present report is based on a subgroup analysis of sexuality and RN.

Methods: The study design was prospective, longitudinal, correlational. The instrument was the Icelandic version of CARES-SF (Cancer Rehabilitation Evaluation System, Short Form), containing 59 problem statements, divided into five QOL dimensions: physical, psychosocial, sexual, marital, and medical interaction. The sexuality dimension contains three problem statements, relating to body image, sexual interest, and sexual performance. After each problem statement the respondent is asked to indicate whether he/she wants help with that particular problem, indicating RN.

Results: Enrolled into the study were 90 women and 54 men, mean (SD) age was 55 (12.1) years and the majority received chemotherapy for breast (31%) or gastrointestinal (26%) cancer. The first measure was completed by 144 patients at the initiation of chemotherapy, 109 and 92 patients completed the second (T2) and third (T3) measure after three and six months, respectively. The majority (60%) had been sexually active after diagnosis. At all time points QOL was worst in the sexual dimension and significantly worse after three and six months compared to the initiation of chemotherapy. At all time point a positive significant relationship was found between the physical and sexual dimensions and younger patients had significantly more sexual problems. Only 4-13% having sexual problems indicated need for help with their problems.

Conclusions: Sexuality is affected in cancer patients during chemotherapy indicating the need for assessment and intervention. However, in this study only few patients wanted help with their sexual problems. The reasons remain unknown but may reflect issues of privacy/embarrassment, expectations, and the way of measurement.

Nadroparin For Prevention Of Thromboembolic Events In Cancer Patients Receiving Chemotherapy. A Randomized Placebo-Controlled Double-Blind Study

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Objectives: The aim of the study was to evaluate the efficacy of the low-molecular-weight heparin nadroparin for the prevention of thromboembolic events in ambulatory cancer patients receiving chemotherapy.

Methods: In a double-blind study, patients with metastatic or locally advanced lung, gastrointestinal, pancreas, breast, ovary or head and neck cancer were randomized in a 2:1 ratio to receive subcutaneous injections of nadroparin, 3,800 anti-Xa IU once daily, or placebo. Study treatment was started on the day of initiation of chemotherapy and planned for its duration or up to a maximum of 4 months. The primary study outcome was the composite of symptomatic venous or arterial thromboembolic events. Major bleeding was the main safety outcome. All study outcomes were evaluated by an independent Adjudication Committee. The study was planned according to a one-sided group sequential design.

Results: Overall, 1,150 patients were included in the primary efficacy and safety analyses. Fifteen of the 769 patients treated with nadroparin (2.0%) and 15 of the 381 patients treated with placebo (3.9%) had a thromboembolic event (P= 0.02). Fourteen of the thromboembolic events occurred in patients with lung cancer (3.5% and 8.8% in nadroparin and placebo patients, respectively). Five patients in the nadroparin (0.7%) and none in the placebo group had a major bleeding (P= 0.18). The incidence of minor bleeding was 7.4% and 7.9% for nadroparin or placebo, respectively.

Conclusions: Nadroparin reduces the incidence of thromboembolic events in ambulatory cancer patients receiving chemotherapy. Future studies should be focused on patients at high thromboembolic risk such as those with lung cancer.

Inhibitory Effect Of Panax Ginseng Polysaccharide In Staphylococcus Aureus Infection

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Objectives: Panax ginseng (PG) polysaccharide, an acidic polysaccharide prepared from Panax ginseng, demonstrated multiple immunomodulatory effects in previous studies. This study was conducted to elucidate the antiseptic mechanism induced by PG polysaccharide in mice infected with Staphylococcus aureus.

Methods: Balb/c mice were treated PG polysaccharide before the bacterial challenge with S. aureus and survival and cytokine response in sera were analyzed. TLR signaling was determined using RT-PCR and western blotting in mouse peritoneal macrophages.

Results: When mice were treated with PG polysaccharide before the bacterial challenge with S.
aureus, they were highly protected from sepsis-induced death. This survival benefit was associated with enhanced bacterial clearance from circulation, spleen and kidney. The numbers of S. aureus recovered from PG polysaccharide-treated mice were considerably lower than those recovered from nontreated mice. The phagocytic activity of PG polysaccharide-treated macrophage against S. aureus was considerably enhanced. The synthesis of inflammatory cytokines, such as tumor necrosis factor (TNF)-α, interleukin (IL)-1β, IL-6, interferon (IFN)-γ, IL-12, and IL-18, was significantly downregulated at the early phase of sepsis in mice that were treated with PG polysaccharide before the bacterial challenge. The expression of Toll-like receptors (TLRs), including TLR2, TLR4, and TLR9, as well as the adaptor molecule MyD88, was considerably reduced in peritoneal macrophages that were treated with PG polysaccharide before a subsequent contact with S. aureus. Similarly, the expression of phospho-JNK1/2, phospho-p38 MAPK, and NF-κB was decreased in the same culture system.

**Conclusions:** These results illustrate that the antiseptic activity of PG polysaccharide can be attributed to enhanced bacterial clearance, and reduced pro-inflammatory cytokines via the TLR signaling pathway. These data indicated that PG polysaccharide protected mice from S. aureus-induced sepsis at an early phase and the enhancement of antimicrobial activities at subsequent phases of infection through the suppression of acute inflammatory responses and the TLR signaling pathway.

**09-069**

**Patient Education As A Complementary Non-Pharmacological Intervention Towards Hospital Acquired Pneumonia Among Patients With Leukemia And Neutropenia: Preliminary Descriptive Results**

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**Objectives:** This PhD. thesis in progress involves two randomized controlled clinical trials performed at a specialized hematological unit at the University Hospital of Copenhagen Rigshospitalet Denmark. Long lasting neutropenia associated with leukemia and intensive chemotherapy establish a well-documented high risk of serious and life threatening infections such as septicemia and pneumonia. Despite improvement in overall survival and new leukemia treatment strategies including outpatient management of neutropenia, prophylaxis with broad spectrum antibiotics has not been convincingly adequate. This challenge may therefore be met with complementary non-pharmacological strategies. The basic tool used in the two randomized intervention studies is individualized patient education to empower patients’ clinical skills and knowledge in self protective techniques compared with traditional professional controlled care. As such we have previously published a more than 50 % reduction in catheter related bloodstream infections among patients providing their own care and handling of Central Venous Catheters. In the present RCT study we examine a three month use of patient performed daily spirometri (FEV1, FEV6, FEV1/FEV6) as an early detective tool for pneumonia as well as exploring the effectiveness of Positive Expiratory Pressure/PEP in preventing or decreasing fatal development of lung infections among 100 myeloid leukemia patients.

**Methods:** Randomized controlled clinical intervention study.

**Results:** By February 2009 26 patients has been enrolled. Daily spirometri tends to be a highly sensitive method early correlated to development of verified pneumonia. The best cut off point for specificity is not known so far. Preliminary descriptive cases will be presented. No analysis for the preventive effectiveness of PEP has yet been performed.

**Conclusions:** Involving and educating patients in infection preventive strategies has huge potentials. Step by step programs’ incorporating detailed clinical information and visual techniques in combination with individualized follow up face to face patient education is fundamental to succeed a complementary infection protection program.

**09-070**

**Antimicrobial Stewardship Program In The Critical Care Unit (Ccu) Of A Comprehensive Cancer Center**

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**Objectives:** At our institution, extended use (≥ 7 days) of carbapenems (C) and vancomycin (V) has been associated with multi-drug resistant Pseudomonas aeruginosa (MDR-P) and vancomycin-resistant enterococci (VRE) respectively. We created a Multidisciplinary Antbiotic Stewardship Team (MAST) to promote antibiotic stewardship in our CCU.
Methods: Our program focused on V and C usage in our CCU starting November 2007. Judicious use was defined as the use of V or C for ≤ 5 days unless clinically or microbiologically indicated. Alternative agents were recommended, and compliance was monitored.

Results: We documented 100% compliance with recommendations for V and C usage from November 2007 to August 2008. MDR-P infection rates fell from 0.85 to 0.22 cases/1000 patient days (p = 0.02) and VRE from 0.64 to 0.15 (p = 0.05) when comparing September 2006 – August 2007 to September 2007 – August 2008. There was a decrease in the absolute number of deaths associated with nosocomial MDR-P from 6 patients to 1. In absolute numbers we documented a decrease in MDR-P and VRE infection from 21 (September 2006 – August 2007) to 6 (September 2007 – August 2008). Previous data from our institution has shown that each resistant infection results in an average length of stay of 27.1 days at a cost of US $194,406. This represents a reduction of 406.5 CCU patient days and potential savings of US $2,916,090 for our institution.

Conclusions: Our data indicate that a dedicated MAST program results in high compliance with antimicrobial stewardship with a reduction in the frequency of infections due to resistant organisms, reduced length of stay in the CCU, and substantial cost savings.

09-071 Assessing Febrile Neutropenia With The Mascc Score: Would Bacteremic Status, If Known, At Fever Onset, Improve The Prediction Rule?
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Objectives: Febrile neutropenic cancer patients represent a heterogeneous population with a relatively small proportion at risk of serious complications. The Multinational Association for Supportive Care in Cancer (MASCC) score has been developed and validated for identifying low-risk patients at the onset of febrile neutropenia. On the other hand, bacteremia, although not documented at baseline, is a predictor of a worse outcome, especially gram-negative bacteremia. The purpose of this study was to describe the validity of the MASCC score for bacteremic patients and to assess whether the early identification of bacteremia would improve the identification of low-risk patients.

Methods: Two consecutive multicentric observational studies were carried out from 1994 till 2005; the study data bases of these studies were retrospectively used for the present analysis.

Results: Data about 2142 patients with febrile neutropenia were collected. Median age was 52 years; 57% of patients had hematological tumor and 69% were predicted at low-risk by the MASCC score with a 91% positive predictive value. Bacteremia was present in 23%. The MASCC score was found prognostic of episode resolution in all strata obtained by stratification for the bacteremic status with odds ratios for successful outcome being, in patients with a score ≥ 21, respectively 6.06 (95%CI : 4.51-8.15), 3.42 (95%CI : 1.95-5.98), 6.04 (95%CI : 3.01-12.09) in patients without bacteremia, gram-positive bacteremia and gram-negative bacteremia. No interaction between the MASCC score and the bacteremic status was present. A clinical prediction rule integrating the MASCC score and the bacteremic status was not helpful in improving the identification of low-risk patients.

Conclusions: Our results suggest that the knowledge, at fever onset, of a bacteremic aetiology of the fever would be of little value to the MASCC score when attempting to identify low-risk patients.

09-072 Antimicrobial Treatment In Hospice: Which And When?
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Objectives: Terminally ill patients are very susceptible to infections. Infection reduces the quality of life but all the symptoms related to infection showed a small improvement after the treatment, only dysuria was statistically significant (Mirhosseini M 2006 and White PH 2003). Actually, there isn’t a shared guideline on antibiotic use in palliative care.

Methods: Retrospective review medical record of 1044 admissions to a hospice unit in Milan (Italy) from July 2006 to January 2009. Identify the pattern of antimicrobial treatment (empirical therapy, route/duration of administration, number and types of antibiotic and antifungal agents).

Results: 286 patients (27.39%) were treated with antimicrobial therapy: males 53%; average age 72 years (4-97). Diagnosis: lung cancer 30%, colorectal cancer 13%, breast cancer 10%. The antimicrobial prescribed were: 43% antymycotic (fluconazole, nistatine), 56% antibiotics (quinolone, cefalosporin, penicillin, macrolide, amynoglicoside, metronidazole) and 1% antiviral. 111 patients (39%) had multiple drugs prescription: 89 twice, 18 three and 4 four. 66% of prescriptions were intravenous, 27% oral and 7% intramuscular. The medium overall survival was 20,08
Infectious Diseases, Houston, USA, 2

8.9% in 2006, 15.8% in 2007. All isolates were ESBL ± isolates from 2007. Quinolone resistance was >60% throughout.

Results: A total of 660 E. coli isolates were identified (181 from 2004, 164 from 2005, 157 from 2006, and 158 from 2007. Quinolone resistance was >60% throughout. (68.5% in 2004 to 63.9% in 2007). ESBL ± isolates increased progressively 2.2% in 2004, 7.3% in 2005, 8.9% in 2006, 15.8% in 2007. All isolates were carbapenem susceptible. The total mortality attributable to E. coli decreased from 18.7% in 2004 to 13.3 in 2007 (p=0.17). ESBL ± isolates were not associated with greater mortality than ESBL negative ones.

Conclusions: A comparative study is in progress to evaluate the burden for the patient and the cost/benefit on the last week and 48 hours of life. Indeed, the decision making process regarding treatment versus non treatment can be complex in terminally ill patients. The bioethical principles on the use of antibiotics and antifungals in palliative care should be a research priority, followed by an appropriate education for physicians and nurses.

09-073 Antimicrobial Susceptibility Profile And Outcome Of Escherichia Coli Bacteremia In Cancer Patients

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Objectives: Escherichia coli is the most common gram-negative organism causing bacteremia in cancer patients. Our objectives were to describe the antimicrobial susceptibility profile and outcomes of E. coli bacteremia at our Comprehensive Cancer Center.

Methods: The study period was January 2004 to December 2007. Susceptibility testing and ESBL detection was performed using CLSI guidelines. MIC (mg/L) breakpoints for resistance were: amikacin ≥ 64, cefepime ≥ 32, ciprofloxacin ≥ 4, meropenem ≥ 4, piperacillin/tazobactam ≥ 32. Outcome information was collected from the patient’s medical records.

Results: A total of 660 E. coli isolates were identified (181 from 2004, 164 from 2005, 157 from 2006, and 158 from 2007. Quinolone resistance was >60% throughout. (68.5% in 2004 to 63.9% in 2007). ESBL ± isolates increased progressively 2.2% in 2004, 7.3% in 2005, 8.9% in 2006, 15.8% in 2007. All isolates were carbapenem susceptible. The total mortality attributable to E. coli decreased from 18.7% in 2004 to 13.3 in 2007 (p=0.17). ESBL ± isolates were not associated with greater mortality than ESBL negative ones.

Conclusions: E. coli bacteremia is common in cancer patients. There is substantial quinolone resistance, probably due to widespread use of these agents for prophylaxis. Quinolone resistant strains remain carbapenem susceptible.

10-074 The Use Of Citrulline Levels For Haematopoietic Stem Cell Transplant Recipients With Mucosal Barrier Injury

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Objectives: Mucosal barrier injury (MBI) is induced by the myeloablative conditioning regimens for haematopoietic stem cell transplant (HSCT). Oral and gastrointestinal mucositis are well known clinical manifestations of MBI but objective assessment of gastrointestinal mucositis is cumbersome. Citrulline is an amino acid that allows small bowel enterocyte mass to be estimated and is a general marker of intestinal failure. We optimised the assessment of intestinal mucositis by exploring the use of plasma citrulline of HSCT recipients after myeloablative conditioning therapy.

Methods: Citrulline was measured by high-performance liquid chromatography (HPLC Shimadzu©) among 145 HSCT recipients after starting high-dose melphalan or BEAM (M&B), TBI based regimens (TBI) or idarubicin-containing regimens (IDA). The severity of intestinal damage was calculated as the area under curve (AUC) by using the reciprocal of the citrulline concentrations over 30 days. Intestinal failure was defined by <10 µM citrulline.

Results: At baseline mean citrulline levels were 23.2 µM ± 1.5 95%CI. A significant decrease of citrulline was seen after all regimens with the nadir being reached 14, 16 and 19 days respectively after starting M&B, TBI and IDA. The mean AUC was 32.8, 32.6 and 44.7 respectively. Intestinal failure affected all patients treated with IDA and 88% and 84% of those treated with the other regimens. The corresponding need for total parenteral nutrition was 19, 11 and 13 days respectively. Patients were often discharged even though their citrulline levels were still low. Bacteraemia, occurred during intestinal failure and not before.

Conclusions: The simplicity of the method and lack of major drawbacks makes the citrulline assay the first choice for monitoring intestinal damage, potentially providing an indicator of intestinal failure that necessitates parenteral nutrition and of bacteraemia that warrants prompt empirical antimicrobial therapy.

10-075 Kinetics Of Chemotherapy-Induced Gene Expression, Apoptosis And Nfkb Signalling Along The Gastrointestinal Tract

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**Objectives:** Anti-cancer treatment is limited by gastrointestinal toxicity. Intestinal damage is likely a result of drug-induced cytostatic, cytotoxic, and inflammatory effects mediated via concerted gene expression changes at the local tissue level. Therefore, we used irinotecan to investigate temporal and regional effects of chemotherapy on gene expression, apoptosis and NfkB signalling.

**Methods:** Archival samples of stomach, jejunum and colon from rats treated with irinotecan were investigated for changes in gene expression, pathway activation and apoptosis over 72h. Gene expression data obtained by microarray was analysed with moderated t-statistics to identify genes significantly altered from baseline at each time point. Differentially expressed genes were ranked and interrogated for known biological functions and pathway signalling using GOstat and Pathway Miner respectively. A subset of genes implicated in NfkB signalling were further investigated by real time PCR. TUNEL staining was used to quantify apoptosis.

**Results:** Biological functions significantly altered at 1h included MAPKKK signalling and apoptosis. This was without a concurrent increase in TUNEL staining. At 6h this was replaced by response to stress and reduced proliferation, combined with a massive increase in TUNEL staining. By 24h, pyruvate and ubiquinone metabolism ranked highest, and TUNEL staining had returned almost to baseline levels. The final time point showed vessel development, proliferation and inflammatory response as top ranked functions. RT-PCR found Nfkb modulator, Ikba, had a peak increase at early time points, while Nfkb1 expression generally decreased early before rebounding. Members of the TNF receptor superfamily had a slightly delayed response, and the kinetics of expression varied somewhat across regions.

**Conclusions:** Apoptotic-specific gene and pathway changes prelude measurable apoptosis in situ, whereas later functional changes parallel observed tissue damage and inflammation. Genes altered along the gastrointestinal tract following irinotecan can have regional specificity in activation profiles. These findings could be used to better target mucosal protectants.

**10-076 Grape Seed Extract: Effects On Chemotherapy-Induced Mucositis And Inflammatory Bowel Disease In Rats**

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**Objectives:** Grape seed extract (GSE) represents a rich source of proanthocyanidins with the potential to exert anti-oxidant and anti-inflammatory activities within the gastrointestinal tract. We investigated GSE for its potential to reduce intestinal injury in rat models of 1) intestinal mucositis and 2) the pre-malignant disorder, ulcerative colitis.

**Methods:** Rats were orally-gavaged with GSE daily (400 mg/kg) from day 0 until the day of kill. **Model 1** was induced in female Dark Agouti (DA) rats by injection of 5-Fluorouracil (5-FU: 150 mg/kg) on day 6, followed by kill on day 9. **Model 2** was induced in male Sprague Dawley rats by ingestion of 2% Dextran Sulphate Sodium (DSS) for 6 days (days 6-11). Intestinal tissues were collected for determinations of myeloperoxidase (MPO) and sucrase activity; qualitative and quantitative histology. Statistical analysis was performed by one-way ANOVA.

**Results:** **Model 1:** GSE significantly reduced MPO activity by 86% (75±51 U/g) and 27% (82±5), respectively in the proximal jejunum (p<0.001) and distal ileum (p<0.05) compared to 5-FU controls (530±46, 114±8) and significantly decreased the qualitative histological scoring (p<0.05, median score=24) compared to 5-FU treated controls (median=29). GSE also significantly decreased the histological severity score by 32% in the proximal colon (p<0.05).

**Model 2:** GSE reduced MPO activity by 33% (69±10 U/g, p<0.05) in the colon compared to DSS controls and decreased ileal villus height by 14% (319±12 µm, p<0.01) relative to DSS controls (370±11). GSE also significantly decreased the histological severity score by 32% in the proximal colon (p<0.05).

**Conclusions:** GSE partially ameliorated several indicators of disease severity in models of intestinal mucositis and ulcerative colitis. GSE may represent a promising new prophylactic treatment strategy for both conditions. Further studies are required to identify the active constituents responsible.
10-077
Predicting Psychological Distress In Head And Neck Cancer Patients With Oral Mucositis
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Objectives: To determine the incidence of anxiety and depression among head and neck cancer (HNC) patients with oral mucositis (OM), and examine whether OM, pain, and quality of life (QoL) scores predicted anxiety and depression after adjusting for demographic and clinical factors.

Methods: Eighty HNC patients were assessed during week 4-6 of radiotherapy (RT) (31%) or chemoradiotherapy (CRT) (69%). Measuring instruments included WHO OM Grading System, 10cm VAS for mouth pain, OM-specific QoL measure (OMQoL), and Hospital Anxiety and Depression Scale (HADS).

Results: The incidence of grade 2 and 3 OM was 20% and 80%, respectively. The mean pain score was 6.5 ± 1.8. Patients with grade 3 OM reported higher incidence of severe mouth pain (VAS rating of ≥7) (64%) than those with grade 2 (13%) (p<0.01). All OMQoL subscales except social function were compromised. Patients with grade 3 OM reported lower OMQoL subscale scores (41.3 – 70.9) (score range is 0-100, with lower score representing poor QoL) than those with grade 2 (55.9 – 87.1) (p<0.01). All OMQoL subscales except social function were compromised. Patients with grade 3 OM reported lower OMQoL subscale scores (41.3 – 70.9) (score range is 0-100, with lower score representing poor QoL) than those with grade 2 (55.9 – 87.1) (p<0.01). The mean anxiety score was borderline (7.2 ± 3.8) (score range is 0-21, with higher score representing severe anxiety), while the depression score was moderately high (mean 10.4 ± 4). The incidence of possible (HADS score of 8 – 10) and probable (HADS score of 11 – 21) cases of anxiety and depression were higher in patients with grade 3 OM (anxiety, 46%; depression, 86%) than in grade 2 (anxiety, 25%; depression, 44%) (p<0.01). Anxiety score was predicted by poor QoL in symptom (β=-0.39, p=0.02) and swallowing (β=-0.28, p=0.04) domains, while depression score was predominantly predicted by poor QoL in symptom domain (β=-0.36, p=0.02). Table. Multiple linear regression for anxiety and depression scores

<table>
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<th>Anxiety R²</th>
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<td>-0.007</td>
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<tr>
<td>Grade 3</td>
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<td>-0.010</td>
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βa, standardized regression coefficient

Conclusions: Severe OM is common during RT or CRT, and is associated with severe pain, poor QoL and increased psychological distress. QoL symptom subscale predominately predicts anxiety and depression.

10-078
Oral Mucositis In Children: Incidence, Oral Function And Quality Of Life
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Objectives: To determine the incidence/severity of oral mucositis (OM), oral dysfunction, quality of life (QoL) and anxiety during the first 7 days after the start of chemotherapy.

Methods: This study used a subset of larger study data from a convenience sample of 50 children with acute leukemia (36%), osteosarcoma (26%), or soft tissue tumor (12%) receiving stomatotoxic chemotherapy. A multicentre approach was used. Measuring instruments included the Mouth and Throat Soreness-Related Questions of the Oral Mucositis Daily Questionnaire, OM-specific QoL measure (OMQoL), and State Anxiety Scale.

Results: The incidence of OM was 58%; 38%, 14%, 4% and 2% were grade 1, 2, 3, and 4, respectively. Children with OM were more likely to experience limitation in eating (mean 0.34 – 0.69) and swallowing (mean 0.28 – 0.41) functions in compared with those without OM.
Predicting Impairment Of Oral Function And Quality Of Life In Patients With Oral Mucositis

Karis, Kin-fong Cheng¹, Sing Fai Leung², Raymond Liang³, Josepha Tai², Rebecca Yeung², David Thompson⁶
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Objectives: First, to determine the incidence of severe (WHO grade 3 and 4) oral mucositis (OM), moderate (rating of 5 or 6 on a scale of 0-10) and severe (rating of ≥7 on a scale of 0-10) pain and oral dysfunction, and clinically significant change of quality of life (QoL) (drop in score to at least 10 points on a scale of 0-100 from baseline). Second, to determine predictors of impairment of oral function and QoL.

Methods: This study used secondary data from a convenience sample of 137 patients treated with CT (45%), HDCT ± TBI (12%), and HNRT ± CT (44%). Measuring instruments included the WHO Mucositis Grading System, 10cm VAS, and OM-specific QoL measure (OMQoL), and data was collected twice weekly or weekly during the first 4-10 weeks after the start of cancer treatment.

Results: Patients treated with HNRT ± CT were more likely to experience severe OM (98-100%) compared with those receiving CT (10%) or HDCT ± TBI (19%) (p<0.01). 57–88% and 55–88% of patients with severe OM reported moderate or severe mouth/throat pain and oral dysfunction, respectively. Chewing (6.8 ± 2.6) and swallowing (6.8 ± 2.6) difficulties were the worst functional problems. Severe OM also has a negative impact on a number of aspects of QoL (mean score, 47.9 to 62.1). Chief among these is diet domain (47.9 ± 17.1). Almost all of the patients with severe OM (86-96%) recorded clinically significant change of QoL. In multiple regression, mouth and throat pain independently predicted for oral dysfunction (mouth, β = 0.33–0.39; throat, β = 0.53–0.83, p<0.01) and diminished QoL (mouth, α = -0.6, p<0.01) and diet (throat, β = -0.33, p<0.05) domains.

Conclusions: Severe OM can cause profound pain, impairment of oral function and QoL. Pain resulting from OM is most predictive of impairment of oral function and QoL. Pain should be the key focus in OM research and management.

Examination Of The Relationship Of Oral Cavity Changes, Pain Intensity, And Pharmologic Management In Hematopoiet Stem Cell Transplantation (Hsct) Recipients

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¹The Nebraska Medical Center, Nursing, Omaha, USA, ²The Nebraska Medical Center, Nursing Research and Nursing Quality, Omaha, USA

Objectives: Pain is the main complaint for individuals experiencing oral cavity changes during HSCT and has led to mucositis being identified as the worst side effect. Although the barrier breakdown is seen as contributing to potential bleeding and placing the patient at risk for life-threatening infections, pain is the major concern for patients. Pain management has been a leading area of concern for greater than four decades, yet remains a particular challenge in the HSCT population. Research is needed to improve management of mucositis pain. The purpose of this study was to explore the relationship of oral cavity changes, mucositis related pain intensity, and pharmacologic management.

Methods: This study involved a retrospective chart review of 170 concurrent adult HSCT patients. Clinicians specially trained in the care of the patients had recorded oral cavity changes using the Oral Assessment Guide and pain severity using a numerical 0 – 10 rating scale. These assessments and the record of pain...
medications administered provided the data for analysis in this study.

**Results:** The majority of the patients had autologous HSCT. Approximately 60 percent experienced oral cavity changes that included mucosal breakdown. Data analysis examined morphine equivalents administered, pain rating scores, and OAG scores during the weeks of the transplant experience. Mucosal changes were most prevalent during the two weeks after infusion of the hematopoietic stem cells and are believed to serve as a trigger for the administration of pain medications.

**Conclusions:** Application of knowledge from other areas of pain management encourages questioning if initiating systemic pain medications earlier in the trajectory of oral cavity changes seen with HSCT could potentially decrease the severity of the pain experience for patients. This data provides a foundation for the development of a pain management protocol with OAG scores serving as a trigger for the administration of pain medications.

10-081
**Gastrointestinal Toxicities Associated With Targeted Therapy Use**

Rachel Gibson¹,², Debby Utama¹,², Joanne Bowen³, Andrea Stringer², Richard Logan³, Dorothy Keefe²

¹University of Adelaide, Anatomical Sciences, Adelaide, Australia, ²Royal Adelaide Hospital, Cancer Centre, Adelaide, Australia, ³University of Adelaide, Oral Pathology, Adelaide, Australia

**Objectives:** Past studies have demonstrated the effectiveness of targeted therapies in improving patient outcomes. However, the administration of these has been associated with gastrointestinal side effects including diarrhea and vomiting. The specific toxicities have not been well characterised, posing a challenge for the management of such symptoms in the clinic. Thus, the aim of this study was to characterise the gastrointestinal toxicities associated with Bevacuzimab administration in patients with colorectal carcinoma and Imatinib administration in patients with Chronic Myeloid Leukaemia (CML).

**Methods:** All patients were treated at the Royal Adelaide Hospital. Patients (n = 14) receiving Bevacuzimab in conjunction with conventional chemotherapy for colorectal carcinoma between 2002 and 2008 and patients (n = 63) receiving Imatinib for CML between 2000 and 2008 were included. A detailed retrospective analysis of case notes was conducted to investigate reported gastrointestinal toxicities. In addition, any non-GIT related toxicity was also reported.

**Results:** Toxicities were reported in all patients receiving Bevacuzimab in conjunction with conventional chemotherapy. Gastrointestinal toxicities included 64% of patients (9/14) with diarrhoea; 57% with nausea (8/14) and 43% with a sore mouth. Non gastrointestinal toxicities included bleeding 86% (12/14) and rashes 29% (6/14). Imatinib administered as a sole agent, also induced gastrointestinal toxicities with 68% of patients (43/63) experiencing nausea and 54% (34/63) experiencing diarrhea. The most prevalent non gastrointestinal symptom recorded was oedema with 71% (45/63) recording this symptom.

**Conclusions:** Targeted therapies have the potential to induce a range of gastrointestinal toxicities in a variety of malignancies. In the case of Bevacuzimab, the diarrhoea and nausea recorded may be amplified due to the concurrent chemotherapy. Imatinib however, is given as a sole agent and induced specific gastrointestinal toxicities. Further larger scale prospective studies are now warranted to identify potential patient risk factors that may increase their vulnerability to targeted therapy-induced toxicity.

10-082
**Comparison Of The Effectiveness Of Glutamine And Triple Gargle For Prevention Of Mucositis Development In Patients Who Have Undergone Bone Marrow Transplantation**

Nurten Kalender¹, Fikret Arpacı², Nuran Tosun¹

¹School Of Nursing, Gülhane Military Medical Academy, Ankara, Turkey, ²Department Of Medical Oncology, Gülhane Military Medical Academy, Ankara, Turkey

**Objectives:** This study was designed as an experimental study to show the effect of glutamine use in addition to the oral care protocol applied in patients undergone bone marrow transplantation (BMT) to prevent mucositis development.

**Methods:** The sample consists of patients who have undergone BMT between October 2008 and May 2009 in the medical oncology clinic of a university hospital in Turkey. Patients were divided into two equal groups as experiment and control groups according to age, gender, diagnosis and the treatment protocol applied. Standard oral care protocol was used in the control group (two ampoules of sodium bicarbonate in 500 cc water+500 cc normal saline+triflucan suspension—to be used one measuring cup in mornings and evenings). In the experiment group, however, glutamine was used in addition to this protocol (two sachets in the morning, noon and evening—total 30 g). Oral mucositis grading system of WHO was used to evaluate mucositis, and evaluation of mucositis was performed by the nurse other than the investigator on days 0, 5, 10 and 15.

**Results:** Results of the pre-application performed on 10
patients are as follows: In the day 5 following BMT, it was observed that mucositis did not develop in 80% of the patients (5 patients) that glutamine serum was applied to; however, in 20% of the patients that triple gargle was applied (5 patients) grade 1 mucositis developed, and in another 20%, grade 2 mucositis developed. While number of patients that mucositis did not develop was 60% in both groups on day 10, grade 1 mucositis developed in 20% and grade 2 mucositis developed in 20% of patients that glutamine serum was applied to; and grade 1 mucositis developed in 40% of the patients that triple gargle was applied to. Application is still going on.

Conclusions: Application is still going on.

10-083
Protective Effect Of Recombinant Epidermal Growth Factor From Radiation-Induced Small Intestinal Injury In Vivo.
Ki Mun Kang, Hye Jung Kim, Ki Churl Chang, Bae Gwon Jeong, Sang Wook Lee, Gyu Young Chai
1Gyeongsang Nat’l University, Radiation Oncology, Jinju, Korea, 2Gyeongsang Nat’l University, Pharmacology, Jinju, Korea, 3Asan Medical Center, Radiation Oncology, Seoul, Korea

Objectives: Intestinal mucositis is a debilitating effect of colorectal cancer therapy including radiation. Epidermal growth factor (EGF) stimulates the proliferation and differentiation of epithelial cells including those of the mucosa, skin, and cornea. Thus, in this study, we aimed to determine the effect of recombinant human EGF (rhEGF) on the inflammatory genes such as ornithine decarboxylase (ODC), COX-2, IL-1β, and TNF-α expression by radiation in mice small intestine.

Methods: Thirty Balb/c mice were randomly divided into three groups. Control group (n = 6), radiation group (n = 12), and radiation + rhEGF group (n = 12). A model of intestinal injury induced radiation was established by radiation (5 Gy/day) exposure to the abdomen on days 1-5. rhEGF was administered subcutaneously on days -1 to 0 and days 3 to 5 (1 mg/kg/day). After irradiation, we collected the small intestine every day from day 1 until day 14. Western blot analysis was performed for the detection of ODC and COX-2 protein expression. IL-1β and TNF-α protein levels were determined by ELISA assay.

Results: Irradiation induced ODC protein expression in a time-dependent manner and reached maximum level at 4 and 5 days, whereas COX-2 protein expression was significantly induced at 1 day and thereafter disappeared. Irradiation-induced ODC and COX-2 expressions were effectively inhibited by rhEGF treatment. In addition, IL-1β and TNF-α protein production was time dependently increased by irradiation, peaked at 7 day and declined thereafter. rhEGF also significantly prevented IL-1β and TNF-α production by irradiation from 6th ~ 11th day. Furthermore, ERK1/2 pathway was activated in irradiated mice small intestine, which was inhibited by rhEGF.

Conclusions: Taken together, ODC, COX-2, IL-1β and TNF-α inflammatory genes are expressed by irradiation in mice small intestine, which was be through ERK1/2 activation, and these genes induction is prevented by rhEGF treatment.

10-084
Cr3294, A New Oral Anti-Inflammatory Compound, Prevents Chemotherapy-Induced Diarrhea In Mice
Ornella Letari, Catherine Booth, Albino Bonazzi, Francesco Makovec, Lucio Rovati, Gianfranco Caselli
1Rottapharm SpA, Pharmacology and Toxicology Department, Monza, Italy, 2Épistem Ltd, Manchester, United Kingdom

Objectives: Mucositis often arises as a dose-limiting toxicity of chemotherapy. Diarrhea is the first symptom of gastrointestinal mucositis, and chemotherapy-induced diarrhea is a major drawback of 5-fluorouracil treatment. The anti-inflammatory agent CR3294 protects the mucosa from injury in animal models of intestinal inflammation. Thus, we tested whether CR3294 had the potential to prevent chemotherapy-induced diarrhea. Additional studies were done to rule out adverse effects of CR3294 on tumor growth or 5-fluorouracil activity.

Methods: Diarrhea assessment—BDF1 mice were pretreated with CR3294 (0, 2 and 20 mg/kg orally) once daily for 3 days. Twenty-four hours later, mice were given 5-fluorouracil (2x 525 mg/kg intraperitoneally). Animals (n=15/group) were checked twice daily, and diarrhea was scored on a 0-3 scale (0-absent; 1-mild; 2-moderate; 3-severe). Tumor growth studies—BALB/c mice bearing HT29 tumor xenografts were treated with 20 mg/kg CR3294 for 2 weeks. Tumor growth rate was measured up to 2 weeks post-dosing. In a second study, mice were given 5-fluorouracil (25 mg/kg on days 1-5) alone or in combination with CR3294 (20 mg/kg on days 1-3 and 8-10). Tumor sizes were measured for 4 weeks.

Results: Thirteen of the 15 mice receiving 5-fluorouracil alone developed diarrhea between days 4 and 11. Pretreatment with CR3294 reduced the cumulative diarrhea score in a dose-dependent manner (by about 23% and 50% at 2 and 20 mg/kg, respectively). At 20 mg/kg, CR3294 reduced the incidence of moderate to severe diarrhea by about 70% and increased by 3-fold the number of mice without diarrhea. CR3294 neither affected the growth rate of HT29 tumor xenografts nor protected tumors from the cytotoxic activity of 5-
fluorouracil.

Conclusions: This study demonstrates that CR3294 reduces diarrhea in mice exposed to 5-fluorouracil, without adversely affecting tumor growth or interfering with 5-fluorouracil activity. Thus, CR3294 may be useful for preventing chemotherapy-induced diarrhea. Supported by Rottapharm SpA

10-085
The Influence Of Low- Level Laser Therapy On Biomodulation Of Collagen In 5-Fluorouracil-Induced Oral Mucositis In Hamsters.
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1 UNIFESP, Experimental Surgery, São Paulo, Brazil, 2 UNIFESP, Experimental Surgery, São Paulo, Brazil, 3 UNIFESP, Radiotherapy, São Paulo, Brazil, 4 Ibirapuera University, Postgraduate Program, São Paulo, Brazil, 5 UNIFESP, Pathology, São Paulo, Brazil

Objectives: The aim of this study was to investigate the mechanisms whereby low-intensity laser therapy may affect the oral mucositis process, and evaluation of collagen fibers in their quality and quantity

Methods: A hamster cheek pouch model of oral mucositis was used with all animals receiving intraperitoneal 5-Fluorouracil followed by surface irritation. Animals were randomly allocated into 3 groups and treated with a 35mW laser, 100mW laser or no laser. Clinical severity of mucositis was assessed at four time-points by a blinded examiner. Buccal pouch tissue was harvested from a subgroup of animals in each group at four time-points. This tissue was used for histology to measure mucositis’s grade and to measure the expression collagen fibers. The resulting staining was quantified and qualified.

Results: On day 15 all animals in the 35mW laser group showed mucositis of grade 1 or no mucositis while most animals in the 100mW laser and control groups showed grade 2. These differences statistically significant (p=0.029). The collagen quantity was highest in control group on day 11, statistically significant (p=0.008). The repair process started earlier in 35mW laser group which collagen was fully organized on day 15.

Conclusions: Low-intensity lasertherapy appears to reduce the severity of mucositis and showed that the 100mW laser and the control groups had higher amount of collagen due to the fibrosis formation. In the 35mW laser group presented better collagen quality.

10-086
Emu Oil Improves Parameters Of Intestinal Integrity In Rat Models Of Inflammatory Bowel Disease And Intestinal Mucositis
Suzanne Mashtoub1,2,3, Ruth Lindsay1,2, Kerry Lynn1,2, Mark Geier4, Ross Butler1,2,1, Gordon Howarth1,2,3
1Women's and Children's Hospital, Gastroenterology, Adelaide, Australia, 2 The University of Adelaide, Agricultural and Animal Science, Adelaide, Australia, 3 The University of Adelaide, Physiology, Adelaide, Australia, 4 SARDI, PIPPI Nutrition Research Laboratory, Adelaide, Australia

Objectives: Inflammatory bowel disease (IBD) is manifested by chronic bowel inflammation, and a precursor to colon cancer. Mucositis is a debilitating side-effect of chemotherapy, characterised by intestinal ulceration and inflammation. Emu Oil (EO) has demonstrated beneficial effects in certain inflammatory disorders. We investigated EO in rat models of IBD and mucositis.

Methods: IBD: Rats (135-150g) were allocated to 6 groups (n=8): Groups 1 and 2 consumed water (days 0-10) with 1ml water (Group 1) or 1ml EO gavage (Group 2). Groups 3-6 ingested 2% DSS in drinking water from days5-10, and were gavaged with water (Group 3), 0.5ml EO (Group 4) or 1ml EO (Group 5). Group 6 received 1ml EO from days6-10. Mucositis: Rats (n=8/group) were gavaged with EO (0.5ml or 1ml) daily. 5-Fluorouracil (5-FU: 150mg/kg) was injected on day5. Histological parameters [damage severity, crypt depth (CD), villus height (VH)] and myeloperoxidase (MPO) activity were examined. p<0.05 was considered significant.

Results: IBD: EO reduced colonic damage severity (up to 3-fold; p<0.001). In the proximal colon of DSS-treated rats, 0.5ml EO lengthened crypts compared with DSS-controls (373±18µm cf. 302±8µm respectively); whilst in the distal colon (DSS control: 271±17µm); CD was greater following 0.5ml EO (352±22µm) and 1ml EO (341±9µm) and also when EO was administered post-DSS (Group 6: 409±16µm). Mucositis: Rats were gavaged with EO (0.5ml or 1ml) daily. 5-Fluorouracil (5-FU: 150mg/kg) was injected on day5. Histological parameters [damage severity, crypt depth (CD), villus height (VH)] and myeloperoxidase (MPO) activity were examined. p<0.05 was considered significant.

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U/g, p<0.05), supported by improvements in ileal VH (230±17µm) and CD (152±18µm) at 96hours following 1ml EO [5-FU control: VH (180±18µm) and CD (106±12µm)].

Conclusions: Protection of the intestine and/or promotion of repair from injury could represent new mechanisms of action for Emu Oil, suggesting potential for this unique formulation to augment conventional treatment approaches for cancer management.

10-087
A Retrospective Match Controlled Study Of Supersaturated Calcium Phosphate Oral Rinse (Scpor) Vs. Supportive Care For Radiation Induced Oral Mucositis (Om)
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Objectives: OM is a significant cause of morbidity during radiation (RT) and chemoradiotherapy for head and neck (HN) malignancies resulting in significant morbidity, treatment delays, premature treatment cessation and increased cost.

Methods: 21 consecutive HN patients treated with intensity modulated radiation therapy (IMRT) who received SCPOR [Caphosol®, EUSA Pharma] from the initiation of treatment were retrospectively match-controlled with concurrently treated IMRT patients receiving other supportive regimens including salt and soda rinses and “magic mouthwash”. Data obtained included demographic and clinical characteristics, RT characteristics, grades of mucositis and xerostomia, weight loss, analgesic requirements, need for PEG tube, and OM related hospitalization during treatment. Costs related to treatment of OM were evaluated using two independent previously published cost models which were based on OM severity in HN patients treated with RT.

Results: SCPOR treated and control patients were very similar with regard to demographic, disease and treatment characteristics. As compared to the control patients, a greater proportion of the SCPOR treated patients experienced mild (Grade 0 or 1) OM (48% vs 29%) and a smaller proportion experienced severe (Grade 3 or 4) OM (38% vs 71%). The reduction in severe OM was accompanied by a decreased need for PEG tube placement (33% vs 57%) and hospitalization (0% vs 19%). No adverse effects associated with the use of the SCPOR were observed. Per patient OM related costs for the treated patients were reduced by $1,700 based on one cost model and $6,900 for the second.

Conclusions: These data suggest that SCPOR is an effective treatment for reducing the incidence and severity of OM in patients undergoing IMRT. Reductions in OM associated treatment costs based on existing models were corroborated by observed reductions in hospitalization and PEG tube requirements for the treated patients.

10-088
Oral Mucositis, Pain And Xerostomia In 135 Head And Neck Cancer Patients Receiving Radiotherapy With Or Without Chemotherapy.
Ouranía Nicolatou-Galitis¹, Vassilis Kouloulias², Anastasia Sotiropoulou-Lounto³, Konstantinos Dardoufas⁴, Argyro Polychronopoulou⁵, John Kouvaris⁶
¹Head, Clinic of Hospital Dentistry, School of Dentistry, University of Athens, Athens, Greece, ²Head, Department of Radiotherapy, Aretaieion University Hospital, School of, Athens, Greece, ³Head, 2nd Radiotherapy Department, Saint Savvas Anticancer Hospital, Athens, Greece, ⁴Associate of the Clinic, Radiation Oncology Department, Higgeia Hospital, Athens, Greece, ⁵Assistant Professor, Department of Preventive and Community Dentistry, School of Dentistry, Athens, Greece, ⁶Director, Department of Radiotherapy, Aretaieion University Hospital, School of, Athens, Greece

Objectives: Oral mucositis, pain, and xerostomia, was assessed in head and neck cancer patients during radiotherapy and compared to that following the completion of radiotherapy, after the treatment and prevention of fungal and viral infections. Patients. The study included 135 patients. The mean total radiotherapy dose was 62.4 Gy. Concurrent chemotherapy was administered to 47% of patients.

Methods: Mucositis was scored weekly according to EORTC/RTOG criteria. Using a 10-point scale, 131 patients self-evaluated their pain and xerostomia. Based on clinical diagnosis of fungal or viral infection, patients were treated with systemic antifungals and antivirals. Medications continued as prophylaxis to the end of RT. Cytology smears were used for the laboratory verification of herpetic infection.

Results: Radiotherapy was completed within the preplanned time in 117 patients (87%). During radiotherapy, the incidence of severe mucositis was 57%, while severe pain and severe xerostomia were reported by 43% and 29% of patients. At the end of radiotherapy, severe mucositis, severe pain, and severe xerostomia were significantly reduced to 33%, (P<0.001), to 24%, (P<0.001), and to 18%, (P<0.05). The overall incidence of mucositis grade 2, 3, and 4 was 82% during and 77.7% at the end of radiotherapy. Antifungals were used in (70%) and antivirals in (71%) of patients. The
Cytology smear showed viral cytopathic alterations in 14 of 45 patients.

**Conclusions:** The above significant reduction of the severity of oral mucositis, pain and xerostomia indicates a significant role of fungal and viral infection in the severity of those symptoms and the potential importance of fungal and viral infection prophylaxis in head and neck radiotherapy.

**10-089 Oral Mucositis In Cancer Patients Receiving Regimens Containing 5-Fluorouracil**

Jennifer Niles¹, Kevin Claffey², Rajesh Lalla¹,², Upendra Hegde³, Linda Choquette¹,², Douglas Peterson¹,²

¹School of Dental Medicine, Oral Health & Diagnostic Sciences, Farmington, USA; ²University of Connecticut Health Center, Neag Comprehensive Cancer Center, Farmington, USA

**Objectives:** Oral mucositis in cancer patients receiving 5-fluorouracil (5-FU) can result in important complications. Early, subclinical oral mucosal changes associated with 5-FU have not been comprehensively reported. This pilot study explored the hypothesis that risk for development of oral mucositis in patients receiving low dose 5-FU is correlated with selected alterations in the oral mucosal microenvironment.

**Methods:** Three adult subjects with gastrointestinal carcinoma were studied before and 48-72 hours following 5-FU administration. Clinical assessment was conducted via a standardized oral mucositis scale. Cytobrush samples were collected and analyzed by Giemsa and by immunofluorescent stains for Ki-67, cytokeratin-10 (CK10) and cytokeratin-14 (CK14). Oral mucosal punch biopsy samples were harvested and flash frozen, followed by staining with H&E and Ki-67, CK14 and CD31. Apoptosis was measured by TUNEL assay. Descriptive analysis was conducted following visualization under light or immunofluorescent microscopy.

**Results:** As anticipated, only one patient developed mild erythematous oral mucositis following 5-FU administration. Cytobrush assays were technique-sensitive and exhibited variable results across specimens. However, biopsy results after 5-FU infusion versus pre-5-FU infusion showed consistent changes across all three subjects including:

- increased epithelial cell vacuolization;
- decreased prominence of epithelial rete pegs;
- increased Ki-67 staining of basal epithelial layer;
- reduced submucosal collagen density and architectural alterations consistent with edema.

No staining differences were evident regarding CK14, CD31, or apoptosis before and after 5-FU infusion.

**Conclusions:** This pilot study identified selected early histological changes that might contribute to oral mucosal injury in patients receiving higher dose 5-FU regimens. Such studies in cohorts at low risk for oral mucositis may be useful in further delineating the continuum of mucosal pathobiologic change across patients at low, moderate or high risk for oral mucositis. Supported by Dental Dean’s Office and the Oral Medicine Research Fund, Department of Oral Health & Diagnostic Sciences.

**10-090 Compounds Secreted From Escherichia Coli Nissle 1917, Streptococcus Thermophilus Th-4 And Lactobacillus Fermentum Br11 Maintain Intestinal Cell Viability Following 5-Fluorouracil Administration In Vitro**

Luca Prisciandaro¹,²,³, Mark Geier², Ross Butler¹, Adrian Cummins³, Gordon Howarth¹

¹The University of Adelaide, School of Agriculture, Food and Wine, Adelaide, Australia; ²South Australian Research and Development Institute, Adelaide, Australia; ³The Queen Elizabeth Hospital, Department of Gastroenterology and Hepatology, Adelaide, Australia

**Objectives:** Whilst live bacteria have demonstrated some efficacy in vivo as a potential treatment for chemotherapy-induced mucositis, probiotic supernatants (SN) have yet to be methodically investigated. We aimed to screen different probiotic supernatants for their ability to protect intestinal cells from 5-Fluorouracil (5-FU) induced damage in vitro.

**Methods:** IEC-6 cells were treated with 1mM of 5-FU for 1 h before being incubated with either Lactobacillus fermentum BR11 (BR11), Streptococcus thermophilus TH-4 (TH-4), Escherichia coli Nissle 1917 (EcN) or Lactobacillus acidophilus LA5 (LA5) SN, or either a PBS or DMEM control. Cells were harvested at 24 hr intervals up to 96 hrs. Viability and cell counts were determined by trypan blue exclusion dye assay. Significance was assumed at (P<0.05) using a Student’s t-test.

**Results:** At 24-96 hrs, cell number was reduced in all 5-FU treated groups compared to untreated controls (P<0.0001). At 24 hrs, cell viability was reduced in the 50% PBS + 5-FU group (65.8 ± 8.2%) compared to untreated controls (95.0 ± 1.5, P<0.05). At 48 hrs, the 50% PBS, 100% DMEM and LA5 (55.2 ± 8.5, 65.0 ± 7.5 and 55.5 ± 10.0) were reduced compared to untreated controls (94.6 ± 1.4, P<0.05). Viability was reduced in all 5-FU treated groups compared to untreated controls at 72 hrs (P<0.05). At 96 hrs only the 50% PBS + 5-FU group showed reduced viability compared to controls (68.2 ± 3.9 vs 94.8 ± 1.0, P<0.05), whereas BR11, TH-4 and EcN SN groups did not show significant reductions.
in viability following 5-FU administration (P>0.05)

Conclusions: Compared to PBS-treated cells, soluble products of BR11, EcN and TH-4 normalised cell viability following treatment with 5-FU, suggesting a protective effect for these probiotic SNs. Further studies in an in vivo model of 5-FU induced mucositis are indicated to confirm their therapeutic utility.

10-091
Factors Secreted From Lactobacillus Fermentum Br11 And Escherichia Coli Nissle 1917 As A Potential Therapy For 5-Fluorouracil Induced Mucositis: A Pilot Study
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Objectives: Soluble factors obtained from Lactobacillus fermentum BR11 (BR11) and Escherichia coli Nissle 1917 (EcN) have been shown to protect intestinal cells from 5-Fluorouracil (5-FU) induced damage in vitro but are yet to be investigated in an in vivo setting. We aimed to determine whether BR11 and EcN supernatants (SNs) are able to protect the intestine in a rat model of intestinal mucositis.

Methods: Dark Agouti rats were allocated to five groups (n=6-8): Water+Saline; or 5-FU: +Water; +DMEM; +BR11 SN; and +EcN SN and treatments were orally administered from days 0 to 6. 5-FU (150mg.kg⁻¹) was administered by intraperitoneal injection on day 3; animals were sacrificed on day 6. Metabolic parameters were measured daily. At kill, intestinal tissues were resected, weighed and subjected to biochemical [myeloperoxidase (MPO) and sucrase activity] analysis.

Results: Food intake was reduced in 5-FU+Water animals on day 5 compared to normal controls (P<0.05), but maintained in the SN groups. On day 5, urine output was normalised in the SN and DMEM groups, while an increase was observed in the 5-FU+Water group compared to normal controls (P<0.05). Duodenum and caecum weights were decreased by 5-FU treatment compared to controls (P<0.05), but no difference was observed between SN, DMEM and healthy control groups. Jejunum and ileum weights were reduced in DMEM+5-FU treated animals compared to 5-FU+water controls (P<0.05). With the exception of 5-FU+EcN, MPO activity was increased in the jejunal fat of all 5-FU treated animals compared to healthy controls (P<0.05). Sucrase activity was reduced in all 5-FU treated groups compared to controls (P<0.05).

Conclusions: The ability of SNs to normalise feed intake, urine output and (in the case of EcN) jejunal MPO levels suggest partial protection from 5-FU induced damage. Further studies are warranted to confirm the therapeutic potential of probiotic supernatants in 5-FU induced mucositis.

10-092
Effect Of A Mouth Rinse Formulation With Human Trefoil Factor 1-Secreting Lactococcus Lactis In Experimental Oral Mucositis In Hamsters.
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Objectives: Oral mucositis (OM) is a painful and dose-limiting toxicity of cancer chemotherapy and irradiation. Trefoil factors (TFFs) are involved in protecting and healing mucosal tissue, and might thus represent a pharmacological tool for treatment of OM. Local delivery of recombinant TFFs at the oral mucosa by living, genetically modified Lactococcus (L.) lactis bacteria seems a promising, safe and cost-effective clinical approach for the prevention and attenuation of OM.

Methods: An environmentally contained L. lactis strain (AG013), engineered to express human (h)TFF1, was formulated for topical administration in the form of a mouth rinse. Efficacy of AG013 was assessed in a clinically relevant hamster model of acute, radiation-induced OM. The dosing regimen was 1.3 x 10⁹ CFU/dose, once (qd) or three rinses (tid) daily, from day 0 (=day of radiation) to day 18. OM was scored using the WHO grading scale, and compared to the score of placebo-treated hamsters. The viability and survival of live L. lactis and the pharmacokinetics of the hTFF1 secreted were studied in healthy and OM hamsters.

Results: Topical application of AG013 to the oral mucosa significantly reduced the severity and course of radiation-induced OM. In the AG013-treated groups, the number of animals days with ulcerative mucositis (grade ≥3) was significantly reduced to 27.5% and 30.8% (qd and tid respectively), compared to 45.8 % in the placebo-treated group. Based on the observed survival and weight changes, AG013 appeared to be well-tolerated. Pharmacokinetic studies demonstrated that both living L. lactis and the hTFF1 secreted could be recovered from the administration site, for maximum 24 hours post-dosing, without systemic exposure.

Conclusions: Oral administration of AG013 is safe and effective in reducing the severity and the course of OM in the hamster model, and therefore supports proof-of-
concept for a mouth rinse formulation of AG013 to treat OM patients.

10-093
Effects Of N-Acetyl-Cysteine In The Prevention Of 5-Fluorouracil Induced-Oral Mucositis In Hamsters - Preliminary Results
Odara Sá1, Nilza Lopes2, Maria Luiza Oliva3, João Tomas Cavalhaes3, Maria Teresa Alves5, Eliana Caran6
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Objectives: Oral mucositis is the most common and dose-limiting complications of cancer treatment. N-acetyl-cysteine (NAC) are antioxidants which minimize oxidative stress and the lipid peroxidation of cellular membranes. Objective: The present study aimed to evaluate the effects of NAC as a treatment of 5-fluorouracil induced-oral mucositis in hamster.

Methods: The animals were divided into two groups: therapeutic NAC (group I; n=15) and control group (group II; n=15). Mucositis was induced in hamster by intraperitoneal injection of 5-fluorouracil an days 0 and 2 and left cheek pouch irritated by superficial scratching on days 3 and 4. In group I, oral mucositis was induced and treated with NAC intraperitoneal infusion during seven days. In group II, mucositis was induced and no treatment was done. Oral mucosa was photographed from day 4 and 7. Photographs were randomly scored according to the severity of induced mucositis (0 to 5). Excisional biopsies of the palatal mucosa were performed, and the hamsters were sacrificed. Tissue sections were evaluated and classified according to scoring histological evaluation (1 and 2). Samples of cheek pouches were removed from animals per group for Malondialdehyde (MDA) measurement.

Results: - preliminary results: Group I had shown better prevention in oral mucosa structural damage than group II. Clinical evaluation demonstrated that group I had better outcome and faster healing. Group I presented more granulation tissue and fibroblasts. According to Malondialdehyde values, group I, showed decrease in lipid peroxidation.

Conclusions: The results suggest that NAC treatment had a positive effect in reducing mucositis severity, and a pronounced effect in treating established mucositis.

10-094
Effects Of Glycine In The Prevention Of 5-Fluorouracil Induced-Oral Mucositis In Hamsters - Preliminary Results.
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Objectives: Mucositis is the most common oral complication of cancer chemotherapy. Diets enriched with glycine demonstrated evidence in favor of the anti-inflammatory, immunomodulatory and cytoprotective effects. Objective: The present study aimed to evaluate the effects of glycine as a treatment of 5-fluorouracil induced-oral mucositis in hamster.

Methods: Animals of experimental (group I; n=20) and control (group II; n= 20) groups received intraperitoneal injections of 5-fluorouracil on days 0 and 2. All animals had their right and left cheek pouch irritated by superficial scratching on days 3 and 4. In group I, oral mucositis was induced and treated with 5% glycine intraperitoneal infusion during seven days. In group II, mucositis was induced, but no treatment was done. The oral mucosa was photographed from day 4 and 7. Photographs were randomly scored according to the severity of induced mucositis (0 to 5). Excisional biopsies of the palatal mucosa were performed, and the hamsters were sacrificed. Tissue sections were evaluated and classified according to scoring histotological evaluation (1 and 2). Samples of cheek pouches were removed from animals per group for Malondialdehyde (MDA) measurement.

Results: - preliminary results: Group I had shown better prevention in oral mucosa structural damage than group II. Clinical evaluation demonstrated that group I had better outcome and faster healing. Group I presented more granulation tissue and fibroblasts. According to Malondialdehyde values, group I, showed decrease in lipid peroxidation.

Conclusions: The results suggest that glycine treatment had a positive effect in reducing mucositis severity, and a pronounced effect in treating established mucositis.
10-095
Oral Mucositis, Pain and Xerostomia in Patients With Head and Neck Cancer Who Received Chemoradiotherapy With or Without Cetuximab: A Comparative Clinical Study.
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Objectives: To compare the severity of oral mucositis, pain and xerostomia in head and neck cancer patients, who received radiotherapy with cisplatinum and cetuximab to that in patients who received radiotherapy with cisplatinum alone.

Methods: Forty-nine head and neck cancer patients entered the study. Twenty-five patients (Group A) received radiotherapy (median total dose 63.6 Gy) and cisplatinum. Twenty-four patients (Group B) received radiotherapy (median total dose 64.8 Gy) and cisplatinum, plus cetuximab at an initial dose of 400 mg/m², followed by 250 mg/m² every two weeks. Patient characteristics were similar in both groups. Oral mucositis was recorded weekly, according to EORTC/RTOG criteria. Pain and xerostomia were assessed using a visual analogue scale. Antifungal and antiviral treatment and prophylaxis were administered to both groups.

Results: During chemoradiotherapy, severe mucositis, pain and xerostomia were observed in 60%, 64% and 52% respectively in Group A, while the same symptoms were observed in 79%, 58% and 29% respectively in Group B. The differences in oral toxicity between the two groups were not statistically significant. At the end of chemoradiotherapy, severe mucositis, pain and xerostomia were recorded in 24%, 32% and 32% respectively in Group A, while in Group B they were 37%, 21% and 17% respectively. The differences between the two groups were not statistically significant. Neither significant differences were found between the two groups with respect to the administration of antifungal and antiviral treatment, the interruption of radiotherapy and weight loss. In both groups, a statistically significant reduction of oral mucositis, pain and xerostomia was observed during and after the completion of radiotherapy, related to antifungal and antiviral treatment and prophylaxis.

Conclusions: The administration of cetuximab in patients with head and neck cancer who received chemoradiotherapy with cisplatinum did not increase the severity of oral toxicity, oral mucositis, pain and xerostomia.

10-096
The Importance of the Gut Microbiome in Gastrointestinal Mucositis
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Objectives: Mucositis is a major side effect of chemotherapy. The microbiome (the extended genome of all microbial genes) is vital for host health, but can transform in response to pharmaceutical input. This is a relatively new area of research, and with the recent establishment of the Human Microbiome Project, the microbiome is likely to receive significant attention as this develops. The aim of this study was to implicate the intestinal microbiome in the development of mucositis in both animal and clinical models.

Methods: DA rats were assigned to groups (experimental/control). Experimental rats were treated with either 200 mg/kg irinotecan (CPT-11) or 150 mg/kg 5-FU (single dose) and faecal samples collected. Sixteen patients experiencing chemotherapy-induced diarrhoea (CID) consented to participating in this study (Cancer Centre, RAH), with two healthy control volunteers. Faecal samples were collected from all participants. Using both qualitative microbiological techniques, and quantitative molecular techniques, the bacterial components of several rat and human samples were analysed. Statistical analysis was performed using the Mann-Whitney U test with Bonferroni correction.

Results: Mucositis was observed histologically in rats receiving irinotecan and 5-FU. Severe diarrhoea was observed in rats receiving irinotecan, but not in rats receiving 5-FU. Changes were observed in the intestinal microbiome of both humans and rats receiving chemotherapy when compared with respective controls. Increases in potential pathogens simultaneous with decreases in anaerobic components of the microbiome were observed in both rats and humans. E. coli increased after treatment with irinotecan (24-48h and 96 h, p<0.05), 5-FU (48 h), and in patients experiencing CID (66%). Various anaerobic components decreased after
treatment with irinotecan, 5-FU and in patients.

Conclusions: The intestinal microbiome is vital for host health. We have shown that chemotherapy transforms components of the intestinal microbiome, effecting intestinal growth and development, colonisation resistance, availability of otherwise inaccessible nutrients and metabolism, resulting in the development of mucositis.

10-097

Chemotherapy-Induced Diarrhoea Is Associated With A Modified Microbiome In Cancer Patients
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Objectives: Diarrhoea is a major clinical manifestation of alimentary mucositis. The underlying pathology of oral and small intestinal mucositis has been well studied, although the mechanisms contributing to chemotherapy-induced diarrhoea (CID) are poorly understood. The primary aim of this study was to obtain preliminary data to determine if changes in microflora observed in previous animal models of chemotherapy-induced mucositis and diarrhoea compared with clinical data, and to determine if the faecal flora of patients with CID was displaced from that of healthy controls.

Methods: Sixteen patients (6 males and 10 females) with a median age of 71 years (range 36–82) receiving chemotherapy provided informed consent. This was a non-invasive study, with patients requested to provide stool samples and blood samples, taken after the onset of CID. Complete blood examination (CBE) and biochemical analyses were performed on blood samples and compared with internal normal reference ranges. Stool samples were analysed using conventional culture techniques and quantitative real time PCR.

Results: The overall culture analysis revealed that 75% of patients had a decreased anaerobic component of their microflora, with respect to the level of growth and diversity of species present. The majority of patients experiencing CID also showed decreases in Clostridium spp., Lactobacillus spp., Bifidobacterium spp., Bacteroides spp. and Enterococcus spp. Increases were also observed in E. coli and Staphylococcus spp.. Antibiotics did not have any noticeable effect.

Conclusions: In conclusion, CID is associated with marked changes in the intestinal microflora. These changes may result in diminished bacterial functions within the gut, altering gut function and initiating intestinal damage, resulting in the onset of diarrhoea.

10-098

Survival Rate Among Patients Receiving Oral Cryotherapy In Connection With Myeloablative Therapy Followed By Bone marrow Transplantation
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Objectives: Oral cryotherapy has been proven to alleviate symptoms of mucositis, a major complication in myeloablative therapy. In a randomised controlled trial it was shown that patients receiving oral cryotherapy had less mucositis and fewer days with and lower dose of i.v. opioids than a control group receiving routine oral care. It is thus of interest to investigate if oral cryotherapy may be harmful to patients. Objectiv: The objective with the present study was to evaluate if there was a difference in survival rate for patients receiving oral cryotherapy in connection with myeloablative therapy followed by BMT compare to patients receiving routine oral care.

Methods: Seventy eight patients (mean age 52.0 (12.9) years, range 19 – 69 years) treated with myeloablative therapy followed by BMT were randomised to oral cryotherapy (n=39) or routine oral care (n=39). Survival data was based on a review of the patient’s medical records after four years.

Results: During follow-up, 25 of the patients receiving oral cryotherapy survived while 16 of the patients receiving routine oral care survived (odds ratio 0.39, 95% CI 0.15-0.97, p<0.05).

Conclusions: Oral cryotherapy provides no evidence of harm in patients receiving myeloablative therapy followed by BMT. Further analyses are needed to explore the difference in survival rate.

10-099

Prospective Alimentary Mucositis Audit With A Day-By-Day Assessment Tool: A Single Center Experience
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Objectives: Mucositis is a major issue in the setting of autologous hematopoietic stem cell transplantation
(aHSCT). Very few data on the pattern of oral (OM) and gastrointestinal mucositis (GIM) are reported, usually related to the incidence and severity of oral mucositis (OM). A prospective observational study was conducted in our BMT Unit to assess the pattern and severity of OM and GIM in patients (pts) undergoing autologous HSCT.

**Methods:** Assessment was conducted daily from conditioning regimen to day +20 or discharge. OM was assessed according to WHO scale; anorexia, nausea, vomiting and diarrhea were assessed according to CTC 3.0 scale.

**Results:** 21 autologous HSCT patients with lymphoma (n=10; median age 38, range 21-61) and multiple myeloma (n=8; median age 52, range 40-63). Three patients with myeloma were treated with a double aHSCT program. All patients received high dose chemotherapy as conditioning regimen, according to the international guidelines for lymphoma or myeloma. Data on the incidence and pattern localization, time of onset, duration and peak of OM, anorexia, nausea, vomiting and diarrhea are presented in the table. Prevention of OM with oral criotherapy indicated an absence of severe OM (0/6) in the treated group, as compared to the control group (2/5).

**Conclusions:** Although preliminary, these data may be helpful to define the impact of gastrointestinal mucositis on patients undergoing high-dose chemotherapy and evaluate preemptive and treatment approach of this complication.

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10-100
**Treatment Of Oral Mucositis Pain By A Bioadhesive Barrier Forming Lipid Solution**
Fredrik Tiberg¹, Eva Cavallin-Ståhl¹, Margareta Linden¹, Kristier Thuresson¹, Tatiana Hadjieva¹
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**Objectives:** Oral mucositis is a common side-effect of radiotherapy and chemotherapy of cancer. It is frequently a painful condition with ulceration of the mucous membranes and opportunistic infections in the mouth. In severe cases, it can be extremely painful and may necessitate hospitalization for opiate pain medication and parenteral nutrition. Development of a locally acting analgesic product with long effect duration would improve the well-being of a large group of cancer patients. The current study investigated intra-oral pain intensity before and up to eight hours after intra-oral administration of a bioadhesive barrier forming lipid solution (Episil®).

**Methods:** After the confirmation of eligibility, 38 patients with head and neck cancer in week 3 to 4 of radiotherapy were randomized to a treatment-sequence of the trial medications; an *in situ* barrier forming lipid solution with and without benzydamine. There was a >24 hour wash-out period between treatments. Analgesic treatment effects were studied by assessment of oromucosal pain intensity (0-10 Likert pain score) before and 5 min, 30 min, 1 h, 2 h, 3 h, 6 h and 8 h after dosing.

**Results:** Evaluations of pain intensity demonstrated an immediate treatment effect of the bioadhesive and barrier forming lipid solution. The maximum effect (mean 40% pain reduction) was reached after 1 hour and was maintained over the 8 hours. Similar treatment effects were obtained with and without benzydamine. This most likely relates to the effective protection of the oromucosal surfaces provided by the *in situ* barrier forming lipid solution. The unique bioadhesive and protective properties of the lipid solution isolates the sensitive irradiated mucosa from external irritation.

**Conclusions:** The results of the trial showed that there was an immediate and sustained clinically significant analgesic effect of the product. Moreover, the product was safe and well tolerated in this group of patients.

10-101
**Controlled, Randomised, Double-Blinded Study Of Prevention And Treatment Of Oral Mucositis With Propolis**
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**Objectives:** Mucositis is an acute side effect of cancer treatment. There are only a few substances that have scientifically proven positive effect in prevention or treatment of mucositis. The aim of our study was to investigate if propolis has any effect on development and
course of oral mucositis.

Methods: In the first 6 months of our ongoing study 25 children (age 1-17 years) who have just started chemotherapy were included. Parents of the children in the control (n=11) and the test group (n=14) were asked to apply 70% propolis in alcohol solution or placebo, respectively, on the child’s buccal mucosa before sleep during chemotherapy and if any signs of developing mucositis would appear. Their oral mucosa status was assessed twice a week by one examiner using Eiler’s Oral Assessment Guide (OAG). Non-parametric Mann-Whitney test was used for statistical analysis.

Results: The average number of episodes of mucositis, ranked second in the OAG (changed appearance, but no loss of function or barrier breakdown) was 0,93±1,07 in the test group and 0,82±1,17 in the control group. They lasted 4-10 days (average 2,57±3,37) and 2-8 days (average 2,0±2,80), respectively. The average number of episodes of mucositis, ranked third in the OAG (loss of function or barrier breakdown) was 0,57±0,51 in the test group and 0,27±0,46 in the control group, lasting from 6 to 24 days (average 7,0±7,98) and 2 to 10 days (average 2,0±3,69), respectively. The difference in the average number of episodes of the second and the third category of OAG was not significant between the test and the control group, neither was the difference in the number of days the mucositis lasted (p>0,05).

Conclusions: Preliminary results of our study show no benefit of 70% solution of propolis in lowering the risk of development of mucositis and has no beneficial treatment effect.

10-102
Changes In The Number Of Resident Bacteria Correlate With The Severity Of Chemotherapy Induced Intestinal Mucositis
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Objectives: Over the past years, a role has been proposed for the intestinal microbiota in the development of inflammatory bowel diseases. It is unclear whether changes in intestinal microflora during chemotherapy treatment also play a role in the evolution of intestinal mucositis. The aim of this study was to explore changes in the intestinal bacterial populations of adult recipients of a hematopoietic stem cell transplant (HSCT) who developed intestinal mucositis after myeloablative conditioning.

Methods: Faecal samples were collected from 23 patients receiving myeloablative treatment for HSCT. Faecal bacterial populations were analyzed by fluorescent in situ hybridisation (FISH). The severity of intestinal mucositis was based on plasma citrulline levels.

Results: Both plasma citrulline levels and the total number of intestinal bacteria decreased significantly during treatment. The decrease in bacteria was mainly accounted for by decreases in anaerobic bacteria such as bifidobacteria and Clostridium group XIVa. However, there was an increase in the number of enterococci. A direct correlation was found between plasma citrulline levels and both the total number of intestinal bacteria and the number of bacteria belonging to specific anaerobic bacterial groups such as Clostridium group XIVa.

Conclusions: A direct relationship was shown between plasma citrulline levels and the number of specific intestinal bacteria indicating a perturbation of intestinal homeostasis. Further research is ongoing to show whether this relationship is a causal one.

10-103
Vascular Endothelial Growth Factor And Chemotherapy-Induced Alimentary Tract Mucositis.
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Objectives: Alimentary tract (AT) mucositis is a debilitating side effect of chemotherapy. Vascular endothelial growth factor (VEGF) is a growth factor involved in the process of new blood vessel formation and is thought to play an important role in healing and maintaining the AT. It has been investigated in a variety of animal models with respect to healing of oesophageal, gastric and duodenal ulceration. There is limited information to date whether VEGF is implicated in the pathobiology of chemotherapy-induced mucositis. The aim of this study was to determine VEGF was expressed in different sites of the AT following administration of either methotrexate or 5-fluorouracil.

Methods: In two separate experiments, female DA rats were given a single dose of either methotrexate (1.5 mg/kg intramuscularly) or 5-fluorouracil (150mg/kg intraperitoneally). Rats were killed at 30, 60, 90 minutes,
Results: VEGF was inconsistently expressed in the different sites of the AT following administration of methotrexate and 5-fluorouracil. Differences were observed in the tissue expression of VEGF between methotrexate and 5-fluorouracil. The 5-fluorouracil treatment group demonstrated a greater increase in VEGF staining in the buccal and tongue mucosa, whilst the methotrexate group demonstrated increased staining of VEGF in the jejunum.

Conclusions: The results from this study suggest that VEGF may have a role to play in mucositis pathobiology. Furthermore, the results support our previous work indicating that there may be differences in the pathobiology of mucosal damage in the AT caused by different drugs. Additional studies are required to further characterise the role that VEGF has, particularly with respect to healing the phase of mucositis.

11-104 Apriori, A Prospective Data Audit From Patients Receiving Darbepoetin Alfa To Treat Chemotherapy-Induced Anaemia
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Objectives: Darbepoetin alfa (DA, Aranesp®) is an erythropoiesis-stimulating agent (ESA) used to treat anaemia in cancer patients undergoing chemotherapy. The European Organisation for Research and Treatment of Cancer (EORTC) recommends that ESA treatment be initiated at a haemoglobin (Hb) level of 9-11 g/dl and discontinued if Hb exceeds 13 g/dl (Bokemeyer et al., Eur J Cancer, 2007;43:258-270). The primary aim of the APRIORI study is to assess whether these guidelines are being followed in central and eastern European countries.

Methods: This observational study will collect, in each of 4 consecutive years, medical record data from at least 800 cancer patients (solid tumors or haematological malignancies) with anaemia who are receiving DA and chemotherapy. This report presents data collected from November 2006 through December 2007.

Results: Data were collected from a total of 1412 patients in the Czech Republic (n=152), Hungary (n=279), Poland (n=467), Slovakia (n=450), and Slovenia (n=64). The mean (SD) age was 59.4 (13.50) years with a minimum and maximum of 19 and 99; the mean ages for the tumour subgroups ranged from 53.3 years for other solid tumours to 64.8 years for multiple myeloma. Patient gender was 52.7% female for multiple myeloma, 44.2% for non-Hodgkin's disease, 98.0% for breast cancer, 34.3% for lung cancer, 100% for gynaecological tumours, 28.4% for other solid tumours, and 58.1% overall. Other results are summarized in the following table.

<table>
<thead>
<tr>
<th>Tumour type (n, % of patients)⁶</th>
<th>Multiple myeloma (201, 14.2%)</th>
<th>Non-Hodgkin's disease (147, 10.4%)</th>
<th>Breast cancer (148, 10.5%)</th>
<th>Lung cancer (204, 14.5%)</th>
<th>Gyn tumours (283, 20.0%)</th>
<th>Other solid tumours (264, 18.7%)</th>
<th>All tumour types (N=1412)</th>
</tr>
</thead>
<tbody>
<tr>
<td>At enrolment, patients with:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Hb &lt;9 g/dL</td>
<td>44.3% 56.5% 27.7% 42.6% 31.4% 55.7% 42.6%</td>
<td>Hb 9-11 g/dL</td>
<td>52.2% 39.5% 62.2% 55.4% 67.2% 43.6% 54.0%</td>
<td>Hb &gt;11 g/dL</td>
<td>3.5% 4.1% 10.1% 2.0% 1.4% 0.8% 3.3%</td>
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<tr>
<td>At EOTP, patients with:</td>
<td></td>
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</tr>
<tr>
<td>Hb &lt;9 g/dL</td>
<td>18.9% 25.2% 15.5% 26.5% 15.9% 25.4% 20.7%</td>
<td>Hb 9-11 g/dL</td>
<td>44.8% 34.7% 41.9% 54.4% 47.3% 40.9 43.7%</td>
<td>Hb &gt;11 g/dL</td>
<td>36.3% 40.1% 42.6% 19.1% 36.7% 33.7% 35.6%</td>
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</tr>
<tr>
<td>Hb (g/dL) at enrolment:</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Mean (SD)</td>
<td>9.06 (1.105) 8.83 (1.150) 9.71 (1.106) 9.11 (0.894) 9.41 (0.919) 8.99 (1.008) 9.20 (1.052)</td>
<td>Mean (SD)</td>
<td>10.47 (1.718) 10.45 (1.806) 10.67 (1.665) 9.82 (1.407) 10.62 (1.727) 10.25 (1.690) 10.41 (1.720)</td>
<td>Mean (SD)</td>
<td>10.30 (1.263) 10.40 (1.513) 10.70 (1.263) 10.90 (1.607) 10.50 (1.708) 10.00 (1.675)</td>
<td></td>
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<tr>
<td>Change in Hb (g/dL)</td>
<td></td>
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</tr>
<tr>
<td>Mean (SD)</td>
<td>1.41 (1.647) 1.62 (1.779) 0.95 (1.513) 0.71 (1.263) 1.21 (1.607) 1.26 (1.708) 1.22 (1.675)</td>
<td>Mean (SD)</td>
<td>10.47 (1.718) 10.45 (1.806) 10.67 (1.665) 9.82 (1.407) 10.62 (1.727) 10.25 (1.690) 10.41 (1.720)</td>
<td>Mean (SD)</td>
<td>10.30 (1.263) 10.40 (1.513) 10.70 (1.263) 10.90 (1.607) 10.50 (1.708) 10.00 (1.675)</td>
<td></td>
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<tr>
<td>Median</td>
<td>0.90 1.30 0.50 0.00 1.00 0.95 0.80</td>
<td>Median</td>
<td>1.41 1.62 0.95 0.71 1.21 1.26 1.22</td>
<td>Median</td>
<td>0.90 1.30 0.50 0.00 1.00 0.95 0.80</td>
<td></td>
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</tr>
</tbody>
</table>

Note: All tumour types were EOTP = end of treatment period, Gyn = gynaecological, SD = standard deviation
a. Five most prevalent tumour types and solid tumours other than gynaecological, breast, or lung.

Conclusions: The EORTC guideline for starting ESA therapy (Hb = 9-11 g/dL) was followed in 54.0% of patients; overall, 96.6% of patients had Hb ≤11 g/dL at enrolment. DA was effective in raising the mean Hb level from 9.20 to 10.41 g/dL; at EOTP, 43.7% of patients had Hb 9-11 g/dL and 35.6% had Hb > 11 g/dL. Overall, only 10.1% of patients required an RBC transfusion. This study is sponsored by Amgen.
The Effect Of Darbepoetin Alfa On Haemoglobin Levels And Transfusion Requirements In Chemotherapy-Treated Patients With Different Tumour Types: Exploratory Data From A Phase Ii Study

Pere Gascon¹, Heinz Ludwig², Jan Vermorken³, Lisa Hamilton⁴, Beatriz Pujol⁵
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Objectives: Several studies have shown that darbepoetin alfa (DA) therapy improves haemoglobin (Hb) levels and reduces blood transfusion needs in patients with non-myeloid cancer who experience chemotherapy-induced anaemia (CIA). The present analysis evaluates the response to DA treatment in patients with different tumour types.

Methods: This post-hoc analysis of data from a randomized, phase 3 trial evaluating two DA dosing regimens was done to assess haemoglobin (Hb) levels and transfusion rates in patients with different tumour types. Outcomes included proportion of patients achieving Hb ≥11 g/dL and transfusion incidence evaluated using Kaplan-Meier analysis. A previous report from this trial showed non-inferiority of 500 µg/kg DA every three weeks to 2.25 µg/kg DA every week for 15 weeks in reducing transfusion requirements, justifying the pooling of data from the two dosing regimens for this analysis.

Results: Of 705 enrolled patients with non-myeloid malignancies and CIA (Hb <11 g/dL), 365 patients are included in this analysis – those with the four most common tumour types: colorectal cancer (CRC), breast cancer, non-Hodgkin’s lymphoma (NHL) and non-small cell lung cancer (NSCLC) (see table). Baseline Hb levels were similar for patients with these tumour types. From week 5 to end of treatment phase (EOTP), approximately two-thirds of patients achieved Hb ≥11 g/dL, and a slightly higher proportion showed Hb values between 10 and 12 g/L. The Kaplan-Meier transfusion incidence ranged from 14% for CRC to 43% for NHL (see table).

Conclusions: For the tumour types assessed in this analysis, a high percentage of patients with CIA achieved target Hb levels and were able to avoid transfusion following treatment with DA. Further research is needed to fully characterize the response to DA treatment in patients with different tumour types. This study was sponsored by Amgen (Europe) GmbH.

Costs Associated With Routine Management Of Febrile Neutropenia In Three Tumor Types In Germany

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¹Klinikum rechts der TUM, Dpt. of Pharmacy, München, Germany, ²Klinikum rechts der TUM, Third Medical Dpt., München, Germany, ³Klinikum rechts der TUM, Dpt. of Gynecology, München, Germany, ⁴Klinikum Freising, Third Medical Dpt., München, Germany, ⁵IMS HEALTH GmbH, Health Economics & Outcomes Research, München, Germany

Objectives: Febrile neutropenia (FN) is the most frequent dose-limiting toxicity of myelosuppressive chemotherapy. To date there is little German data on the economic consequences of FN management.

Methods: Prospective, multi-centre, longitudinal, observational study with lymphoma, NSCLC and primary breast cancer (PBC) patients, enrolled consecutively at the start of 1st or 2nd line (immuno-)chemotherapy in 4 German hospitals. Patients receiving myeloablative chemotherapy with stem cell support were
excluded. ADRs were monitored according to the NCI CTCAE v3.0 and WHO causality criteria. FN was defined as fever $\geq 38^\circ$C associated with an ANC $<1\times 10^9$/L. In case of non-availability of the nadir-ANC, febrile leucopenia (FL) was assessed (LC $<2\times10^9$/L and fever $\geq 38^\circ$C). Data were collected from pre-planned chart reviews. Costs are presented from hospital perspective.

**Results:** 325 medical charts (47% lymphoma, 37% NSCLC, 16% PBC; 46% women; 38% age $\geq 65$ years) including 68 FN/FL-episodes were reviewed. FN/FL occurred in 22% of lymphoma, 8% of NSCLC, 27% of PBC and 18% of all patients. The table shows a comparison of FN/FL patient characteristics stratified by tumor type. 55 FN/FL-episodes were associated with at least one hospital stay (lymphoma n=34, NSCLC n=10, PBC n=11). Median (min-max) cost per FN/FL-episode requiring hospital treatment amounted to €2,355 (€134-€31,924) and varied between €3,056 (€135-€12,782) for lymphoma, €2,255 (€134-€12,782) for NSCLC and €1,969 (€293-€12,782) for PBC. 12 FN/FL-episodes (lymphoma n=9, NSCLC n=3) were associated with costs higher than the two-fold median (>€4,710) and accounted for 60% of total economic burden. Hospital basic services represented 60% of total costs (lymphoma 55%, NSCLC 71%, PBC 83%), followed by expenses for drugs (lymphoma 22%, NSCLC 11%, PBC 9%).

**Conclusions:** FN/FL-associated costs vary between tumor types and are highest for lymphoma patients. Cost drivers are hospitalization and drugs. The impact of clinical characteristics on asymmetric distributed costs needs further evaluation.

<table>
<thead>
<tr>
<th>FN/FL pts (%)</th>
<th>All (n=58)</th>
<th>Lymphoma (n=35)</th>
<th>NSCLC (n=9)</th>
<th>PBC (n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regimen:</td>
<td>54% CHOP-like</td>
<td>80% platinum-based</td>
<td>100% anthracycline-based</td>
<td></td>
</tr>
<tr>
<td>Female:</td>
<td>33 (57)</td>
<td>16 (46)</td>
<td>3 (33)</td>
<td>14 (100)</td>
</tr>
<tr>
<td>Age $\geq 65$:</td>
<td>22 (38)</td>
<td>16 (46)</td>
<td>3 (33)</td>
<td>3 (21)</td>
</tr>
<tr>
<td>ECOG$\geq 2$:</td>
<td>6 (10)</td>
<td>4 (11)</td>
<td>2 (22)</td>
<td>0</td>
</tr>
</tbody>
</table>

**11-107**

**Chemotherapy Induced Changes In Gene Expression Of Lymphocytes**

Manuel Morales$^{1,2}$, Eugenia Meiler$^3$, Haridian Cañete$^3$, Rebeca González$^1$, Julio Ávila$^2$, Pablo Martin-Vasallo$^3$

$^1$Service of Medical Oncology, University Hospital NS de Candelaria, Santa Cruz de Tenerife, Spain, $^2$Service Of Medical Oncology, Hospiten Rambla, Santa Cruz de Tenerife, Spain, $^3$Department of Biochemistry and Molecular Biology., University of La Laguna, La Laguna, Spain

**Objectives:** To identify genes which expression is altered by chemotherapy and to find the signalling pathways involved in non-desirable effects of these drugs.

**Methods:** We constructed and screened a cDNA subtraction library. Subtractive hybridization was performed between double stranded cDNA’s obtained from lymphocytes isolated from three patients in both situations: 1, previous to chemotherapy and 2, after undergoing three cycles of treatment with paclitaxel and carboplatin. Probes used were subtracted cDNA obtained from lymphocytes (prior and post chemotherapy) digoxigenin-dUTP labelled (Roche) using Klenow enzyme (Roche). Statement: all patients signed informed consent and the study was approved by the Ethical Committee of the hospital.

**Results:** From 800 screened colonies a total of 35 clones were selected corresponding to 24 different genes of variable expression intensity. This list of 24 includes genes coding for metabolic proteins (mitochondrial and cytosolic), signal transduction proteins and transcription factors. Examples of them are: Homo sapiens MORC family CW-type zinc finger 3 (highly represented in all intensities), Homo sapiens ataxia telangiectasia mutated (ATM) (medium grade of representation at high intensity), and Homo sapiens sortilin-related receptor, L(DLR class) A repeats-containing (SORL1), Homo sapiens protein-L-isoaspartate O-methyltransferase and Homo sapiens adducin 3 (gamma) (low intensity and low grade of representation). Most of these genes (24) show a differential expression in lymphocytes of a series of patients undergoing chemotherapy.

**Conclusions:** Some of the up-regulated genes found in this study could be adaptative changes to the non-desirable effects of chemotherapy, but most of them could be causative themselves of nasty effects, target of supportive care. *This study has been supported by a financial aid from Hospiten Grupo Hospitalario.*

**11-108**

**Factors Associated With Oncology Nurses’ Use Of National Comprehensive Cancer Network (Nccn) Clinical Practice Guidelines (Cpg)For Chemotherapy-Induced Neutropenia (Cin) And Febrile Neutropenia (Fn)**

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$^1$Columbia University, School of Nursing, New York, USA, $^2$Columbia University, School of Nursing, New York, USA, $^3$Columbia University, School of Nursing, New York, USA, $^4$Columbia University, School of Nursing, New York, USA

11-107

**Chemotherapy Induced Changes In Gene Expression Of Lymphocytes**

Manuel Morales$^{1,2}$, Eugenia Meiler$^3$, Haridian Cañete$^3$, Rebeca González$^1$, Julio Ávila$^2$, Pablo Martin-Vasallo$^3$

$^1$Service of Medical Oncology, University Hospital NS de Candelaria, Santa Cruz de Tenerife, Spain, $^2$Service Of Medical Oncology, Hospiten Rambla, Santa Cruz de Tenerife, Spain, $^3$Department of Biochemistry and Molecular Biology., University of La Laguna, La Laguna, Spain
Objectives: By means of investigator-developed survey, eligible registered nurse members of Oncology Nursing Society responded about their professional and personal characteristics and use of NCCN CPG for CIN/FN. Relationships were examined using constructs of Ajzen’s (1991) Theory of Planned Behavior (TPB). These constructs included attitude, perceived competence/confidence, subjective norm, perceived barriers and reported use of the CPG.

Methods: Data were collected from random, sample of 309 eligible Oncology Nursing Society (ONS) members with active e-mail addresses who were sent Web-based Neutropenia Oncology Nurses’ Survey (NONS) in partnership with ONS. The NONS included 21 measurable items in 5 subscales based on TPB and 20 professional and personal characteristics. Data were analyzed using appropriate non-parametric statistical tests and multiple logistic regression.

Results: Oncology nurse respondents were significantly older, reported more oncology experience, had higher educational levels, achieved advanced oncology nursing certification and held ONS chemotherapy/biotherapy provider card in comparison to ONS members. Respondents practiced in community oncology settings and not academic or comprehensive cancer centers; reported greater feelings of competence/confidence when holding advanced oncology certification and were older; fewer perceived barriers with frequent use of on-line web sites for oncology education; holding advanced oncology certification were 2.5 times more likely to use CPG than those with generalist or no certification. Significant relationships were found between higher use of the CPG and higher subjective norm and fewer perceived barriers that explained 23.4% of the variance.

Conclusions: This study was first to investigate oncology nurses’ reported practices for CIN/FN and feasibility of electronic survey methodology through ONS. Results suggested that 2 TPB subscales predicted oncology nurses’ use of NCCN CPG for CIN/FN. The findings are valuable means to develop resources by oncology nurses’ use of NCCN CPG for CIN/FN. The use of CAPN-related prescriptions (including tricyclic anti-depressants, anti-epileptics, opioids, amifostine, amitriptyline, gabapentin, glutamine, and NSAIDS) during the study period was also evaluated. Comparisons of treatment pattern measures and use of CAPN-related drugs between patients with and without CAPN used non-parametric rank sum Wilcoxon and chi-square tests.

Results: A total of 202 patients with CAPN and 201 without CAPN were included. Patients with CAPN on average received the same number of chemotherapy agents and lines of chemotherapy, and experienced a similar duration of first-line chemotherapy as did patients without CAPN. Patients with CAPN had more claims for CAPN-related drugs during the study period than non-CAPN patients.

<table>
<thead>
<tr>
<th></th>
<th>Metastatic Breast</th>
<th>Metastatic NSCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CAPN</td>
<td>Non-CAPN</td>
</tr>
<tr>
<td>Sample Size</td>
<td>101</td>
<td>107</td>
</tr>
<tr>
<td>Mean (SD) Number of distinct chemotherapy agents</td>
<td>3.0 (1.1)</td>
<td>2.9 (0.9)</td>
</tr>
<tr>
<td>Mean (SD) Number of identified chemotherapy lines</td>
<td>1.7 (0.6)</td>
<td>1.7 (0.6)</td>
</tr>
<tr>
<td>Duration of first identified chemotherapy line (days)</td>
<td>121.7 (81.9)</td>
<td>107.2 (63.8)</td>
</tr>
<tr>
<td>Duration of chemotherapy during the study period (days)</td>
<td>164.2 (97.2)</td>
<td>146.6 (80.5)</td>
</tr>
<tr>
<td>Mean (SD) Number of claims for CAPN-related drugs</td>
<td>6.3 (6.8)</td>
<td>2.5 (6.3)</td>
</tr>
</tbody>
</table>

12-109
A Pilot Study: Impact Of Chemotherapy-Associated Peripheral Neuropathy On Chemotherapy Related Treatment Patterns In Metastatic Breast And Non-Small Cell Lung Cancer Patients
Crystal Pike1, Howard Birnbaum1, Rebecca Kaufman1, Catherine Muehlenbein2, Gerhardt Pohl2, Ronald Natale3
1Analysis Group, Inc., Boston, USA, 2Eli Lilly and Company, Indianapolis, USA, 3Cedars-Sinai Medical Center, Los Angeles, USA

Objectives: Chemotherapy-associated peripheral neuropathy (CAPN) is a painful side-effect of chemotherapy that may affect decisions to continue, stop, delay, or modify treatment. This pilot investigation studied the real-world impact of CAPN on chemotherapy treatment patterns and on efforts to manage CAPN with prescription medications in metastatic breast or metastatic non-small cell lung cancer (NSCLC) patients.

Methods: Data were obtained from an administrative claims database of privately insured companies covering years 1999-2006. Metastatic breast or metastatic NSCLC patients were derived from an existing sample of patients with and without CAPN that was used to evaluate the costs associated with CAPN. Patients were excluded if their claims for chemotherapy did not allow the precise identification of treatment. CAPN was defined as claims for services indicative of peripheral neuropathy (PN) within 9-months of chemotherapy. Treatment patterns evaluated during the 12 month study period included number of chemotherapy agents used, lines of therapy received, and the duration of first-line chemotherapy. The use of CAPN-related prescriptions (including tricyclic anti-depressants, anti-epileptics, opioids, amifostine, amitriptyline, gabapentin, glutamine, and NSAIDS) during the study period was also evaluated. Comparisons of treatment pattern measures and use of CAPN-related drugs between patients with and without CAPN used non-parametric rank sum Wilcoxon and chi-square tests.

Results: A total of 202 patients with CAPN and 201 without CAPN were included. Patients with CAPN on average received the same number of chemotherapy agents and lines of chemotherapy, and experienced a similar duration of first-line chemotherapy as did patients without CAPN. Patients with CAPN had more claims for CAPN-related drugs during the study period than non-CAPN patients.
Conclusions: This pilot study provided no statistically significant evidence that CAPN is associated with perturbations to the treatment, including delaying, modifying, or switching chemotherapy. Rather, the data suggest that CAPN symptoms appear to be managed via prescription medications. * Supported by Eli Lilly

12-110
The Effect Of Leuprolide On Cognitive And Abeta Amyloid Levels In Patients Prostate Cancer With Biochemical Recurrence
Winston Tan1, Graff-Radford Neill1, Crook Julia1, Younkin Linda1, Younkin Steven1, Buskirk Steven1
1Mayo Clinic, Hematology/Oncology, Jacksonville, USA, 2Mayo Clinic, Neurology, Jacksonville, USA, 3Mayo Clinic, Biostatistics, Jacksonville, USA, 4Mayo Clinic, Neuroscience, Jacksonville, USA, 5Mayo Clinic, Neuroscience, Jacksonville, USA, 6Mayo Clinic, Radiation Oncology, Jacksonville, USA

Objectives: 1. To evaluate the effects of leuprolide on cognition in patients with prostate cancer.
2. To investigate the effects of leuprolide on the plasma beta amyloid levels in patients with prostate cancer.

Methods: We enrolled patients with prostate cancer with biochemical recurrence and measured AB40, AB42 levels with sandwiched enzyme-linked immunosorbent assay (ELISA), Mini-mental status examination (MMSE) at baseline, 2, 4 months and 1 year. None had a diagnosis of Alzheimer's.

Results: A total of 50 patients were included with a median age of 71 years (range 58-89 years). We found evidence of an increase in plasma AB40 levels at 2 months (0.11, P=0.031) and 4 months (0.11, P=.0096) compared to baseline but did not find evidence of change of plasma AB42 levels at 4 months (0.04, P=0.73) or any time point. On average, plasma AB40 levels were increased by 8% (95% CI from 2 to 14%) at 4 months relative to baseline. There were no evidence of change in MMSE scores at any time point.

Conclusions: We found elevated plasma AB40 levels in prostate cancer patients at 2 and 4 months after the start of leuprolide treatment. Further studies should be conducted to confirm the finding as well as to understand the clinical implications.

13-111
Can Omega-3 Poly-Unsaturated Fatty Acids (Pufa) Added To Total Parenteral Nutrition (Tpn) Prevent Neutropenic Colitis In Adults With Acute Myelogenous Leukemia (Aml)? A Prospective, Open Label, Single Arm, Single Center Phase II Study (Lunch 1 Trial)
Johannes Bükk1, Zeno Stanga1,2, Thomas Pabst3
1Department of Internal Medicine, Inselspital, Bern University Hospital, and University of Bern, Bern, Switzerland, 2Division of Endocrinology, Diabetes and Clinical Nutrition, Inselspital, Bern University Hospital, and University of Bern, Bern, Switzerland, 3Department of Medical Oncology, Inselspital, Bern University Hospital, and University of Bern, Bern, Switzerland

Objectives: Malnutrition in cancer patients often remains undiagnosed and untreated, and is associated with a poorer response to treatment, lower quality of life, reduced survival and higher health-care costs. These patients often experience significant psychological distress at some point over the cancer trajectory. The aim of this study is to examine the relationship between malnutrition and psychological distress in patients participating in a cancer nutrition rehabilitation program.

Methods: Enrolled patients were assessed for their nutrition status and level of psychological distress using the Patient-Generated Subjective Global Assessment (PG-SGA) and the Distress Thermometer (DT) respectively. The PG-SGA calculates a grouping of nutritional scores after combining information from food intake, weight change, nutrition-related symptoms, and performance status and categorizes patients into three distinctive classes of nutritional status; well nourished, moderately malnourished and severely malnourished. The DT is a self reported measure using an 11 point scale from 0 (no distress) to 10 (extreme distress). Simple correlations and linear regression to adjust for age and sex, between the DT and the total score and sub-scores of the PG-SGA were performed.

Results: Data from 213 patients with advanced cancer was analyzed. The DT was positively correlated with the total score of the PGSGA (higher distress with worse nutrition state; r= 0.17, p= 0.01), and especially with weight lost (r= 0.18645, p= 0.0064). Adjusting for age and sex did not contribute to the level of distress.

Conclusions: Our data suggest that nutrition status may contribute to the level of distress in patients with cancer. Evaluation of the nutrition status should be included in the evaluation of distress experienced by these patients.
adverse event with substantial mortality in the absence of standard treatment or prevention strategies. Experimental and clinical data attribute anti-inflammatory effects to omega-3 PUFA, mediated by their eicosanoid metabolites, with the strongest evidence in cardiovascular and inflammatory bowel disease. Therefore, we decided to study this effect in AML patients with chemotherapy-induced colitis.

Methods: AML patients in need of TPN were co-administered omega-3 PUFA 100 mL/d intravenously (Omegaven™, Fresenius Kabi) in addition to their standard TPN regimen. Simon’s minimax two-stage design was employed to calculate sample size and numerical cutoffs. Performance and abdominal status, serum albumin, and liver enzymes were monitored regularly. Endpoints were incidence of colitis≥3 and safety. Charts of a historical cohort (n=57) were reviewed to estimate the net effect of the intervention.

Results: Between November 2007 and August 2008, 18 subjects have been enrolled (11 males, 7 females, median age 54y, range 25-68y), 13 being evaluable for safety and efficacy endpoints. Median TPN duration was 16d, range 5-32d. Apart from transient liver enzyme elevations, Omegaven™ was well tolerated. Of the entire cohort, four patients (23%) developed colitis≥3-4. Two cases of cholecystitis, one of them fatal, and several infectious events occurred, whereas major bleeding was associated with heparin administration or sepsis. In comparison, 40% of the historical patients had suffered severe colitis, four of them with a fatal outcome.

Conclusions: The addition of omega-3 PUFA to TPN is safe and feasible: while cholecystitis is a well-documented adverse effect of TPN in general, the other events are not related to the study drug. Our observed incidence of colitis≥3 lies below the pre-specified cutoff and is lower than the historical cohort’s. A randomized controlled trial is warranted. Supported by: FreseniusKabi and Mundipharma, Switzerland

13-113
Microbiologic And Physicochemical Stability Of Parenteral Nutrition Solutions
Annabianca Calzona, Giovanni Guarany, Gerardo Miceli Sopo, Grazia Mingolla, Roberto Tazza
Sandro Pertini Hospital, Rome, Pharmacy, Rome, Italy

Objectives: Parenteral Nutrition Solutions for patients of Sandro (Azienda Sanitaria Locale Roma B) are prepared in the Clinical Pharmacy, under the responsibility of pharmacists. Pertini Hospital The aim of this study was to examine the microbiologic and physicochemical stability of Parenteral Nutrition Solutions.

Methods: Stability studies were carried out on 352 all-in-one admixtures. Stability assays consisted of the assessment of the admixture's (1) macroscopic aspect, (2) LAL test (3) Bacteriological test (E. Coli, P. aeruginosa, S. Enterici, S. Aureus, Bacillus Cereus,etc.). For the measurements, the admixtures were stored at 2 different temperatures, 4°C (storage) and 25°C (compounding), and then analyzed at a starting time, 24 hours, 48 hours, and 7 days after compounding.

Results: The investigation was held from January 2007 to November 2007, involving the screening of 352 all-in-one admixtures. The all-in-one parenteral admixtures were shown to be physically and microbiologic stable under analysis conditions, and there were no particles visible to the naked eye and there were no microbiologic contaminations

Conclusions: The admixtures examined were relatively chemically and microbiologic stable for 72 hours. The specific procedure will be published in the guidelines of Parenteral Nutrition Preparation.

13-114
Prescription Appropriateness Evaluation In The Equipment Of Parenteral Nutrition Solutions
Anna Bianca Calzona, Giovanni Guarany, Gerardo Miceli Sopo, Grazia Mingolla, Roberto Tazza
Sandro Pertini Hospital, Rome, Pharmacy, Rome, Italy

Objectives: To value the appropriateness in prescriptions of Parenteral Nutrition Solutions administrated to patients of Sandro Pertini Hospital (Azienda Sanitaria Locale Roma B) and analyse the reduction of the clinical risk sequel of introduction of the new procedure in the Centralised Unit.

Methods: Prescriptions by Asl specialists are analysed by pharmacists in the Centralised Unit: parameters such as osmolality, content (in grams) of nitrogen, glucose and lipids, E/T index, composition of electrolytes, components compatibility are controlled. The specialist is informed of errors to correct the prescription. The object of our study was number and type of indications and modifications of the original prescription. The investigation was held in 2005, involving the screening of 2463 medical prescriptions by 18 hospital departments. The 80.9% of prescriptions was by medical doctors division. Prescriptions are then elaborated using a software linked to an automatic filling system.

Results: The analysis shows 419 erroneous prescriptions. The subdivision in % is defined as follows: 70.1% due to the hiperosmolality; 10.9% due to the quantity in grams of nitrogen being omitted, 9.9% to mistakes in the transcriptions of electrolyte values. The remaining 8.8% were caused by errors in the lipids/total calories and 0.7% were caused by errors in the
transcription of patient personal details.

Conclusions: Equipment of Parenteral Nutrition Solutions under the direct responsibility of the pharmacist allowed to avoid errors of administration in the 17.2% of cases.

13-115
Patients Of Intensive Care Unit: Parenteral Nutrition Solutions
Anna Bianca Calzona, Giovanny Guarany, Gerardo Miceli Sopo, Grazia Mingolla, Roberto Tazza, Rossella Distilo
Sandro Pertini Hospital, ASL RMB, Pharmacy, Rome, Italy

Objectives: To value the Nutrition Support in Parenteral Nutrition Solutions administrated to patients of Intensive Care Unit of Sandro Pertini Hospital (Azienda Sanitaria Locale Roma B).

Methods: In the Centralised Unit of the Clinical Pharmacy of Sandro Pertini Hospital are equipment by pharmacists Parenteral Nutrition Solutions for patients of Intensive Care Unit. The investigation was held in five years, since 2002 to 2007, involving the screening of 125 Parenteral Nutrition Formulations in 2005, 2410 in 2006, 2755 in 2007. Before 2005 was administrated to critically ill patients “standard care” (glucose infusion). The analysis was conducted of studies comparing Parenteral Nutrition Solutions to “standard care”

Results: The analysis shows that, on average are administrated to patients of Intensive Care Unit: * 46.7g/die of protein, 145.4g/die of glucose and 37.9g/die of lipids in 2002; * 53.0g/die of protein, 271.9g/die of glucose and 45.7g/die of lipids in 2006; * 62.8g/die of protein, 232.1g/die of glucose, and 52.6g/die of lipids in 2007. On average the Kilocalories administrated to patients are 864 Kcal/die in 2005, 1423 Kcal/die in 2006 until 1395 Kcal/die in 2007.

Conclusions: Patients with critical illnesses are at nutrition risk. Equipment of Parenteral Nutrition Solutions, under the direct responsibility of the pharmacist, allowed to administrated to critically ill patients all nutrient in an amount adequate to meet the daily requirements.

13-116
Nutritional Status In Pre-Operative Oral Cavity Cancer Patients In Taiwan
Yu-Ching Chen, Yen-Ju Chen, Yeur-Hur Lai
College of Medicine, National Taiwan University, Department of Nursing, Taipei, Taiwan

Objectives: Nutrition status is one of the major factors related to cancer patients’ quality of life and responses to anti-cancer treatments. Thus, pretreatment nutrition assessment is essential for a better cancer care outcome. However, limited information has known about oral cavity cancer patients’ nutrition status before surgery. The purpose of the study was to explore the nutrition status, symptom severity and their relationship in pre-operative oral cavity cancer patients in Taiwan.

Methods: A Cross-sectional survey was conducted to recruit oral cavity cancer patients from a medical center in Northern Taiwan. Patients were interviewed during 1 to 3 days before surgery by a trained oncology research nurse. Nutrition status was assessed by Mini Nutrition Assessment (MNA); and the symptom status was assessed by Symptom Severity Scale (SSS). Patients’ background and physical condition were also assessed by background information form. Nutrition status was categorized as three levels (Protein-calorie undernutrition, at risk of malnutrition, and adequate nutrition status) based on MNA cutoff point.

Results: We recruited 65 oral cavity cancer patients in this study. Based on the MNA cutoff point, 50.8% of subjects were at risk of malnutrition and 7.7% of patients had protein-calorie under-nutrition. Nutrition status was significant associated with total symptom severity. Selected individual were examined for their relationship with nutrition level. The results showed that nausea, poor appetite, swallowing difficulty, constipation, and insomnia were those most significant symptoms related to patients’ nutrition status.

Conclusions: The results suggest that more than half of oral cavity cancer patients had at risk of malnutrition before surgery. It suggests that preoperative nutrition status should be enhanced in oral cavity cancer patients to promote the better treatment outcomes.

13-117
Impact Of A Multidisciplinary Cachexia Clinic At A Tertiary Cancer Hospital On Patient Related Outcomes.
Shalini Dalal, David Hui, Zohra Noorruddin, Egidio DelFabbro, Gina Freer, Eduardo Bruera
U.T. MD Anderson Cancer Center, Palliative Care and Rehabilitation Medicine, Houston, USA

Objectives: Cancer cachexia is associated with symptom distress and adversely impacts survival and quality of life. Treatments focused on appetite stimulation alone have been largely unsuccessful. Our study objective was to evaluate if a multidisciplinary care cachexia clinic improves symptoms, anthropometric measurements and survival.
**Methods:** We conducted a retrospective chart review of 159 consecutive patients who underwent structured multidisciplinary assessments and management at our cachexia clinic. We included 89 (56%) patients with two sets of body composition analysis (Tanita) available within 2 months of initial consultation. Demographics, CRP, weight loss, symptom scores (assessed by Edmonton Symptom Assessment Scale, ESAS), survival data were analyzed. Symptom distress scores (SDS) were obtained from summation of individual scores on ESAS items. Median values were used in analysis.

**Results:** Baseline characteristics at initial consultation included age 60 years, 42% males, majority (45%) with gastrointestinal malignancies, CRP 13.6 (Q1-Q3 5.1-34.9), BMI 21.7, appetite score 6, fatigue 5, depression 2, anxiety 2, wellbeing 5, and SDS 32. Patients presented with percentage weight loss of 7.3% (Q1-Q3 5.7-9.6), and weight loss rate of 0.32 kg/week (0.18-0.58) in the preceding 59 days. At follow-up (median 39 days after initial consultation) the rate of weight loss decreased to 0 kg/week (Q1-Q3 -0.25-0.26), with significant improvements in appetite (p <0.001), anxiety, wellbeing (p <0.01), fatigue, depression (p 0.02) and SDS (p <0.01). Overall median survival was 381 days (240-521). Patients who maintained or gained weight (group A) survived longer (518 days) than those (group B) who lost weight (239 days, logrank 0.049). Characteristics of the two patient groups are shown in table 1. Changes in fat or fat free mass did not contribute to survival.

**Conclusions:** This study provides preliminary evidence that our multidisciplinary cachexia clinic has the potential to improve symptoms and weight measures in cachectic cancer patients, and that these improvements can influence survival.

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>42</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>21.7</td>
<td>21.7</td>
<td>0.69</td>
</tr>
<tr>
<td>Appetite score</td>
<td>6</td>
<td>6</td>
<td>0.56</td>
</tr>
<tr>
<td>Fat free mass</td>
<td>3.8 kg/m²</td>
<td>3.5 kg/m²</td>
<td>0.03</td>
</tr>
<tr>
<td>Weight loss %</td>
<td>7.3%</td>
<td>7.8%</td>
<td>0.97</td>
</tr>
<tr>
<td>SDS</td>
<td>32</td>
<td>30</td>
<td>0.78</td>
</tr>
</tbody>
</table>

**Conclusions:** Nutritional status has significant influence on acute radiation reactions in head& neck and esophageal cancer, though has no statistically significant impact on pelvic radiotherapy.

**13-119 Support And Information From Nurses Could Increase Nutritional Status And Decrease Anxiety.**

Kerstin Lugnet1, Anncarin Svanberg2
150c, hematology, Uppsala, Sweden, 250c, hematology, Uppsala, Sweden

**Objectives:** Malnutrition can lead to cancer cachexia, a debilitating and lifethreatening syndrome for patients with haematological diseases treated with chemotherapy/radiation. Treatment itself often leads to Objective with the present study was to emphasise patients subjective experiences of the eating situation. an increased risk of vomiting/nausea, low calorie intake and weight loss. A challenge at the haematological ward is nutrition. It is stressful for the patients when they can’t
eat. There is a lack of knowledge concerning the importance of nutritional intake among patients with haematological diseases and therefore it is important to find out the subjective experiences of the patients eating situation. There is a lack of knowledge and support from hospital staff about nutritional counselling to the haematological patient.

**Methods:** Sixteen patients, >18 years, treated at a haematological ward for a minimum of 4 days at a period of 2 weeks 2007, were included consecutively. They were randomised to experimental group (EXP) with expanded information about nutrition/calorie intake and presented to extra opportunities to eat according to a specific protocol. The EXP group kept a diary about eating and daily state of gastrointestinal problems. The control group (CTR) received standard treatment regarding nutrition. Weight and calorie intake was collected from the patient’s medical and nursing record (presented at EBMT April 2008).

**Results:** The result showed that the EXP group kept a higher calorie intake over study period Both groups maintained weight. Diary notes showed loss of appetite and nausea/vomiting increased. No mouth problems but some swallowing difficulties occurred. Half of the EXP group felt some anxiety.

**Conclusions:** Standard nutritional care at the ward needs to be changed. More support and information from nurses could increase nutritional status and decrease anxiety.

**13-120**

Changes In Frequency And Severity Of Anorexia According To The Conditioning Regimens In Cancer Patients Underwent High Dose Chemotherapy And Stem Cell Transplantation

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Gulhane Medical Academy, Department Of Medical Oncology, Ankara, Turkey

**Objectives:** This study was done to evaluate the frequency and severity of anorexia in the early period of stem cell transplantation (SCT) and the relation of conditioning regimens with anorexia.

**Methods:** Patients with hematologic or solid tumors who underwent high dose chemotherapy (HDC) were asked to score anorexia severity daily from the first day to the tenth day of stem cell infusion. Patient-reported scoring was performed according to a five-grade scale (0: no symptom; 1: mild; 2: moderate; 3: severe; 4: very severe). Total anorexia score (TAS) was defined as the addition of symptom severities of anorexia in 10 days. A total of 108 SCT (95 autologous and 13 allogeneic) patients, 76 men (70%), were included to the study. Median age of patients was 32.5 (range 15–78) years. The most frequent diagnosis were non-Hodgkin’s lymphoma (31%, n=33), Hodgkin’s lymphoma (19%, n=21), leukemia (12%, n=13), and Multiple Myeloma (11%, n=12). BEAM (n=43), ICE (n=28), Melphelan 200 mg/m² (n=12) and TBI+C (total body irradiation+Cyclophosphamide) (n=25) were used as conditioning regimens.

**Results:** All of the patients experienced anorexia at any grade. TAS in the sixth day was higher than TAS in the first day (p<0.001). TAS was not related to the diagnosis or gender (p>0.05). When compared BEAM with ICE regimen TAS was not significant. TAS at M200 regimen was higher than TAS at BEAM and ICE (p<0.05). The mean percentages of patients who scored severe or very severe anorexia in 10 days was 23.3% in BEAM, 25.4% in ICE, 54.3% in M200 and 24.8% in TBI+C groups.

**Conclusions:** Patients experience anorexia frequently following HDC. Determining of the timing and severity of anorexia in each conditioning regimen may help in planning when to support patients in the early period of SCT.

**13-121**

Nutritional Status Of Advanced Lung Cancer Patients And Its Effect On Survival

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McGill University, Cancer Nutrition Rehabilitation Program, Montreal, Canada

**Objectives:** Weight loss and malnutrition are common in patients with non-small cell lung cancer (NSCLC) and have a negative impact on survival. The Patient Generated Subjective Global Assessment (PG-SGA) is a validated tool for screening and triaging the nutritional status of cancer patients.

**Methods:** We screened 118 newly diagnosed advanced NSCLC outpatients prior to any treatment using the PG-SGA. Patients were triaged into 4 Nutritional Triage (NT) groups: scores of 0-1 (NT I) required no intervention, 2-3 (NT II) required education, 4-8 (NT III) required nutritional intervention and 9 or greater (NT IV) were in critical need of intervention. We investigated the association between NT groups and weight loss, survival, CRP, LDH and albumin.

**Methods:** We screened 118 newly diagnosed advanced NSCLC outpatients prior to any treatment using the PG-SGA. Patients were triaged into 4 Nutritional Triage (NT) groups: scores of 0-1 (NT I) required no intervention, 2-3 (NT II) required education, 4-8 (NT III) required nutritional intervention and 9 or greater (NT IV) were in critical need of intervention. We investigated the association between NT groups and weight loss, survival, CRP, LDH and albumin.
Nutritional Risk Screening Predicts Tumor Response
In Lung Cancer Patients

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Objectives: We evaluated relationships between nutritional risk screening and both the tolerance and tumor response after therapy of newly diagnosed lung cancer.

Methods: Nutritional Risk Screening 2002 (NRS) adapted for oncological patients was used to assess the risk of undernutrition in 122 lung cancer patients. The risk was evaluated on the 0-6 point scale according to common signs of nutritional status (weight loss, BMI, dietary intake) and tumor parameters.

Results: Mean age was 62.5 years, males/females 84/38. Tumor stages from I to IV were classified in 11.5 %, 5.7 %, 33.7 % and 45.8 % patients, respectively. Non small cell lung cancer was diagnosed in 68 % of patients. Deterioration of nutritional status was only mild in most patients with median BMI 26.5 kg/m² and median weight loss before treatment 5.4 %. Acceptable score of NRS 0-2 points was found in 50.0 %, while in 46.7 % the score of 3-5 suggested the risk of malnutrition. The rate of treatment response evaluated by imaging techniques was significantly higher in patients with acceptable compared to high risk, 70 % versus 45 %, respectively (p=0.005). In patients with the highest NRS (4-5 points) response rate was only 21 % (p

Conclusions: Nutritional risk screening is a significant predictor of tumor response in lung cancer patients. Worse response in patients with high risk of undernutrition is probably not caused by higher toxicity of anticancer therapy. The question remains whether concurrent nutrition support has the potential to improve tumor response in patients with high risk of undernutrition.

Meals And Motivation -A Nutritional Project In Hematological Clinic

Lotte Vittinghus Stokbro¹, Anna Eckereth², Vibe Rasmussen²
¹RN, Hematological Clinic, Copenhagen, Denmark, ²RN, Hematological Clinic, Copenhagen, Denmark, ³RN, MEd, Hematological Clinic, Copenhagen, Denmark

Objectives: Previous studies has shown that every fifth patient admitted to Danish Hospitals is either malnourished or at nutritional risk. Only 25-30 % of patients get more than 75 % of their need of energy and proteins fulfilled. The care of one specially trained nutritional nurse has proven to increase the food intake of hematological inpatients at risk of malnutrition (21 %-60%). The aim of this project is to improve hematological inpatients’ nutritional status primarily with food and drink by involving the entire nursing staff.

Methods: A 2-year four-phase intervention project was designed to focus on nurse development in order to engage and strengthen the nursing staff’s competences in relation to nutrition therapy to hematological inpatients at risk of malnutrition. 12 nurses at 3 hematological units were included and went through education, questionnaires, audits, workshops, and focus group interviews in order to plan the best possible practice for the nutritional care at the units and encourage and motivate the entire nursing staff. Measuring of food intake, enteral nutrition, parenteral nutrition and i.v. fluids were recorded on a daily basis before project start (historical control group) and during the project (intervention group).

Results: 151 patients at risk of malnutrition were included in the project and were measured in 1258 admission days. In the intervention group, 57,1 % of the patients fulfilled ≥75 % of their need for energy and proteins compared with 38,4 % in the control group (p=0,006). Looking only at food intake, 31,2 % of the intervention group fulfilled ≥ 75% of their need for energy and proteins.
energy and proteins compared with 16.4% in the control group (p=0.007).

**Conclusions:** By involving the entire nursing staff, hematological inpatients at risk of malnutrition can improve their food intake during admission.

**14-124**

**Problem Solving Among Oncology Nurses**

Özlem Aslan¹, Yavuz Sanisoglu², Mesut Akyol³
¹Turkish Naval Forces, Department of Health, Bakanliklar/Ankara, Turkey, ²Turkish Ministry of Health, Department of Evaluation and Monitoring, Kizilay/Ankara, Turkey, ³Gulhane Military Medical Academy Hospital, Department of Biostatistics, Etilk/Ankara, Turkey

**Objectives:** Problem solving is a critical process. Oncology nurses face with various challenging problems during cancer care process which need particular consideration. The aim of this research was to determine the problem solving skills of oncology nurses and to define the relationships between demographic variables and these skills.

**Methods:** It was planned as a descriptive and cross-sectional study. 117 oncology nurses working in an oncology research and education hospital were included in the study. Data were collected with the Problem Solving Inventory (PSI) developed by Heppner and Peterson, and a demographic data form. Descriptive statistics, Mann-Whitney U test, student’s t test, Kruskall-Wallis Variance Analysis and ANOVA test were used to analyze the data by using SPSS program. Total PSI scores and subscale scores of oncology nurses were standardized in a 100 points scale in order to be understood easily. Higher points indicated inadequate level of problem solving. In the reliability analysis of PSI, Cronbach’s alpha was 0.87.

**Results:** The mean age was 31.63 ± 6.03 years. The mean working duration in oncology was 70.73 ± 75.09 months. The mean PSI score of nurses was 42.01 ± 10.43 which indicated adequate level of problem solving skill. The mean PSI scores and the mean “Avoidance” subscale scores of nurses in the “30 years and less” age group were statistically higher than those of nurses in the “31 years and above” age group (p<.05). Total PSI scores and subscale scores didn’t differ by education, marital status, working duration in nursing, working duration in oncology, having any child (p>.05).

**Conclusions:** This study implied that oncology nurses had an adequate level of problem solving skill. However the level of problem solving of oncology nurses can be reached to the higher levels by planned educational activities.

**14-125**

**The Effect Of A Skin Care Project On Radiation Patients Care Competencies Among Nurses**


Siriraj Hospital, Faculty of Medicine, BKK., Thailand

**Objectives:** to evaluate competency for supportive care on radiation patients 'skin management.

**Methods:** The study population for pilot study was nurses who had experienced 1-3 years in faculty of Medicine Siriraj Hospital and had attended Competency Fair Program emerged on 5 February 2009. A set of questionnaires was sent out for before and after test. The returned completed questionnaires according to inclusion criteria were 82 cases. The data were analyzed in term of paired T test, percentage, mean, standard deviation (S.D.).

**Results:** There were many nurses from many divisions (Radiological Nursing Division 24.4%, Surgical and Orthopedics Division 20.2%, Private Patient Nursing Division 18.5%, Outpatient Nursing Division 13.4% and others 23.5%). The skin care competency questionnaire composed of 10 sub-items of Radiological Nursing Division’ s Gold Standard Inventory had Mean₁ = 7.9, S.D.₁ = 1.4, Min₁-Max ₁= 2-10 for pre-test but Mean₂ = 9.2, S.D.₂ = 0.7, Min₂ -Max ₂= 8-10 for post- test after this project intervention ). The paired T- test elicited a significant level at p <0.0001.

**Conclusions:** After the project intervention, their scores fell with in The Pass Level and 99.2 % of 82 cases could obtain the gold standard of organization ( each total score per one nurse must ≥ 90 % of total score). This competency workshop project effected on nurse competency not only through positive effects on this fair, non-distress program, but also through the ability to facilitate the more traditional learning organization as a catalyst to achieve competency of enhanced professionalism by building constitutive capacity around positive aspects, rather than focusing on formal classroom. The findings may enable the nursing organization ( particularly in action learning organization for supportive care patients ) to focus more attention on seeking many-strategies to improve supportive care for all.

**14-126**

**Oncology Risk Management**

Anna Bianca Calzona, Giovanni Guarany, Gerardo Miceli Sopo, Grazia Mingolla, Roberto Tazza

Sandro Pertini Hospital, ASL Roma B, Pharmacy, Rome, Italy
Objectives: Accordino to “Associazione Italiana di Oncologia Medica” (AIOM) the first cause of error in Hospitals, 40%, is administration of erroneous drugs. To limit clinical risk in oncology, in the Clinical Pharmacy of Sandro Pertini Hospital (Azienda Sanitaria Locale Roma B) has maked a new method to analyse and reduce this type of error.

Methods: Prescriptions by Asl specialists are analysed by pharmacists in the Centralised Unit. Are controlled parameters such as patient personal details (age, sex, corporeal surface, pathology); therapeutical protocol (correspondence between pathology); control of drugs and theirs dosage in therapeutical protocols; administration times; chemical - physical compatibility and stability of preparations. The specialist is informed of errors to correct the prescription. The object of our study was number and type of indications and modifications of the original prescription. The investigation was held in June 2006 to May 2007, involving the screening of 3271 medical prescriptions by DH Oncologia, Oncologia Reparto, DH Ematologia, Ematologia Reparto, Ematologia Trapianti, I.M.E. Prescriptions are elaborate using a software.

Results: The analysis shows 3271 prescriptions, about which 419 are erroneous. The subdivision of error in % is defined as follows: 58.6% due to used of solvents incompatible with drugs; 12.4% due to low stability of preparations (etoposide >0.4mg/ml), 18% erroneous dosage of drugs (correspondence between the pathology and corporeal surface), 6.5% erroneous administration times, 4.5% incomplete protocols (patient personal details, dosage...)

Conclusions: Equipment of oncology therapy under the direct responsibility of pharmacist allowed to avoid errors of administration in 22% of cases.

14-127 Health Technology Assessment Trastuzumab
Anna Bianca Calzona, Giovanni Guarany, Gerardo Miceli Sopo, Grazia Mingolla, Roberto Tazza, Daniela Checquolo
Sandro Pertini Hospital, ASL RMB, pharmacy, ROME, Italy


Results: A Markov model was used to synthesize data for the study “Cost Effectiveness of Adjuvant: Trastuzumab in Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer”. The Markov model is able to value the consequences of the therapy about healthy and resources in the future. The Markov model calculated that adjuvant trastuzumab cause an incremental cost-utility ratio of 17.536€ for patient (14.861 € per QALY), which is lower than the common threshold values (in Italy 12.000-60.000€ for Messori et al.). From August 2006, at Sandro Pertini Hospital, about 41 women were undergo to treatment with adjuvant Trastuzumab. The incremental cost-utility ratio for patient compared to standard chemotherapy, for an year, was of 8060€ (6830€ per QALY)

Conclusions: Trastuzumab extend the clinical advantage of adjuvant chemotherapy to an appropriate cost for the value added: the authors concluded that, in the longer term, adjuvant trastuzumab is a cost-effective therapy for women with early breast cancer, better than expected.

14-128 Cancer Navigation: Improving Access To Supportive Care Throughout The Cancer Journey
Sandra Cook1 2
1Cancer Care Nova Scotia, Supportive Care, Halifax, Canada, 2Canadian Partnership Against Cancer, Cancer Journey Action Group, Toronto, Canada

Objectives: Cancer imposes tremendous burdens in many areas of life for both the person with cancer and their care givers. Psychosocial distress, including anxiety and depression, changes in social roles, work life and relationships, as well as financial, physical and instrumental challenges all take a toll. Satisfaction surveys suggest that while persons with cancer are relatively satisfied with the physical/medical care, they are far less satisfied with the ways such programs address the psychosocial aspects of cancer. In Nova Scotia, one response to meet the supportive care and psychosocial needs of persons experiencing cancer was the creation of a Cancer Navigator role. This health professional, an oncology nurse, provides practical, counseling and education interventions. This presentation will discuss the key findings and conclusions about cancer navigation and how the program has continued to evolve to become an innovative model to improve access to supportive care.

Methods: A program evaluation was conducted to determine the effectiveness and impact of the program. Both qualitative and quantitative methods were used to determine key findings and draw conclusions. Taped discussion of focus groups and
review of journey maps were analyzed and compared to similar discussions recorded in districts without cancer navigators. A telephone patient survey and data base created to track issues and concerns were analysed using SPSS.

Results: The evaluation concluded that the role was extremely successful in dealing with the informational, emotional and logistical challenges associated with cancer. It has improved the quality and consistency of cancer care and have become an important source of support in dealing with the emotional turmoil, educational needs and logistical challenges associated with cancer.

Conclusions: The evaluation concluded that Cancer Patient Navigation has demonstrated that it is an innovative and successful program that has improved access to supportive care, improved integration and continuity of care and made more efficient use of scarce resources. The program should be widely implemented.

14-129
Family Care Needs, Quality Of Life, And Symptoms Of Anxiety And Depression Of Family Members Of Cancer Patients
Nanna Fridriksdóttir1, Sigridur Gunnarsdóttir1,2, Thorunn Saevarsdóttir3, Arndis Jónsdóttir1, Kristín Lára Ölafsdóttir1, Hrefna Magnúsdóttir1
1Landspitali University Hospital, Medical & Radiation Oncology, Hematology & Palliative Care, Reykjavik, Iceland, 2University of Iceland, Faculty of Nursing, Reykjavik, Iceland

Objectives: It is well known that the challenges of cancer affect the well-being of family members of cancer patients. The needs of family members have been well documented but many are often unmet. One important goal of oncology nursing is to identify the needs of the patient’s family members in order to fulfill the major needs and in order to achieve the best possible quality of life (QOL). The purpose of this study is to assess the needs of family members of cancer patients; to evaluate to what extent those needs are met; to evaluate the relationship between needs and feelings of anxiety and depression, and to evaluate the relationship between needs and QOL.

Methods: Descriptive, correlational. Participants: 300 adult family members of cancer patients receiving treatment and care at Landspitali University Hospital, the Division of Medical & Radiation Oncology, Haematology & Palliative Care. Instruments: Family Inventory of Needs (FIN), Quality of Life Scale (QOLS), and Hospital Anxiety and Depression Scale (HADS).

Data Analysis: Descriptive and inferential statistics.
can be demanding for families and that nurses have to identify ways to strengthen their ability in providing effective ways to support PCs.

14-131
The Psychometric Properties Of The Icelandic Version Of The Distress Thermometer And Problem List
Sigridur Gunnarsdottir1,2, Nanna Fridriksdottir1, Svandis Iris Halfdanardottir1, Gudbjorg Gudmundsdottir1
1Landspitali University Hospital, Medical & Radiation Oncology, Hematology and Palliative Care, Reykjavik, Iceland, 2University of Iceland, Faculty of Nursing, Reykjavik, Iceland

Objectives: Family members of cancer patients are at risk of developing both psychological and physical problems. Studies have shown that spouse caregivers of cancer patients report as much or even higher psychological distress than patients. Therefore, it is as important to screen for distress experienced by family members as well as patients. In preparation of the integration of NCCN’S clinical practice guidelines on Distress Management in Cancer Patients, the psychometric properties of the Distress Thermometer were evaluated for use with cancer patients at Landspitalinn University Hospital in Iceland. The DT is a single-item screening measure in the form of a thermometer where each person rates their level of distress by marking from 0 (no distress) to 10 (extreme distress) and answers a Problem List where they can choose from a 35 item list issues that have been problematic for them in the past week. The instrument was found to be both reliable and valid. In this study the goal is to evaluate the reliability, validity and feasibility of the DT among family members of cancer patients.

Methods: The design is descriptive, correlational. Participants are 300 adult family members of cancer patients receiving treatment and care at Landspitalinn, the Division of Medical & Radiation Oncology, Haematology & Palliative Care. The instruments used are the Distress Thermometer and Problem List (DT), Hospital Anxiety and Depression Scales and Quality of Life Scale.

Results: This study is part of a larger research project which started in October 2008 and is ongoing. Data collection is estimated to be completed in March 2009. Validity of the DT will be established by comparing it to results from HADS and the Quality of Life Scale. Descriptive statistics and correlations will be presented and a Roc analysis will be performed on the DT.

Conclusions: To be completed in March 2009.

14-132
Effects Of A Structured Evidence-Based Nursing Intervention For Reduction Of Chemotherapy-Induced Anorexia, Nausea And Emesis: Results Of A Cluster-Randomized Multi-Centre Trial
Patrick Jahn1,2, Margarete Landenberger1, Petra Renz1,3, Anette Thoke-Colberg2, Ingrid Horn1
1Martin-Luther-University Halle-Wittenberg, Department for Health and Nursing Science, Medical Faculty, Halle (Saale), Germany, 2Munich Technical University, University Hospital rechts der Isar, München, Germany, 3University Hospital Halle (Saale), Halle (Saale), Germany

Objectives: The purpose of this present study was to evaluate Self Care Improvement through Oncology Nursing - SCION program to reduce distressing anorexia, nausea and emesis (ANE) in cancer patients undergoing chemotherapy.

Methods: 208 patients receiving chemotherapy with moderate to high emetogenic potential participated in a cluster randomized trial on 14 wards in 2 German university hospitals. Additionally to standard antiemetic treatment, patients from the intervention wards received, the SCION program consisting of 4 modules: advisory consultation, optimizing emesis prophylaxis, nutrition counseling, and relaxation. Patients from the control group received standard antiemetic treatment and standard care. Primary outcome was the group difference in ANE intensity assessed by Common Terminology Criteria for adverse events (CTCAE).

Results: The SCION program did not result in a significant difference in the incidence of ANE-Symptoms as compared to standard care: mean difference on CTCAE-Scale was 0.24 pts (95%CI, -1.17 pts. to 1.66 pts; P=0.733). No difference could be found regarding patients knowledge of side effects, self care interventions and -agency. Quality of life was significantly better for patients in the control group, mean difference 10.2 pts (95%CI, 1.9 to 18.5; P=0.017).

Conclusions: Contrary to our expectations, the groups did not differ in ANE intensity, caused by the overall low acute or delayed symptom intensity. Symptom hierarchy in cancer patients alters and challenges nursing interventions targeting the patients’ self care strategies.

14-133
Anxiety Of Endocrine Therapy Relation To Menopausal Symptoms In Japanese Women With Breast Cancer
Midori Kamizato, Yuko Aihara, Kaori Saeki, Sayuri Jahana
Okinawa Prefectural College of Nursing, Nursing, Okinawa, Japan

Objectives: The purpose of this present study was to evaluate Self Care Improvement through Oncology Nursing - SCION program to reduce distressing anorexia, nausea and emesis (ANE) in cancer patients undergoing chemotherapy.

Methods: 208 patients receiving chemotherapy with moderate to high emetogenic potential participated in a cluster randomized trial on 14 wards in 2 German university hospitals. Additionally to standard antiemetic treatment, patients from the intervention wards received, the SCION program consisting of 4 modules: advisory consultation, optimizing emesis prophylaxis, nutrition counseling, and relaxation. Patients from the control group received standard antiemetic treatment and standard care. Primary outcome was the group difference in ANE intensity assessed by Common Terminology Criteria for adverse events (CTCAE).

Results: The SCION program did not result in a significant difference in the incidence of ANE-Symptoms as compared to standard care: mean difference on CTCAE-Scale was 0.24 pts (95%CI, -1.17 pts. to 1.66 pts; P=0.733). No difference could be found regarding patients knowledge of side effects, self care interventions and -agency. Quality of life was significantly better for patients in the control group, mean difference 10.2 pts (95%CI, 1.9 to 18.5; P=0.017).

Conclusions: Contrary to our expectations, the groups did not differ in ANE intensity, caused by the overall low acute or delayed symptom intensity. Symptom hierarchy in cancer patients alters and challenges nursing interventions targeting the patients’ self care strategies.
**Objectives:** Women with breast cancer may experience treatment-induced menopausal symptoms during endocrine therapy or natural menopause. Also, they might feel fear of endocrine therapy to breast cancer because of lacking estrogen. The purpose of this study is to describe anxiety of endocrine therapy and the relation to menopausal symptoms during endocrine therapy to breast cancer.

**Methods:** Design: This is a descriptive, cross-sectional study of breast cancer patients during endocrine therapy. Setting: A national medical cancer center and research cancer institute hospital in Japan. Sample: One hundred and sixty two adult breast cancer patients with endocrine therapy. Methods: Breast cancer patients at the outpatients ward completed self-recording questionnaire: Simplified Menopausal Index which call SMI (10 items), Anxiety of Endocrine Therapy Questionnaire (11 items) and demographic or medical data from medical records. Descriptive analysis and chi-square test used for date. SMI scores were divided to two groups (mild or severe). The two group’s SMI scores and anxiety of endocrine therapy were analyzed.

**Results:** The mean time since after surgery was 3.3+/-.5.9 years. “I feel fear to side effect for hormonal therapy” was 82.7 %, “I feel fear to taking hormonal therapy such a long period” was 82.1 %, “I feel very painful in symptoms of menopause” was 63 %, “I am concern about cervical cancer” was 89.5 %, “I am concern about gaining weight” was 75.4 %, “I am concern about osteoporosis” was 75.2 %, “I am concern about having period time again after finishing hormonal therapy” was 58.9 %. High SMI scores group which mean severe menopausal symptom were significantly high percent of anxiety of endocrine therapy.

**Conclusions:** Nurses or medical providers need to pay attention for patient’s anxiety during endocrine therapy and inform to them about right endocrine therapy’s knowledge and self-care management.

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**Objectives:** Describe the substance abuse and smoking behavior of the street children.

**Methods:** Descriptive cross sectional study through convenience sampling technique.

**Results:** Among the 100 conveniently chosen street children, 74 were Indians and 26 were Nepalese. Among the total 70 substance abusers, 49 had history of alcohol intake, 48 had history of smoking, 42 had history of tobacco chewing and 3 had history of injectable drugs as mentioned in figure 9. Similarly, fifty-one subjects had history of addiction to various other drugs like rati, pan, silo Chan, gutkha, Tab. alprazolam and cannabis. The minimum age of beginning alcohol was 7 years in 2 subjects, while 8 subjects consumed alcohol only once in life. Thirty-nine subjects continued abusing alcohol. Majority of the subjects i.e.33, started smoking at the age of 14 and 13 and 12 years i.e. 9, 8 and 6 subjects. The minimum age to start smoking was 6 years by one subject and rest started at various years. The minimum age to start tobacco chewing was 7 years where as one subject was unaware of the age he had started tobacco chewing. All the 42 subjects continued abusing tobacco.

**Conclusions:** 1. Substance abuse in the form of drugs or tobacco is very common among the street children. 2. High risk behaviour for Sexually transmitted diseases and cancer are common among the street children.

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**14-135**

**Supporting Patients With Chemotherapy Induced Peripheral Neuropathy**

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**Objectives:** The incidence of chemotherapy-induced peripheral neuropathy is increasing due to the development of more neurotoxic drugs and due to the fact that patients are living longer and receiving multiple chemotherapy regimens. The purpose of this study is to critically review current approaches to supporting patients suffering by neurotoxicity caused by chemotherapy.

**Methods:** A critical review. Source material were MEDLINE and CINHALL databases. The material of the study was selected on the basis of published articles and books during the period 1985-2007.

**Results:** Nurses play an important role in the early detection of neurotoxicity, the success of treatment, and the patient’s quality of life both during and after treatment. Nurses support the patients with peripheral...
neuropathy in three levels. The first level is the assessment of the patient, the second level is the prevention and the treatment of peripheral neuropathy and the third level is the patient’s education.

**Conclusions:** Neurotoxicity as a side effect of specific chemotherapeutic drugs, is an important factor of the quality of patient's life. Nursing interventions should be aimed at preventing, detecting and managing neurotoxicity. But all of these objectives are directly related to the education of the patient and the family. Proper education is achieved only through the systematic study of literature and research data and of course the full and effective evaluation of patient's needs. The approach of the patient with Peripheral Neuropathy is a very important challenge for the oncology nurses of the future.

14-136
The Clinical Nursing Practice Guideline To Manage Sleep Problems In Patients With Breast Cancer Undergone Chemotherapy
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**Objectives:** To develop a clinical nursing practice guideline (CNPG) for managing sleep problems in breast cancer patients undergoing chemotherapy. Sleep problem management can promote healthy physiological function and help patients in adapting to chronic illness, treatment and altered life styles which result in better quality of life.

**Methods:** The investigator reviewed relevant literature, text books and empirical evidence, through which 8 research papers were obtained comprising 3 randomized control trial studies, 4 quasi–experimental studies, and 1 descriptive study.

**Results:** Given this literature review, the recommendations extracted for CNPG development were divided into 3 categories as follows: 1) Recommendation on sleep problem assessment and triage procedures 2) Recommendation on sleep problem management methods 3) Recommendation on follow-up assessment. The CNPG was checked for validity of content by 5 experts yielding the following recommendations: 1) The administrator of the sleep problem assessment and triage form should be trained adequately, 2) Sleep problem assessment and triage forms should be clearly separated between the patient’s self assessment and the assessment performed by nurse for ease of application, 3) The language in the educational intervention as well as the educational pamphlet and Power Point media should be simple and comprehensive.

**Conclusions:** The investigator improved and revised the CNPG according to these expert recommendations in order to obtain a CNPG that was suitable for actual clinical implementation. This CNPG should be tested for effectiveness by means of research procedures which can enhance its reliability and promote sustainable nursing quality development.

14-137
The Lived Experience Of Venous Access
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**Objectives:** The aim of the study presented in this paper is to bring forth the voice of the oncology patients who have undergone venous access/cannulation, as there is a paucity of literature regarding this topic. This qualitative study used phenomenology to explore the lived experiences of participants in order to better understand the impact of repeated cannulation on the cancer journey from the patients’ perspective.

**Methods:** This phenomenological study explored the participants' 'lived experience' of being cannulated. Two rural oncology units in New South Wales, Australia, were chosen to recruit participants. Fifteen participants were recruited who had either completed a course of chemotherapy or were currently being treated. During individual interviews the participants were asked to discuss what it is like to be repeatedly cannulated. Individual interviews were audiotaped and the transcripts analysed using a thematic approach.

**Results:** The themes that emerged as preliminary findings revealed that the patients’ choices about how, when and where to be cannulated was limited and they felt that a “holistic” approach to care was often absent. Examples of patient vulnerability and medical paternalism are demonstrated via direct quotes from the participants. Adjunct to these findings, participants’ also discussed how the experiences of cannulation broadly impacted on their cancer journey and on their experiences seeking further health care.

**Conclusions:** It is anticipated that the outcomes of this study will improve understanding of the experience of being cannulated from the patients’ perspective, which may contribute to best-practice and improved patient outcomes.
The Relationship Between Hope And Caregiver Burden In Family Caregivers Of Patients With Pain From Bone Metastasis
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Objectives: Family caregivers (FCs) play a crucial role in the support of patients with advanced cancer. However, little information is available on how FCs’ level of hope influence various aspects of their caregiver experience. Therefore, the aim is to describe FCs level of hope and to examine the relationships between FCs’ level of hope and various aspects of the caregiver experience.

Methods: 112 FCs were included and the majority were female (59%) and spouses (94%). The mean age of the FCs was 63 years (SD 11), 33% were retired, and 36% had university/college education. The FC reported that their overall rating of their health status was 5.4 (SD 1.3) on a scale that ranged from 1 (bad) to 7 (excellent). The FC completed the Herth Hope Index (HHI) and the Caregiver Reaction Assessment (CRA) scale. HHI consists of 12 items and a global score is calculated that can range from 12 to 48. CRA consists of 5 subscales: self esteem, lack of family support, impact on finances, impact on daily schedule, and impact on health. Descriptive statistics were performed to characterize the sample and Pearson Product Moment correlations were calculated between the total HHI score and each of the subscales of the CRA.

Results: The mean HHI score for this sample of FCs was 36.8 (SD 4). While no gender differences were found in mean HHI scores, female FCs reported significantly higher scores on the health subscale on CRA (p=0.019). In addition, significant negative correlations were found between each of the subscales of the CRA and the total HHI score except for impact on finances (all p<0.05).

Conclusions: This study is the first to examine the relationships between hope and caregiver burden in FCs of patients with cancer pain. Lower levels of hope were associated with higher levels of perceived burden on the part of FCs.

Blue Line Gauze In Hdr Brachytherapy: Pilot Study
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Objectives: To identify the anterior rectal wall by using the blue line vaginal gauze packing in the vagina during the high dose rate brachytherapy procedures in cervical cancer patients.

Methods: The high dose rate brachytherapy cases during November 2008 to January 2009 using a tandem and two ovoids were included. Firstly, 4-feet blue line vaginal gauze was placed anterior and posterior to the ovoids in order to push the rectum and the bladder away from the applicators and to stabilize the applicators. Orthogonal radiography were taken to check the applicators position and vaginal gauze packing after each insertion. The position of vaginal gauze packing was examined by looking at the blue line inside the gauze. The vaginal gauze was ensured to be placed just posterior and anterior to the ovoids. The repacking was performed if the packing was inappropriate. A reference volume definition for rectal and bladder dose calculations were carried out. The rectal dose was defined at the position of 0.5 cm. posterior from the posterior most of the blue line vaginal gauze packing compared with the dose of the rectal probe. The bladder was not defined by using the blue line gauze packing, in fact using the posterior wall of the Foley balloon.

Results: 62 applicators insertions with blue line vaginal gauze packing were excluded in this study. Repacking were performed in 3 out of 62 insertions due to unsatisfied packing. Among the 62 insertions, 6 insertions demonstrated higher rectal doses by using blue line marker compared to rectal probe. The dose differences less than 10% were detected in 4 out of 6 insertions. The other 2 insertions were found to have more than 25% rectal dose differences.

Conclusions: The blue line vaginal gauze packing is useful to demonstrate the appropriate packing and likely the represent the accurate anterior rectal wall doses.

The Effects Of Mood Status On Coping Strategies And Hope In Oncology Patients On Regularly Scheduled Opioid Analgesics
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Objectives: Mood disturbances are highly prevalent in advanced cancer patients with pain. The purpose of the
study was to evaluate for differences in the use of pain coping strategies and hope in oncology patients who were categorized into one of four mood groups based on self-reports ratings of anxiety and depression.

Methods: A total of 225 adult patients who were receiving regularly scheduled opioid analgesics, had a verified cancer diagnosis, and were able to sign the informed consent were recruited for this study. Patients completed the Symptom Severity Checklist (SSC), the Coping Strategies Questionnaire (CSQ), and the Herth Hope Index (HHI). Patients were categorized into a mood group based on their responses to the SSC. One-way analyses of variance and Chi Square analyses were used to evaluate for differences in demographic, clinical, and outcome variables among the four mood status groups.

Results: 31.6% of the patients had neither depression nor anxiety, 12% only anxiety, 12.4% only depression, while 44% had both anxiety and depression. Younger patients and women were more likely to be in the both depression and anxiety group. In addition, while no differences were found among the four mood groups on diverting attention, reinterpreting pain sensations, coping self statements, ignoring sensations, praying/hoping, increased behavioral activities, control over pain, and able to decrease pain, significant differences were found in catastrophizing. For three of the items on HHI, as well as the total HHI score, patients with both depression and anxiety reported significantly lower scores than the neither depression nor anxiety group (all p < 0.05).

Conclusions: Given the fact that 44.0% of these patients had both anxiety and depression, oncology nurses need to evaluate patients for the co-occurrence of these two symptoms, evaluate their impact on coping strategies and hope, and develop appropriate interventions to manage these symptoms.

14-141
The Post Discharge Experiences Of Patients Following Surgery For Colorectal Cancer - A Question Of Support.
Barbara Worster
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Objectives: Colorectal cancer is associated with significant morbidity and mortality; many patients undergo surgical resection (Cunningham and Lindsey, 2007) following which they are discharged home to await adjuvant therapy. Several studies have indicated that some patients with cancer felt abandoned by healthcare professionals upon completion of their treatment (Kjeldsen et al, 1999; Olsson et al, 2002).

Methods: Using a phenomenological approach, patients’ experiences during this period were investigated arising from a concern that their needs may be overlooked. The participants had much to endure. Following discharge from hospital the participants all had increased physical needs associated with elimination, pain, fatigue, low energy levels and their attempts to regain health were dependent, in part, on family members and friends whose pragmatic, tangible support was necessary and highly valued. The role of the Colorectal Nurse Specialist was found to be pivotal, but unfortunately not a resource available to all.

Results: This input was greatly appreciated and, in conjunction with family members, may have facilitated the participants’ coping through the provision of both informational and psychological support. For the majority of the participants this was the only clinical support received during this period. Uncertainty was repeatedly expressed about what could be perceived as normal with respect to many aspects of their recovery. Supportive care has been described as being concerned with the optimal well-being of cancer patients in all stages of their complex disease journey (Stiefel and Guex, 1996).

Conclusions: It is, therefore, important that healthcare professionals help survivors and their carers cope with the impact of uncertainty on their lives and address the loss experienced when in-patient care is over and they are sent away from a very intense, secure environment by providing detailed information and a service that meets their needs.

15-142
Oral Late Effects Of Hsct
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Objectives: Chronic graft-versus-host diseases (cGVHD) lead to mucosal and salivary gland damages. The aim of this study was to evaluate oral health, and salivary flow, hyposalivation and xerostomia in 45 adults patients submitted to allogeneic and low reduced intensity HSCT.

Methods: A prospective cross-sectional study was performed during March 2006 and April 2008 at the BMT Unit of the University of Campinas, SP, Brazil. Patients were classified in two groups. Group I (n=29), with oral cGVHD and Group II (n=16), without cGVHD. Oral health was evaluated before and after HSCT by the DMFT index. Periodontal status was evaluated by Silness-Loe Plaque Index (PI) and Gingival Index (GI). Hyposalivation was clinically observed by visual parameters, such as, absence of the sublingual lake, higher adherence of a wood spatula to the buccal
mucosal lesions. The second patient presented with extreme vascular fragility causing extra- and intra-oral bruises upon gentle touch. The third patient presented with fatal macroglossia. All patients died within days to months post oral diagnosis.

Conclusions: Orange oral mucosal lesions, extreme intraoral vasculature fragility and macroglossia may be the presenting symptom of AL and possibly multiple myeloma. Oral involvement with amyloidosis may be the cause of death. All patients with suspected AL should undergo oral examination that may shorten time to diagnosis. Early diagnosis of AL, when visceral organ involvement is minimal, is essential for optimal treatment and better prognosis.

15-144 Dental Treatment Needs And Efficacy Of Conscious Sedation Procedure In Children With Paediatric Cancer.
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Objectives: Mucoisitis, oral infections or hemorrhage and pain are common acute effects found in children treated for oncology malignancies. Dental caries and abscesses constitute also a significant source of bacteraemia during neutropenic episodes in oncology patients. Thus, an oral preventive care programme is necessary to avoid the development of oral infections. Childhood cancer patients may have experienced repeated invasive medical procedures which are risk factors for dental anxiety. Adequate analgesia and sedation during dental procedures is needed to diminish the behaviour management problems. The first aim of the study was assess the dental treatment needs in a group of children immediately before and during the cancer treatment. The second objective was to evaluate the behavioural impact and tolerance of inhalation sedation for dental treatment in these patients.

Methods: Seventy-five patients, aged from 3 to 19 years, treated in the paediatric oncology service, Strasbourg, France, have been examined from 2005 to 2007. Their oral status and needs of dental care have been evaluated. Inhalation sedation has been performed using a fixed 50% N2O/O2 mixture as a single agent. The behaviour was rated using the modified Venham scale.

Results: Thirty-three percent of the patients needed dental care. General anaesthesia was required in 8% of the cases. The planned treatment has been performed under inhalation sedation for 62% of the sessions. This technique was effective to reduce discomfort and anxiety.
during dental care in 93% of the patients. No major or minor adverse event was encountered.

Conclusions: Paediatric dentists should play an important role for the assessment of the patients’ oral health before, during and after the oncology therapy. Furthermore, the control of pain and anxiety is essential and conscious inhalation sedation with 50% nitrous oxide premix constitutes an adequate solution to be used by dentists to treat paediatric oncology patients.

Objectives:

Experience Feedback Of Cancer Patients Treated For Xerostomia

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Objectives: Xerostomia is a frequent symptom, affecting quality of life and nutrition, in cancer treated patients, mainly due to radiotherapy (head and neck cancer) and to cytotoxic chemotherapy or antidepressive or analgesic drugs. Many xerostomia treatment’s are not very effective. So, when a salivary flow stimulant (« SST® ») and an oral linseed extract became available effective. So, when a salivary flow stimulant drugs. Many xerostomia treatment’s are not very cytotoxic chemotherapy or antidepressive or analgesic quality of life and nutrition, in cancer treated patients,

Methods: 64 patients (male: 29; female: 35) prospectively treated in several oncological departments gave their feedback, using Visual Analog Scale (VAS) for xerostomia and being evaluated by their oncologist.

Results: Median age: 64 years (34-84 years). - Xerostomia : 1) Before treatment: grade 1 : 35 ; grade 2 : 26 ; grade 3 : 3 2) After treatment : grade 0 : 10 ; grade 1 : 33 ; grade 2 : 10 ; grade 3 :0 ; non evaluable : 11 - VAS: 1) Before treatment: mean = 5,4 (extreme : 2-10) 2) After treatment : mean = 3,51 (extreme : 0-10) - Mean number of daily intake: 1) « SST® » : 3,34 2) Linseed extract: 2,54 - Mean number of days on treatment: 1) « SST® » : 23,9 2) Linseed extract: 19,3 - Patient’s satisfaction: 1) Very good: 14 2) Good : 23 3) Mild : 10 4) None : 10 - Side effects: 15; prickling : 3 ; gingival irritation : 1 ; burning sensation: 2 ; thirst: 1 ; linseed solution painful : 1 ; vomiting : 1 ; nausea : 1 ; unpleasant taste : 8 - Mucositis: 3 (1 grade 2 with fever and 1 grade 2 at the end of radiotherapy)

Conclusions: SST® and linseed extract seem to be a valuable option in treatment of xerostomia’s symptoms.

Conclusions:

Oral Manifestations Of Chronic Graft Versus Host Disease In Hematopoietic Stem Cell Transplant Recipients From Rio De Janeiro / Brazil

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Objectives: Oral lesions and salivary gland dysfunction are main manifestations of oral chronic graft versus host disease (cGVHD). The purpose of this study is to evaluate the prevalence of oral manifestations of cGVHD in a population of hematopoietic stem cell transplant recipients in Brazil.

Methods: A transversal oral evaluation of hematopoietic stem cell transplant (HSCT) recipients was conducted at the University Hospital of Federal University of Rio de Janeiro. Age, gender, underlying disease, time post-HSCT, type of GVHD, prophylaxis for cGVHD, xerostomia, salivary flow rates (SFR) and oral lesions were assessed. Oral lesions were diagnosed according to clinical aspects, with histological examination when necessary and evaluated through a validated scale. Moisture perception was measured through visual analogue scale (VAS), and xerostomia was considered when >2cm. Resting SFR was used for assessment of salivary function, and SFR was considered normal when ≥0.3 mL/min.

Results: A total of 23 HSCT recipients were evaluated: 10 had been previously diagnosed for cGVHD and 1 for acute GVHD. Oral lesion of cGVHD were observed in five other patients. From the 15 patients presenting cGVHD, 60% were males and 40% females, with mean age of 42.5. The most frequent diseases were chronic and acute mielogenic leukemia. Mean time post-HSCT was 715.3 days. Most common medications for cGVHD prophylaxis were prednisone (40%) and ciclosporine (20.1%), while 46.7% of patients were not under prophylaxis. Oral lesions were observed in 80% of cGVHD patients assuming the following aspects: hyperkeratosis (53.3%), atrophy (46.7%), lichenoid (26.7%), erythema (20%), ulcerative (13.3%) and pseudomembranous (6.7%). Xerostomia was registered for 38.5% of patients and 50% presented reduced SFR.

Conclusions: Oral manifestations of cGVHD are highly prevalent in HSCT recipients, affecting both the oral mucosa and the salivary glands, and require special attention from health care providers. Study supported by FAPERJ and CNPq.
Knowledge Of Head And Neck Cancer Therapy, Its Orodental Manifestations And Considerations Amongst Dentist In Benin City, Nigeria
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Objectives: The objective of this study is to obtain an insight into the level of knowledge of head and neck cancer therapy, its orodental complications, prevention and management among dentist and final year medical students in Benin City, Nigeria. This is against the background that there is no multidisciplinary cancer team.

Methods: One hundred and four dentists and final year dental students were administered a 15-item validated continuing education (CE) test questions obtained from the National Institute of Dental and Craniofacial Research. These questions address orodental complications of cancer therapy and the role of the dentist in the prevention and management of these complications. Descriptive and bivariate analysis were carried out.

Results: Of the 104 respondents; 3(2.9%), 20(19.2%), 21(20.2%) and 60(57.7%) were specialists, resident doctors, general dentists and final year dental students respectively. Overall correct answers ranged from 13.3% - 93.3% and a mean of 64.2%. The status of respondents and years of clinical experience did not significantly affect the correct response to the questions (P<0.05).

Conclusions: There is an urgent need to review curricula of dental undergraduates, resident doctors and CE courses for specialist and general practice dentist in the prevention and management of complications arising from cancer therapy. This is to reflect international best practices to improving the quality of life of cancer patients.

Oral Healthy Characteristics And Dental Management Of Hematopoietic Stem Cell Transplantation Patients In A Single Public Hospital
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Objectives: Brazil is often referred as a country holding the highest rates of oral diseases prevalence, particularly dental caries and periodontal disease. These indicators are similar to general health of the population. It’s a country with a framework of morbidity and mortality typical of countries with big social inequalities and high concentration of income, where a significant portion of our population is excluded from access to the most basic social rights, such as oral health. It became more difficult when a person has any systemic disorder. Dental management of patients who have to be submitted to HSCT requires to be treated by a specialized dentist but who performs like a general practitioner. The aim of this study was to present the oral health characteristics of 227 patients of the BMT Unit of University of Campinas and the dental management.

Methods: Dental treatment protocol aims to evaluate these patients for identifying and treating all sources of potential infections. All patients were followed up during and after the period of transplant. Standardized oral examinations included: radiological and oral clinical exam. Oral health was measure by DMFT index. Post HSCT oral complication was also observed. Complementary exams, oral cytology or biopsies, were performed when necessary.

Results: The DMFT median was 17, comparable with the DMFT of the Brazilian population (22.5). 134 extractions were performed during the patient’s dental follow-up. Oral mucositis was observed in 181 patients: 40 presented grade III, 12/40 were co-infected with HSV and 50 grade IV, 12/50 were positive for HSV, confirmed by cytological exams. Acute GvHD occurred in 216 patients and chronic in 185.

Conclusions: These results represent the oral health condition of patients referred to our Ambulatory. Despite of these results is from a regional hospital, it can confirm the necessity of a participation of a general dentist in a HSCT team.

Interobserver Agreement In Chronic Gvhd Histological Classification Of Minor Salivary Glands?
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Objectives: Establishing interobserver agreement is crucial for standardization of diagnosis and for ensure validity of findings in multi-institutional trials. Most GVHD literature does not specify what criteria were used to evaluate and diagnose GVHD involving the salivary glands (SG). Two classification systems were proposed for chronic GVHD (cGVHD) in SG: the Horn’s et al. (1995) and the Shulman’s et al. (2006, NIH consensus) systems. The aim of this study was to evaluate the interobserver agreement in each, Horn and
Shulman systems, for cGVHD classification in minor SG.

Methods: Sixty-five patients treated by conventional hematopoietic stem cell transplantation entered the study. The criteria of both systems as well as final grades were blindly and separately evaluated by 2 observers in specimens stained by H&E, Masson’s trichrome and leukocyte common antigen. Interobserver agreement was measured by the kappa (k) statistics.

Results: The strength of agreement in four of Shulman’s criteria was considered to be ‘slight’ (k = 0 - 0.16); three to be ‘fair’ (k = 0.22 - 0.39); and only one ‘moderate’ (k = 0.44). Nevertheless, the strength of agreement of Shulman’s final classification was considered ‘moderate’ (k = 0.49). The strength of agreement in three of Horn’s criteria was considered to be ‘slight’ (k = 0.6 - 0.18); two to be ‘fair’ (k = 0.34 and 0.39), three to be ‘moderate’ (k = 0.41 and 0.58) and one was considered ‘poor’ (k = 0.09). The strength of agreement of Horn’s final grade was considered ‘substantial’ (k = 0.80).

Conclusions: Both classification systems criteria showed not satisfactory strength of agreement. However, Horn grades exhibited better agreement when compared with Shulman ones. Horn system encompasses some stratified criteria (mild, marked and diffuse). In the other hand, Shulman criteria are dichotomic (yes or no). It can be the reason for better interobserver agreement obtained in Horn grades.

15-151
Cytotoxic Chemotherapy-Induced Odontalgia: A Suggested Differential Diagnosis For Dental Pain
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Objectives: Peripheral neurotoxicity and neuropathic pain are well-known complications of several anti-cancer chemotherapeutic agents, including cyclophosphamide. Neurotoxicity in the orofacial structures was described as diffuse jaw pain or numbness. No reports are available of chemotherapy induced localized pulpal pain. The aim of the study is to suggest cytoxics-induced neurotoxicity as a differential diagnosis for toothache during anti-cancer therapy.

Methods: Describing the diagnostic process in a patient suffering from severe pulpal pain, in apparently intact teeth, during cytotoxic chemotherapy.

Results: A non-Hodgkin lymphoma patient complained about two episodes of severe pulpal pain (pain was rated as 9 and 10 on 0-to-10 pain ladder). Pain was evoked by mouth breathing and caused nocturnal awakenings. Both episodes were developed immediately following cyclophosphamide administrations. Clinical parameters, radiographic characteristics and cytologic...
evaluation of pulp tissue eliminated other possible etiologies (caries with pulp involvement, perio-endo lesion, vertical root fracture and infiltrate of lymphoma cells to the pulp chamber). Exirperation of the pulp tissues and intra-canal dressing with combined antibiotics-steroids paste resulted in an immediate pain relief.

**Conclusions:** This case presented a circumstantial relation between the clinical presentation of dental pain and the timing of high-dose cyclophosphamide administrations. It suggests that cyclophosphamid-induced toxicity may manifest as pulpal-type toothache which is a diagnostic challenge for the dental practitioner. The associated significant impairment of the patient’s quality of life exemplifies the role of palliative endodontic (pulp extirpation) therapy in cytotoxic-induced dental pain.

**16-152**
**Risk Factor Analysis For Hospital Admission In Cancer Outpatients**
Giuseppe Aprile¹, Federica Edith Pisa², Alessandro Follador¹, Paola Costantini¹, Emiliana Iaiza¹, Gianpiero Fasola¹
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**Objectives:** Cancer symptoms and treatment-related toxicities increase the need for supportive care and in-hospital admission. Aim of this analysis was to identify reliable predictors for hospitalization in cancer outpatients accessing a 12-hour dedicated ward, open daily on business days.

**Methods:** Electronic medical records of patients using the service from October 2006 to March 2008 were reviewed. Data regarding tumor type, demographics, reasons for visiting, and date of last oncologic treatment were all recorded. Toxicities were graded according to CTC, while cancer-related symptoms were scored as mild, moderate, severe, or life-threatening. Considering hospitalization as the independent variable, univariate (log-rank) and multivariate (Cox’s model) analyses were used to identify risk factors and estimate their values.

**Results:** Over 18 months, we registered 1943 accesses in patients with breast (34.4%), lung (16.7%), gastrointestinal cancer (28.2%), or other solid tumors. Hospitalization rate was 7.6% (147 cases). In univariate logistic regression, having a lung cancer (OR 2.12, p=0.001), male gender (OR 1.4, p=0.049) or presenting with multiple symptoms (OR 3.98, p=0.001) were all risk factors for hospitalization. Specifically, the odds ratios were 6.5 and 8.3 in those presenting with 3 or 4+ symptoms, respectively. In patients receiving chemotherapy, the grade of toxicity strongly predicted the risk for admission (OR 21.7 p<0.001, OR 52.1 p<0.001 if grade 3 or 4 toxicity), while no increased risk was found depending on lag-time from last treatment (OR 1.16, p=0.86). Multivariate analyses confirmed the number of presenting symptoms and the grade of toxicity as the major risk factors for admission.

**Conclusions:** The growing proportion of patients on active treatment produce more unplanned visits, that should be managed not to adversely impact on the regular daily planning and selected for appropriate hospital admissions. Number of referred symptoms, type of cancer and grade of toxicity emerged as simple clinical predictors for in-hospital admission.

**16-153**
**What Level Of Care Is Provided To Advanced Non-Small Cell Lung Cancer Patients Who Successfully Complete First-Line Therapy? Results Of A Uk Survey**
Yumiko Asukai¹, Astra M Liepa², Nicola Bell³, Jodie Webber¹, Claire Grant⁴, Kristina S Boye⁵
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**Objectives:** Clinical guidelines for advanced non-small cell lung cancer (NSCLC) generally recommend a maximum number of cycles of first-line chemotherapy to be followed by second-line chemotherapy upon disease progression. For those patients who successfully complete first-line therapy, this study aimed to assess the level of care provided to these patients prior to disease progression or terminal care.

**Methods:** We developed a survey to be completed by nurse specialists in the UK who monitor most of the care of lung cancer patients from diagnosis to death. The survey included questions about health care providers (HCPs), settings of care and interventions. The surveys were conducted as telephone interviews.

**Results:** Nine nurse specialists from England and Scotland completed the survey; each managed 150-520 lung cancer patients annually. After successful first-line therapy, patients were commonly referred to oncologists (57% of patients), lung cancer nurse specialists (54%), respiratory consultants (44%), and general practitioners (GPs) (33%); in the majority of cases, patients were managed by a team of HCPs. The majority of care was provided in the outpatient setting (see table).

<table>
<thead>
<tr>
<th>Proportion of medical care needs reported to be</th>
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<table>
<thead>
<tr>
<th>Setting</th>
<th>Mean</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient hospital or cancer center</td>
<td>7%</td>
<td>10%</td>
<td>0-13%</td>
</tr>
<tr>
<td>Outpatient hospital or cancer center</td>
<td>45%</td>
<td>46%</td>
<td>5-95%</td>
</tr>
<tr>
<td>Outpatient GP</td>
<td>22%</td>
<td>20%</td>
<td>0-50%</td>
</tr>
<tr>
<td>Outpatient hospice (non-terminal care)</td>
<td>4%</td>
<td>3%</td>
<td>0-10%</td>
</tr>
<tr>
<td>Home</td>
<td>22%</td>
<td>5%</td>
<td>0-80%</td>
</tr>
</tbody>
</table>

At the outpatient hospital clinic, patients were most commonly seen by their physician or nurse and underwent x-ray or CT every 6 to 8 weeks. GPs were visited 1-2 times per month. Almost half of the surveyed nurse specialists indicated that consolidation radiotherapy was provided to ≥50% of patients. Although infrequent, inpatient admission was most commonly due to dyspnea, followed by pain control and social reasons (inability to live independently).

**Conclusions:** According to nurse specialists, although these advanced NSCLC patients are not receiving active chemotherapy, health care resources are still utilized. This study is limited by the size of the sample and the type of HCP perspective. There is apparent variability in terms of services provided which may be attributable to differences in organization of available resources and staff.

**16-154**

**Economic Impact Of Oral Cancer: Duration Of Hospitalization And Ambulatory Follow-Up After Complete Resection Of Oral Squamous Cell Carcinoma In 63 Patients**

Johann Beck-Mannagetta¹, Markus Hoepflinger², David Kummer², Wolfgang Hitzl³

¹Paracelsus Medical University, Maxillofacial Surgery, Salzburg, Austria, ²Paracelsus Medical University, Graduate Student, Salzburg, Austria, ³Paracelsus Medical University, Graduate Student, Salzburg, Austria

**Objectives:** Oral cancer is a debilitating disease. Therefore every effort has to be made to minimize the consequences of therapy and to keep the patient socially acceptable. This leads to rather long hospitalization and frequent follow-up visits. Our aim was to investigate the economic aspects of hospital care of patients who had undergone primary complete resection of their tumor. They were followed until death.

**Methods:** Between 1990 and 2007 205 patients underwent primary surgical resection for oral squamous cell carcinoma (OSCC). Of these, 63 patients died between 1990 and 2008. The medical records of the latter group were retrospectively reviewed.

**Results:** The mean duration of hospitalization was 67 (15 – 186) days, in some cases including periods for intensive care, tracheostomy, reconstructive procedures, radio- and/or chemotherapy or complications (e.g. flap failure, kachexia). The mean number of post-op follow-up visits was 33 (3 – 166), including visits for prostodontic rehabilitation.

**Conclusions:** Oral squamous cell carcinoma severely affects quality of life (facial appearance, speech, mastication, deglutition, dentition, smell, taste, sensitivity etc.). In some cases these persons are also socially handicapped and experience periods of depression. Therefore it is our obligation to ameliorate these deficits as much as possible. Oftentimes this will necessitate numerous therapeutic interventions by hospital specialists and not only for cancer cure. This in turn will be reflected in the costs of care. Considering the fact that OSCC is in the majority of cases a preventable disease every effort should be made for prophylaxis and early detection.

**16-155**

**Is C-Reactive Protein A Prognostic Indicator In Solid Tumors? A Systematic Review**

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**Objectives:** Numerous studies link serum C-reactive protein (CRP) levels to prognosis and survival in malignancy. We systematically searched the literature to answer: In patients with solid malignancies, does serum CRP predict prognosis and survival?

**Methods:** MeSH terms used [(prognosis OR treatment outcomes OR Survival) AND (C-reactive protein OR CRP) AND (cancer OR Neoplasms)] to search the following databases up until 2007: PubMed, EMBASE, Web of Science, SCOPUS, EBM-Cochrane Central Register of Controlled trials and EBM-Cochrane Database of Systematic Reviews. Inclusion criteria: English articles; solid malignancies in adult population; prognostic studies with CRP measurement. Letters/comments were excluded. A quality assessment (QA) scoring system was developed based on existing guidelines for observational cohort prognostic studies.

**Results:** We retained 98 research articles, along with 14 review papers. Upon quality assessment of selected articles, three studies were deemed inadequate and
CRP is valuable as predictor of survival and treatment outcomes in various tumor types.

**Conclusions:**

CRP is a predictor of survival and treatment outcomes in various tumor types.
mg/m²; 1.6%) were common HEC, while carboplatin (34.4%), doxorubicin (22.8%) and cyclophosphamide (<1500 mg/m²; 16.6%) were common MEC. CINV prophylaxis included 5-HT3 antagonists (94.9%), dexamethasone (84.9%) and NK1-RA (2.1%). 10.3% of patients had a CINV visit (HEC: 13.4%; MEC: 9.5%), with a median time-to-event of 9 days. CINV visits were distributed as inpatient (IP) (62.9%), outpatient (OP) (26.4%), and emergency room (ER) (10.7%). CINV was the primary ICD-9 code for 34.9% of visits. Mean CINV visit costs were: overall ($4958; SD=$6099), IP (mean=$7029; SD=$6705), OP ($1624; SD=$2246), and ER ($877; SD=$985). Mean CINV costs were $508 (SD=$2464) per patient/cycle.

Conclusions: CINV visits in the delayed phase of a first HEC or MEC cycle were common and costly, most notably CINV hospitalizations. Strategies to reduce delayed CINV are likely to reduce healthcare utilization and costs.

16-158
A Month In An Acute Palliative Care Unit; What Is Acute?
Ahmed Elsayem, Bianca Calderson, Jennifer Marriott, Eduardo Brueca, Nada Fadul
M.D. Anderson Cancer Center, Palliative Care and Rehabilitation Medicine, Houston, USA

Objectives: Inpatient acute palliative care units (APCU) are not available in the majority of cancer centers in the United States. Financial reimbursement, which relies on acute care criteria for hospitalization, is a major barrier for APCU development. These criteria depend on the acuity of clinical condition, and use of medications and interventions that are not available at outpatient or hospice care settings. The purpose of this study is to highlight acute clinical interventions performed simultaneously with other palliative care interventions during a typical one month period on an APCU.

Methods: We evaluated all patients admitted to our APCU during a one month period. We reviewed demographic information, sources of admissions, clinical diagnosis, medications used, interventional procedures, discharge location, and financial data.

Results: Forty patients were evaluated during the one month period. Of these 31 (78%) were admitted from the inpatient consultation team and 8 (21%) from our outpatient clinic. Eighteen (45%) were female. The most common primary cancer diagnoses were gastrointestinal 11 (28%) and thoracic 8 (20%). Table 1 shows the main medications and interventions provided. Eight (20%) patients had a full code status on admission, and 6 were changed to Do Not Resuscitate prior to discharge. Nineteen (48%) patients were discharged home with hospice, 12 (30%) died in the APCU, and 9 (22%) were discharged home with outpatient follow up visits. The median length of stay in the APCU was 6 days (range 1-14 days). All patients met acute care criteria for hospitalization and financial reimbursement was satisfactory and comparable to other oncology patients.

Conclusions: The APCU assists in the care of very complex advanced cancer patients. Palliative interventions are given simultaneously with other medical interventions. The majority of patients were discharged alive. The APCU is labor intensive and well reimbursed.

<table>
<thead>
<tr>
<th>Medication/Intervention</th>
<th>Number of patients (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid rotation</td>
<td>15 (38%)</td>
<td></td>
</tr>
<tr>
<td>Intravenous antiemetic</td>
<td>25 (60%)</td>
<td>19 (66%) started in APCU</td>
</tr>
<tr>
<td>Antihypertensive for diuretic</td>
<td>25 (60%)</td>
<td>21 (59%) hypotenised, 3 (9%) of these patients needed another agent!!</td>
</tr>
<tr>
<td>Supportive care</td>
<td>4 (10%)</td>
<td>midazolam infusion</td>
</tr>
<tr>
<td>Ambulance call</td>
<td>6 (15%)</td>
<td>New diagnosis of serious thromboembolic event</td>
</tr>
<tr>
<td>Interventional procedures</td>
<td>7 (18%)</td>
<td>3 (6%) thrombectomy, 5 (13%) other procedures: 1 (assisted ventilation), 1 (dialysis)</td>
</tr>
<tr>
<td>Radiation therapy</td>
<td>3 (8%)</td>
<td>For palliation of pain</td>
</tr>
</tbody>
</table>

16-159
The Burden Of Chemotherapy Induced Toxicity In Routine Hospital Care
Bernadette Paessens¹, Christoph von Schilling²,¹, Karin Berger³, Christian Peschel², Rudolf Bernard¹, Angela Ihbe-Heffinger¹
¹Klinikum rechts der Isar der TU Muenchen, Krankenhausapotheke, Munich, Germany, ²Klinikum rechts der Isar der TU Muenchen, 3. Medizinische Klinik, Munich, Germany, ³Klinikum Freising, Medizinische Klinik 3, Freising, Germany, ⁴Ludwig-Maximilians-Universität München, Abteilung für Transfusionsmedizin und Hämostaseologie, Munich, Germany

Objectives: The majority of chemotherapy (CT) patients receive care outside of clinical trial settings. In contrast little is known about frequency and severity of CT-induced toxicity and its economic consequences in routine care.

Methods: Prospective, multi-centre, longitudinal, observational study with lymphoma and NSCLC patients enrolled consecutively at the start of 1st or 2nd line (immuno-)chemotherapy in 4 German hospitals. Patients receiving myeloablative chemotherapy with PBSCS were excluded. ADRs were monitored according to the NCI CTCAEv3.0 and WHO causality criteria. Data were collected from pre-planned chart reviews. Costs in €2007 are presented from provider perspective.
Results: 273 patients (n=153 lymphoma, 47% of courses were CHOP-like, n=120 NSCLC, 78% of courses were platinum-based) undergoing a total of 1004 CT-cycles were evaluable. Mean age was 60.1 years (SD 13.0; age ≥65 years 40%; female 36%; ECOG ≥2 11%; tumour stage ≥3 56%; history of comorbidity 80%. 50% of cycles were associated with grade 3-4 toxicity and 37% (n=371) with at least one hospital stay (normal care n=257, intensive care n=19; outpatient/day care: n=154). Mean toxicity related costs amounted to €1,032 (SD 3,187 per cycle. 5% of CT-cycles (n=53) were associated with costs ≥€5,000 and accounted for 56% of total expenses. The table shows cost stratified by severity and number of ADRs. Hospital basic services and personnel represented 74% of total costs, followed by expenses for drugs (18%) and diagnostics (6%).

Conclusions: Our findings highlight that half of CT-cycles in lymphoma and NSCLC routine care are affected by grade 3-4 toxicity. Toxicity associated costs were particularly high in these cycles and rose exponentially with number of severe ADRs. With 5% of cycles contributing to 60% of total costs this entails not only clinical but also economic consequences and emphasizes the importance of targeted supportive care strategies.

<table>
<thead>
<tr>
<th>Cycles</th>
<th>n</th>
<th>Mean cost/cycle in € (95% CI)</th>
<th>Multiples of reference subgroup</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>1004</td>
<td>1,032 (835-1,230)</td>
<td></td>
</tr>
<tr>
<td>No grade 3/4 toxicity</td>
<td>502</td>
<td>319 (225-413)</td>
<td></td>
</tr>
<tr>
<td>grade 3/4 toxicity</td>
<td>502</td>
<td>1,746 (1,372-2,120)</td>
<td>1 (ref.)</td>
</tr>
<tr>
<td>1-2 AEs grade 3/4</td>
<td>402</td>
<td>866 (689-1,042)</td>
<td>2.71*</td>
</tr>
<tr>
<td>3-4 AEs grade 3/4</td>
<td>80</td>
<td>3,884 (2,727-5,042)</td>
<td></td>
</tr>
<tr>
<td>&gt;4 AEs grade 3/4</td>
<td>20</td>
<td>10,881 (4,698-17,064)</td>
<td></td>
</tr>
<tr>
<td>No grade 3/4 infections</td>
<td>923</td>
<td>500 (413-588)</td>
<td>1 (ref.)</td>
</tr>
<tr>
<td>grade 3/4 infections</td>
<td>81</td>
<td>7,093 (5,299-8,887)</td>
<td>14.19*</td>
</tr>
</tbody>
</table>

*P<0.05 versus reference group

Consort - A Randomized Controlled Trial Comparing Two Different Treatments

Reduced Esa Use - How Does This Affect Thrombosis Rates And Transfusions?: A 3 Year Longitudinal Analysis Of Resource Utilization Data From A Large Comprehensive Oncology Program

Harry Raftopoulos, Richard Gralla, Kathleen Pelc, Karen Gleason, Iulianna Shapira
North Shore-LIJ Health System, Lake Success, USA

Objectives: ESA use in the USA has decreased substantially after randomized trials and meta-analyses revealed an increase in thrombosis rates with ESAs as well as decrements in survival (Bohlius, JNCI, 2006; Raftopoulos, Proc ASCO, 2008; Bennett, JAMA 2008). The benefits with ESA use have resulted in a reported average 1-1.5g/dl rise in hemoglobin with the impact on quality of life and fatigue with this small increase now felt to be unclear. The toxicity issues led to restricted labeling by the FDA and reimbursement decisions by the Centers for Medicare and Medicaid Services (CMS). Even with the demonstrated thrombotic risks associated with ESA use, concerns regarding increased use of transfusions and strain on the blood supply persist. We conducted a longitudinal study to assess the impact of the new ESA policies on thrombosis, rates, demand on transfusion services and ESA use.

Methods: Our center comprises a large comprehensive combined hematology and oncology program with a non-restrictive transfusion policy. We analyzed ESA use over the 3 year period, 2006-2008. Simultaneously, we assessed hospital discharges including both a thrombosis and malignancy diagnosis. 2006 was our baseline; 2007 was the year of initial FDA and CMS changes; 2008 allowed us to see if practice changes persisted.

Results: The table below presents our data on ESA use, transfusion utilization and hospital thrombosis admissions.

These findings document a significant decrease in ESA use (78% relative decrease) with a non-significant change in transfusion rates (3% relative increase) and a significant decrease in thrombosis discharge rate (21% relative decrease, resulting in an estimated 93 fewer thrombosis discharges per year).

Conclusions: At our center, marked cutbacks in ESA use over a 3 year period have had little effect on transfusion rates and have lessened overall thrombotic events. Our findings 1) support the meta-analysis results of marked risk with little benefit with ESA use; and 2) document that decreased ESA administration need not lead to increased transfusion rates and can result in greater patient safety.

Mellissa Yong1, Hema Viswanathan1, Anders Riis2, Henrik Toft Sørensen2, Henrik Toft Sørensen2, Jon Fryzek1, Søren Paaske Johnsen2

1Amgen Inc., Global Epidemiology/Global Health Economics, Thousand Oaks, USA, 2Aarhus University Hospital, Department of Clinical Epidemiology, DK-8200 Århus N., Denmark

Objectives: Cancer patients receiving chemotherapy are at increased risk of anemia. International guidelines recommend transfusions in patients whose hemoglobin (Hb) level is below 7-8g/dl. As limited data exist on actual practice, we examined red blood cell (RBC) transfusion use in newly diagnosed cancer patients with chemotherapy-induced anemia (CIA) in Denmark.

Methods: We conducted a population-based cohort study of newly diagnosed cancer patients between January 1, 1998 and December 31, 2003, using the Danish Transfusion Database, Danish Cancer Registry, and Danish National Registry of Patients. Within the four-month post-cancer diagnosis period, the identification of CIA patients included chemotherapy and Hb less than or equal to 10.9g/dl. Demographics and transfusion characteristics of CIA patients were examined, and the rate of at least one RBC transfusion was computed.

Results: A total of 1,655 (46.2%) CIA patients were identified among 3,580 newly diagnosed cancer patients on chemotherapy. CIA patients were predominantly female (58.6%) with a mean age of 56 years. The number of CIA patients who received at least one RBC transfusion within four months after cancer diagnosis was 713 (43.1%). Approximately 95% of the initial transfusions were administered in the inpatient setting, while the remaining occurred in the outpatient setting. The Hb level distribution prior to initial transfusion was as follows: 16 (2.3%) less than or equal to 6g/dl, 79 (11.1%) 6.1–8.0g/dl, 486 (68.4%) 8.1–10.0g/dl, and 130 (24.1%) 10.1–10.9g/dl. A total of 600 of the 713 (84.2%) patients receiving at least one transfusion within four months, received subsequent transfusions within the following 90 days.

Conclusions: Over 40% of all CIA patients in Denmark received a RBC transfusion within four months of being diagnosed with cancer. The majority of these patients had Hb levels above the recommended transfusion threshold of 7-8g/dl at first transfusion and a high proportion received subsequent transfusions, suggesting that these patients may have symptomatic anemia.
subscales. It was ascertained that male, not married patients, patients with a chronic disease other than cancer, patients whose “average pain” level is >5 and who use inadequate analgesic have more beliefs that may be barriers to optimal pain management.

**Conclusions:** BQ-II was a valid and reliable scale for Turkish defining patient related barriers in cancer pain management. Items suggested by patients such as “family related barriers” and “family members’ role and responsibilities” could be added to the BQ-II for future studies.

17-163
**Barriers To Pain And Fatigue Management In Medical Oncology**
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1City of Hope, Nursing Research & Education, Duarte, USA, 2City of Hope, Medical Oncology, Duarte, USA,
3City of Hope, Nursing Research & Education, Duarte, USA, 4Scottsdale Healthcare/University of Arizona, College of Nursing, Scottsdale, USA, 5City of Hope, Nursing Research & Education, Duarte, USA

**Objectives:** Relief of symptoms is critical for supportive care in medical oncology. This NCI funded study compared usual care to an educational and systems change intervention in a Comprehensive Cancer Center. Based on the NCCN Pain and Fatigue guidelines, interventions included a four part patient education program, professional education and strategies to integrate symptom management into routine oncology practice comparing the total N=184 patients including Breast (40%), Lung (25%), Colon (20%) or Prostate (15%) cancer.

**Methods:** This trial compared symptom management in outpatient oncology patients experiencing pain and/or fatigue who received either usual care (N=83) or the intervention (N=101). Outcome measures included Pain and Fatigue Knowledge Scales, Psychological Distress Thermometer, City of Hope QOL Tool, Karnofsky Scale and Piper Fatigue Scale. Patients were assessed at baseline and 1 and 3 months post intervention endpoints.

**Results:** To determine the immediate effect of the intervention and differences from the usual care condition, 2x2 repeated measures ANOVAs were conducted on instrument scales and single item measures. Compared to the usual care sample, the intervention had an immediate salutary effect on anxiety, depression, and social support (p=.007, p=.006, and p=.048, respectively). Barriers to pain management decreased significantly only for the intervention sample. Knowledge of pain decreased in the usual care sample but increased significantly in the intervention sample (p<.001). Fatigue decreased significantly in the intervention sample (p=.006 to p<.001) and often increased in the usual care sample. Knowledge of fatigue also increased significantly for the intervention sample (p<.001), while falling in the usual care sample.

**Conclusions:** Structured patient and professional education and systems change efforts can reduce barriers to pain and fatigue management resulting in improved outcomes for patients in treatment for solid tumors.

17-164
**International Pain Policy Fellowship: Improving The Availability And Accessibility Of Opioids In Serbia**
Snezana Bosnjak1, Karen Ryan2, John Ely3, Jody Moen2, Martha Maurer2
1Institute for Oncology and Radiology of Serbia, Belgrade, Serbia, 2Pain & Policy Studies Group, Madison, USA, 3Hennepin County Medical Center, Minneapolis, USA

**Objectives:** A health professional from Serbia was awarded an International Pain Policy Fellowship (IPPF, 2006-2008) to learn how to evaluate national opioids control policy and work with government to remove regulatory barriers to cancer pain treatment. The aim of the IPPF is to improve patient care by improving the availability and accessibility of opioids.

**Methods:** An Action Plan was developed to address the following barriers: 1) Lack of availability of and access to oral opioids, 2) No recognition that opioid analgesics are absolutely necessary for the relief of pain and suffering and that it is government’s obligation to ensure their adequate availability while preventing abuse and diversion, and 3) Overly restrictive laws and regulations related to opioid use.

**Results:** Immediate Release oral morphine was officially registered for the first time in the country’s history. A National Commission for Palliative Care was established by the Ministry of Health (MoH) to which the Fellow was appointed as Vice-President. The Commission formulated the strategy recognizing: 1) opioids as absolutely necessary for pain relief/palliative care, 2) the need for opioids control policy that balance concerns about abuse and the need for medical use, 3) MoH responsibility to make opioids available to patients, and 4) MoH willingness to examine drug control policies for potential barriers. The Commission approved the proposal written by the Fellow for improving overly restrictive laws and regulations related to opioid use.

**Conclusions:** Working with experts and local partners since 2006, the Fellow has made significant progress towards overcoming barriers and improving the availability and accessibility of opioids in Serbia.
Cementoplasty For Long Bone Metastasis: Advantages In Pain Relief, Autonomy Support And Improvement Of The Quality Of Life Of Two Cases

Estelle Botton1, Yan Rolland2, Isabelle Lecouillard3, Agnès Brissot1, Catherine Le Roux1, Elodie Vauléon1
1oncology, medicine, Rennes, France, 2oncology, radiology, Rennes, France, 3oncology, radiotherapy, Rennes, France

Objectives: Methods: Results: Mrs T, 58 years old, suffering of an hepatocellular carcinoma from September 2006, develops in January 2008 a fracture of the upper extremity of the humerus due to a voluminous osteolytic metastasis of the entire humeral head. She is given opiate and there is no question of an orthopaedic operation. The case of this patient is then considered as a cancerous bone pain and she is treated by cementoplasty and analgesic radiotherapy (8 grays just once). The arm is immobilized and there are no major problems afterwards. Without any medication the pain completely disappears when the patient does not do any movement, but is still present when she has a wash. She, then, successfully benefits from an interscalene brachial plexus block and from a phenolisation, which allow a good quality of life at home until she dies in april 2008, without any other additional pain killer needed. Mrs G, 60 years old, suffering from an endometrial cancer develops a spontaneous and acute pain of the right ankle eight weeks after her hysterectomy in December 2007. She cannot move any more her joint, and a bone scintigraphy recovers many hypofixations including on the ankle. An X ray and a scan reveal an osteolytic metastasis of the medial malleolus. In march 2008 a cementoplasty is performed in order to release the patient from pain and to consolidate the joint; a radiotherapy is added (30 grays in 10 sessions). The ankle pain disappears in the hours that follow the treatment allowing the patient to walk normally. She never complains any more of this pain until she dies in may 2008.

Conclusions: The cementoplasty of metastatic long bones has a good analgesic effect and allows the patients to be greatly self sufficient with a good quality of life until the death.

Escapain (Escape Pain): A Nova Scotia Research Study On Standardized Cancer Pain Assessment Forms

Larry Broadfield1,2,3, Judy Simpson1
1Cancer Care Nova Scotia, Halifax, Canada, 2Dalhousie University, Faculty Health Sciences, Halifax, Canada, 3Capital District Health Authority, Pharmacy Department, Halifax, Canada

Objectives: In 2005, Cancer Care Nova Scotia (CCNS) published the “Guidelines for the Management of Cancer-Related Pain in Adults”, in which standardization of cancer pain assessment was a specific objective. A set of assessment forms were developed and tested in the research project ESCAPAIN.

Methods: We developed or adapted 4 tools for pain assessment, two for use by the patients or families (Brief Pain Inventory- BPI and Pain Management Diary-PMD) and two for use by health professionals- HCPs (Pain Assessment and Care Plan- PACP and Pain Management Flowsheet-PMF). Each group had one tool for initial assessment and one other for on-going assessment and monitoring. The ESCAPAIN study was a simple Before-After study, with questionnaires for HCPs before and after the use of these assessment tools in clinical practice. A sample size of 80 HCPs was planned, with representatives from all health care districts, multiple disciplines and practice types (palliative care, cancer clinics, inpatient services, home care nursing, etc.).

Results: 63 HCPs were recruited to participate in the study; 27 completed both the pre- and post-questionnaires. The sample was representative of the groups identified for recruitment. In the pre-questionnaire, many potential barriers to pain assessment were identified, consistent with literature findings. Face validity questions identified that participants felt the forms addressed important aspects of pain assessment, however, the usefulness was less positive after the forms were tested in clinical practice. In paired t-tests, only the PMF was statistically significantly different in the validity tests.

Conclusions: Participants strongly agreed that standardized assessment forms should be used (87% Pre vs 85% Post, NS), but there were several suggestions for improvements to the tools tested in ESCAPAIN.

Fentanyl Pectin Nasal Spray (Fpns) With Pecsys®: Speed Of Onset, Efficacy, Tolerability, And Acceptability In The Treatment Of Breakthrough Cancer Pain (Btcp)

Allen Burton1, Nashat Gabraily2, Donald Taylor3, Mark Watling4
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Objectives: BTCP affects up to 95% of patients with cancer pain. Oral fentanyl formulations do not consistently match the typical time course of BTCP (rapid in onset and lasts for 30–60 min). Many cancer patients have oral difficulties such as mucositis and
Methods: To assess efficacy and safety/tolerability of FPNS, patients (N=114) experiencing 1–4 BTCP episodes/day whilst taking >60 mg/day of morphine (or equivalent) entered a randomised, placebo-controlled, double-blind (DB) study. Patients who successfully titrated (N=83) entered a DB phase in which 10 episodes of BTCP were randomly treated with either the identified effective dose (7) or placebo (3). Pain intensity (PI) was determined using an 11-point scale, pain relief (PR) on a 0–10 visual analog scale (VAS) and safety/tolerability were assessed by adverse events (AEs); no significant nasal effects were reported. Only 5.3% of patients withdrew from titration due to adverse events. Pain intensity difference at 30 min (SPID30). Secondary endpoints included pain outcomes at 5, 10, 15, 30, 45 and 60 min post-dose. Safety/tolerability were assessed by adverse events (AEs) and objective and subjective nasal assessments.

Results: Compared with placebo, FPNS significantly improved mean SPID30 scores (p<0.0001; modified intent-to-treat N=73) and significantly improved SPID scores as early as 10 min (p<0.05) and up to 60 min (p<0.0001). Significant differences in favour of FPNS were found in PI as early as 5 min (p<0.05); benefits were also observed with PID, with a trend at 5 min (p=0.07) that was significant from 10 min onward (p<0.01). PR was significantly superior from 10 min (p<0.001) and at all time points to 60 min (p<0.001). Only 5.3% of patients withdrew from titration due to AEs; no significant nasal effects were reported.

Conclusions: FPNS is safe, efficacious, and has a rapidly onset of action in patients with BTCP. FPNS is safe, efficacious, and has a relatively rapid onset of action in patients with BTCP.

Conclusions: Despite the described differences only few family doctors and oncologists, who mainly prescribe strong opioids for cancer patients, are familiar with these dissimilarities, mistakenly supposing that Pantopon has properties of the two strong opioids used in the country. However, it is well known that Papaverine Hydrochloride 0.72 mg, and three weak opioids, such as Noscapine (Narcotine) 5.4 mg, Codeine 1.44 mg and Thebaine 0.1 mg. It is clear in case of the chronic cancer pain becomes more severe the single dose of medication should be increased accordingly, but it appears impossible using Pantopon. While morphine has not maximum dose for administration, Pantopon has due to its multi-component composition. Accordingly to the rules of correct pain control composition of strong and weak opioids is inappropriate.

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Control Of Cancer Pain In Oncological Wards: The Experience Of Patients Vs The Perception Of Health Professionals
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Objectives: Pain, common symptom among cancer patients, is “an unpleasant sensory and emotional experience…” (IASP), therefore, an objective evaluation is problematic as well as its management. Aim of this study was to assess the degree of agreement between patients and health professionals (clinicians and/or nurses) about control of pain, in cancer patients receiving analgesics.

Methods: A cross-sectional multicentre (48 hospitals) and multidisciplinary (clinicians, nurses, pharmacists) survey was performed, in 6 index-days, to identify patients receiving analgesics. Patients were interviewed by pharmacist concerning their pain intensity at interview and during the previous 24-hours. Pain
Results: Using Cochran-Armitage trend-test, the linear trend between increasing intensity of pain and patient/health professionals disagreement was assessed.

Results: Among 526 patients observed, 426 (80.9%) answered to interview and of these 354 (83.1%) had pain. The intensity of pain was mild, moderate or severe in 24.6%, 24.6% and 33.9% of patients respectively. The agreement between patients and health care professionals was only for 99 patients (28% of 354). Pain was underestimated by health professionals in 72% (255/354) of the patients. The degree of disagreement decreased with intensity of pain reported by the patient: 90.5%, 80.0% and 52.8% among patients with mild, moderate and severe pain respectively (p<0.0001).

Conclusions: Our results showed that too many patients (83%) had still pain despite the analgesic treatment and that the perception of health professionals was different from the experience of patients. The agreement between patients’ pain intensity and health professionals’ evaluation was poor, even if it increased with intensity of pain. A greater attention to patients as well as specific educational interventions are necessary to improve the knowledge of health professionals and so the management of patients with cancer pain.

17-170 Cancer Pain Management In Two Different Hospital Wards: Oncology Vs Non-Oncology
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Objectives: A cross-sectional survey (ItJClinPharm 2008;22:300) was performed in 164 Italian wards to identify patients receiving analgesics. Cancer pain was the main cause of analgesic therapy both in oncological and non-oncological wards. The study aimed to compare cancer pain management in these different wards.

Methods: Epidemiological-clinical-therapeutic data and pain intensity during previous 24-hours were collected. Pain Management Index (PMI) to compare and evaluate the suitability of therapy was used (NEngJMed 1994;330:592). Non-oncological wards were: surgery, medicine, orthopedics. The ordinal-logistic regression for proportional-odds was used to assess association between analgesic therapy and wards, adjusting for age, sex, pain intensity, metastasis effects.

Results: Overall 1023 patients reported cancer pain: 526 in oncology and 497 in non-oncology. Among these patients statistically significant differences were found to related age and metastasis: patients in oncology, compared to non-oncology, were younger (mean age: 63.4 vs 68.4 years; p<0.0001) and more frequently with metastasis (79.9% vs 63.2%; p<0.0001). The use of analgesics only as needed was more frequent in non-oncology than in oncology (9.1% vs 3.6%). Patients in oncology were twice as likely to receive high levels of analgesic therapy compared to patients in non-oncology (OR=2.02, 95%CI 1.52-2.70). Eight-hundred-nineteen patients (80.1%) answered to the interview: 83.1% (354/426) in oncology and 84.2% (331/393) in non-oncology had pain. It was moderate in 24.6% and 30.5% respectively, severe in 33.8% and 30.5%. An inadequate pain therapy (negative PMI) was more frequent in non-oncology than in oncology (18.8% vs 11.3%; p<0.0001).

Conclusions: Cancer pain is present both in oncological and non-oncological wards. The pain intensity according to patients evaluation was comparable in the wards but the treatment used was different. Considering the high percentage of patients suffering pain in spite of treatment, the improvement in the management of cancer pain seems to be necessary not only in non-oncology but even in oncology.

17-171 Fentanyl Pectin Nasal Spray (Fpns) With Pecsys® In Breakthrough Cancer Pain (Btcp): Consistency, Satisfaction And Ease Of Use
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Objectives: BTCP affects most patients with cancer pain, with a time course that is faster in onset than the analgesia provided by oral drugs. Many cancer patients have oral difficulties and feel discomfort taking oral medications. The nasal route offers potential for rapid drug delivery, and is safe and convenient. Fentanyl is a well-established, effective analgesic, making it suitable for nasal administration. FPNS was developed to consistently match the typical time course of BTCP, providing rapid and controlled nasal delivery of fentanyl.

Methods: Patients (N=114) experiencing 1–4 BTCP episodes/day whilst taking ≥60 mg/day of oral morphine (or equivalent) for underlying cancer pain entered a randomised, placebo-controlled, double-blind (DB), multi-centre study. Those who successfully titrated
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Results: Six patients (5.3%) failed to titrate to an effective dose due to adverse effects and seven (6.1%) for lack of efficacy. 91% of randomised patients completed the study and 659 BTCP episodes were analysed (FPNS N=459; placebo N=200). Compared with placebo, 33% of FPNS-treated episodes showed onset of PI improvement at 5 min (P<0.05), 61% at 10 min, and 75% at 15 min (both P<0.0001). By 30 min, 62% of episodes had a clinically meaningful (≥33%) fall in PI (P<0.0001). Satisfaction (satisfied/very satisfied) with the convenience and ease of use of FPNS was reported by 70% and 68% of patients, respectively; 87% of patients elected to continue treatment post-study.

Conclusions: FPNS provided rapid, consistent analgesia in BTCP and was well accepted by patients. Sponsored by Archimedes Development Ltd.

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The Role Of Ketamine As Adjuvant To Opioid For Intractable Cancer Pain
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Objectives: There has been growing evidence of the importance of the N-methyl-D-aspartate (NMDA) receptor in intractable pain. There is good evidence from experimental animal models and clinical trials that ketamine as a NMDA receptor antagonist relieves neuropathic pain. We evaluated whether ketamine in low doses as an adjuvant to opioid treatment improves analgesia with tolerable adverse effects.

Methods: 58 patients with intractable cancer pain received ketamine for 3 days. Each pain type was classified as a somatic, visceral, or neuropathic pain. We assessed pain at 6 hourly intervals with vital signs using a numeric rating scale. Data on opioid doses, ketamine dose, and adverse effects were recorded daily on an assessment chart. To be designated as a responder, a patient had to show a 50% or greater reduction in the mean pain scale.

Results: The overall response rate was 34.5%. The results according to the type of pain mechanism showed that 47% (15/32) patients with neuropathic and 25% (5/20) patients with somatic pain responded. In 24 cases (41.4%), the requirement for an opioid dose was reduced after infusion of ketamine. The most common adverse effects were nausea and vomiting. Eleven patients complained of drowsiness or transient hallucination. However, most adverse effects were mild to moderate and were easily relieved by treatment.

Conclusions: This study demonstrates that the infusion of ketamine in low doses may have an effect on intractable cancer pain and in reducing opioid requirements, especially neuropathic pain with acceptable toxicities. Therefore, ketamine may be useful as an adjuvant to opioid treatment in cancer patients who are receiving palliative care.

17-173
A Cross Sectional Study About Taking Sustained Release Opioids Of Korean Cancer Patients
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Objectives: To evaluate the present status of taking sustained release opioids of Korean cancer patients.

Methods: This is a multicenter cross sectional survey conducted in 56 hospitals in Korea between June and November, 2008

Results: A total of 104 medical oncologists and 1506 cancer outpatients were involved. Patients who were prescribed sustained release oral opioids(morphine or oxycodone) or transdermal fentanyl were included. Pattern of opioid prescription by medical oncologists, actual condition of patient’s taking medication, pain severity, and aspects of medical service were analyzed. Regarding to doctor’s questionnaire, monotherapy which is composed of single sustained release oral opioid or transdermal fentanyl patch was prescribed to 84%. Combination therapy like sustained oral opioids and transdermal fentanyl patch together were given to 16%. Sustained release oral opioids were prescribed more than two times/day to 20%. Average morphine equivalent dose was 118.3 mg/day with 164.3 mg/day in severe pain group. High dose opioids(morphine equivalent dose ≥120mg/day) were prescribed to 37%. Patient’s mean VAS(visual analog scale) was 4.14. 36.3% had mild

Pattern of opioid prescription by medical oncologists, actual condition of patient’s taking medication, pain severity, and aspects of medical service were analyzed. Regarding to doctor’s questionnaire, monotherapy which is composed of single sustained release oral opioid or transdermal fentanyl patch was prescribed to 84%. Combination therapy like sustained oral opioids and transdermal fentanyl patch together were given to 16%. Sustained release oral opioids were prescribed more than two times/day to 20%. Average morphine equivalent dose was 118.3 mg/day with 164.3 mg/day in severe pain group. High dose opioids(morphine equivalent dose ≥120mg/day) were prescribed to 37%. Patient’s mean VAS(visual analog scale) was 4.14. 36.3% had mild
pain, 39.1% had moderate pain, and 18.1% had severe pain. Patients who were prescribed monotherapy showed a better VAS (oral sustained opioids: 4.18, transdermal fentanyl patch: 3.76, oral sustained opioids and transdermal fentanyl patch together: 4.78). 50% experienced pain worsening before the next around clock medication even with the coverage of sustained release opioids. Patients tend to take opioids more frequently as pain intensity got higher. The most inconvenient aspect when taking medication was about the fear of pain getting worse just before the next medication.

**Conclusions:** This study suggests that insufficient pain control and inadequate opioid dose is being given to Korean cancer patients who are taking sustained release opioids. More effective and sustained pain control should be provided to these patients. Supported by Janssen Korea

**17-174**

**Development And Evaluation Of Pain Education For Terminal Cancer Patients**

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**Objectives:** In Korea, under treatment of pain is increasingly receiving attention. Korea cancer patients have reported myths and fear of opioids use, which interfere adequate pain control. This study aimed to develop the pain education program for terminal cancer patients and their caregivers and test the effects of the pain education on barriers to pain management.

**Methods:** A quasi-experimental study that was pre- and post-test design with a nonequivalent control group was conducted. Data collection was conducted on 32 in experimental group and 33 in control group who were terminal cancer patients and their family caregivers from April 2007 to April 2008.

**Results:** The pain education program was developed in four steps: literature review, pilot program development, pilot study, and detailed program structuring. Individualized pain education was delivered by both hospice nurses and a pharmacologist with pain education handbook at the day or the day after admission. BQ II (Barrier Questionnaire II) which developed by Gunnarsdottir, et. al., and modified by Yoo et. al. was measured as an outcome variable. The experimental group reported significantly lower score of barriers to pain management than control group (p<0.001).

**Conclusions:** This study indicated that the pain education could be effectively delivered to terminal cancer patients and their caregivers and to lower the barriers to pain management. This suggests that the pain management education may be beneficial and feasible to terminal cancer patients and their caregivers. It is expected to contribute to improve pain management in hospice setting.

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**Impacts Of Cancer Pain: Patients And Family Caregivers' Experiences In Taiwan**

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**Objectives:** The purposes of this study were to: (1) examine the differences in symptom severity, pain catastrophizing thoughts, perceived uncertainty, and emotional distress between cancer patients with or without pain; and (2) compare the differences in caregivers’ burdens, perceived uncertainty, emotional distress, and sleep quality between caregivers who took care of cancer patients with or without pain.

**Methods:** A cross-sectional survey study was conducted. Cancer patients (with pain and without pain) and their primary family caregiver dyads were recruited and interviewed separately by trained research nurses in two medical centers in Northern Taiwan. We used several measures to assess patients and primary caregivers’ pain related experiences. These are: Brief Pain Inventory – short form (BPI), Symptom Severity Scale (SSS), Pain Catastrophizing Scale (from CSQ), Mishel’s Uncertainty of Illness Scale, Hospital Anxiety and Depression Scale, Caregivers’ Reaction Assessment, and Karolinska Sleep Diary. Data were analyzed by t-test, correlation analysis, and descriptive statistics. IRB approval was received before conducting the study.

**Results:** A total of 245 cancer patients-family dyads were recruited. The major results showed that patients with cancer pain had significantly higher symptom distress, pain catastrophizing thought, perceived uncertainty, and emotional distress than those without pain. Primary family caregivers who took care of patients with cancer related pain perceived higher level of caregivers’ burdens, perceived uncertainty, emotional distress, and worse sleep status while compared to those cared for patients without cancer pain.

**Conclusions:** Our results showed that cancer patients with pain and their family caregiver both had more negative life outcomes than those without cancer pain. Intervention to help cancer patients with pain and their family caregivers should be developed to further improve their life qua.
Methadone In Patients With Severe Cancer Pain - An Open Study Assessing Its Usefulness In Rotation From Morphine And Transdermal Fentanyl

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Objectives: Aim of the study: To assess methadone analgesia, adverse effects, calculation method of equianalgesic doses with oral morphine

Methods: Patients and methods: Methadone was administered to 31 opioid – tolerant cancer patients because of pain (numerical rating scale NRS > 5) on morphine (15 patients), TF (transdermal fentanyl) (9), morphine and TF (4), tramadol (1), pethidine (1), pain with nausea on morphine (1). Dose ratios of equivalent daily dose of oral morphine (ddom) to daily dose of oral methadone (ddomet) were as follows: 4 : 1 (ddom to 100 mg), 6 : 1 (101 – 300 mg), 12 : 1 (301 – 1000 mg) and 20 : 1 (over 1000 mg). Previous opioids were stopped completely (stop-start approach) in 29 patients, 2 patients received methadone and other opioids. The mean ddom before switch was 810 ± 484 mg. Methadone was administered regularly 3 times daily, 30 patients received oral methadone and 1 patient was treated with rectal suppositories. Breakthrough pain was treated with methadone (half of regular dose), morphine, fentanyl, metamizol and ketamine

Results: The mean time of methadone treatment was 35.3 ± 26.1 (range 3 – 95) days, mean daily doses at the start of treatment 47.2 ± 19.5 mg, maximal 148.5 ± 104.1 mg and 132.1 ± 105.3 mg at treatment completion. Good analgesia (NRS <4) was achieved in 15, partial (NRS 4 – 5) in 13, unsatisfactory effect (NRS > 5) in 3 patients. The most frequent adverse effects were drowsiness (9 patients), constipation (8), nausea and vomiting (4), sweating (3), respiratory depression (1) resolved by methadone cessation and naloxone

Conclusions: Results of this study confirmed high analgesic efficacy, acceptable methadone adverse event profile, safety and effectiveness of of ddom to ddomet dose calculation method

Assays Of Tramadol, Dihydrocodeine And Metabolites Level In Patients Treated With Controlled Release Dihydrocodeine And Tramadol - Results Of A Prospective, Randomised, Cross-Over Study

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Objectives: Aim of the study: Assessment of tramadol, dihydrocodeine (DHC) and metabolites level in patients treated with controlled release dihydrocodeine and tramadol

Methods: Patients and methods: Thirty opioid – naïve patients with nociceptive pain (VAS>40) treated previously with non-opioids were randomised to receive either tramadol or DHC for 7 days, then cross – over, 7 days treatment. Blood samples taken 2nd, 4th, 7th day during each study period. HPLC used for drug assays, statistical analysis by ANOVA and LSD test

Results: Results: When tramadol administered in first week a trend (p=0.067) of increase in third compared to first measurement. Tramadol level increased in second and third measurements in comparison to first assay when tramadol administered after DHC (in second week). During this time active tramadol metabolite (M1) increased in second and third compared to first assay, in the first week M1 levels did not change. DHC level increased in second and third compared to first assay during DHC administered first week. When DHC administered in second week a trend (p=0.9) DHC level increase compared to first DHC assay. DHC metabolites: Trend of fall of dihydronormorphine (DHNM), between first and third assay (p=0.095), during DHC administered first week. Dihydromorphine (DHM) trend towards increase in second comparing to first assay (p=0.057) and fall in third comparing to second measurement (p=0.1) both when DHC first week. DHNM and DHM level stable when DHC administered in second week. Dihydrocodeine-6-glucuronide (DHC6) levels increased in second and third comparing to first assay when DHC administered in both weeks

Conclusions: Conclusions: Tramadol and M1 increased in second week. DHC6 increased both weeks, DHC increased in first week. DHNM and DHM stable in second week, DHNM fall, DHM rise and decrease (all trends) in first week. Observed changes caused by analgesic demand, equianalgesic ratio used (tramadol : DHC 10 : 6), other drug interactions

Breakthrough Pain: The “Best Unknown Pain Syndrome”

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Objectives: Breakthrough pain is a syndrome defined by: Rapid onset of acute pain, lasting from seconds to hours (range 30 minutes), known factors as movements,
cough, miction, respiration, deglutition or unknown: like neuropathic pain, co-existing chronic pain syndrome and/or an adequate chronic treatment. The underlying disease is often cancer. Differential diagnosis relies on clinical signs and symptoms. Treatment is usually disappointing.

Methods: We conducted a one year survey in our supportive care department in order to analyze BP. 42 admissions on 209 (35 patients) were related to BP. Some patients have been hospitalized twice or more. Median duration of hospitalization was 7 days. All patients had progressive cancer disease with metastatic lesions. All had opioids (i.e morphine, fentanyl, hydromorphone) and co-analgesics (antidepressants, anti epileptics or steroids). BP episodes occurred more than four times a day.

Results: Treatment options were methadone (oral or IV) or opioid rotation, gabapenten or pregabaline and or ketamine IV. We used oral transmucoscal fentanyl citrate (OTFC) in four cases (compassionate use). All patients improved but side effects were of concern especially with high doses of opioids (constipation, somnolence, myoclonus). Beside the treatment, the estimated cost of hospitalization for one patient with BP was 3 758 € (for 7 days). This is of importance if we note that patients receiving OTFC stayed less than 3 days at hospital.

Conclusions: BP remains a challenge in supportive and palliative care. Diagnosis requires expertise and the cost of treatment has to be taken into account. Avoid long stay at hospital a priority. All data will be presented in details.

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Opioid Rotation Versus Combination For Cancer Patients With Chronic Uncontrolled Pain: A Prospective Randomized Study
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Objectives: For cancer patients with inadequate pain relief, a switch to an alternative opioid is one of the preferred options for symptomatic improvement. However, multiple opioids are often simultaneously administered for anecdotal reasons.

Methods: Patients suffering with uncontrolled cancer pain were randomly assigned to opioid rotation group or opioid combination group. Patients answered a questionnaire that included items on pain severity (0 to 10) and interferences at baseline and after one week.

Results: Of the 50 patients registered, 39 patients answered the questionnaire after one week of treatment. After one week, the mean pain scores were significantly improved in both groups. Ten patients (42%) in the rotation group and 16 patients (62%) in the combination group reported that they achieved relief from pain (p=0.08). The incidence of adverse events was similar in both groups, but fewer patients experienced constipation with opioid rotation than with combination (17% vs. 42%, respectively; p=0.05). The frequency of rescue analgesics (50% vs. 69%; p=0.17) and dose modification (29% vs. 38%; p=0.49) were similar in the rotation and combination groups.

Conclusions: For patients with chronic uncontrolled cancer pain, both opioid rotation and combination strategies appear to provide significant relief of pain and improved patient satisfaction.

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Cancer Pain Management In Developing Countries: An Affront To Human Dignity!
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Objectives: Methods: Results: Conclusion: In the era where man is bent upon conquering nature whether air, sky, sea or mountains, one contribution of nature has been defying him all through generations. That happens to be pain. In fact pain is being considered as the fifth vital sign along with pulse, blood pressure, temperature and respiration. The human suffering due to pain is an affront to human dignity. The origin of pain is often in the physical realm, but manifested through an array of psychological, social, and cultural factors. Since dawn of civilization, pain management is enslaved by myths, irrationality, ignorance, and cultural bias, the situation is even worse in developing countries; Myths include that pain is a punishment for human folly and enduring pain builds strength and character. They are further confounded with concerns about opioids; Opiophobia among health care providers and opioignorance. These entrenched attitudes to pain and its rationalization makes suffering from cancer pain biblically preordained contributing to the myth that if one suffers here, paves his way to heaven. The bioethical principle of justice, seeking equitable distribution of health care, is the greatest challenge to inadequate pain management. However admirable the ideal of pain management as universal human right, reality is a world in which massive resource discrepancies preclude fulfillment of such a right. Societal attitudes toward pain relief illustrate the complex interactions between cultural concepts of pain, pain relief, and social behavior. Some
patients may want to be awake for religious considerations and suffer pain, delirium may be mistaken for possession of spirits. Pain control is arguably the past, present, and future of oncology. Much work is required to make transition from asserting pain management as fundamental human right, to actually shift the societal attitudes so as to echo as humanitarian triumph of pain relief.

18-181
Development Of An Interdisciplinary Supportive Care Plan For Patients With Lung Cancer
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Objectives: Lung cancer impacts all dimensions of physical, psychological, social, and spiritual well being. This two phase study of QOL and symptoms in lung cancer included Phase I to determine usual care at a NCI designated comprehensive cancer center. Phase II gained input from patients regarding QOL concerns and pilot tested a palliative care intervention.

Methods: In Phase I, 100 patients were randomly selected by the tumor registry from 125 new lung cancer patients seen over a 12 month period. An audit tool reflecting aspects of quality care as described by the NCCN was developed, peer reviewed and tested to establish reliability. Care was audited for a 6 month period. In Phase II 10 patients completed 4 quantitative tools and participated in a tape-recorded interview. Data was summarized into a care plan and shared with the interdisciplinary team at a case conference whereupon the care plan incorporated the team’s suggestions. Follow-up with the patient occurred one and three months post conference to evaluate the impact of the intervention.

Results: Phase I data revealed 85% were stage III-IV, 82% had comorbidities, 81% received chemotherapy and 43% had radiation therapy. Thirty percent received no supportive care services. Uncontrolled symptoms were reasons for outpatient visits and for 38% of hospital readmissions. Phase II data revealed 60% had stage III-IV with COPD/emphysema and cardiac disease as common comorbidities. Symptom specific scores were moderate (X=20.6) as were overall scores for QOL using the FACT-L (X=87.8). Emotional well-being scores were the lowest (X=18.4) followed by functional (X=21.1), social/family (X=23.8), and physical (X=24.5). Supportive care services recommended included nutrition, psychology/psychiatry, social work, rehabilitation, and chaplaincy.

Conclusions: QOL/symptom concerns are often neglected in usual care in lung cancer. An interdisciplinary palliative care intervention can prospectively meet these needs.

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The Assessment Of Quality Of Life In Palliative Cancer Care: Single Versus Multiple Item Tools
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Objectives: The improvement of quality of life (QOL) is a cornerstone of good palliative care. QOL is a subjective and complex multi-dimensional concept, so it is usually measured using multi-dimensional instruments. Recently, authors have suggested that brief single-item global assessments can provide a reliable measure of overall QOL. Using the Functional Assessment of Cancer Therapy - General (FACT-G) instrument as a gold standard, we assessed the performance of the Edmonton Symptom Assessment System ‘feeling of well-being’ item (ESAS WB).

Methods: After obtaining IRB approval, we retrospectively reviewed the data from six prospective clinical trials conducted by our group in advanced cancer patients. We determined the levels of association between baseline ESAS WB and FACT-G total and subscale domain scores (Physical (Pwb), Social/Family (Swb), Emotional (Ewb), and Functional (Fwb) Well-Being) and also between the nine ESAS symptom intensity scores using Spearman correlation coefficients. We also calculated the change between the baseline (T1) and second (T2) observations of ESAS WB and of FACT-G total score and determined their level of association using a Pearson correlation coefficient. We also predicted the change in FACT-G as predicted by the ESAS WB score using regression analysis.

Results: Mean age of the 218 trial participants was 60 (SD 12) years and 48% were female. Spearman correlations between ESAS WB and FACT-G and ESAS scores are shown in the table. The Pearson correlation coefficient for T1 – T2 in ESAS WB and FACT-G for 146 patients was -0.36 (p<0.0001). The regression analysis was highly significant (p<0.0001). The change in ESAS WB corresponding to FACT-G published minimally important difference (MID) was -0.24 for 3, -1.55 for 5, and -2.87 for 7, respectively.
Conclusions: ESAS WB is a practical instrument for the clinical setting but appears to correlate less well with the Swb domain of FACT-G.

Sociodemographic, Clinical And Economic Factors Associated With The Place Of Death Of Older Mexicans.

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Objectives: To describe the factors associated with the place of death in a group of older Mexicans and to inform policy decision-makers on palliative care and end-of-life issues in Mexico.

Methods: A retrospective study using the Mexican Health and Aging Study survey (MHAS). Cases included were older adults (borne before 1951) and their spouses/partners who participated in the MHAS 2001 and 2003 baseline and follow-up interviews. Cases with missing information were excluded. The main study outcome was place of death (hospital vs. home). The associations between sociodemographic, clinical and economic factors and place of death were examined by using logistic regression analysis.

Results: A total of 473 cases met the inclusion criteria. Fifty-three percent died at home and the mean age at death was 74 years. The most frequent causes of death were cardiovascular disease (22%) followed by cancer (19%). Independent predictors of dying in a hospital were: living in a city of 100,000 or more inhabitants [OR=2.30 95% CI 1.16, 4.54], dying in a city away from the city of usual residency [OR=4.77 95% CI 2.24, 10.15], dying of stroke [OR=4.26, 95% CI 1.27, 14.26] and not having paid for any hospital stays during the last year of life [OR=3.75 95% CI 1.74, 8.08]. Old age [OR=0.97 95% CI 0.95, 0.99] and dying of cancer [OR=0.46 95% CI 0.22, 0.95] were protective against dying in hospitals.

Conclusions: Patients who were residents of small cities, of older age, diagnosed with cancer or who spent money for hospital stays during the last year of life, were more likely to die at home. Efficient allocation of resources for end-of-life care for the oldest should include community based home-care programs. Table 1. Bivariate analysis of sociodemographic, clinical and economic factors associated with the place of death of older adults who participated in the MHAS Study.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hospital or Institution</th>
<th>Private Home</th>
<th>P - value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Place of death</td>
<td>223 (47.1)</td>
<td>250 (52.9)</td>
<td>NA</td>
</tr>
<tr>
<td>Mean age (median)</td>
<td>71.1 (72)</td>
<td>75.7 (76)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cause of death</td>
<td>0.17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>47 (21.1)</td>
<td>57 (22.8)</td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td>37 (16.6)</td>
<td>54 (21.6)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>41 (18.4)</td>
<td>50 (12.0)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>22 (9.9)</td>
<td>17 (6.8)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>76 (34.1)</td>
<td>92 (36.8)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>0.82</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>111 (49.8)</td>
<td>127 (50.8)</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>112 (50.2)</td>
<td>123 (49.2)</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td>0.10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married or in a married-like situation</td>
<td>125 (56.1)</td>
<td>121 (48.4)</td>
<td></td>
</tr>
<tr>
<td>Not married</td>
<td>98 (43.9)</td>
<td>129 (51.6)</td>
<td></td>
</tr>
<tr>
<td>Died in city of usual residency</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>154 (49.1)</td>
<td>222 (88.8)</td>
<td></td>
</tr>
<tr>
<td>Size of city of usual residency</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 100,000 inhabitants</td>
<td>53 (23.8)</td>
<td>103 (41.2)</td>
<td></td>
</tr>
<tr>
<td>100,000 or more inhabitants</td>
<td>170 (76.2)</td>
<td>147 (58.8)</td>
<td></td>
</tr>
<tr>
<td>Education in years (median)</td>
<td>3 (3)</td>
<td>2 (2)</td>
<td>0.14</td>
</tr>
<tr>
<td>During the last year had to pay for hospital overnight stays</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>44 (19.7)</td>
<td>54 (21.6)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>141 (63.2)</td>
<td>80 (32.0)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>38 (17.0)</td>
<td>116 (46.4)</td>
<td></td>
</tr>
<tr>
<td>If yes, mean amount paid for hospital stay (median)</td>
<td>$24650.00* (8000)</td>
<td>$27855.00* (9900)</td>
<td>0.74</td>
</tr>
<tr>
<td>During the last year had to pay for doctor visits</td>
<td>&lt;0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>69 (42.0)</td>
<td>105 (30.9)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>107 (48.0)</td>
<td>83 (33.2)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>47 (21.1)</td>
<td>62 (24.8)</td>
<td></td>
</tr>
<tr>
<td>If yes, mean amount paid for doctor visits (median)</td>
<td>$12379.00* (3500)</td>
<td>$14805.00* (2000)</td>
<td>0.09</td>
</tr>
</tbody>
</table>

*Mexican pesos 2003
Age And Gender Differences In The Symptom Patterns Of Advanced Cancer Patients
Winson Cheung¹, Lisa Le², Camilla Zimmermann³
¹British Columbia Cancer Agency, Medical Oncology, Vancouver, Canada, ²Princess Margaret Hospital, Biostatistics, Toronto, Canada, ³Princess Margaret Hospital, Psychosocial Oncology and Palliative Care, Toronto, Canada

Objectives: Certain cancer symptoms have been observed to frequently occur together. Our aims were to explore symptom clusters among patients with advanced cancers and to examine age and gender differences in cancer symptom patterns.

Methods: Symptom scores by the Edmonton Symptom Assessment Scale (ESAS) were collected for patients attending the Oncology Palliative Care Clinics at Princess Margaret Hospital from 2005 to 2007. Principal component analysis (PCA) was performed for the entire patient cohort and for age and gender subgroups (men > and ≤ 60 years; women > and ≤ 60 years) in order to determine inter-relationships of the nine ESAS symptoms and to compare symptom patterns among older and younger men and women. We defined a cluster as accounting for ≥ 10% of the total variance, and a symptom within a cluster as having a loading score of >0.60.

Results: A total of 1,366 patients was included: 682 (50%) were male and 684 (50%) were female. The median age was 64 years (range 18 to 74): 824 (60%) were >60 and 542 (40%) were ≤ 60. The most common primary cancer sites were gastrointestinal (27%), lung (14%), and breast (11%). The three most distressful symptoms were: fatigue, decreased appetite, and poor general wellbeing for both men and women >60; and fatigue, pain, and poor general wellbeing for both men and women ≤60. PCA for the entire patient cohort revealed two major symptom clusters: cluster 1 included fatigue, drowsiness, decreased appetite, and dyspnea; and cluster 2 included depression and anxiety. Stratified analyses based on age and gender revealed differences in the pattern of symptom clusters (see Table).

Conclusions: In patients with advanced cancers, distinct symptom clusters can be identified, which are influenced by age and gender. Palliative interventions tailored for symptom clusters that are prominent in specific patient subgroups may offer greater therapeutic benefit.

<table>
<thead>
<tr>
<th>Table: Age and Gender Differences in Symptom Clusters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>Fatigue</td>
</tr>
<tr>
<td>Nausea</td>
</tr>
<tr>
<td>Depression</td>
</tr>
<tr>
<td>Anxiety</td>
</tr>
<tr>
<td>Discomfort</td>
</tr>
<tr>
<td>Appetite</td>
</tr>
<tr>
<td>Wellbeing</td>
</tr>
<tr>
<td>Dyspnea</td>
</tr>
</tbody>
</table>

Values listed represent factor loading scores in the principal component analysis where * indicates symptom clustering within the age/gender subgroup.

Diseases Coexisting With Tumours In Patients Provided With Home Palliative Care
Aleksandra Cialkowska-Rysz, Leszek Gottwald, Sylwia Kazmierczak - Lukaszewicz
Palliative Care Unit Medical University of Lodz, Oncology Department, Lodz, Poland

Objectives: In Poland the basic form of palliative care is home care. Patients are entitled to receive medical assistance from general practitioners and other specialists, however, complex treatment is most often provided by hospice doctors. Frequency of tumour occurrence increases with age, just as it is in the case of chronic internal, neurological and other diseases. The most common symptoms that require pharmacotherapy and occur among patients provided with palliative care are among others: pain, shortness of breath, nausea and vomiting, constipation, cancer cachexia, anxiety, depression. When planning a therapy for patients already treated for other chronic diseases palliative care specialists face the problem of choosing the safest therapy necessary to control pain and other symptoms caused by developing tumour.

Methods: Non-clinical and non-invasive research based on analyzing medical documentation of patients provided with palliative care. The group included 208 patients over the age of 18 with advanced stage of tumour. All the patients required symptomatic treatment. Coexisting diseases were selected for which patients took medicines temporally or permanently.

Results: The age of patients subject to research was between 25 and 90; the average was 69.4. The most common types of tumour diagnosed are lung, breast and alimentary tract tumours. The most common chronic diseases were ischeamic heart disease, hypertension and peripheral vessel disease. About 25% of patients suffered from type II diabetes. 78% of patients over the age of 65 suffered from coexisting diseases. Patients most often reported 2-3 coexisting diseases, the maximum number was 7.

Conclusions: Most patients provided with home palliative care were people of advanced age and suffered from ischeamic heart disease, hypertension, peripheral
vessel disease and diabetes as coexisting diseases with tumours. Estimation of costs of treatment for this group of patients should also include treatment of coexisting diseases.

18-186

**Phase Angle Is A Better Predictor Of Survival Than Muscle Mass In Advanced Cancer**

Mellar P. Davis¹, Nabila Bennani-Baiti¹, Dilara Seyidova-Khoshkhabi¹, Ruth Lagman¹, Matt Karafa², Declan Walsh¹

¹Cleveland Clinic Taussig Cancer Institute, Solid Tumor Oncology, Section of Palliative Medicine & Supportive Oncology, Cleveland, USA, ²Cleveland Clinic, Department of Quantitative Health Sciences, Cleveland, USA

**Objectives:** Single frequency 50 KHZ bioelectrical impedance analysis (BIA) measures reactance, resistance and phase angle (PA). PA is determined by quantity and quality of membrane function. Low PA inversely correlates with C-reactive protein and directly with survival in cancer. A BIA equation for predicting smooth muscle mass (SMM) has been validated by MRI - with a correlation ($r^2 = 0.86$ SE 2.71 kg, 9%). We compared survival predictability of SMM with PA during hydration.

**Methods:** 50 individuals with advanced cancer underwent daily BIA for 3 days by standard technique during hydration. Resistance at day 1 was used to calculate SMM using the equation $\text{SM} (\text{kg}) = \left[ \text{HT}^2 / R \times 0.401 \right] + \left[ \text{gender (0 or 1)} \times 3.875 \right] + \left[ \text{age} \times -0.071 \right] + 5.102$. Spearman correlations were used for comparisons. Kaplan-Meier survival estimate at 30- and 60-days post-hydration was the outcome. Hazard ratios based on Cox Proportional Hazards model were calculated.

**Results:** Patient-reported weight loss ($P = 0.014$) and increased PA over 3 days ($P = 0.01$) predicted poorer survival. Higher PA on day 1 ($P = 0.057$) and weight gain during hydration ($P = 0.007$) predicted better survival. HR for mortality increased by 1.17 for increased PA d1-3, 0.7 for weight gain. SMM did not correlate with survival (HR 1.0 $P = 0.82$). Assuming the change in resistance from day 1 to 3 changes the estimate of skeletal muscle mass, neither D3 skeletal muscle mass nor change in day 1 to 3 SMM predicted survival (HR 1.04 and HR 1.01, respectively) ($P = 0.96$ and $P = 0.88$). Phase angle is determined by qualitative cell membrane function and is a better predictor of survival than SMM.

**Conclusions:** BIA-determined phase angle predicts survival independent of skeletal muscle mass. Future studies using BIA spectroscopy should be done to confirm these results.

18-187

**A Preliminary Study On The Association Of Spiritual Distress And Physical And Emotional Symptoms In Advanced Cancer Patients Admitted To An Acute Palliative Care Unit (Pcu)**

Maxine de la Cruz¹, Steve Thorney¹, David Hui¹, Henrique Parsons¹, Marvin Delgado², Eduardo Bruera¹

¹MD Anderson, Palliative Care, Houston, USA, ²University of Texas Medical Branch, Geriatric and Palliative Care, Houston, USA

**Objectives:** Suffering is a multidimensional construct that includes physical, emotional, and spiritual distress that is reported to be associated with poor physical outcomes and higher rates of mortality. However, very little research has been done focusing on the relationship between physical and emotional distress and spiritual distress. Our aim was to determine if spiritual distress is associated with physical and emotional symptoms.

**Methods:** We reviewed patients admitted to the PCU and determined association of patient characteristics (age, gender, ethnicity, religion, length of PCU stay, reason for PCU admission), the severity of patient’s symptoms using the Edmonton Symptom Assessment Scale (ESAS) and spiritual assessment as reported by the chaplain on initial visit. Seven domains were used in the spiritual assessment and the presence of 2 or more domains was used to define spiritual distress. Univariate (UV) and multivariate regression (MR) analyses were utilized in data analyses.

**Results:** A total of 113 patients were included, 68 (60%) males, 92 (81%) Christians, and 69 (61%) Caucasians. 50 (44%) patients had spiritual distress. Median age of patients with spiritual distress was 56 years vs. 67 years for those without ($p=0.005$). Gender, ethnicity, religion, length of PCU stay, and reason for PCU were not different between groups. Those with spiritual distress reported worse pain than those without ($p<0.05$). Spiritual distress was associated with age ($p=0.005$), pain ($p=0.012$), and depression ($p=0.006$) (UV) and age (OR=0.96, $p=0.012$) and depression (OR=1.272, $p=0.020$) (MR).

**Conclusions:** Our findings that spiritual distress is associated with age, pain and depression, provide evidence that a multi-dimensional approach to symptom management is essential and that addressing spiritual distress could likewise improve patient’s symptoms. Hence, more research is needed in the development of assessment tools for spiritual distress.
Association Between Inflammatory Markers, Symptom Burden, Hypogonadism And Survival In Cancer Patients With Cachexia.
Egidio Del Fabbro, David Hui, Zohra Nooruddin, Shalini Dalal, Lynn Palmer, Eduardo Bruera
MD Anderson Cancer Center, palliative Care, Houston, USA

Objectives: Cancer Cachexia is characterized by muscle wasting, anorexia, and elevated inflammatory markers. Similarly, in patients without cancer, hypogonadism is associated with lower lean body mass, increased symptom burden and decreased survival. Hypogonadism in cancer cachexia could exacerbate symptom distress, facilitate a pro-inflammatory state and decrease survival. Currently, there are no guidelines for testosterone replacement therapy in cancer patients. We evaluated the relationship between hypogonadism, symptom severity, inflammation and survival in patients with cachexia.

Methods: A retrospective chart review of 159 consecutive patients (61 females, 98 males) referred to a specialized cachexia clinic at a comprehensive cancer center. 98 patients (62%) had C-reactive protein (CRP) levels measured, and 68(69%) males had serum total testosterone evaluated. Testosterone levels were not evaluated in female patients. Symptoms were assessed by the Edmonton Symptom Assessment Scale (ESAS).

Results: All patients reported weight loss of >5% within the preceding 6 months; Median age was 62, CRP 26mg/L and in males median total testosterone186ng/dL (normal level ≥240 ng/dL). Spearman correlation revealed higher CRP levels (r=0.57, p<0.01) increased dyspnea (r=0.27, p<0.05) and poorer sleep scores (r=0.29, p<0.05) in males with low testosterone. In 46 males and females who underwent CRP testing within 30 days of their ESAS evaluation, pain (r=0.48, p<0.01), fatigue (r=0.39, p<0.01), poor appetite (r=0.49, p<0.01), insomnia (r=0.42, p<0.01) anxiety (r=0.29, p<0.05), and dyspnea (r=0.31, p<0.05) correlated with an elevated CRP. Survival of male patients with testosterone<186 ng/dL was decreased compared to those with levels ≥186ng/dL (13 vs.62 weeks, p=0.004). Patients with CRP>10 mg/L had decreased survival compared to those <10 mg/L (30 vs. 66 weeks, p=0.017).

Conclusions: Elevated C-RP levels in cancer cachexia are associated with poorer survival and increased symptom burden. Low testosterone is strongly associated with decreased survival in cachectic male patients and correlates inversely with C-RP levels, dyspnea and insomnia.

Sleep Disturbance And Symptom Variables In Patients With Advanced Cancer In The Palliative Care Setting
Marvin Delgado Guay1, Henrique Parsons2, Zhijun Li2, J Lynn Palmer2, Eduardo Bruera2
1The University of Texas, Medical School at Houston, Geriatrics and Palliative Medicine, Houston, USA, 2The University of Texas, M.D. Anderson Cancer Center, Palliative Care and Rehabilitation Medicine, Houston, USA

Objectives: Sleep disturbance (SD) can be distressing for advanced cancer patients (pts). The Edmonton Symptom Assessment System subscale sleep (ESAS-S) has not been validated as screening tool for SD. Purpose: To determine the symptom variables (ESAS) that are associated with SD [Pittsburgh Sleep Quality Index (PSQI)] in pts evaluated in the palliative care setting.

Methods: A retrospective chart review of 101 charts from pts from clinical trials being conducted by our group. Demographic data and baseline assessments of ESAS and PSQI were collected. The diagnosis of SD was made when patients score 5 or more in PSQI. Frequency (ESAS≥1) and intensity of symptoms was statistically analyzed with Chi-Square test and Wilcoxon rank-sum test, respectively. The sensitivity and specificity values for ESAS-S were calculated.

Results: Of 101 pts analyzed, the median age(range) was 60 years (25-84). 53 patients (52%) were female. 74(73%) were White, 15(15%) Hispanic, and 12 pts(12%) African American. Primary cancer: 21(21%) lung, 20(20%) breast, 15(15%) gastrointestinal, and 45(44%) others. The frequency of SD was 86/101(85%). Pts with SD expressed higher frequency of pain [76/86(88%) vs 9/15(60%), p=0.0132], depression [61/86(71%) vs 6/15(40%), p=0.0193], and anxiety [57/86(66%) vs 5/15(33%), p=0.0156]. Pts with SD expressed higher frequency of pain [76/86(88%) vs 9/15(60%), p=0.0132], depression [61/86(71%) vs 6/15(40%), p=0.0193], and anxiety [57/86(66%) vs 5/15(33%), p=0.0156]. Pts with SD presented worse well-being [ESAS(Q1-Q3)= 5(3-6) vs 4(2-4), p=0.035]. Spearman’s correlation showed a significant association between PSQI and pain (r=0.27, p=0.0055), dyspnea (0.25, 0.0002), well-being (0.35, <0.0001), and sleep (0.44, <0.0001). A cut off of 2, 3, and 4 out of 10 or more in the ESAS gave sensitivity of 86%, 74%, and 64%; and specificity of 53%, 74%, and 64% respectively.

Conclusions: SD is associated with increased frequency of pain, depression, and anxiety, but with variable intensity, affecting more well-being of the pts. The ideal cutoff point of ESAS-S for the screening of SD is 3 out of 10 or more. More research is needed.
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Relationship Between Symptom Distress, Opioid Therapy, And Endocrine Abnormalities In Patients With Advanced Cancer
Rony Dev, David Hui, Zohra Nooruddin, Mark Munsell, Egidio Del Fabbro, Eduardo Bruera
University of Texas - M. D. Anderson Cancer Center, Supportive Care & Palliative Medicine, Houston, USA

Objectives: Patients with advanced cancer often have increased symptom burden including pain, weight loss, insomnia and fatigue. Opioid therapy for the management of cancer pain may result in neuro-hormonal dysfunction which may contribute to a patient’s symptom distress. We examined the relationship between opioid therapy, serum cortisol and testosterone levels, and symptom distress in cancer patients.

Methods: A retrospective chart review was performed on 77 consecutive patients with advanced cancer referred to a cancer cachexia clinic. We collected information regarding cortisol levels (AM and random), testosterone (male only), morphine equivalent daily dose (MEDD), and symptom severity by Edmonton Symptom Assessment Scale (ESAS). Non-parametric correlation analysis was performed.

Results: The median age was 63 (range 24-79) and predominantly males, (n=48, 62%). Thirty-three patients (43%) had gastrointestinal malignancies. The median random cortisol was 19.1 (Q1-Q3 13.4-23.8 (normal 4.3-22.4)) which correlated with MEDD (Spearman’s coefficient: 0.25, p=0.032), pain (0.50, p<0.001), fatigue (0.29, p=0.012), nausea (0.34, p=0.003), depression (0.24, p=0.032), and anxiety (0.25, p=0.031), although only pain and nausea remained significant after Bonferroni correction. Median morning cortisol (n=28) was 20.6 (Q1-Q3 16.6-25.4), and significantly correlated with pain (0.55, p=0.003) with Bonferroni correction. In patients with a MEDD≤30, mean random cortisol levels was 16.8, while patients with a MEDD>30 had a mean random cortisol level of 20.6, p=0.006. In 44 male cancer patients, MEDD was inversely correlated with total testosterone level (-0.52, p=0.001).

Conclusions: Elevated random cortisol had a strong association with pain and opioid use, while elevated morning cortisol was associated with pain only. Advanced cancer patients on higher opioid therapy (MEDD>30) had increased cortisol levels and in male patients, lower testosterone levels. Our study suggests that opioid therapy may result in gonadal dysfunction while sparing the adrenal axis. Future prospective research is needed to confirm our findings.

18-191
Supportive Therapy In Multiple Myeloma
Aneta Dimitrovska, Simonida Crvenkova, Petar Cakalaroski, Nenad Mitreski, Ilir Ismaili, Maja Popova
Institute of Radiotherapy and Oncology, Malignant Lymphomas, Skopje, Macedonia

Objectives: To examine the impact of supportive therapy on the performance status and treatment outcome of patients suffering from multiple myeloma (MM).

Methods: Histories of 97 patients with symptomatic MM were retrospectively reviewed. Clinical signs, radiological findings and laboratory tests were scored as well the kind of supportive therapy used.

Results: The pain was the most dominant clinical sign presented in 82% of patients. It was successfully managed by anti-tumor therapy, radiotherapy plus corticosteroids and only 11 (11,3%) patients continued to take analgesic medication after completing the chemotherapy (CT). Osteolytic bone destruction were treated with bisphosphonates (pamidronate or zolendronic acid) and 76% of patients responded well. Vertebral collapse secondary to osteolytic lesions was found in 58 (60%) patients with bone disease. Radiotherapy and/or surgery ensured good palliation and relieved the pain in 88%. Symptoms of hypercalcemia confirmed by laboratory examination were present in 34 (35%) patients. They were normalized with prompt rehydration, corticosteroids and i.v. bisphosphonates. Renal impairment, seen in 38% of patients at presentation, was reversible (creatinine more than 2 mg/dl and urine flow of more than 3l) in 73% (27/37) after administration of i.v. fluids and CT. Only 2 patients were candidates for dialysis at diagnosis. Anemia was present in 64% (62/97) and hemoglobin was less than 8g/dl in 6% of patients. After a 3-6 months’ erythropoietin treatment a response rate of 78% (48/62) was achieved. Blood transfusion received only patients with severe anemia, mostly at the beginning of CT. 9% of MM patients required antibiotics. Repeated bacterial infections were more common in relapsed (29%) cases when intensive broad-spectrum antibiotic therapy had to be given.

Conclusions: Our results confirmed that supportive therapy can successfully ameliorate disease and therapy-induced complications and improve patients quality of life.

18-192
Orally Administered Lectin Atl-104 Ameliorates Intestinal Damage Caused By 5-Fluorouracil In Rats
Michelle Duncan1, George Grant1, Neil Fish2
1Rowett Institute of Nutrition and Health, University of Aberdeen, Aberdeen, United Kingdom, 2Alizyme
**Objectives:** Anti-cancer therapies can damage healthy tissue of the alimentary tract, leading to severe ulceration in the oral cavity and intestine. Oral mucositis in peripheral blood SCT patients was reduced by treatment with ATL-104 (Hunter et al, 2008. Bone Marrow Transplantation 10 Nov 08, 1-7.). The mode of action of ATL-104 in ameliorating intestinal damage caused by 5-Fluourouracil (5FU) has been investigated.

**Methods:** Rats (3-5 / group) given ATL-104 orally (200 mg/kg) once daily for up to 3 days (day -1, days -1 & -2. or days -1, -2 & -3 or day -3 & -2 but not -1 or day -3 but not -2 or -1), dosed with 5FU (one dose, 150 mg/kg, ip) on day 0 and euthanased and small intestine collected up to 4 days post-5FU. Standard histology was done.

**Results:** 5FU caused loss of crypt epithelial cells and collapse of villi. By 2 days, few dividing cells were detectable in the crypt region. The intestinal sub-epithelial myofibroblast sheath (ISEMF) was also disrupted. The dividing cell population re-established by 4 days but the ISEMf was not restored. As a result, regenerating crypts and villi were disorganised. Treatment with ATL-104 for 1, 2 or 3 days immediately prior to 5FU ameliorated its effects. One day (-1d) of pre-treatment gave considerable protection but 2 or 3d was more effective. Initially, there was loss of epithelial cells but by 2 days micro-crypts (clusters of dividing, goblet & Paneth cells in a myofibroblast sheath) were evident. At 4 days, the crypt epithelium, ISEMf and villi were returning to normal. The protective effects were reduced, if ATL-104 omitted on the day -1. In this case, crypts / villi were disrupted and similar in appearance to those after 5FU only.

**Conclusions:** ATL-104 altered epithelial / sub-epithelial cellular responses to 5FU, limited the damage caused by 5FU and aided gut repair. Acknowledgement: MD supported by Alizyme; TL, GG by Scottish Government Rural and Environmental Research and Analysis Directorate.

**Results:** 47 male patients were included in this study. Median age was 59 (20–79) and 63% were Caucasians. AD defined as Ewing score >2 was present in 80% (38/47). Median Ewing score was 3 (1-5) indicating moderate to severe AD. Spearman correlation for Ewing and SDNN was 0.44 (p=0.002). There was a significant association between abnormal Ewing score and survival (p<0.0001), and abnormal SDNN HRV and survival (p=0.056). Spearman correlation for Ewing score and survival and SDNN HRV and survival where r = - 0.27620 (p=0.0602) and r =0.24198 (p= 0.1013) respectively.

**Conclusions:** AD is associated with shorter survival in male patients with advanced cancer. Further longitudinal research in a large cohort is justified based on these findings.

**Objectives:** Autonomic nervous system dysfunction (AD) is a common syndrome in patients with advanced cancer. It is associated with decreased survival in several patient populations including diabetes mellitus. Based on this available evidence, we hypothesized that AD is associated with decreased survival in patients with advanced cancer. The objective of this preliminary study was to test the association between AD as measured by the standardized Ewing test and Heart Variability (HRV) measures and survival in this patient population.

**Methods:** We examined the relationship between survival and parameters of AD in subjects who participated in a prospective study of AD and hypogonadism in male patients with advanced cancer. Eligibility criteria were defined based on the prospective study protocol. We collected demographic information, date of death (obtained from the online Social Security Death Index database), date of study entry and Ewing and HRV scores. We defined survival as the interval between study entry and date of death. A survival analysis was used to test the association between survival (days) and Ewing test (0-5) and measures of heart rate variability (HRV) including time domain and frequency domain measures.

**Conclusions:** AD is associated with shorter survival in male patients with advanced cancer. Further longitudinal research in a large cohort is justified based on these findings.

**18-194**

**Referring Practitioners’ Self-Rated Versus Actual Knowledge About Palliative Radiotherapy**

Alysa Fairchild¹, Sunita Ghosh²

¹Cross Cancer Institute, Radiation Oncology, Edmonton, Canada, ²Cross Cancer Institute, Experimental Oncology, Edmonton, Canada

**Objectives:** In Canada, patients with incurable or metastatic cancer are commonly followed by Medical Oncologists (MO) or Palliative Care physicians, or discharged to the care of their general practitioners (GP). It is assumed that these health care providers will refer
patients as needed for palliative radiotherapy (PRT) to assist with symptom control. However, PRT is generally underutilized, potentially due to referring practitioners’ uncertainty about the efficacy or appropriate indications. Our objectives were to assess referring practitioners’ confidence with their level of PRT knowledge.

Methods: 1360 family physicians, MOs, and Palliative Care physicians practicing in our referral area were faxed or mailed a 23-item questionnaire for a larger study investigating barriers to PRT referral. The survey contained questions on demographics and PRT, and requested respondents to self-rate their level of PRT knowledge. Completed surveys were anonymized and descriptive statistics compiled. Chi-square test was used for categorical and student’s t-test for continuous variables.

Results: The overall eligible response rate was 31.8% (412/1294), of whom 65.3% of respondents were male, 44.9% practiced in a rural setting, and 85.4% were GPs with an average 20 years’ experience (range 1-60yrs). 97.6% had seen cancer patients in the last month, 80.5% sometimes or often provided Palliative Care, and 71.0% had referred patients for PRT in the last year. Respondents’ self-rated knowledge was poor for 74.0% (305/412), fair for 24.5% (101/412), and good (6/412) for 1.5%. Actual knowledge score was classified as poor for 46.6% (192/412), fair for 36.7% (151/412) and good for 16.7% (69/412). Self-rated and actual knowledge were significantly associated (p 0.0001) and both correlated with having referred patients for palliative RT in the past (p 0.0001).

Conclusions: Although our results suggest that referring practitioners have less than optimal knowledge about common PRT indications, they are more well-informed than they believe themselves to be.

18-195
International Efforts In Disseminating End-Of-Life (Eol)/Palliative Care (Pc)
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Objectives: At the competition of this session, the participants will be able to: 1. Describe the ELNEC: End-of-Life Nursing Education Consortium project’s efforts to promote palliative care in nursing education in the United States and internationally. 2. Identify challenges and strategies to enhance end-of-life education in nursing. This presentation describes findings of a comprehensive national educational project, the End-of-Life Nursing Education Consortium (ELNEC), which has implemented a palliative care curriculum in the United States and internationally. The ELNEC project started in 2000 with the partnership of the American Association of Colleges of Nursing (AACN) and the City of Hope Medical Center (COH) to coordinate national nursing efforts related to end-of-life (EOL) care in undergraduate schools and continuing education programs.

Methods: The ELNEC curriculum focuses on nine EOL content areas. The ELNEC training includes detailed teaching materials to integrate content into existing nursing curriculum and clinical teaching. The project’s training programs have been attended by over 5,400 nurses representing all 50 states who in turn implemented this curriculum in their own settings. Extensive evaluation includes pre course assessment and detailed follow up evaluation at 6 and 12 months post attendance.

Results: The ELNEC project now includes 4 curricula of ELNEC-Pediatric Palliative Care, ELNEC-Critical Care, ELNEC-Geriatrics focused on long-term care settings and the ELNEC Core curricula. ELNEC has also been implemented in 55 countries and translated in several languages.

Conclusions: The ELNEC project has been extremely successful in improving faculty knowledge, curriculum change and clinical changes and has been a major step towards strengthening nursing knowledge in EOL care to improve care of the dying. This project has major implications for basic preparation of nurse’s worldwide.

18-196
Does A Structured End Of Life-Care Protocol (Liverpool Care Pathway For The Dying Patient, Lcp) Improve Treatment Quality And Caregiver Morbidity? First Results Of A Prospective, Semi-Quantitative Survey
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Objectives: The LCP is a structured protocol for end-of-life care which aims to improve inter-professional communication, quality of death and support of informal caregivers. Extensive qualitative research has demonstrated substantial advances in end-of-life care by the LCP. However, no data exist on long-term morbidity of bereaved family members regarding mental health
issues (incidence of posttraumatic stress disorder, depression). Therefore, we explore the effect of the LCP on caregiver stress and morbidity and investigate effects on bereavement and health.

**Methods:** Semi-quantitative, validated questionnaires for medical/nursing staff (n=55) on medical inpatient units at baseline 7-8/08, repeated 4/09 after implementation of the LCP. Relatives of 10 dying patients (5 within the LCP and 5 controls) are interviewed during the phase of dying and contacted again 6 months later. Questionnaire findings are evaluated by T-test for unrelated/related samples and regression analysis, effects on bereaved relatives by qualitative content analysis.

**Results:** As of February 2009, data are available only for staff members (n=22, 19 nurses, 3 physicians) who started using the LCP in September 2008. 70% have a work record of >5 years. At baseline, performance of „inadequate“ procedures and perceived lack of patient information by doctors constitute a major burden for 80% of the nursing staff. Both professions identified incomplete information of family caregivers as a source of ongoing dispute and dissatisfaction in the course of dying and bereavement. Surprisingly, conflicts arising from hierarchical structures were of minor significance.

**Conclusions:** A decision tool ensuring continuous quality of interprofessional and professional-to-patient communication may significantly reduce unnecessary stressors. As the LCP is designed to meet this need, upcoming trial results are expected to reveal important insights how professionals and relatives cope with the dying process. Results related to effects of the LCP on bereavement are expected by September 2009.

**18-197**

**Zolendronic Acid (Za) And Tretment Of Skeletal Events In Patients With Advanced Multiple Myeloma (Amm)**

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**Objectives:** The aim of this study was to evaluate the efficacy and safety of Za infused over 15 minutes in a group of AMM patients with skeletal events.

**Methods:** AMM patients received intravenous Za 4 mg or placebo via a 15-minute infusion every 4 weeks for 24 months. Study endpoints included the proportion of patients who developed skeletal related events and time to first event.

**Results:** In a group of 20 AMM patients with bone metastases, intravenous Za significantly reduced the proportion of patients who experienced an skeletal related event compared with placebo (p=0.014). Time to first skeletal related event was also delayed significantly (p=0.007). In a multiple-event analysis, Za reduced the risk of developing an skeletal related event (p=0.002). Za was well tolerated, with a renal adverse event profile comparable to placebo and no clinically relevant changes in serum creatinine levels.

**Conclusions:** Za is a safe and effective treatment in preventing the skeletal related events in AMM patients compared with placebo, and without significant renal toxicity.

**18-198**

**Suboptimal Anticoagulation In Hospice Patients With Lung Cancer**

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**Objectives:** Patients with lung cancer are at high risk for thromboembolic disease, and despite recent guidelines advocating low-molecular weight heparin (LMWH) over warfarin for thromboembolic disease and active cancer, no guidelines exist in hospice. Warfarin may be less safe in hospice patients, but hospices may prefer warfarin due to lower cost and less invasiveness compared to LMWHs. We sought to identify disparities in the use of warfarin vs. LMWHs in patients with lung cancer in hospice.

**Methods:** Using a dataset from a national pharmacy provider for more than 800 United States hospices, we selected patients admitted to hospice for lung cancer who enrolled and died in 2006. Patient characteristics, including age, gender, race, length of hospice service, and number of medications prescribed as well as hospice region were evaluated for differences in anticoagulation. The Kruskal-Wallis test was used to compare continuous variables, and the Chi-square test was used for categorical variables.

**Results:** Of 16,951 patients, 1547 (9.1%) were prescribed anticoagulation. Most (1210, or 78.2%) were prescribed warfarin, 271 patients (17.5%) were prescribed LMWH, and 66 patients (4.3%) were prescribed both. The most common indication for anticoagulation was thrombosis. Patients prescribed anticoagulants had a longer length of service in hospice (40.4 versus 35.9 days) and were prescribed more
medications (a mean of 15.5 vs. 12.4 medications). Characteristics of patients prescribed warfarin and LMWH are shown in Table 1. Patients prescribed warfarin were more likely to be older (OR 1.037, 95% CI 1.024-1.051) and had more comorbidity (OR 1.396, 95% CI 1.247-1.564). Patients in hospices in the Northeast were more likely to be prescribed LMWH over warfarin.

### Table 1. Factors Associated with Death in APCU or Home Discharge by Multivariate Logistic Regression in 2611 Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Warfarin (N=1210)</th>
<th>LMWH (N=271)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age in years</td>
<td>71.6</td>
<td>65.8</td>
</tr>
<tr>
<td>Gender, N (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>690 (57)</td>
<td>146 (54)</td>
</tr>
<tr>
<td>Female</td>
<td>520 (43)</td>
<td>125 (46)</td>
</tr>
<tr>
<td>Race, N (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>982 (81.2)</td>
<td>200 (73.8)</td>
</tr>
<tr>
<td>Black</td>
<td>73 (6.0)</td>
<td>25 (9.2)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>21 (1.7)</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>Other</td>
<td>134 (11.1)</td>
<td>43 (15.9)</td>
</tr>
<tr>
<td>Mean length of service in hospice, days</td>
<td>42.0</td>
<td>28.5</td>
</tr>
<tr>
<td>Mean number of medications prescribed</td>
<td>15.6</td>
<td>15.1</td>
</tr>
<tr>
<td>Mean duration of anticoagulation, days</td>
<td>25.3</td>
<td>18.3</td>
</tr>
</tbody>
</table>

**Conclusions:** Patients most vulnerable to suboptimal prescribing with lung cancer are prescribed less optimal anticoagulation with warfarin in hospice care. This study raises the need to establish guidelines for appropriate anticoagulation in hospice.

18-199

Discharge Outcomes And Survival Of Advanced Cancer Patients Admitted To An Acute Palliative Care Unit (Apcu) At A Comprehensive Cancer Center

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**Objectives:** APCUs are new programs aimed at integrating palliative and oncology care. Few outcome studies from APCUs are available. We examined the frequency, predictors and survival associated with home discharge and death in our APCU.

**Methods:** All patients discharged from APCU between September 1, 2003 and August 31, 2008 were included. Demographics, cancer diagnosis, discharge outcomes and overall survival were retrieved retrospectively. For patients with multiple admissions, only one visit was selected at random for analysis.

**Results:** A total of 2611 APCU admissions had the following characteristics: median age 59 (range 18-101), male 51%, median hospital stay 12 (Q1-Q3 8-17) days, median APCU stay 7 (Q1-Q3 4-10) days and median survival 23 days (95% confidence interval (CI) 22-24 days) from admission. The overall mortality rate per admission was 32%, 534 (21%), 75 (3%) and 1090 (42%) were discharged to home, healthcare facilities and hospice, respectively. Multivariate logistic regression analysis revealed that specific cancer primaries, admission from oncology wards, and shorter APCU stays were associated with death in the APCU, while younger age, non-Christians, and direct admissions to APCU were associated with home discharge (Table 1). Patients who died in APCU had a median survival of 10 days, compared to 71, 62 and 29 days for patients discharged home, healthcare facilities and hospice, respectively (p<0.001, log rank test). The 6 month survivals for patients discharged home, healthcare facilities and hospice were 25%, 9%, 3%, respectively. Home discharge (hazard ratio=0.23, 95% CI 0.21-0.26, p<0.001) was associated with improved survival in multivariate analysis.

**Conclusions:** Our APCU successfully discharged home a significant proportion of advanced cancer patients, with a 6 month survival of 25%. These results suggest a pattern of care different from traditional hospice and palliative care services.
18-200
Long Term Tramadol-Metoprolol Association For Control Dyspnea Related To Intrapulmonary Malignancies
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Objectives: It was shown that Tramadol improves dyspnea related to intrapulmonary malignancies; constantly it was observed associated tachycardia. Metoprolol is a selective beta1 receptor blocker which, at dose lower than 100mg/day, doesn't induce bronchospasm. Long term Tramadol – Metoprolol association could be more effective than Tramadol alone.

Methods: We studied 20 patients with III grade dyspnea due to various intrapulmonary malignancies and evaluated dyspnea using MRC scale (a scale grading dyspnea from 0 - not troubled with breathlessness except with strenuous exercise to 4 - too breathless to leave the house or breathless when dressing or undressing). We gave Tramadol 100 mg x 3/day to 10 patients and evaluated again the intensity of dyspnea and the duration of the effect. Others 10 patients received an association of Tramadol 100mgX3 and Metoprolol 50mg/day. The period of follow-up was between 4 weeks and 4 months. The treatment has been considered effective for a decrease with one step on ladder.

Results: Tramadol given alone decreases dyspnea intensity with 1 step for 6 pts; Tramadol – Metoprolol association decreases dyspnea intensity with 1 step for 7 pts and even with 2 steps for another 2 pts from this subgroup. The relapse was seen after a various period of time at 3 pts from monotherapy subgroup and only at 2 pts from association subgroup. Providing Tramadol supplementary dose doesn’t show any benefit.

Conclusions: Addition of Metoprolol at Tramadol seems to be more effective to control dyspnea related to intrapulmonary malignancies than Tramadol alone.

18-201
Comorbidity And Polypharmacy In Patients With Advanced Cancer Disease
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1Rikshospitalet - The Norwegian Radium Hospital, Dept. of Anaesthesiology, Oslo, Norway, 2Ullevål University Hospital, Dept. of Palliative Care, Oslo, Norway, 3The Norwegian Radium Hospital, Dept. of Oncology, Oslo, Norway

Objectives: Comorbidity and polypharmacy increase the risk for adverse drug advents and can also affect drug compliance. We wanted to assess comorbidities and the use of different drug classes in palliative cancer patients.

Methods: A prospective study of palliative care outpatients was performed. 25 consecutive outpatients at a palliative unit were followed weekly for 8 weeks with 3 visits and 5 telephone interviews. Use of different drugs and number of organ systems affected was recorded. Additionally, symptoms with special focus on pain, nausea and constipation were assessed.

Results: 14 women and 11 men. Median age 65 (33-82). 6 patients had pancreatic cancer, 6 patients breast cancer, 6 patients colon cancer and 7 patients had other cancers. 17 patients had confirmed metastases. Only 15 patients completed the 8 weeks follow-up. Major reason for dropout was disease progression. Pain was the major subjective complaint and well controlled in 50 % of the patients. 10 patients had at least 2 comorbidities, 4 patients had at least 3 comorbidities, and 1 patient had 4 comorbidities. 1 patient did not use any drugs, 2 patients used 2 drug classes, 6 patients used 4 drug classes, 5 patients used 5 drug classes, 6 patients used 6 drug classes, 3 patients used 7 drug classes, 2 patients used 8 drug classes and 1 patient used 9 different drug classes.

Conclusions: Multiple drug use in patients with comorbidities is a challenge, even more so in cancer patients with advanced disease that progresses. As death approaches, symptom burden will increase with a need for continuous adjustment of symptom-medication. In this situation some drug groups may be more important than others in order to sustain the best possible quality of life. Recognition and surveillance of polypharmacy and continuous adjustment of medication is of increasing importance as the patients’ condition deteriorates.

18-202
Therapeutic Interventions In Hospice Care: A Decade Of Change Between 1997 And 2007
Peter Lawlor, Kate McLoughlin, Gillian Gormley, Liam O’Siorain

Objectives: Clinical experience suggests that there is increasing complexity and intensity of therapeutic interventions in the past decade in Ireland. This is based on the perception that there is an increased use of chemotherapy, monoclonal targeted therapeutic agents, and stenting procedures. Such changes are likely to require an increased number of trips from hospice to cancer centres and acute hospitals in order to access more medically complex levels of care. We aimed to conduct an audit of patient demographics, admission rates, length of stay and the level of clinical therapeutic interventions in our inpatient hospice unit in 1997 and 2007.

Methods: We conducted a chart and database review of all inpatients with a cancer diagnosis who were admitted to in 1997 and 2007. For each first patient admission,
data were collected regarding their use of palliative chemotherapy, radiotherapy, platelet and blood transfusions, PICC lines, antibiotic and bisphosphonate use, and out of hospice trips for therapeutic interventions or other specialist consultations. The Mann Whitney test was used to compare differences in the frequency of interventions during the two respective time periods.

Results: There were a total of 329 and 343 evaluable first patient admissions with a cancer diagnosis in 1997 and 2007, respectively. There were increased rates of palliative targeted and cytotoxic chemotherapy, central line use, intavenous cannulation, red cell transfusions, parenteral bisphosphate use, and out of hospice trips for access to other specialist care in cancer care or acute centres in 2007 when compared to 1997 (p<0.001 for all). Results from a Poisson or loglinear regression model are pending. This will help to adjust for differences in length of stay, which were shorter for 2007.

Conclusions: The complexity of therapeutic interventions has increased substantively between 1997 and 2007. This has major clinical and resource funding implications. Further studies with an emphasis on patient reported outcomes are necessary in order to evaluate the benefits of these changes.

18-203
A Decade Of Change In Hospice Care In Relation To Laboratory And Radiological Investigations
Peter Lawlor, Kate McLoughlin, Brian Creedon, Liam O'Siorain

Objectives: Clinical experience suggests that the overall complexity and intensity of therapeutic interventions has increased over the past decade for patients with advanced cancer who are under hospice care. To date there are no published literature data on longitudinal trends in the level of clinical investigational interventions in an Irish hospice setting. We aimed to conduct an audit of patient demographics, admission rates, length of stay and the level of clinical investigational interventions in our inpatient hospice unit for the years 1997 and 2007. A comparative audit of these two years will help to identify evidence of practice and other changes, which might require further prospective evaluation and also inform future planning of hospice services.

Methods: We conducted a chart and database review of all patients with a cancer diagnosis who were admitted to the 36 bed palliative care unit in 1997 and 2007. In the case of each first patient admission during the years 1997 and 2007 data was collected in relation to their entire admission period in relation to routine clinical investigations

Results: Chart data was unavailable for 31 and 7 patients from 1997 and 2007, respectively. As a result, there were a total of 329 and 343 evaluable first admissions to our hospice with a diagnosis of cancer in 1997 and 2007, respectively. There were increased rates of haematological, biochemical, microbiological and radiological investigations in 2007 when compared to 1997 (p<0.001 for all). A Poisson or loglinear regression analysis is pending. This will help to adjust for differences in length of stay, which were shorter for 2007.

Conclusions: We conclude that the frequency of investigational interventions has increased substantively in the decade between 1997 and 2007. This has financial and resource implications for our institution. These findings are likely to represent an index of changing trends in hospice care in Ireland, but further studies are warranted to determine this.

18-204
A Hypofractionated 3Dcrt In The Control Of Pain And Hemorrhage In A Massive Infiltrative Cancer Of The Skin.
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Physician, Department of Radiotherapy-Oncology, Attikon General University Hospital, Athens, Greece,

Objectives: A hypofractionated 3DCRT is an effective palliative treatment in the control of symptoms in a large infiltrative squamous skin cancer. We present our experience in a large skin tumor treated with external beam irradiation.

Methods: A man 52 years old presented in our department with an infiltrated mass located to the right temporal region. The histology showed a squamous cell carcinoma, grade II. The patient received chemotherapy with no response. The imaging evaluation showed extensive invasion of temporal bone and neighboring structures. The tumour (dimensions around 12cm x 12 cm) resulted in pain (score 4-5 in Wong-Baker facial pain scale) and massive hemorrhage. The anti-inflammatory and opioid drugs were no effective. After CT simulation and 3D conformal planning, he received a total dose of 60 Gy in 4 Gy fraction per day.

Results: After 1 month, he was free of pain and the hemorrhage was totally controlled. After 3 months, the evaluation showed complete response.

Conclusions: The hypofractionated external radiotherapy is an effective and quick palliative method even if all other palliative supportive treatments had failed.
18-205
Edmonton Symptoms Assessment Scale (Esas) As Symptoms Improvement (Si) Assessment Is A Prognostic Factor For Survival In Advanced Cancer Patients (Pts) Undergoing Palliative Care (Pc): An Observational Prospective Study
Filomena Narducci1, Isabella Sperduti2, Tiziana Trapasso1, Giovanni Cianci1, Lucia Mentuccia1, Teresa Gamucci1
1MD, Medical Oncology S.S. Trinità Hospital, Sora, Italy, 2PHD, Biostatistics Regina Elena National Cancer Institute, Rome, Italy

Objectives: ESAS is a validated tool for physical symptoms assessment in PC clinical practice which evaluates main symptoms through a numeric ranging from 0 to 10. The use of Si as a prognostic factor is controversial. To this purpose, an observational prospective study in advanced cancer pts previously treated with anti-cancer treatments and now undergoing only PC was conducted

Methods: Pts were considered eligible if no longer able to receive any active anticancer treatment; they were scheduled to undergo ESAS assessment: 1) at the hospitalization time-point (TH); 2) at the hospital discharge time-point (TD). Symptoms’ scores were divided into 3 severity-classes (SC): mild (0-3, MI), moderate (4-6, MO) and severe (≥7, S). Differences across symptoms’ classes between TH and TD was analyzed with the paired-data McNemar-test, according to tumor types. Kaplan-Meier method was used for overall survival, according to ESAS score classes. Multivariate survival analysis including age, sex, tumour, symptoms number, symptoms’ score class, PaP (Palliative Prognostic)-score, KPS, were carried out using the Cox regression model

Results: ESAS was administered to 68 pts, gastrointestinal (GI)/lung (NSCLC): 39/29, median age: 69-yrs, KPS ≤50/>50: 27 (39.7 %)/ 41 (60.3%), PaP-score A/B/C: 26 (38.2%)/37 (54.4%)C (7.4%)A statistically significant reduction of S-SC rates was observed, as shown in the table:

<table>
<thead>
<tr>
<th>Pts</th>
<th>Symptoms</th>
<th>TH</th>
<th>TD</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI</td>
<td>Pain</td>
<td>33.3</td>
<td>7.7</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>Nausea/Vomiting</td>
<td>17.9</td>
<td>0%</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>Anorexia</td>
<td>53.8</td>
<td>28.2</td>
<td>0.01</td>
</tr>
<tr>
<td>NSCLC</td>
<td>Pain</td>
<td>37.9</td>
<td>3.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Asthenia</td>
<td>72.4</td>
<td>62.1</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>Dyspnoea</td>
<td>58.6</td>
<td>27.6</td>
<td>0.001</td>
</tr>
</tbody>
</table>

SI correlates with survival improvement: PaP score (HR 2.95, 95% CI 1.35-6.41, p=0.006) and anorexia (HR 3.21, 95% CI 1.33-7.72, p=0.009) appear to be prognostic factors for survival at the multivariate analysis for GI pts; asthenia is the only significant variable (HR 5.11 CI 95% 1.86-14.03, p=0.002) for NSCLC pts

Conclusions: SI according to ESAS after PC treatment represents an important prognostic factor for survival in pts no longer suitable to receive any anticancer active therapies

18-206
Treatment Of Cancer Related Anorexia With Olanzapine And Megestrol Acetate.
Rudolph Navari1,2, Marie Brenner2
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Objectives: Cancer related anorexia (CRA) and weight loss is a major clinical problem in up to seventy percent of patients with advanced disease. The use of megestrol acetate (MA) has resulted in weight gain in some CRA patients, but MA has had less effect on improving appetite and quality of life (QOL). Olanzapine (OLN) has been shown to be effective in preventing chemotherapy-induced nausea and vomiting and has been used successfully to treat chronic nausea and emesis.

Methods: Adult patients with advanced gastrointestinal or lung cancer (Stages III-IV) with 5% or more loss of pre-illness stable weight were randomized to receive MA (800 mg/day) or MA (800 mg/day) plus OLN (5 mg/day) for eight weeks. Patients were excluded if they had undergone major surgery, chemotherapy, or radiotherapy in the previous four weeks, had active dysphasia, or GI tract obstruction, or were receiving systemic corticosteroids. Patients were assessed weekly using the M.D. Anderson Symptom Inventory (MDASI) with specific measurement of weight, appetite, nausea, and QOL measures. Eighty patients (median age 63, range 39 – 81, 36 females, Eastern Cooperative Oncology Group Performance Status 1 or 2) consented to the protocol and 76 were evaluable.

Results: Twenty one of the 37 patients receiving MA experienced a 5% weight gain at 4 and 8 weeks. There was no significant change in appetite, nausea, or QOL measures at 4 weeks or 8 weeks. Twenty of 39 patients receiving MA plus OLN had a significant improvement (p<0.01) in weight, appetite, nausea, and QOL measures at 4 and 8 weeks. There was also improvement in activity, mood, work, walking, and enjoyment at 8 weeks. There were no Grade III or IV treatment related toxicities in patients receiving MA or the combination of MA plus OLN.

Conclusions: The combination of OLN and MA appears to be an effective intervention for patients with CRA.
18-207
Creating An Educational Partnership In Palliative And End Of Life Care
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Objectives: 3 faculty members of Columbia University (CU) School of Nursing (SON) with clinical experience in palliative and EOL care and teaching experience developed unique collaborative learning experience; multi-disciplinary seminar in palliative and EOL care offered to graduate students from 4 Health Sciences Schools (CU-HSS). By applying concepts associated with palliative care to actual clinical practice within challenging learning environment, students learned to integrate palliative and EOL care into respective practices or fieldwork by applying concepts associated with palliative and EOL care to actual clinical practice. All students were in clinical placements or field work experiences.

Methods: CU-HS students were notified about registration for two 6 week seminars, using students’ case study presentations with faculty and student discussion. Guest faculty experts from each of CU-HSS, (College of Physicians and Surgeons, School of Public Health, School of Dental Medicine) provided input into cases and participated in cognitive debriefing sessions at course completion. Validated, reliable instruments were used appropriate to the health specialty in pre-test/post test design.

Results: Only nursing students registered but with multiple areas of specialty, including several in oncology. Barriers to measuring impact of palliative and EOL seminar included; only nursing students, small sample size, unable to evaluate impact on practice due to small number of post-tests returned. Barriers to cross-school registration included; time of day; differences in tuition; students required school’s permission to register for course in SON.

Conclusions: We found significant systemic barriers to implementation and evaluation of impact on practice that required SON faculty to offer 6 week seminar as 2 hour instructional session in appropriate sections of each of 4 CU-HSS. As result, CU-HS students had exposure to palliative and EOL multi-disciplinary care. Advantages include increased collaboration amongst faculty of various disciplines in palliative care education and research. Clinical, legal and health policy decisions need to be informed by knowledgeable clinicians, researchers and public policy practitioners.

18-208
Medications At The End Of Life Care Of Terminal Cancer Patients ; A Retrospective Study In Single Academic Hospital In Korea
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Objectives: To evaluate the medications for Korean terminal cancer patients at the end of life care

Methods: Medical records of last admission of terminal cancer patients between July 2005 and April 2008 were evaluated. Patient's characteristics, comorbidities, therapeutic drug classification during their last admission and on the day of patient’s death, and the administrated route and the number of medications on the patient’s day of death were analyzed.

Results: Total 81 patients were included. The median age was 63 years. The median length of admission was 18 days(range: 1-101). 54% of the patients had more than one comorbidities. The most frequently prescribed drugs during the last admission were opioid analgesics(63%), followed by antibiotics(58%) and antacids(53%). On the day of death, common medications were antibiotics(59%), antacids(58%), and opioid analgesics(46%). Intravenous injection was given to 81% of the patients and intramuscular injection was given to 16% of the patients on the day of patient’s death. The number of medications prescribed to patients was between 0 and 11(median: 3) and 12%(10/81) of the patients took over 8 medications including intravenous and oral drugs on the day of death. 6%(5/81) of the patients took potentially futile medications, like multivitamin or statin until the day of death.

Conclusions: This study suggests that potentially futile medications and uncomfortable care were given to Korean terminal cancer patients. Multicenter-based studies are necessary to diminish futile medications by essential medication at the end of life care for terminal cancer patients in Korea.

18-209
Single Fraction Radiotherapy For Bone Metastases: Reasons For Physician Non-Compliance With Evidence-Based Practice Guidelines
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Objective: Level I evidence and practice guidelines support single fraction radiotherapy (RT) for uncomplicated painful bone metastases. We aim to report compliance and explore potential reasons for variability in the choice of RT fractionation within our Palliative Radiation Oncology Program (PROP).

Methods: Patient and disease factors, treatment intent and proposed dose/fractionation were recorded prospectively for patients referred to PROP. The database was searched to identify referrals for RT to bone metastases between January 2007 and December 2008. A univariate hierarchical logistic regression model was used to determine the significance of treatment intent, treatment site, primary cancer, life expectancy, weight loss, ECOG performance status and sex for the choice of single versus multiple fractions.

Results: 422 events involving 389 patients were eligible for analysis. Reasons for RT included symptom relief (393/422, 93%), symptom prevention (41%), and local control (29%). Neuropathic pain was described in 93/422 (22%), neurologic compromise in 11% and soft tissue disease in 11%. Overall, 38% received a single fraction and 62% received multiple fractions. Treatment site, patient age and uncomplicated cases were significant predictors for single versus multiple fractions (p<0.0001, p=0.002, p=0.001 respectively). Bone metastases with uncomplicated pain represented 137 cases (32.5%) and 48.9% (67/137) of these received a single fraction. Treatment site was the only significant predictor for dose/fractionation choice in this subgroup (p=0.002), with 86% of chest wall treatments being single fractions compared with 34% of treatments to the spine. For complicated bone metastases (including treatment for symptom prevention or local control), 92/285 (32.3%) received single fractions, with treatment site (p<0.0001) and age (p=0.008) as significant predictors.

Conclusions: Physicians were non complaint with practice guidelines recommending the use of single fraction RT in half of the patients with uncomplicated painful bone metastases. Treatment site and age were significant factors shaping clinicians' treatment decision making.

18-210
10 Years Experience In Home-Care With Cancer Patients.
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Objective: G.R.A.D.O. Association (Gruppo Ricerca Assistenza Domiciliare Oncologica) was begun in June 1998 to carry out the home-care for cancer pts. The drawing thought of our work is that the best place of treatment should be the patients' home, considering that house is the natural container of persons' life which, with a convenient help, would prefer to spend the terminal phases of their life at home rather than in hospital.

Methods: Pts were visited at home by an oncologist with a professional nurse. The professional team is also composed of an internist, a physician for pain therapy, a psychologist, a physiotherapist. Assistance is completely free for the pts and their families. The professional team is also supported by a group of trained volunteers who are responsible for the social aspects of the pts' life.

Results: 588 pts, the mean age was 67.4 yrs (16-90), have been followed: they requested 6420 oncological visits, 2143 medical visits, 25 chemotherapies, 382 paracenteses, 345 thoracenteses, 3853 nurse interventions, 3976 supportive treatments, 35 physiotherapeutic interventions and 945 psychological supports. The mean/median follow up were 65.4/56 days (3-359).

Conclusions: the data showed us that this specifically medical assistance permits education and adaptation of patients and their families with the disease and diminishes the hospitalization of these patients, resulting in an improvement of their quality of life (better preserved in their family environment). We have distributed 38.497 days of medical services and it has certainly helped in saving the expenses of the welfare state. So considering the mean cost of a day in a general hospital approximately equivalent to 600,00 € and considering a day of medical services= a day of non-hospitalization, our work allowed an economical benefit of 23.098.200,00 € for the public health resources. Home-Care models could be the successful instruments and strategies of treatment in advanced cancer care.

18-211
The Concept Of Family Needs And Necessities In Palliative Care
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Objective: In palliative care, both patient and their family are the focus of the team's intervention. This team has got the responsibility of check family general and specific needs. Objective: To reflect about the concepts: family general necessities (family needs) and specific family necessities (family necessities). Key words: family needs e family necessities.

Methods: Meta-analysis on line (www.b-on.pt) in 26th August 2008 on "family needs" - 119 articles, and
"family necessities" - 89 articles. Both concepts were ReFINE for "palliative care" - 67 articles. There were taken into consideration all the articles between 2003 and 2008, and there excluded those that were not dated, paid and pediatric articles. There were selected 27 articles.

Results: The word "need" (to need), is always used as verbal tense. This term refers to a general need and a necessary duty like an obligation, desirable or useful that people need for their physiological or psychological well-being. Ex: I need some support. The word "necessity" is used as a name and not as a verbal tense. So this term is related to a more specific and personal feeling, that defines what is indispensable or unavoidable, a pressing need or a desire. Different people have different necessities and these ones can change at each moment. Ex: At this time of my life, I have the necessity to have an economic support.

Conclusions: In palliative care the words "need" and "necessity" are both used to express what is general or specific for each family. The analysis shows us that palliative care professionals should agree about the real meaning of these words in order to identify what is general and what is specific.

18-212
Palliation Of Advanced Or Recurrent Esophageal Carcinoma By Ct- Image Based Brachytherapy : An Indian Experience.
Subrata Saha, Aparna Gangopadhyay
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Objectives: Durable palliation of dysphagia and improvement of QOL in advanced or recurrent esophageal carcinoma is a challenge. Currently available methods e.g. surgery, dilatation, laser, chemotherapy and external radiotherapy yield dismal outcome. Brachytherapy is being considered to be a useful method for quick restoration of swallowing in several reports. This study aims to evaluate improvement of dysphagia, treatment complication and overall survival, following CT-based HDR brachytherapy in advanced or recurrent esophageal cancer. Study endpoints are dysphagia score, dysphagia free survival, overall survival and radiation toxicity.

Methods: Between September 2004 and January 2007, 91 patients with advanced or recurrent squamous cell carcinoma of esophagus, not amenable to curative treatment, were salvaged by HDR brachytherapy alone with individualized CT based planning. The group comprised of 58 previously untreated patients and 33 having recurrence after concomitant chemoradiotherapy. Previously untreated patients received 42Gy in 3 fractions in 3 weeks at 1cm from source center with 2cm margin. Recurrent patients (33/91) were re-irradiated by 16Gy/2 fractions/2weeks. Individualized CT-based planning was done for each insertion. Dose homogeneity index and conformational index were recorded from DVH data. All patients were followed until death. Pre and post treatment swallowing status were scored by the PASS scoring system.

Results: Overall improvement of dysphagia was recorded in 44/58 (84.5%) previously untreated and in 22/33 (66.6%) previously irradiated patients. Duration of dysphagia-free-survival and overall survival was a median 7.5 months and 8.2 months in recurrent patients. Among previously untreated patients the corresponding figure was 8.5 months and 10 months respectively. Radiation stricture was found in 2/58 untreated and 6/33 recurrent patients and tracheo-esophageal fistula in none.

Conclusions: HDR brachytherapy is an effective treatment to achieve durable palliation in advanced and previously irradiated esophageal carcinoma. Minimum hospital attendance, lack of toxicity (with CT based 3D planning) and swallowing improvement persisting 85% of survival period are key features.

18-214
Professionals’ Experience Of Palliative Care (Pc) In A Swiss University Hospital
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Objectives: In November 2007, the Bern University Hospital “Inselspital” in Switzerland has launched a palliative care programme, a part of which is the implementation of an inpatient PC consultation service. However, utilization of this service has been rather limited so far, possibly due to varying implications of the term “palliative”. The aim of this study is to explore what health care professionals in the different departments of the Inselspital Bern mean when using the term “Palliative Care”. The results will provide a basis for a common definition and understanding of PC, which is necessary to establish and expand service volume as well as research and education programmes.

Methods: A qualitative design is applied. Health care providers from across a wide range of clinical specialties are recruited by purposive sampling until data saturation is reached. After verbal and written information of the study, participants are asked for informed consent. Data are collected by narrative interviews exploring the participants’ individual experience of PC and the meaning they associate with PC. Interviews take place in the hospital, they last about
30 to 60 minutes. The tape-recorded, anonymized and transcribed interviews are analysed according to an interpretative phenomenological analysis strategy. Major and sub-themes are generated from the interview data and a constitutive pattern is elaborated by interpretation. The results are then discussed in a group of PC experts.

Results: This study is currently in progress. First results of the interpretative process show that a clear understanding of palliative care is important to develop a PC framework in a large university hospital.

Conclusions: Participation in this process educates health care professionals to be aware of PC situations and to integrate PC principles into their everyday practice. Final results will be presented at the MASCC/ISOO International Symposium June 25 – 27, 2009 in Rome.

18-215
Age Bias To Inpatient Palliative Care Referral For Cancer Patients
KarLeung Siu1, James D'Olimpio

Objectives: The objective of this study was to determine there is an age related bias that delays palliative care consultation for hospitalized cancer patients.

Methods: A query of our hospital’s adult palliative care consult database for encounters for patients with cancer from 2005 to 2008 extracted data on patient's age, disposition, time from hospitalization to consultation, and length of stay, which were estimated using the Kaplan-Meier product limit method. The age groups (≤44, >44-64, >64-84, >84) were compared using the log-rank test.

Results: We queried consults between 2005 and 2008 (total of 3764 patients) for cancer diagnosis yielding 1619 patients of which 753 died and 866 survived to discharge. Patients ranged from 20.6 to 99.3 years old. The median time to consult and length of stay were 6 and 13 days for all patients. Younger patients that died during hospitalization had a trend to later palliative care consultation as well as greater length of stay compared to older patients that died. Patients who died ages ≤44, >44-64, >64-84, >84, had a median time to consult of 12, 8, 7, 5 days, median length of stay of 15, 14, 12, 11 days, respectively, with significant difference associated with 95% confidence intervals, p<0.0211; the greatest difference seen between age groups >44-64 and >84, p=0.0038. This trend was not observed in patients who survived to discharge with median time to consultation of 5, 6, 4, 5 days.

Conclusions: There is a bias towards later referral to palliative care in younger cancer patients that died in the hospital. This may lead to increase symptom burden for younger advanced cancer patients.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Median Time to Consult for patients that died in hospital (days)</th>
<th>95% CI</th>
<th>Median Time to consult of patients that survived to discharge (days)</th>
<th>95% CI</th>
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<td>≤44</td>
<td>12</td>
<td>7-17</td>
<td>4.5</td>
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<td>&gt;84</td>
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18-216
Evaluation Of A Palliative Care Needs Assessment Intervention
Amy Waller1, Afaf Girgis1, David Currow2, Christophe Lecathelinais1, David Sibbritt3
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Objectives: To assess the impact of the introduction and systematic use of the Palliative Care Needs Assessment Guidelines and Palliative Care Needs Assessment Tool (PC-NAT) on needs and service utilisation of people with advanced cancer and their caregivers.

Methods: A prospective cohort of patients and their caregivers completed bi-monthly telephone interviews for up to 15 months, to assess unmet needs, depression, anxiety, service utilisation, quality of life and satisfaction with care. After 8 months, participants’ health professionals were trained in use of the Guidelines and PC-NAT and asked to complete a PC-NAT approximately monthly for each participant. Changes in outcomes were compared pre- and post-intervention.

Results: The use of the Guidelines and PC-NAT was associated with a significant reduction in health system and information needs as well as patient care and support needs. The PC-NAT exhibited a high rate of completion (83%) and had no impact on consultation length. It appears to be a highly efficient tool to assist clinicians to identify issues of concern, particularly in areas that are not routinely well addressed. Of the issues identified, most were managed by the clinician or someone from their care team.

Conclusions: The delivery of palliative care is inequitable and often ill-timed in Australia. A shift toward a more needs based model may offer a potential solution to these delivery issues. The PC-NAT is a highly acceptable and efficient tool and the routine,
systematic and regular use of the Guidelines and PC-NAT in a range of clinical settings can facilitate the timely provision of needs based palliative care.

18-217
Palliative Care Audit In Kenya
John Weru
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Objectives: To assess use of audit in Palliative Care Practice in Kenya

Methods: The monthly medical audit feedback at the Nairobi Hospice was reviewed with the reason of appraising and assessing the information in them. The audit contains 2 parts: a family feedback form and the clinical team's assessment of care form. Using HINARI, articles on audit were appraised. The articles described different aspects that need auditing in Palliative Care. Calls were made to the other 6 Hospices in the country enquiring whether they undertook auditing.

Results: All reviewed articles agreed on the need of auditing in Palliative Care in its entirety. Of the 14 medical audits done at the Nairobi Hospice in the last 2 years, bereavement is identified as the biggest challenge for the team and through auditing, a bereavement assessment questionnaire has been developed and trainings undertaken. None of the other Hospices do auditing in their practices.

Conclusions: Palliative care is growing rapidly in the country and it is imperative to ensure that as this occurs, the largest possible number of patients and families is served in an effective way. Use of audit will lead to development of the field and avoid our comfort in status quo at its risk. It will allow the sponsors to monitor the appropriate use of resources and ensure quality care to patients and families. Other aspects that need auditing include: resource management, education, standard setting, work load analysis, organizational, research, nursing, day care and quality assurance. Research need to be done to evaluate the impact of different audit approaches in use and come up with the most suitable for our country. The fact that the specialty is new coupled with the skepticism met, means that the way forward really is to evaluate self and show the reason for existence.

19-218
Health Promotion In Haematologic Cancer Patients
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Objectives: this descriptive research aimed to examine health-promoting behaviors in 100 patients with hematological cancer who were admitted to the Private Patient Nursing Division, Siriraj Hospital.

Methods: Using the Pender’s Health Promotion Model as a conceptual framework. The study instrument was a questionnaire consisted of personal information and health-promoting behaviors. Data were analyzed by descriptive statistics and Chi-Square test at the significant level of .05.

Results: The result showed that the overall health-promoting behaviors in patients with hematological cancer were high. When looking at each aspect of the health-promoting behaviors, high levels of health-promoting behaviors were found in behaviors related to: (1) their overall health, (2) nutrition, (3) interpersonal relationships, and (4) anxiety management. However, the moderate levels were found in behaviors related to physical activities and spiritual development. Using the Chi-square test, the relationships between personal characteristics and health-promoting behaviors were found as follows; 1. Education level and housing were each significantly associated with health-promoting behaviors of patients with hematological cancer (p.05).

Conclusions: The study findings suggested that the participants’ health-promoting behaviors were more passive than proactive. By paying attention to patients’ specific personal characteristics, such as their education levels and employment status, nurses may be able to help patients with hematological cancer realize the importance of proactive health-promoting behaviors. Introducing physical activities appropriate for them, using certain teaching approaches, or using certain teaching programs/models may be beneficial to the patients’ spiritual development.

19-219
A Multidisciplinary Summer Studentship In Palliative & Supportive Care In Oncology
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Objectives: The optimal context for the interprofessional education of pre-licensure health care trainees is currently unclear, especially in a field as
complex and emotionally challenging as Oncology. We describe the initiation of a multidisciplinary (MD) clinical placement in Palliative and Supportive Care in a tertiary cancer centre, designed to introduce trainees to issues facing patients and their families following a diagnosis of cancer, incorporating features of best-practice cooperative learning.

**Methods:** An MD steering committee composed of department heads, clinical program leads, nursing and patient education was convened to establish studentship goals, structure, eligibility criteria, application process, funding, and a consensus approach to instruction and evaluation. On the first and last day of the studentship, trainees completed questionnaires investigating attitudinal changes.

**Results:** Clinical Nutrition, Medicine, Nursing, Occupational Therapy, Pharmacy, Physiotherapy, Respiratory Therapy and Social Work students were invited to apply. The two successful candidates (a medical student and post-graduate Clinical Nutrition intern) completed the five studentship components: mandatory and flexible clinical time, an exploratory investigation, weekly discussion groups and a final presentation. At elective’s end, both students described a more positive opinion of MD practice, with dietitians viewed as more caring and less subservient, and physicians seen as more caring and more subservient, compared to baseline. Both students gained an appreciation of the roles of other disciplines, practiced clinical and communication skills, and improved their awareness of the patient experience.

**Conclusions:** Our six-week, elective MD placement is feasible, successful, and potentially transferable to other academic settings. Even over a short period, objective perceptual changes were seen. Trainees practiced both team-process and clinical skills which are transferable to future clinical placements and ultimately post-licensure practice. Acknowledgements. Supported by the Alberta Cancer Research Institute and an unrestricted educational grant from Ortho-Biotech.

**19-220**
**The Wellness Community International Network Program: Innovative Models Of Multi-National Collaborative Psychoeducational Training And Program Delivery**
Mitch Golant
*The Wellness Community, Research & Training, Los Angeles, USA*

**Objectives:** Globally, there are more than 11 million new cases of cancer diagnosed. By 2020, that number will grow to 16 million. Research indicates that psychoeducational programs provide a safe haven for patients to learn new information, develop adaptive ways of coping, express emotions, and better communicate with their medical team.

**Methods:** In 2007, The Wellness Community (TWC), created an International Network Program designed to test the feasibility of delivering the *Frankly Speaking About Cancer Treatment Take Control of Side Effects Through Medicine, Mind, and Body* (FSACT) in four countries—Canada, the UK, Ireland, and Italy—through partnerships with British Columbia Cancer Agency and Hope & Cope in Canada; Maggie’s Centre in England and Scotland; ARC Cancer Support Centre in Ireland; and the University of Ferrara and Associazione Italiana Malati di Cancro (AiMAC) in Italy. Materials were translated into French and Italian. Each site replicated a TWC pilot study (*Cancer Nursing, vol.26, 1, 37-46pp*) which showed significant decreases in anxiety from baseline to 30-day follow-up; and, the ability to manage side effects were associated with greater improvements on the SF-36. Concomitantly, TWC created an international training manual entitled, “Innovative Models of International Psycho-oncology Training.” Two trainings occurred in Spring 2008 in Canada and England and combined: (1) training professionals in the FSACT program; (2) delivering and evaluating the program to patients and carers at each of the sites.

**Results:** We report findings on: (1) training 23 international psychosocial oncologists in the FSACT program; (2) delivering 9 programs in 4 countries with nearly 100 patients and caregivers; and (3) outcomes from the pilot studies (pretest and 30-day follow-up using the SF-12, BSI-18), qualitative surveys, experiences at each of the International sites in delivering the program.

**Conclusions:** International collaboration provides a successful method of delivering evidence-based psychoeducational programs to patients.

**19-221**
**The Importance Of Education Of Ostomy Patients In Improving Of Self-Care**
Jurgita Gulbiniene, Arvydas Seskevicius
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**Objectives:** The aim of the study was to determine the role of nurse in improving ostomy patients’ knowledge.

**Methods:** Patients were prospectively randomized into three groups: I group - patients with the preoperative stoma siting and adequate preoperative and postoperative teaching. II group - patients were seen by the nurse after operation and have received the adequate teaching. Neither stoma siting nor preoperative teaching was
performed for that group of patients. III group – patients without preoperative stoma siting and adequate teaching by the nurse. Patients were asked to answer the questionnaires the day day of the discharge, 3 months and 6 months after the operation. There were used the questionnaire “Patients knowledge survey”, constructed by our group.

**Results:** 117 patients suffering from colorectal cancer and after stoma creation operation were included in our study Mean age of the patients was 66.9 (SD±10.3) years. The results of postoperative education, performed by stoma care nurse were assessed at the day of discharge. The level of knowledge in group I and group II differs significantly from the group III. Mean level of knowledge was 9 points in group I, 8.8 points in group II and 6.5 points in group III (p<0.05). The level of knowledge in group I and group II differs significantly from the group III, 3 months after operation. Mean level of knowledge was 9 points in group I and II, whereas in group III it was 8 points. Level of knowledge 6 months after operation improved in all groups, nevertheless, patients from group III had significantly less level of knowledge when compared with taught patients (Group I and II).

**Conclusions:** Patients who were taught before and after operation and those - after operation had significantly better knowledge concerning self stoma care than patients who were not taught nurses.

**19-222**

**End-Of-Life And Palliative Care Education For Final-Year Medical Students And Interns In China.**

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1XinQiao Hospital, Gastroenterology, ChongQing, China, 2M D Anderson Cancer Center, Palliative Care and Rehabilitation Medicine, Houston, USA

**Objectives:** To assess Chinese final year medical students’ and interns’ awareness in palliative care concepts and compare to Austrian final year medical students and interns.

**Methods:** Using a self-administered questionnaire adapted from an earlier study from Austria, Chinese medical school students and intern were surveyed.

**Results:** One hundred and nine final-year students and 107 interns from one Chinese medical school (response rate 97%) were surveyed; thirty eight percent were female (82/216). Average ages were 22 and 23 years old for students and interns, respectively. Only 28% of final year medical students and 36% of interns were familiar with pain scales. Only 12% of final year medical students and 28% of interns were familiar with the concept of pain management; only 5% of final year medical students and 8% of interns felt adequately trained in basic pain management. Only 3% of final year medical students and 13% of interns felt adequately trained to manage symptoms of a dying patient. Less then 13% of students and interns reported that they have been educated adequately to talk about death. Over 83% of students and interns felt that more education about palliative care should be included in curriculum. Compared to the previous survey on Austrian medical students and interns, we found that significantly lower percentages of Chinese students and interns were familiar with pain assessment and pain management concepts and felt adequately trained in basic pain management (all p<0.01).

**Conclusions:** Palliative care education, from the perspective of Chinese medical students and interns, is lacking. Improvement in Chinese medical school curriculum is needed.

**19-223**

**Dissemination Of The Mascc Teaching Tool For Patients Receiving Oral Agents For Cancer**

Sultan Kav1, Anita Nirenberg 2, Lisa Schulmeister 3, Linda Barber 4, Judi Johnson 5, Cynthia Rittenberg 5

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**Objectives:** Oral agents increasingly are used in cancer treatment. The need for patient teaching is recognized as a global issue. MASCC’s Patient & Professional Education Study Group developed a Clinical Teaching Tool (CTT) to assist healthcare providers in teaching patients who receive oral cancer agents and held a “Train the Trainer” (TTT) session in June 2008. The aim of this project is to disseminate the tool in different countries and then assess the effectiveness of the tool in a variety of settings.

**Methods:** Seventeen nurses and one pharmacist from 15 countries participated in the TTT session. Each coordinator was expected to: use back translation if needed; hold workshops for at least 40 nurses; select 6 nurses to use the CTT in practice; and complete CTT score/sheet logs for ten weeks. Logs and post-evaluation forms provide outcome data for assessing effectiveness of nurses’ use of the CTT. Faculty and coordinators worked together to solve problems.

**Results:** The tool has been implemented in 9 countries and translated and adapted into seven languages to date. (Reasons for non-participation include IRB issues, political instability, and 4 non-responders.) A total of
336 healthcare professionals have participated in workshops (Turkey: 102; Denmark: 81; China: 40; Greece: 40; Serbia: 38; Kenya: 20; USA: 15). China, Denmark, Greece and Kenya completed clinical implementation with 162 patients educated.

**Conclusions:** This project targeted nurses and other healthcare professionals who work with patients receiving oral agents for cancer treatment to improve their role and to assist them in the assessment and education. After finalizing this project, CTT will be available for general use. *Supported by grants from Eli Lilly and OSI Pharmaceutical Companies*

**19-224**

**Permanent Personalized Cancer Patient Advocacy Program Ease: 10 Years Of Experience**

Ivans Kuznecovs, Sergejs Kuznecovs, Galina Kuznecova, Klara Jegina

Preventive Medicine Research Society, Supportive Care Unit, Riga, Latvia

**Objectives:** Cancer Patient Advocacy Bureau (CPAB) in Riga, Latvia was established in 1997 with permanent personalized program for the needs of cancer patients “EASE”. (E)Education disease course, treatment options side effects, patient and family implications. (A)Adaptation: adjusting to physical changes; setting priorities and conserving energy; incorporating self care and healthcare activities into activities of daily living. (S) Support: counseling for the patient and family; affiliating with support groups; obtaining needed entitlements. (E)Enhancement: enhancement of self-care skills, facilitation of communication about needs and concerns.

**Methods:** 15455 cancer patients and 21019 relatives have been the visitors of CPAB and in the beginning of 2008. There are leastwise two main problems faced by cancer survivors in Latvia, which are in focus of cancer patient advocacy: 1) cancer survivor working life, 2) relationship and sexuality.

**Results:** More than 75% of cancer patients were still working after the diagnosis was defined, more than 12% during the course of chemotherapy and radiotherapy, 82% returned to their previous job. 50% considered themselves to be a victim of the conflicts at work. The positive influence of returning to labor activity on life expectancy in 6% of cases. It was found that one of the most commonly occurring secondary sexual symptom among women and men is fatigue (92,7%). “False sexual unattractiveness” (28,6%), “Complex of invalid” – 15,9%. The main causes for reduction of life expectancy: Spouse alcoholism -25%, Matrimonial changes -7%, “biological incompatibility” -12%.

**Conclusions:** EASE supports cancer patients in decision-making for changes in the way of life as major condition to prevent maintenance of relapses of disease and increase of life quality and expectancy. The reason for this program is an absence of the governmental plan to control a cancer and support the cancer patients. These problems try to carry out as possible cancer patient advocacy organization and volunteers.

**19-225**

**Patients And Education In Palliative Care**

Irena Laska¹, Marsela Prifti², Gerla Koleci³, Ornela Xherahu⁴

¹Korca Palliative Care, Palliative Care, Korce, Albania, ²Fan S. Noli University, Nursing, Korce, Albania, ³Regional Hospital Teni Konomi, Internal Medicine, Korce, Albania, ⁴Korca Palliative Care, Palliative Care, Korce, Albania

**Objectives:** The goal of this presentation is to introduce educational programs with healthcare professionals and carers on cancer prevention, oncology and improving quality of life for the terminally ill patients, organized by Korca Palliative Care Centre. Demonstrating the impact of these trainings on daily patients care and the organization of the training programs.

**Methods:** The outcomes of training courses organized with caregivers and healthcare professionals on palliative care and cancer prevention during the last two years 2007 and 2008 have been evaluated. Evaluation of questionnaires completed before and after the trainings.

**Results:** During 2007 Korca Palliative Care Centre has organized 31 trainings for healthcare professionals on oncology, cancer prevention and palliative care in Korca region. 10 courses have been organized for caregivers. The number of healthcare professionals trained was 980 and the number of caregivers 106. During 2008, we have organized 29 training courses with healthcare professionals, 9 trainings with caregivers and 20 training courses with students. The number of healthcare professionals trained during these courses was 953, the number of caregivers 100 and the number of students 740.

**Conclusions:** Educational trainings of healthcare professionals and caregivers have increased knowledge on cancer and palliative care and influenced direct patient care. The trainings organized have increased networking and cooperation with the healthcare governmental institutions.
Compliance With Oral Anticancer Agents: Single Center Prospective Cohort Analysis
Helena Linardou, Dimitra Kanaloupiti, Anthi Tarampikou, Argiro Panagiotakou, Nikolaos Arvanitakis, Dimitrios Bafaloukos
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Objectives: Administration of anticancer therapy orally is increasing with the development of several oral chemotherapeutic and biological agents. Optimal dosing and adherence to planned treatment cannot be assumed in a less controlled environment as is the patient’s house. Timely recognition and management of side effects is also critical. The present study is prospectively evaluating the compliance of a cohort of patients to common oral anticancer medication and analyzing possible influencing factors.

Methods: Patients with solid tumours (lung, breast, colorectal, pancreas, renal) receiving oral anticancer therapies (capecitabine, navelbine, erlotinib, lapatinib, sunitinib, sorafenib) as monotherapy or in combination with intravenous chemotherapy, enter the study. Patients receive written instructions on dosing, storage, and side effects, and record intake and adverse effects in a patient diary daily. Compliance is monitored with personal interviews at each patient visit and counting of unused tablets. Data are transferred to a detailed questionnaire and analyzed. Differences according to age, sex, PS, type and stage of disease, are evaluated.

Results: A total of 60 patients have entered the study until today, 20 with breast cancer (capecitabine, lapatinib), 15 with colorectal cancer (capecitabine), 10 with lung cancer (erlotinib), 10 with pancreatic cancer (erlotinib), 5 with renal cancer (sunitinib, sorafenib). Median age was 60 years and 48% were men. The majority (88%) were considered as having very good compliance (no intake mistakes), while patients with incomplete compliance reported as major reasons for treatment interruption side effects (25%), personal reasons, forgetting (40%), unclear instructions (22%). Data regarding differences according to type of malignancy, drug and disease stage will be presented.

Conclusions: The analysis of compliance to oral anticancer treatment reveals the differences and reasons for non-satisfactory adherence, the need for closer monitoring with patient diaries and for patient ‘education’ to adhere to optimal oral dosing and to recognize early and manage treatment-related side effects.

Importance Of A Palliative Care Training Curriculum
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Objectives: For the extension of effective and appropriate Palliative care, training for both health care professionals (HCP) and Non health care professionals (NHCP) cannot be overemphasized. Training the volunteers, care takers, “community doctors” who are usually the link between the patients and the hospices ensure basic quality care provision. The Kenya hospices and palliative care association (KEHPCA) identified the gap for lack of a standard curriculum for training both groups following a survey conducted in the training hospices in Kenya. The Association therefore took it up to lead in the process of development of a National curriculum.

Methods: Palliative care training is critical for the relief of pain and suffering since it affects practice and hence provision of quality service. Palliative care knowledge enables those trained to make proper diagnosis, make right decisions and hence influence implementation of the plan of care. However, palliative care training without availability, affordability and accessibility of essential drugs as well as relevant government policy doesn’t go far. KEHPCA has been keen in her mandate to advocate for policy review in Kenya to ensure availability of such essential drugs like morphine, creating awareness on the importance of a unified curriculum for training in the training universities and medical training colleges and scaling up palliative care service provision through the hospices.

Results: Challenges
• Limited funding for further learning and training
• Lack of standardized syllabi and curricula for training

Conclusions:
• Continued lobbying and advocacy for standardized curriculum and standards in palliative care by all stakeholders
• Increased accessibility and support for continuing education in palliative care

Friendships Among Parents In The Paediatric Oncology Setting.
Libba O'Riordan

Objectives: Parents of children with cancer often spend long periods of time with their child in hospital. Although friendships between parents in the paediatric oncology setting are common research in this area is
limited. In this presentation, part of the findings from a prospective longitudinal study which examined parents’ experiences of caring for their child as they progressed through the cancer illness trajectory will be presented. In particular, the nature of the friendships parents established with other parents of children with cancer, the factors that influenced the development and maintenance of these over time and the potential difficulties that can arise with such relationships will be discussed.

**Methods:** In-depth interviews, documentary evidence and observations were the strategies used to collect data. A total of 37 audiotaped face-to-face interviews were conducted with parents. Data collection and analysis were guided by the hermeneutic-dialectic process.

**Results:** Although parents felt they shared a common bond by virtue of the fact that they were all parents of a child with cancer the friendships that developed were complex, fragile and varied. Friendships ranged from casual acquaintances to deeper more meaningful relationships. The intensity of the oncology setting, the dynamic nature of the illness and treatment had the potential to facilitate or inhibit the formation and maintenance of these friendships. Although friendships with other parents were perceived as supportive, some negative aspects were also reported.

**Conclusions:** It is important that in the clinical setting the friendships among parents are recognised and utilised in a supportive way. The challenge for health professionals is to assist parents to derive the support they need from such friendships while minimising the potential negative consequences of these relationships.

**19-229 Developing Supportive Care Program For Men After Prostate Cancer Treatment In Thailand**

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**Objectives:** The diagnosis of cancer threatens the individual’s survival and future hopes, sense of self, and relationships. Fear about cancer recurrence and uncertainty about the future are common, as are concerns about the physical effects of treatments and disturbances in self image, intimacy and sexuality. The impact of the cancer extends beyond the patient to influence the quality of life of partners and families as well, such that many partners report higher levels of distress than do the men themselves. The aim of this study was to assess the supportive care needs of men post treatment in prostate cancer.

**Methods:** A convenience sample of 60 prostate cancer post 1 month prostate cancer treatment such as surgery, radiation and hormonal therapy were asked to answer the questionnaires. Data collection include demographic data, the Supportive Care Needs Survey which an investigator developed tool to assess prostate cancer specific needs and Social Support Survey.

**Results:** The findings show that men actively try to find a way to cope with the feelings of loss of control by seeking extensive information as rapidly as possible. Information is a basic form of support. Correct and adequate information is essential to helping patient and family adapt to a diagnosis of cancer and develop coping skills.

**Conclusions:** Men report unmet needs for support about sexuality, psychological distress and treatment information up to 1 year after treatment. Many men report longer term decision related distress and decision regret is associated with poorer quality of life after treatment. Problematically, men are generally disinclined to seek help for psychological distress and are consistently under-represented as clients to cancer support service

**19-230 The Impact Of Breast Cancer In A Family And The Community At Large**

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**Objectives:** To explore the difficulties a family undergoes while taking care of a cancer patient at village level

**Methods:** A survey done at Ruiri village, Meru District has shown that in every six [6] families there are two patients with breast cancer undergoing treatment or newly diagnosed. The immediate families are more depressed and suffer along way with the patient, hence reducing their performance at work.

**Results:** There is increasingly poverty in the family forcing them to sale their properties in order to afford the treatment, more affected are the young mothers whose children depends on. Having a patient means stopping most of daily activities especially when a patient becomes paraplegic, 2 out of 5 patients ends up being paralyzed increasing dependence to others and half of the patients partners ends up remarrying hence stopping the support. The illness mostly spread to the bones especially of the spinal cord [back] complicating the support,
treatment and increasing finances problems. Many families got problems in accessing strong painkillers making their life a night mere. It has shown that most of the patients needs wheelchairs which our health intuitions not able to supply to all patients hence becoming a challenge to the family members. Buying is another issue since by the time patient is paralyzed the family has spent all the savings.

Conclusions: There is need to increase palliative/hospice care to village level and availability to strong painkillers in affordable prices. Health care providers need to understand the patient’s background first in order to be able to assist the patients and also the community is aware of the hospice services being offered. More health care providers are needed in palliative care field to enlighten the community the importance of the services through community health education and school health programs.

19-232
Cultural Economical & Social Perceptions Of Cancer Patients Education : Status In Developing Nations
Pramod Sankpal
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Objectives: Health-education policy matters are vastly affected by sociocultural & economic factors. we studied six educational methodologies for one year about health [Cancer] education.

Methods: May 2008, six conventional methods taken for analysis. 84 Cancer sufferers community divided in 4 groups, divided on basis of economic, social, cultural & ethnic background. For one year, conventional health education methods were modified to study the impact of newer methods in population sciences. We conducted this by series of lectures, symposia & seminars in four subgroups. Each included peers [60%], medical school workers [12%], health care associates[ 23%], community-leaders [5%]. Evaluators was done by questionnaire before & after study. After exposure of above population to modified health education/teaching methods over 20 session’s revaluation was done. objective was change in grasping & practical-implementation of gained knowledge by cancer-sufferers to support/educate newly diagnosed cancer-patients

Results: 83% of the population showed perceptive change in learning abilities. 11% did not show this change. 6% population was non-respondent [failure in follow-up].Social factors in 28%, cultural factors in 27%, economic criteria in 40%, religious factors in 5%.

Conclusions: We urgently need to focus on cultural economical & social perceptions in population
demography education & evaluation. For developing nations this approach will certainly have positive impact on exploring and problematizing socio-cultural diversity and difference with special significance to educational policy implementation in the rural/tribal areas of developing nations with limited resources. This issue needs more further studies. At Rome-venue we exchange our Indian-Cancer-NGO experiences in handling cancer-education-efforts. Recommendations: We need newer educational strategies in our constant endeavour to decide culturally-socially-economically embedded perceptions in educational system. Community of educators/evaluator’s need to devise/practise specific-conditions on socio-political level, so that reforms towards organisational/institutional level implemented for cancer-education. We wish to form model-approach on cancer patients education by interactions with seniors/nurses at MASCC-2009 Rome-symposium.

19-233
Cancer-Related Lymphedema: An Educational Intervention For Genitourinary And Gynecologic Oncology Outpatient Nurses
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Objectives: Cancer-related lymphedema (CRLE) is a chronic, progressive, incurable condition that negatively impacts patient quality of life. Though CRLE is often associated with breast cancer treatment, it can occur following treatment for many solid tumors. Published literature acknowledges a lack of understanding of CRLE among healthcare professionals. The aim of this study was to assess CRLE knowledge before and after an educational intervention designed for nurses in an oncology outpatient clinic.

Methods: Nurses staffing genitourinary and gynecologic oncology outpatient clinics were invited to a CRLE educational program. This program highlighted CRLE risk factors, natural history, and modalities of assessment and treatment. Knowledge assessments and practice surveys were administered before and after the program.

Results: The 32 attendees averaged 10.1 (range 0 - 30) years of clinical cancer care experience, with 9.8 yrs spent at the host institution. They reported an average of 7 patients with swollen legs within the previous 6 months and attributed more than half to CRLE. If patients expressed concern about swelling, 56.7% of respondents would recommend additional evaluation. Dramatic improvements were demonstrated in nurses’
understanding of CRLE with averages of 61.2% of assessment items correct before the presentation and 93.2% correct following the presentation. The greatest areas of improvement were in understanding risk for developing lymphedema (from 37% to 85% correct) and in treatment and management of lymphedema (from 45% to 95% correct). All improvements were highly significant (p <0.001).

Conclusions: Experienced oncology nurses have knowledge deficits in CRLE risk development, assessment and management. A 45 minute educational session was effective in improving nurses’ understanding of these issues. Follow-up assessment will be needed to determine if this increase is sustained over time.

19-234
Education To Communicate With Head And Neck Cancer Patients, As A Skill Of Health Care Providers
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Objectives: Communication skills are essential to the practice of the oncology. The interactions with patients, family members, and significant others are the vehicle through which the professionals achieve positive clinical care.

Methods: Our concern is to purpose an Educational programme for Communication in Cancer Care to this specific patients, to all the clinical staff that will interact with patients and family members during the all process of cancer care and treatment.

Results: The head and neck region is unique among the sites requiring care for cancer. The complex interaction of the face, oral cavity, voice, and air passages in personal presentation, food intake, and comfort makes treatment planning highly demanding. Tumors of the head and neck always create functional and cosmetic problems that required specific skills in communication from the practitioners of oncology, patients, family members, and significant others.

Conclusions: A good practice of communication minimize fears associated with stigma of cancer, providing instruction about self-monitoring and symptoms management to empower patients and their family members, facilitating informed decision-making about options for treatment and care, interpreting complex medical information about disease and treatment to permit patients and family members to understand the concepts as applied to their clinical situation, providing interaction through the health care system.

19-235
Patient With Cancer And Their Relatives’ Beliefs, Information Needs And Information-Seeking Behaviors About Cancer And Treatment
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Objectives: Recent studies showed that the majority of cancer patients desire as much information as possible about their disease and treatment; however, not all patients want that much information. The amount and timing of information desired varied in those with a blunting style (avoiding threatening information) or for those trying to maintain hope. This study was conducted to identify cancer patient and their relatives’ beliefs, information needs, information-seeking behaviors and information sources about cancer and treatment.

Methods: This research was conducted at two hospitals of a university. Data was collected via questionnaires and Turkish version (Gencturk, 2004) of Miller Behavioral Style Scale (MBSS) to evaluate information-seeking behavior. Inclusion criteria were: cancer diagnosis within last 3 months, over than 18 years old, aware of their diagnosis and volunteer to participate. We have started data collection in March 2008; have reached 64 patients and 36 relatives.

Results: Patients receiving treatment mostly for breast, gynecologic, lung cancer and leukemia/lymphoma. All of them indicate that they want to be informed by doctor about their diagnosis and treatment first. Other information sources were internet, media and nurses. Majority of patients and half of their relatives were agreed on “cancer is curable and preventable disease”. Only 3.3 % of patients agreed with the statement “I don’t want to get information about disease which disturbs me”. According the data obtained from MBSS; the mean patients’ MBSS score (6.41 ± 3.2) were higher than their relatives’ mean MBSS score (5.46 ± 3.1). Respondents with higher education and younger age indicated more information-seeking behaviors.

Conclusions: Patient and their relatives differ in some of their information-seeking behaviors. Patients’ beliefs and their strategies for coping with their illness can constrain their wish for information and their efforts to obtain it. Healthcare professionals need to assess and be sensitive to the information-seeking behaviors of cancer patients and their relatives.
20-236
Symptom Trajectories Of Children Undergoing Cancer Chemotherapy
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Objectives: Children with cancer experience a myriad of untoward disease and treatment-related symptoms. Preliminary studies have evaluated the characteristics of these symptoms, yet none have investigated the trajectories of these symptoms during the course of treatment. The purposes of this study were to determine the occurrence and severity rates of children’s symptoms and how a select group of these symptoms (i.e., pain, fatigue, nausea, drowsiness, sadness, and anorexia) changed during a chemotherapy cycle.

Methods: Patients (n=60), from two treatment centers were predominantly male (52%), minority (65%), and 14.7 years of age (range 10 to 18 years). The Memorial Symptom Assessment Scale for 10 to 18 year olds (MSAS 10-18) was administered at the start of a chemotherapy cycle (T1) and weekly for the next two weeks (T2 and T3). The MSAS 10-18 is a checklist that evaluates the occurrence, frequency, severity, and distress of 31 symptoms with a one week recall period.

Results: The mean number of symptoms per participant was 10.5 at T1, 10.6 at T2, and 8.4 at T3. The number of symptoms experienced did not vary by age or gender. Of the 31 symptoms evaluated, 26 had occurrence rates of 20% or higher at T1 and T2. At T3, 20 symptoms had occurrence rates of at least 20%. Symptom occurrence trajectories were tested with multilevel logistic regression. Two of the 5 selected symptoms (i.e., sadness, feeling drowsy) showed a decreasing linear trend. Changes in symptom severity over time were evaluated with multilevel Poisson models. No significant differences, over time were found in any of the symptom severity scores on the MSAS.

Conclusions: Children experienced a high number of symptoms at the initiation of a treatment cycle that persisted over the two weeks following the administration of chemotherapy.

20-237
"My Beads, The Story Of Me..." A Review Of The First Year Of A Bravery Bead Program
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Objectives: Since 2007, at the Oncology Unit of The Children’s Hospital at Westmead (CHW), when a child begins their difficult journey with cancer, they are given a bead necklace with their name on it and they then start collecting a different bead for each procedure or treatment they undergo. The goal of this Bravery Beads program is to create a string of colourful beads that represent the unique and personal journey of each child and to make something that they are proud of and want to share with family and friends. The beads document and honour the experience of their cancer treatments, enabling the children to tell their unique & special story in a visual way. The beads become precious keepsakes that are viewed as medals or badges of courage and hope. This paper discusses & describes a review of the first 12 months of the Bravery Bead program at CHW with a focus on parents & children’s perspective.

Methods: Parents & children were surveyed to understand if the Bravery Bead program made a comparable difference in 3 areas; 1. If the beads helped them cope better with their treatment. 2. Whether the beads offered improved opportunities for communication & discussion 3. If they helped form lasting and valuable memories of treatment and hospital experiences.

Results: Of the parents & children surveyed most reported some positive benefits of collecting and keeping the beads.

Conclusions: The Bravery Bead program has proved a valuable addition to care to support Paediatric Oncology patients & their families. Discussion from this review has lead to some changes to the program, including the inclusion of extra beads, improved explanations at diagnosis and greater choice for patients to allow their beads to be a truly unique and individual expression of treatment.

20-238
Influenza Vaccination In Children Being Treated With Chemotherapy For Cancer A Cochrane Review
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Objectives: Influenza infection is a potential cause of severe morbidity in patients with cancer. Therefore
vaccination against influenza is recommended. However, there are conflicting data concerning the immune response to influenza vaccination in children with cancer and the value of vaccination remains unclear. To assess the efficacy of influenza vaccination in children with cancer compared to other control groups in providing serological response, and/or prevention of confirmed influenza and influenza-like illness and to determine adverse effects.

Methods: We searched CENTRAL, EMBASE and MEDLINE and Web of science (March 2007). Reference lists of relevant articles and conference proceedings were searched. We considered randomised controlled trials (RCTs) and controlled clinical trials (CCTs) in which serologic response clinical and immunological response to influenza vaccination of children with cancer were considered.

Results: One RCT and 8 CCT’s were included. None of the included studies reported on clinical outcome. In 5 studies immune responses to influenza vaccine were compared in 272 children on chemotherapy with 166 children off chemotherapy. In 3 studies responses to influenza vaccine compared 204 children on chemotherapy with 112 healthy children. Measures to assess immune responses were a four fold rise in antibody titre after vaccination, development of haemagglutination inhibition (HI) titre>32, and pre and post vaccination geometric mean titres (GMT). Immune responses in children receiving chemotherapy were weaker (fourfold rise of 25-52%) than those in children off chemotherapy (50-86%) and in healthy children (71-89%). The described side effects were mild local reactions and low grade fever. No life threatening or persistent adverse effects were reported.

Conclusions: Paediatric oncology patients receiving chemotherapy are able to generate an immune response to the influenza vaccine, but it remains unclear whether this ‘weak’ immune response protects them from influenza infection or its complications. RCT’s are needed to address the clinical benefit.

20-239
Procalcitonin And Febrile Neutropenia
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Objectives: Infectious complications in neutropenic patients are a major cause of morbidity and mortality. It would be valuable to determine which patients with febrile neutropenia are at high risk for bacterial infection and need antibiotics and in whom antibiotics can be withheld. In this pilot study we examined procalcitonin (PCT) as a predictor for bacterial infection in febrile neutropenia and in chemotherapy-induced gastro-intestinal mucositis.

Methods: Plasma was collected from 42 pediatric cancer patients at presentation of febrile neutropenia, and of 11 patients also 24-48 hours later, to determine PCT, IL-8 and CRP. The patients were divided into 2 groups, one with and one without bacterial infection. Of another 28 patients 2 plasma samples were collected, one in absence, the other in the presence of mucositis.

Results: The median PCT at presentation of febrile neutropenia was significantly higher in the bacterial infection group (0.81 ng/ml versus 0.11 ng/ml, p=0.001). This also applied for IL-8, but not for CRP. PCT cut-off values for bacterial infection of 0.25 ng/ml and 0.50 ng/ml displayed 79% and 64% sensitivity and 77% and 83% specificity, respectively. After 24-48 hours sensitivity was 100%, specificity 56%, for both cut-off values. Patients with or without mucositis showed no difference in median PCT (0.06 ng/ml versus 0.06 ng/ml, p=0.602), whereas IL-8 did show significant difference (52.4 ng/l versus 5.0 ng/l, p=0.000).

Conclusions: In this pilot study we found that PCT at presentation of febrile neutropenia, although significantly higher in bacterial infection, cannot be used in a clinical risk-assessment model, since sensitivity is not 100%. After 24-48 hours PCT might be useful in identifying bacterial infection. According to our results PCT is not elevated in response to mucositis, in contrast to IL-8. PCT might therefore be useful as predictor for bacterial infection when children with mucositis present with febrile neutropenia.

![Figure 1. Median Procalcitonin on the first 5 days of febrile neutropenia in patients with and without bacterial infection](image-url)

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Objectives: To explore if it is wise to let the children know that their parents are terminally ill/dying

Methods: A survey was done at the Hospice with the families cared for by the team.

Results: Children often perceive that something is wrong even if they are not told, because routines are disrupted and people close to them may look and act differently. Working at a palliative care/ Hospice set up, it has come up strongly that it is better to explore with the children of what they understand of the sickness and death first, since our culture forbid adults to discuss death with children especially if it involves parents or close relatives. Research done at the hospice, shows that three out of five children cope well with the information being paced well and relating the situation to the previous one especially of illness/death such as loss of a grandparent. Children who are supported, cared for and loved, with extra kisses, hugs and time spent together cope well with bad information than who are left without information. Two out of five don’t cope due to lack of proper support and the way information are given and this affect them in later life. Allowing children to express their feeling and answering questions simply and honestly has shown improvement in coping with illness/ death. Half of patients cared for by the hospice team shown that their children were being left out of the correct information. Children need a lot of support and understanding especially when bereaved by parent and know they are cared for, understood and can contribute in any way.

Conclusions: We need to change our African culture and start involving our children in decision-making and let them understand what is going on and there is need for further researches on parent’s illness and death.

Documented Reality Of Emesis In A Paediatric Oncology Unit
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Objectives: To evaluate the documented occurrence of emesis in a paediatric oncology unit.

Methods: 51 patient records (31 boys and 20 girls) were retrospectively evaluated from patients finished their treatment according to the entity-specific chemotherapy-protocols between 2006 and 2007 at the department of Paediatric Haematology and Oncology at the University Hospital of Muenster (median age: 9,4 years [range: 1 month – 18 years]). The event emesis was extracted corresponding to the NCI-criteria and documented for each chemotherapy block.

Results: The most frequent observed entity in this cohort was the childhood leukaemia (22 patients: 43%) followed by the Ewing-sarcoma (6 patients: 12%). According to the appropriate leukaemia protocol the highest documented event of emesis grade over the entire treatment period was in 68 % (15 patients) NCI grade 2 (emesis of 2-5x/day), in 9% (2 patients) emesis NCI grade 3. NCI grade 1 (emesis of 1x/day) was documented for 23% (5 patients). There were no patients observed without any emesis at all. So overall about 10% of all documented children treated according to the leukaemia protocol experienced at least once a severe event of emesis despite of administered antiemesis medication. Looking at the Ewing sarcoma patients, all 6 patients monitored developed at least once emesis NCI grade 2 along their complete treatment.

Conclusions: It is noticeable that there were no patients without any event of emesis during their entire treatment period in both entities. Further investigations according to covariants for emesis like gender, age and different risk or protocol elements are ongoing. Overall this dataset provides a sound basis for further investigations according to the incidence, therapy and burden of emesis in childhood cancer treatment.

Mannose-Binding Lectin (Mbl) As Prognostic Factor In Pediatric Oncology Patients
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Conclusions: It is noticeable that there were no patients without any event of emesis during their entire treatment period in both entities. Further investigations according to covariants for emesis like gender, age and different risk or protocol elements are ongoing. Overall this dataset provides a sound basis for further investigations according to the incidence, therapy and burden of emesis in childhood cancer treatment.
Objectives: To determine whether mannose-binding lectin (MBL) is a prognostic factor for disease severity in childhood cancer. The need for and complications during pediatric intensive care unit (PICU) admission, relapse of malignancy or death were investigated.

Methods: Children with cancer expected to become neutropenic due to chemotherapy were included in a prospective cohort study (inclusion 2003-2006, follow-up Dec 2008). Demographics, tumor type, frequency, severity and duration of PICU admissions, relapse of malignancy, and death were recorded. Microbiological, laboratory and clinical parameters of each PICU admission were recorded. MBL2 genotype (wild-type: A, exon-1 variant: O) and MBL plasma levels were measured.

Results: Sixty out of a total of 222 children (27%) accounted for 80 PICU admissions for reasons other than surveillance. The number of PICU admissions was similar in children with wild-type versus variant MBL2 alleles (p=0.30) and in children with MBL deficiency, defined by plasma levels <0.2 µg/mL (p=0.22). The median duration of all PICU admissions with febrile neutropenia was 18 days (IQR: 16-21 days) in O/O patients and 6 days (IQR: 4-13 days) in A/A and A/O patients (p=0.03). All other microbiological parameters not significantly different. However MBL-deficient patients relapsed significantly earlier than the remaining patients (p=0.04), especially the lymphoma patients (p=0.02).

Conclusions: MBL2 genotype is not associated with frequency or severity of separate PICU admissions, but the O/O genotype seems to be a risk factor for the cumulative duration of PICU admissions associated with febrile neutropenia. Moreover, MBL deficiency appeared to be associated with earlier relapse overall, and in particular in lymphoma patients. Febrile neutropenic pediatric oncology patients have been proposed to benefit from MBL substitution but the specific target group and/or the condition in which they may benefit most from MBL replacement, has yet to be identified.

Patient Care, Houston, USA

Objectives: To characterize input from bereaved FM and HCP to inform development of a Pediatric PC Program.

Methods: National standards for skill sets considered integral to the provision of expert PC and common themes from discussions with parents and HCP were used to create 12 domains of care. During monthly PSCC meetings, members worked in small facilitated workgroups to determine recommendations pertinent to each domain. Recommendations for each domain were summarized; priorities for each domain and the domains overall were achieved by consensus. Data were collected from PSCC meeting minutes. Analysis is descriptive. Per IRB policy, the protocol was exempt from review and appropriate for waiver of informed consent.

Results: Committee members included 10 FM and 16 multi-disciplinary HCP. Domains of care included communication, decision-making, symptom management, spiritual care, emotional care and support, in-hospital resources, community resources, financial information, support for staff and faculty, caregiver/extended family support, end-of-life care and post-death support. FM (n=10) ranked communication (n=9) as the highest priority for pediatric PC program development, followed by decision-making (n=4) and in-hospital resources (n=5). HCP (n=11) ranked communication first (n=10), with symptom management ranked as both the second (n=6) and third (n=4) priorities. Recommendations for each domain and their prioritization will be presented.

Conclusions: Communication was overwhelmingly the highest priority domain for pediatric PC program development. Given the differing priorities of FM and HCP placed on other domains, incorporating a family-centered model of care into PC program development offers new insights, with the potential to favorably impact on pediatric cancer patients and their families.

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Protective Effect Of Anthocyanins From Black Soybean Seed Coats Against Radiation-Induced Inflammation In Human Fibroblast
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Gyeongsang Nat’l University, Pharmacology, Jinju, Korea, 2Gyeongsang Nat’l University, Agromony, Jinju, Korea, 3Gyeongsang Nat’l University, Chemistry, Jinju, Korea, 4Asan Medical Center, Radiation Oncology, Seoul, Korea

Objective: Radiation therapy results in inflammation such as mucositis in several tissues including...
gastrointestinal (GI) tract. Fibroblast plays an important role in wound healing process against various stimulants. Anthocyanins are known to be powerful antioxidants and previously we reported that anthocyanins from black soybean seed coats inhibited UVB-induced COX-2 gene expression. Thus, in this study, we investigated the protective effect of anthocyanins from black soybean seed coats on inflammatory genes expression induced by radiation.

Methods: Human fibroblast was irradiated at a dose fraction of 8 Gy once using a 6MV linear accelerator. After irradiation, cells were immediately treated with anthocyanins (50 mg/ml). Cell lysates for western blot analysis and media for ELISA assay were harvested 1 day, 2 day and 3 day, respectively, after anthocyanins treatment. COX-2 and iNOS were detected by Western blot analysis, TNF-a, IL-1β and PGE2 levels were determined by ELISA assay, and NO production was quantified using Griess reagent.

Results: COX-2 and iNOS expressions were increased 1 day after irradiation, and iNOS but not COX-2 was effectively inhibited by anthocyanins (50 mg/ml). TNF-a and IL-1β productions at 1 day and PGE2 production at 2 day were significantly induced by radiation and declined thereafter. However, NO production by radiation showed significant induction until 3 days after irradiation. Radiation-mediated PGE2, TNF-a and IL-1β as well as NO induction was prevented by anthocyanins.

Conclusions: As a result, it is suggested that anthocyanins from the seed coat of black soybeans may modulate radiation-induced inflammation.

22-245
Pathfinders: A Pilot Study Of An Integrative Psychosocial Care Program For Cancer Patients
Amy Abernethy1, Tina Staley1, James Herndon2, April Coan2, Jane Wheeler1, H. Kim Lyerly3
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Objectives: Pathfinders, is a psychosocial program that complements cancer care by providing counseling, coping skills training, patient navigation, mind/body techniques, and lifestyle advice. Does Pathfinders improve psychosocial outcomes?

Methods: This prospective, single arm, pilot study enrolled adult metastatic breast cancer patients with prognosis ≥6 months. Patients interacted with a Pathfinder (trained social worker), following a program manual focused on “living fully.” At 5 timepoints over 6 months, patients completed multiple validated surveys including the Patient Care Monitor (PCM) and FACT-B. Six month results update 3-month results presented previously.

Results: Participants (n=50) were: mean age 51 (SD 12); 76% white; 76% married/partnered; 50% less than college degree. Attrition at 6 months was 34% (9 died, 5 withdrew, 3 missing assessments). 42 and 33 patients completed the 3 month and 6 month assessments, respectively. Despite severity of illness and worsening disease, multiple psychosocial symptoms and QOL improved including distress, despair, and emotional functioning (Table). Select patient-reported symptoms (PCM) showed improvement from baseline to 6 months among the 28 patients with both assessments: worry (43%,29%), nervous/tense/anxious (43%,25%), sad/depressed (29%,11%), feeling hopeless (21%,7%), feeling guilty (25%,7%), crying/feeling like crying (25%,11%).

Conclusions: In this pilot study, Pathfinders had significant positive impact on patient distress/despair and emotional functioning. Quality of life improved, despite the severity of participant illness.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Change at 3 months</th>
<th>Change at 6 months</th>
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<tr>
<td></td>
<td>N (Mean SE)</td>
<td>N (Baseline Mean SE)</td>
<td>Change Mean SE</td>
</tr>
<tr>
<td>PCM Distress</td>
<td>4 (11.37 (1.49)</td>
<td>36 (11.36 (1.82)</td>
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<td>PCM Depair</td>
<td>4 (10.43 (2.14)</td>
<td>36 (11.53 (2.68)</td>
<td>-4.53 (1.56)</td>
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<td>PCM QOL</td>
<td>4 (-13.07 (1.44)</td>
<td>30 (-13.52 (1.85)</td>
<td>2.88 (0.97)</td>
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<td>FACT (Emo)</td>
<td>4 (15.69 (0.72)</td>
<td>36 (15.56 (0.81)</td>
<td>2.07 (0.46)</td>
</tr>
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</table>

22-246
Pathfinders: A Pilot Study Of An Integrative Psychosocial Care Program For Cancer Patients
Amy Abernethy
Duke University Medical Center, Medicine, Division of Oncology, Durham, USA

Objectives: To determine the impact of a psychosocial program (Pathfinders) on patient-reported outcomes,
psychosocial measures, quality of life, and perceived performance status.

**Methods:** This prospective, single arm, pilot study enrolled adult metastatic breast cancer patients with prognosis ≥6 months. Patients interacted with a Pathfinder (trained social worker), following a program manual focused on “living fully.” At 5 time points over 6 months, patients completed multiple validated electronic surveys including the Patient Care Monitor (PCM), a review of symptoms with seven subscales (Table 1).

**Results:** Participants (n=50) were: 100% female; mean age 51 (SD 12); 76% white, 20% black; 76% married/permanent partner; 50% less than college degree. The cohort had very advanced disease; attrition at 6 months was 34% (9 died, 2 withdrew, 6 missing data). Forty-two (42) and 33 patients completed the 3 month and 6 month assessments, respectively. Despite the severity of illness, multiple psychosocial symptoms improved. Select patient-reported symptoms (PCM) showing improvement from baseline to 3 months and to 6 months, respectively, were: worry (48%, 33%, 29%), nervous/tense/anxious (48%, 22%, 25%), sad/depressed (28%, 17%, 11%), feeling hopeless (20%, 11%, 7%), feeling guilty (24%, 11%, 7%), crying/feeling like crying (28%, 17%, 7%). Several scale/subscale scores also demonstrated significant improvement or trend toward improvement (Table 1); change means should be viewed in the context of dramatically worsening disease. From baseline to both timepoints (3 months, 6 months), participants did not show significant improvement or decline in objective performance status (Eastern Cooperative Oncology Group, ECOG), but perceived/patient-reported performance status (PCM Impaired Performance Subscale) trended toward improvement while observed performance status (ECOG) trended toward decline.

**Conclusions:** Results of this pilot study indicate that Pathfinders may have significant impact on psychosocial symptoms and attributes, quality of life, and perceived performance status in metastatic breast cancer patients.

**22-247**

**Cancer And Identity. Processes Of Stigmatization In Cancer Treatment. A Multi-Level Study Of Cancer Communication In Denmark**

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**Objectives:** To develop anti-stigmatization processes aiming at releasing cancer patients from the social label of being a victim who is weakened and stigmatized. This includes an exploration of communication processes and interventions in the dialogue with and about cancer patients on individual and societal levels.

**Background:** Society labels people, and those with a cancer diagnosis are no exception. In our assuming world, cancer patients are threatened by death; and are viewed as being weak while undergoing painful treatment episodes. They are perceived differently from the healthy population, both in terms of physical appearance and function, and may be temporarily or permanently left out of their social circles. Cancer attacks the body both objectively and subjectively, affecting one's personal and social identity. Additionally, cancer patients live with being labeled as stigmatized while experiencing painful deficiencies. Recent studies in Danish cancer patients show that feeling stigmatized might lead to social rejection, withdrawal and concealment.

**Methods:** Design: Prospective, cross-scientific study with triangulation of methods and data including video, participant observation, individual in-depth interviews, focus group interviews and questionnaire. Theory: The study is inspired by sociologist E. Goffmann’s theory on stigmatization and concepts of construction and negotiation of meaning and identity within narrative psychology.

**Results:** Findings and Perspectives: Three distinct levels of analysis of stigmatization are presented: the macro-level comprise the societal discourses presented in the media, popular and medical literature, the meso-level represents patient organizations, political health boards and the scientific community, the micro-level constitutes communication between the individual patient and health professionals and/or the patient’s relatives.

**Conclusions:** In particular, we propose reflections on whether stigmatization of cancer patients may be a unique Danish phenomenon associated with the Scandinavian welfare system or if it represents a general issue across cultural and political systems.

**22-248**

**Coping Strategies In Men And Women With Cancer**

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**Objectives:** Cancer is the biggest fear for most women and men. Coping strategies that patients use when confronted with the disease could influence their response and compliance to treatments which could influence survival. The main objective is to relate the search or not for psychological support with the use of coping strategies in men and women with cancer.
Methods: Our sample was composed by 103 women and 119 men, in total 222 patients. Data collection included socio-demographics, disease and social support and it was conducted through a semi-directive interview. For collecting coping strategies data we used Brief-COPE adapted from COPE Inventory for the Portuguese population. This instrument has 28 items and assesses 14 coping strategies.

Results: Statistical significant differences were found in the use of four coping strategies: “Use of Instrumental Support” p<0.025; “Use of Social and Emotional Support” p<0.005; “Religion” p<0.05 and “Expressing feelings” p<0.005.

Conclusions: The group favourable to psychological support uses a set of coping strategies considered less adaptative and uses less a set of coping strategies that are considered more adaptative. On the other hand, the group that didn’t need psychological support uses a set of strategies considered more adaptative. Thus, one should consider that not all cancer patients need psychological support, maybe because the strategies they have adopted are the ones that best serve them in dealing with the fact they have cancer and those who want it, probably do it to try to adopt other strategies that help them with a better adaptation to cancer disease.

Romantic Relationships In Adolescents With Cancer
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1Indiana University School of Medicine/Indiana University Simon Cancer Center, Indianapolis, USA, 2Oklahoma State University, Stillwater, USA, 3University of Mississippi Medical Center, Jackson, USA

Objectives: A diagnosis of cancer in adolescence occurs at a critical time of individual and interpersonal development which involves a shift from dependence on parents to reliance upon close peer and romantic relationships. Adolescents with cancer may be more vulnerable than younger children from the standpoint of impact of diagnosis on their close relationships; however, research examining such relationships is scarce. The purpose of the current study was to describe the nature of romantic relationships in adolescents with cancer. The current study also examined how discrete dimensions of romantic relationships (i.e., dating anxiety, fear of intimacy) correspond with ratings of psychological distress in adolescents with cancer.

Methods: Forty-two adolescents on active treatment for cancer were recruited as they presented for outpatient treatment to four cancer centers. Mean adolescent age was 15.9 years, while mean illness duration was 9.3 months. Primary cancer diagnosis was leukemia (42.9%), followed by sarcoma (28.6%). Adolescents completed a series of paper-based questionnaires assessing the variables of interest.

Results: A majority of adolescents with cancer reported that they were not currently dating and rarely dated, although they would prefer to date at least one person casually. Reasons for not dating were unclear, although some endorsed they were “just not ready to date.” Results also indicated that dating anxiety and fear of intimacy were significantly related to self-reported psychological distress (r = .52, p = .00; r = .26, p = .05, respectively) such that higher levels of dating anxiety and fear of intimacy were associated with higher levels of psychological distress.

Conclusions: A diagnosis of cancer in adolescence has the potential to impact discrete aspects of romantic relationships and psychological outcomes. Given the salience of romantic relationships in adolescence, continued attention is warranted into the impact of cancer during this developmental period, particularly across time and with larger sample sizes. Supported by Walther Cancer Foundation.

22-249
Exploring Distress Among Patients Undergoing Cancer Rehabilitation
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1McGill University Health Centre, Cancer Rehabilitation Program, Montreal, Canada, 21 McGill University Cancer Nutrition Rehabilitation Program, Oncology, Montreal, Canada, 3McGill University Health Centre, Cancer Rehabilitation Program, Montreal, Canada

Objectives: A potentially distressing aspect of having cancer is the loss of control over one’s ability to carry out routine activities. Undergoing a Cancer Rehabilitation program may be a way to give patients back some of that control, as it aims to help them attain maximum physical, occupational, psychological and social functioning within the limits imposed by the cancer and its treatment. The aim of the present research was to describe distress, its correlates, and change over time in patients attending a cancer rehabilitation program.

Methods: The Distress Thermometer and Problem Checklist, Edmonton Symptom Assessment Scale were completed at initial assessment and at the end of the 8-week-program. A subset of participants also completed a Beck Depression Inventory and a Beck Anxiety Inventory at initial and end-evaluation by the psychologist.

Results: Sixty-five participants who were referred for a psychological consultation participated. Of these, there
were 34 men and 31 women, and the average age was 51. Most (75%) endorsed a score of 4 or above on the Distress Thermometer. The most common problems patients reported as sources of their distress were fatigue, pain, difficulty eating, worry, sleep, and getting around. Greater distress was significantly correlated with symptoms on the ESAS, such as poor quality of life (r=.55, p<.001), pain (r=.47, p<.001), depression, (r=.46, p<.001) nervousness (r=.43, p<.001) and strength (.40, p<.001). A subset of this sample (n=25) completed measures of anxiety and depression. Paired T-tests revealed significant improvement on the DT, ESAS, BDI and BAI at end of program in comparison to pre-program scores.

Conclusions: These preliminary findings suggest that distress is related to physical symptoms, and as these improve, distress decreases. This research also points to the positive impact that participation in a Cancer Rehabilitation program may have on patients' emotional distress.

22-251
Family Members As Caregivers During Hematopoietic Stem Cell Transplantation (Hsct)
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Objectives: Family members are assuming increasing levels of responsibility for the care of their loved ones during the transplant process. The caregiving actions span a wide range of physical, psychosocial, and medication administration/monitoring behaviors. Historically transplant was identified as an intensely stressful process for families. The current study was designed to provide attentiveness to the voice of these caregiving family members and serve to inform healthcare professionals.

Methods: This qualitative study involved audiotaped interviews during the acute phase of HSCT. The interviews were transcribed verbatim, verified and then analyzed by the research team using Spradley's domain analysis.

Results: Eleven spousal caregivers provided the voice for this study. Their mean age was 47 years (31-62). They were 170 -1,300 miles from home. Spouses described the experience as riding a rollercoaster in the dark as they lived the uncertainty of this therapy that offered hope and included the potential of life-threatening complications. They used rituals to structure the uncertainty, attempted to maintain a positive perspective, and envisioned the future. They articulated their caregiving role and a need to balance "me and my world" with "us and our world". Caregiving in this uncertain world of transplantation involved knowing and protecting the person and providing care.

Conclusions: The findings add to a body of knowledge about informal caregivers in a manner that can increase our awareness of the HSCT trajectory and guide interventions to prepare caregivers for their experience. As healthcare continues to change and lay caregivers are being expected to provide more care, it is important to remain sensitive to the impact it has on them and to strive to provide the support necessary to avoid negative effects for the caregivers and their families.

22-252
A Comparison Of Two Different Strategies Of Psychological Interventions On Resilience Patterns For Adult Cancer Patients (C-Pts).
Michela Fortugno1, Sabina Gobi1, Loretta Aluigi1, Paolo Giordani2, Vincenzo Catalano2, Stefano Luzi Fedeli2
1Psicology Unit, Oncology Unit, Pesaro, Italy, 2Medical Oncology Unit, OncoHematology, Pesaro, Italy

Objectives: Distress and negative mood in C-Pts are usually related to diagnosis, cancer symptoms and treatment toxicities. The Resilience is the ability to face and answer to these stress conditions. Several studies find the advantage of delivering psychological intervention in Group vs Individual Support. We want to evaluate the effect of Individual (IPln) vs Individual plus Group psychological interventions (GPInt) in improving resilience patterns.

Methods: In a quantitative/qualitative evaluation from the psychology unit in the Pesaro Oncology Department, performed in the 2007-2008, 105 C-Pts attended Individual Psychological Counselling (1 hour weekly session) and 22/105 C-Pts (20%) agreed to attend a Psychological Group Support (2 hour biweekly meeting of ten C-Pts in the Reunion room consisting of discussion the more relevant problems and in distracting activities as art therapy, relaxation therapy). The C-Pts were requested to fill in a Connor-Davidson Resilience Scale (CD-RISC) at the entry and after three months. We compare the average of CD-RISC scores with T-test and ANOVA test.

Results: The average of CD-RISC score was 74 ± 10 of GPInt C-Pts vs 67 ± 12 of IPInt show a difference between the two groups, but not significative, showing an improvement in resilience patterns of the C-Pts GPInt. The CD-RISC Scores at the entry in C-Pts of IPInt were lower than GPInt. The subgroup analysis didn’t show difference between disease state.

Conclusions: This preliminary analysis found that combined modality of psychological support (Individual...
and Group Support) may improve resilience in C-Pts reducing the distress and increasing the well-being better than Individual Psychological support alone. However this improvement was shown in selected C-Pts and actually we are investigating if CD-RISC may help to find the most useful psychological strategy for C-Pts.

**22-253**

**Benefits Of A Brief Existential Intervention For Cancer Patients And Their Families.**

Robert W. Garlan¹, Lisa D. Butler¹, Ernest Rosenbaum², David Spiegel¹

¹Stanford University School of Medicine, Psychiatry, Stanford, USA, ²University of California, San Francisco, San Francisco, USA

**Objectives:** This study assessed a range of potential benefits from, and improvement in aspects of psychosocial adjustment following participation in, a brief semi-structured videotaped interview with cancer patients and their families (The Life Tape Project [LTP]).

**Methods:** The LTP consists of a 2 hour semi-structured videotaped interview with the cancer patient and family and/or other loved ones. The interview begins with a biographical focus (patient’s forebears, early life history, and major life events and transitions), and gradually becomes “deeper” (how the patient has coped with having cancer, personal philosophy, “lessons learned,” and beliefs and attitudes towards death, dying, and the afterlife). The patient is encouraged to express feelings about these issues, and friends and family are encouraged to share memories and feelings about the impact the patient has had on their lives. The videotape is edited and given to the patient as a keepsake and legacy for the family. Perceived benefits, mood, well-being and overall quality of life, social support, cancer-related posttraumatic growth, and the degree to which patients perceived their diagnosis to be life-threatening were each assessed at baseline, at two weeks following the interview, and then again at three months.

**Results:** Results indicated a substantial majority of the sample reported benefits from the experience, particularly in the areas of symbolic immortality (passing on personal values and philosophy), self-reflection and growth, and improved family cohesion and communication. Participants, particularly those who had at some time perceived their cancer as life-threatening, also reported reductions in mood disturbance, improvements in aspects of well-being (including quality of life) and satisfaction social support, and enhanced cancer-related posttraumatic growth.

**Conclusions:** The LTP is a brief, inexpensive intervention that yields broad positive psychosocial changes for a substantial majority of participants, suggesting that almost anyone can benefit from participation in this innovative intervention.

**22-254**

**Randomized Control Trial Of The Meaning-Making Intervention (Mmi) For People Newly Diagnosed With Advanced Ovarian Cancer: A Pilot Study**

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**Objectives:** Existential well-being is a key determinant of QoL for cancer patients. In 2006, a Meaning-Making intervention (MMi) was standardized, manualized and then assessed for efficacy in a randomized control trial (RCT) of positive adaptation by patients recently diagnosed with mostly early-stage breast or colorectal cancer (Lee et al.). Our present purpose was to estimate the effect of the MMi on patients with a poor prognosis (since initial distress upon diagnosis can be more intense).

**Methods:** A pilot-study was conducted using a RCT design, with 26 people newly diagnosed with Stage III/IV ovarian cancer (13 experimental;13 control). We measured the impact of the MMi on psychological, existential and social quality of life, meaning in life, anxiety, depression and self-efficacy at 1 and 3 months follow-up. Repeated measures ANCOVA were carried out for post-test scores on each outcome controlling for baseline scores.

**Results:** At 1 month, women in the experimental group had a better sense of meaning in life as measured by the FACIT-Sp-meaning subscale (mean:25.2;SD:6.4) than women in the control group (mean:22.8;SD:8.5;p<0.05); this enhanced meaning was maintained at 3 months (25.3vs.22.3;SD:6.1 and 7.4;p<0.05). At 3 months, the MMi also showed a beneficial effect on sense of support (MQOL subscale)(mean:9.4;SD:0.9) compared with the control (mean:7.7;SD:2.0;p<0.05). The effect sizes for meaning were 0.33 and 0.41, at 1 and 3 months, respectively; the effect size for sense of support was 1.3.

**Conclusions:** Advanced stage ovarian cancer patients seem to benefit from the MMi in the immediate and short term, reporting enhanced meaning in life and feeling more supported. Future research would include a full RCT to further investigate the efficacy of the MMi, and to identify people who would be most (or least) likely to benefit from such an approach. Until then, the MMi
seems a promising avenue to improve the quality of life of advanced stage cancer patients.

22-255
Matching Of Cognitive Appraisals And The Psychological Impact On Couples Facing Advanced Breast Cancer
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1IUPUI, Psychology Department, Indianapolis, USA, 2Depauw University, Psychology Department, Greencastle, USA, 3IU Simon Cancer Center, School of Medicine, Indianapolis, USA

Objectives: Cognitive appraisals are the perceptions that individuals have regarding a stressor and can either be viewed positively, as a challenge to be overcome, or negatively, either as a threat or a situation that will cause harm or loss to the individual. Cognitive appraisals determine the coping strategies that will be used to deal with stressors. A positive appraisal will lead to very different outcomes than a negative one. We do not know whether having a different appraisal than a partner impacts outcome.

Methods: Fifty-five married couples (N=110) consisting of women diagnosed with metastatic breast cancer and their spouses were recruited. Average age was 52 (SD = 12.23) for patients and 53 (SD = 12.17) for husbands. ANOVAs comparing four groups (both positive, n = 16; both negative, n = 10; patient positive-spouse negative, n = 19; and patient negative-spouse positive, n = 10) were significantly different on the Impact of Illness Scale, the Impact of Events Scale, and the anxiety, depression, and fatigue subscales of the Profile of Mood States (all p < .05).

Results: Both patients and husbands did best psychologically when both appraised the cancer positively. Patients had worst outcome when both appraised it negatively as either threat or harm/loss. For husbands the worst outcome was when he appraised negatively and she appraised positively. Possibly in this group, husbands were unable to discuss their concerns with their wives because of this mismatch, and therefore were lacking this important support.

Conclusions: These findings suggest that both patients and their husbands are impacted by the appraisals of their partners. The best appraisal for both is challenge, which suggests avenues for interventions. Husbands who are not able to appraise the cancer as a challenge may be especially in need of outside sources of support given the findings of this study.

22-256
The Views On Euthanasia Of Polish Medical Students - A Comparison Of Two Polish Medical Universities
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1Poznan University of Medical Sciences, Chair and Department of Palliative Medicine, Poznan, Poland, 2 Lodz Medical University, Palliative Medicine Department, Lodz, Poland

Objectives: Aim of the study: The aim of the study is to explore attitude towards euthanasia of the sixth year medical students at two universities.

Methods: A questionnaire survey was distributed to all medical students of the sixth year who completed palliative care classes (one week at Poznan Medical University and 3 days at Lodz Medical University) – currently 203 students completed the questionnaire. This anonymous survey comprises demographic data (age, gender, religion, place of living), knowledge of EAPC definitions of euthanasia and physician assisted suicide (PAS). The next questions concern the attitude towards euthanasia legalization and possible impact on patients treatment, hypothetical euthanasia practice by students and the choice of euthanasia, PAS or natural death in case of students’ incurable disease. Other questions concern the impact of palliative medicine course on attitudes towards euthanasia

Results: Nearly 95% of students know EAPC definitions of euthanasia and PAS. Over 70% of students are against euthanasia legalisation and over 90% stated that it could lead to a breaking the law and medical ethics in patients’ treatment. The possible will of euthanasia practice was expressed by 13% of students surveyed and among reasons of such choice students mentioned mainly the alleviation of patients’ suffering. In case of own incurable disease 74% indicated natural death, 18% euthanasia, 6% PAS and 2% did not respond. According to 79% of students palliative medicine course did not change their attitude towards euthanasia. The possible will of euthanasia practice was expressed by 13% of students surveyed and among reasons of such choice students mentioned mainly the alleviation of patients’ suffering. In case of own incurable disease 74% indicated natural death, 18% euthanasia, 6% PAS and 2% did not respond. According to 79% of students palliative medicine course did not change their attitude towards euthanasia, however for 11% it confirmed their opposition to such an approach and for 10% the classes changed their attitude to be against euthanasia practice. There were no differences in responses between students of Poznan and Lodz Medical Universities

Conclusions: Most of medical students of both universities are in opposition to euthanasia legalization and practice. Palliative medicine classes increased percentage of euthanasia opponents to limited extent
22-257
Rapid Diagnostic Assessment For A Suspicious Breast Abnormality: Impact On Uncertainty, Stress And Anxiety
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Objectives: In 2008, an estimated 22,400 Canadian women were diagnosed with breast cancer. During the diagnostic period, after a breast lump is discovered or a mammogram displays suspicious findings, women experience great psychological distress including uncertainty, stress and anxiety. Waiting for diagnostic test results is cited as one of the most distressing aspects of the cancer experience. Rapid diagnostic clinics help to decrease this wait time. The idea of a rapid diagnostic clinic is conceptually attractive. However, the literature is unclear as to the effect the rapid diagnostic process may have on patient uncertainty, stress and anxiety. The primary aim of this pilot study is to compare uncertainty, stress, and anxiety of women undergoing a rapid diagnostic process and women receiving the standard process for investigation of a suspicious breast abnormality.

Methods: A comparison cohort, repeated measures design will be used to investigate uncertainty, stress and anxiety in women undergoing a rapid diagnostic process (with a same-day diagnosis), compared with women undergoing the standard investigational approach (with a delay in diagnosis of several days). Recruitment will continue until each cohort comprises twenty women with breast cancer. Uncertainty, stress and anxiety will be measured using the following questionnaires: the Mishel Uncertainty in Illness Scale, the Speilberger State Anxiety Inventory, and the Stanford Acute Stress Reaction Questionnaire. Data will be collected at three time points: pre-diagnosis, three days post-diagnosis, and three weeks post-diagnosis.

Results: This study is on-going and up-to-date results will be presented at the symposium.

Conclusions: This pilot study will help to assess whether uncertainty, stress and anxiety can be successfully compared in women undergoing a rapid diagnostic process versus the standard investigational approach. The results may or may not support proceeding with a similar, larger scale study.

22-258
Necessary Concealment - A Qualitative Study Of The Lived Experiences Of Neglect In Women With Breast Cancer Who Have Developed Malignant Wounds
Betina Lund-Nielsen¹, Julie Midtgaard¹, Mikael Roerth², Finn Gottstrup³, Hans Joern Kolmos⁴, Lis Adansen¹
¹CPH University Hospital, dept. 7331, University Hospitals Centre for Nursing and Care Research, Copenhagen, Denmark, ²Copenhagen University Hospital, Department of Oncology, Copenhagen, Denmark, ³Bispebjerg Hospital, Wound Healing Centre, Copenhagen, Denmark, ⁴University Hospital Odense, Department of Microbiology, Odense, Denmark

Objectives: In Denmark 4,000 women are diagnosed annually with breast cancer; 2-5% of these will suffer from malignant wounds, which are occurring when the underlying localized tumour filtrates into the skin. A contributing factor to the development of malignant wounds is continuous neglect of symptoms resulting in delayed treatment. Little is known about the psychosocial factors and rationale behind the development of malignant wounds as a result of self-determined delay of seeking help. The objective of this study was to describe the lived experiences of symptom neglect of malignant wounds in women with breast cancer.

Methods: A qualitative, phenomenological study was conducted based on audio-taped, semi-structured interviews. The study is part of a larger ongoing PhD Study estimating the effect of silver vs. honey-based wound treatment in combination with psycho-social support and relaxation training in cancer patients (n=75) suffering from malignant wounds. Interviewee selection was carried out through purposeful sampling. Seventeen women with breast cancer (average 70.1 years, range 47 to 90), who had developed malignant wounds and who had omitted to seek medical treatment despite symptom awareness, participated in the study. Transcripts from the audio-taped interviews were used for text condensation analysis, inspired by phenomenological methodology.

Results: The women lived with the wound in secrecy for an average of 23 months. Reasons for neglecting symptoms and not seeking support included (1) feeling of helplessness; (2) fear of losing control; and (3) adherence to a feeling of normality. The women described the neglect of preliminary symptoms as a conscious and necessary strategy, which however developed into an everyday life characterized by extreme loneliness.

Conclusions: This study suggests that women experiencing persistent emotional and social strain are in risk of neglecting symptoms of breast cancer potentially resulting in the development of breast cancer wounds.
Disclosure demands persistent physical and psychoeducational/psychological support.

22-259
Effect Of Supervised Multimodal Exercise On Body Image In Cancer Patients Undergoing Chemotherapy - A Randomized Clinical Controlled Trial (The Body & Cancer Study).
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1CPH University Hospital, dept. 7331, University Hospitals Centre for Nursing and Care research, Copenhagen, Denmark, 2Copenhagen University Hospital, Department of Oncology, Copenhagen, Denmark, 3Danish Cancer Society, Institute of Cancer Epidemiology, Copenhagen, Denmark

Objectives: Cancer and chemotherapy can provoke an altered body image (BI). Exercise has been shown to improve physical performance and QOL in cancer patients undergoing chemotherapy. However, little is known about the effect on BI. The aim was to examine the effect of a six-week multidimensional structured exercise program (The Body & Cancer Project) on BI in male and female cancer patients undergoing adjuvant chemotherapy or treatment for advanced disease.

Methods: Ninety-seven patients (78 women, 19 men, median age 48) with different cancer diagnoses were randomised to either a six-week structured exercise program (9 hours/week) comprising cardiovascular and heavy resistance training, massage, relaxation- and body-awareness training, or a wait list control group. The Body Image Scale (BIS) was used to measure BI at baseline and after the exercise period (six-week). Null in BIS represented no concern about BI and higher score represented higher level of concern. Analysis: T-test, χ²-test and Pearson’s correlation coefficient was used in the analysis (P£.05 was considered significant). The difference in outcome on BIS between baseline and six weeks were used as dependent variables in a General Linear Model.

Results: At baseline male patients had a significantly lower BIS-score than women (p<.05), and patients living together with a partner had a significant lower BIS-score compared to patients living alone (p<.05). The intervention group significantly improved their BI compared to the control group (P=:.046). The intervention group reduced the BIS score with an estimated effect size of -1.608 points compared to the control group.

Conclusions: The results of this study suggest gender-specific and socio-demographic differences in BI in cancer patients undergoing chemotherapy. The study furthermore indicates that exercise during treatment may be a viable and effective strategy to help the individual to maintain or develop a positive BI.

22-260
Comparison Of Values Of Palliative And Internal Medicine Workers In Ukraine
Vladyslav Mykhalskyy, Alexander Zubov, Olga Senchenko
AMIPT, Donetsk, Ukrenia

Objectives: The study was conducted on comparative analysis of professional values and motivation of doctors, nurses and supportive workers in Palliative Medicine (PM) and Internal Medicine (IM) in Ukraine.

Methods: 85 people underwent psychological testing using the following methods: Questionnaire (by AMIPT), Senin’s Questionnaire of Terminal Values, Rokich Values Inventory, Personal Value Orientations method, and Motivational Affiliation Questionnaire.

Results: The study demonstrated PM workers have less material interests (including voluntary work), more interest in continuing education, developing PM by participating in NGO, and spreading hospice network, and showed more humanistic values. PM workers demonstrated lower (p<0,05) denial rate comparing to IM, and were more work-centered, comparing to self-centering in IM. For PM spiritual development and education were more important. IM demonstrated interest in higher income and higher standing.

Conclusions: PM workers showed more important terminal values in interesting work and professional development, work satisfaction and responsibility. IM workers had more interest in income and family happiness, responsibility, demanding their interests and accuracy. Interestingly, the education level had the reverse influence on the difference, which was more pronounced in support workers and less in doctors.

22-261
Impact Of Cancer, Age And Stress On Cortisol, Depression And Fatigue
Oxana Palesh1, Janine Giese-Davis2, Karen Mustian1, Ruth O'Hara

Objectives: Cortisol dysregulation is implicated in fatigue and depression in cancer, but it is unclear whether this dysfunction is associated with cancer, age or stress. This study compared diurnal cortisol rhythms, fatigue and depression between cancer patients and individuals without cancer.

Methods: Depression and fatigue were assessed using the BDI and SF-36 Vitality Score, and salivary cortisol
was assessed using an enzyme-linked immunoassay. Fatigue, depression and group membership and their interactions were regressed on cortisol markers in a set of multiple regression analyses.

**Results:** 274 subjects were selected from 3 large studies of women with metastatic breast cancer (N=92), Alzheimer caregivers (N=92) and older adults at risk for cognitive decline (N=90). Greater fatigue (β = -0.20) and depression (β = -0.20) predicted steeper Baseline Diurnal Log Cortisol Slope across all groups and; (p-values <.05). Greater fatigue predicted greater 2-Day Mean Log Waking Cortisol across all of the populations studied (β = 0.16; p = 0.05). A significant interaction was seen between greater fatigue plus greater depression in breast cancer and caregivers (but not the elderly) with higher Waking Mean Log Cortisol levels (β = 0.26 and β = 0.22 respectively; p-values <.05). Greater depression predicted blunted Cortisol Rise (β = -0.25, p = 0.009) in all 3 groups. A significant interaction between fatigue and depression produced the lowest 2-day Mean Log Wake + 30 Rise in Cortisol (β = -0.18, p = 0.015).

**Conclusions:** Our exploratory analyses identified predictors for 3 patterns of cortisol, and they were not the same across our samples. These data suggest the fatigue and depression in these groups may have different etiologies, which might explain why similar approaches to the treatment of fatigue may be effective in one patient group but may fail in another. Populations that share the same symptoms (e.g., fatigue, stress) but that are etiologically different might have different diurnal cortisol rhythms.

22-262
The Oncologist/Patient Relationship: Were Have We Got? To Inform Or To Communicate?
Mario Ranuzzi
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**Objectives:** The “oncologist-cancer patient” relationship constitutes a most complex problem, one of the most difficult aspects of which is sincere communication with the patient. Among the main dilemmas is whether the patient should be told the truth.

**Methods:** The American model is willing to inform the patient first, the European model is in favor of telling the family first. Should the cancer patient be told the whole truth even when the disease is advanced and there is no chance of cure, or should the patient be cheated, the seriousness of the situation be minimized, while telling the truth to the family? Is it possible to separate truth and honesty respecting the patient?

**Results:** Patients are within their rights in knowing what they got and what they underwent (we have to enable everyone to reorganize their own life). Before entering into discussion with patients or family it is prudent to establish the level of knowledge amongst the parte. In communicating bad news it is important to be positive as there is always something useful to do even in patients with hours to live; emphasizing the positive it is always important to express regret for negative news.

**Conclusions:** Knowing what to say and what not to say is an important skill. Anyway, we absolutely need more research directed to identifying ways to train oncologists how to impart difficult information in a way to help the patients and don't compromise the physicians' emotional survival. The patients needs information about their disease but also needs time and space for shaping thoughts about their situation. Even patients with incurable disease who are aware of the seriousness of their illness need the possibility of dreaming and fantasizing about their future; this is not denial, but coping with the vicinity of giving up one’s life.

22-264
Carcinomas Of Lung & Tobacco Use : Supportive Care Needs In Asian Community To Bring Down Mortality/Morbidity.
Vaishali Sankpal, Nirmal AR, Pramod Sankpal
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**Objectives:** This is Phase-IV continuation of our NGO-Project in Indian-adolescents. Studied influence of counselling on reduction in tobacco-smoking eventually reducing lung-cancer-incidence. 218 deaths/year due to lung-cancer. Crude-Tobacco-smoking socially accepted in rural/tribal India. From May 2007 our NGO conducts project “ BIDI [Locally made crude-Indian-tobacco] Or Health”. Aims to reduce tobacco-products-consumption & provide de-addiction guidance/counselling.

**Methods:** 11 villages from rural India included. Total-participants 511, age 14-24. Tobacco-addicts graded clinically. Counseling-effect monitored for four-months. counseled for cause tobacco-use, educational/social factors. conducted 20 follow-up-sessions during course of study.

**Results:** Of 511 tobacco-users 493 continued to participate. [18 dropouts]. 32% COPD & respiratory disorders, 12% Tuberculosis. 8 healthcare personals from rural-Govt-clinics trained in counseling with community-leaders. 431 participants showed positive-attitude towards quitting tobacco use. Of these 431, 410 smokers quit habit of tobacco. 21 able to abstain for short-period but eventually restarted habit. Post-project-surveillance showed need for community help & Rehabilitation.
Conclusions: NGO-activists with scientific knowledge/expertise are only available resource for influencing cancer incidence in India. They act as channel to implement Supportive cancer care/prevention-programmes. NGOs should utilize this approach to reduce cost-factor in cancer-control-strategies & better de-addiction-facilities in rural/tribal areas where qualified Oncologists are rarity. Recommendations: Developing-nations have little manpower/resources/technologies in de-addiction. nicotine replacement therapies are expensive & available in metro-cities only. Government must carry out supportive-care-programmes with NGO-counsellors to bring down mortality/morbidity of lung-cancer. Anti-tobacco-activists trained in counseling provide better cancer care with reduced cost. We intend to form an Umbrella group of anti-cancer activists to workout more planned approach to this issue at MASCC-2009-Rome-symposium.

**22-265**

**Ngo Peer-Education Models To Conduct Tobacco-Induced Cancer Education : Hard Lessons Learned In Rural/Tribal India**

Pramod Sankpal, Vaishali Sankpal, Rawandale Nirmal

Health Alert Organisation of India, [NGO], Community medicine, Dhule, India

Objectives: In poor health-care-set-up, Tobacco-Induced-Cancer care-services restricted. Primary Health Care backbone of rural/tribal india. Tobacco-Induced-Cancer is well-recognized challenge over world. Tobacco-Induced-Cancer Affected community is rising, but treatment option are inaccessible to rural/tribal communities. NGO’s cater to this vast gap, but have limited resources/training. Young people potentially vulnerable to cancer-risk-behaviors. this results from illiteracy and peer pressures. Our NGO devised model of peer-education-pattern to conduct tobacco-Cancer prevention programs since November-2003. Especially vulnerable adolescents who make choices out of lack of parental support and ignorance.

Methods: Our 10 year-old cancer-NGO workers reduce burden of existing healthcare system & can be trained for peer-model by voluntary services[NGO]. Youth oriented programs achieve effective results. Lack of skill building services for youth reflected in number of youth who risk exposure to Tobacco-Induced-Cancer . But despite their vulnerability, young people are force for fighting respiratory-cancer. This was Phase-III project.

Results: Launching youth’s Peer program with training from NGO’s increases awareness on Tobacco-control. Establishing care and counseling centers and handing over peer-education-programs to local communities is best suited to resource-poor-developing nations. Our NGO-model-functioning graphically shown to MASCC-2009-symposium participants. Our approach provide opportunities for reaching youth by integrate sustainable cancer awareness education programme.

Conclusions: challenge of distance/isolation/low infrastructure can be overcome through committed and trained NGO-Peer-Education-Model. BUT we need to provide regular hands-on training at field level. Peer educators are trained to promote knowledge and develop capacity of youth members for further Tobacco-Induced-Cancer related support-service. Skills and knowledge gained Rome-MASCC-symposium will provide tools to make impact on tobacco-cancer control. Youth education is ongoing process, because each generation need to be informed about how they can protect themselves.

**22-267**

Psychosocial Issues Faced By Women With Incurable Cervical Cancer In Developing Countries: The Cross Cultural Aspect Of Psycho-Oncology!

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Objectives: Cancer has the potential to provoke worries; patients encounter a number of issues like death, disfigurement, disability, dependence and disruption of relationship. In addition, cancer cervix raise concerns related to sexuality, femininity and feeling of motherhood. In many cultures, illness and death may be considered with equanimity and acceptance as a natural course of life, but in developing world men plays a ‘productive’ role while women have more of a ‘reproductive’ role leading to a tendency of their social devaluation. Women often feel ostracized and isolated from the main stream of life which adds further metaphorical meaning to their cancer. Common psychosocial problems identified are stigmatization from the family and community, and varied belief in meaning and causation of the disease. The associated gynecologic symptoms is humiliating, and thus not something easily spoken about. Sexual difficulties and fear of being deserted by the husband are important, but often unexpressed concerns. Men and women encounter dissimilar experiences and needs. Many of these differences relate to inequalities in relationships, unequal social positions. Gender has enormous implications for economic security, access to resources, and survival. Social roles become proxies for obligations, mores and
norms, which have consequences for careers and available resources for women. The challenge in the developing world is to evolve a culturally socio-economically appropriate and acceptable system of care, while addressing psychosocial issues along with long-term care needs that is accessible to the majority of those who need it. We also need to be aware of macro level issues such as poverty, inadequacy of health care services and gender issues such as patriarchy which contribute to the oppression, submission and exploitation of women which is not only a wife a sister or a friend but also the mother because of which we are in this world.

22-268
Cancer Treatment At Home Pilot Project: The Psychosocial Impact For Patients And Their Family Members
Shawn Steggle1,2, Cathy Duong3
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Objectives: The Cancer Treatment at Home Program (CTHP) is a multidisciplinary, pilot project involving home chemotherapy and tele-health. This poster will present the approach used in the planning and implementation of the project, and its evaluation procedures. Preliminary results focusing on the psychosocial impact on cancer patients and their family members will be provided.

Methods: The goals of the CTHP are to reduce patient and family burden, support safe management of patients receiving chemotherapy at home, and provide cost effective delivery of home chemotherapy and tele-health services. The evaluation strategy was designed to assess project safety and effectiveness. It was also designed to provide information about individual perspectives on the project, including those of clinicians, cancer patients and family members. Data are collected qualitatively using individual interview techniques. Other data are also collected using quantitative techniques, including those in the cost-effectiveness evaluation.

Results: The projected enrollment in the study is 100 patients and their family members. Accrual began in January 2009 and it is expected that by the six month point 50% of the study enrolment will be accomplished. Preliminary results of the evaluation procedures will be presented in the poster, with predominant focus on the psychosocial impact on patients and their family members.

Conclusions: Preliminary results of the evaluation strategy will be presented including the psychosocial impact of the program on patients and their family members. To date, the involvement of diverse health disciplines at all levels of program planning, from Steering and Planning Committees to various working groups, has created a supportive environment for cooperation and exploration of new clinical opportunities. Ultimately, the purpose of the evaluation strategy is to determine whether the goals and objectives of the pilot project will be achieved.

22-269
Four Case Studies Illustrating The Use Of Cognitive-Behaviour Therapy In The Treatment Of Peripheral Neuropathy In Cancer Patients
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Objectives: Four case studies are presented, in this poster, to illustrate the use of a cognitive-behavioural therapy approach to assist in the treatment of peripheral neuropathy for cancer patients who were undergoing chemotherapy treatment at two different cancer centres, St. Luke’s Hospital, in Dublin, Ireland and at the Cross Cancer Institute, in Edmonton, Alberta, Canada.

Methods: Case study participants who were suffering from peripheral neuropathy, a common side effect of some cancer chemotherapy regimen, underwent an initial assessment involving a clinical interview and the administration of several questionnaires to assess the problems related to their peripheral neuropathy. The clinical intervention provided by a Clinical Psychologist involved multiple sessions and included: a) Psycho-education – education about medical issues related to peripheral neuropathy (chronic pain) the cognitive-behavioural model of anxiety and chronic pain, with emphasis on learning self-help skills to cope with these problems; b) hypnosis/self-hypnosis – participants were taught self-hypnosis, focusing on both relaxation and pain reduction strategies; and c) cognitive restructuring – participants were taught to recognize, challenge and replace maladaptive cognitions with more adaptive substitutes.

Results: On the outcome measures, the case study participants showed varying degrees of improvement and this is illustrated in a series of graphs on the poster.

Conclusions: Findings suggest that the clinical interventions utilized were effective in assisting to ameliorate peripheral neuropathy related problems for the case study participants. Caution should be exercised in generalizing the efficacy of the clinical intervention based upon these four case studies.
Psychological Distress, Needs And Quality Of Life In People With Inoperable Lung Cancer At The Commencement Of Treatment

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Objectives: People with lung cancer report a higher burden of unmet needs, specifically psychological and daily living unmet needs. They experience more psychological distress and more physical hardship than other tumor sites. This project examined the levels of unmet needs, psychological distress and quality of life in inoperable lung cancer patients towards the start of a treatment plan.

Methods: This is a secondary analysis of baseline data from a randomised controlled trial testing the effectiveness of a tailored informational and supportive care intervention. Eligible lung cancer patients were approached to participate at a suitable time towards the start of their treatment plan. Consenting patients completed baseline questionnaires prior to randomisation. Data was collected on Perceived Needs, Anxiety and Depression, Psychological Distress and Quality of Life from established reliable and valid scales.

Results: Data was collected for 109 participants. Most self-reported needs related to medical communication/information. Anxiety and depression means (and standard deviations) were 4.37 (2.85) and 4.39 (3.18) out of 21 respectively. Twenty-six patients (38.2%) reported a likely case of significant distress. Global quality of life was assessed at 61.94 out of 100, with several differences across specific subscales outlining the burdensome nature of their symptoms and the impact on quality of life.

Conclusions: This data indicates that many lung cancer patients report levels of unmet medical information needs, depressive symptoms, psychological distress and a high burden of physical symptoms.

The Role Of Carers Of People With Advanced Cancer And The Impact Of Their Caring

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1Peter MacCallum Cancer Centre, Nursing and Supportive Care Research, East Melbourne, Australia, 2University of Melbourne, School of Nursing and Social Work, Parkville, Australia, 3University of Melbourne, School of Behavioural Science, Parkville, Australia

Objectives: As cancer progresses, patients experience an increase in severity and number of symptoms. Responsibility for care of patients at this challenging time increasingly falls to family carers. This project aimed to investigate the role and impact of caring for someone with advanced cancer and the salience of self-efficacy as a theoretical framework upon which to develop an instrument to quantify the carer role. This paper reports on qualitative data gathered during the first phase of a larger study.

Methods: Semi-structured interviews were conducted with nineteen carers – fourteen currently caring for someone with advanced cancer, and five bereaved carers. Carer involvement in the patients’ illness and treatment, subsequent changes to their life and supports were discussed. Data was analysed with grounded theory methodology.

Results: Several themes emerged from the data. Carers assume a significant role during the patient’s illness. The role is made more difficult by challenges, such as financial or work commitments. While supports can help, they often come at a cost, such as reduced privacy. Furthermore, the data indicated that caring can result in changes to self-identity, linked to depression, anxiety and high levels of sadness. Self-efficacy appeared to be an important construct to carers, relevant to resilience regarding challenges, accessing supports, asking for assistance when needed and maintaining a sense of self-identity.

Conclusions: Carers of patients with advanced cancer take on what can often be an overwhelming role. This study indicates that assessing and developing interventions to promote self-efficacy may offer valuable support to carers of people with advanced cancer. The next phase of this study will develop and test an instrument to measure self-efficacy in carers of people with advanced cancer. This project has been funded with a National Health and Medical Research Council Palliative Care PhD scholarship.

Psychosocial Health Of Late Stage Breast Cancer Patients And Their Husbands

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Objectives: Researchers have documented the
deleterious psychological and physical consequences of breast cancer for both patients and their spouses, illustrating how difficulties in adjustment for one partner may negatively impact the other partner. Unfortunately, couples confronting late-stage cancers remain under-represented in the literature. As treatment goals shift from cure to palliation, spouses may become particularly vulnerable as they confront the prospect of losing their wife in the near-future. The present study explored the relationship between the psychosocial health of women diagnosed with late stage breast cancer and their husbands.

**Methods:** Fifty-five women undergoing adjuvant treatment for breast cancer (73% stage IV diagnosis) and their husbands completed surveys measuring appraisals, psychological distress (Profile of Mood States), intrusive and avoidant thoughts (Impact of Events Scale), social support (Northouse Social Support Scale, Duke/UNC Functional Support Scale), social constraints, and relationship satisfaction.

**Results:** Correlations and analyses of variance were conducted to determine whether outcomes were related between partners and whether significant differences emerged between patients and their spouses. Surprisingly, the only significant correlations between husbands and wives were found for confusion and avoidant and intrusive thoughts, with both partners reporting mild distress. Spouses reported significantly more anger, anxiety and depressive symptoms and less social support (p < .01) than patients. Husbands and wives reported equivalent appraisals, social constraints, and marital satisfaction.

**Conclusions:** These findings lend further support to studies highlighting the vulnerability of spouses of breast cancer patients during breast cancer treatment and suggest areas for intervention. Interventions focused on reducing confusion and avoidant and intrusive thoughts should be targeted at couples, while spouses might benefit from increased social support and individual counseling to reduce anxiety, anger and depression. Supported by The National Cancer Institute.

**22-273**

**Spiritual Needs Of Cancer And Spiritual Supports Need From Nurses**

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**Objectives:** The purpose of this research was to study what is the spiritual needs of cancer patients and what is the supports that nurse can do and they want. In present most of our care patients by physical.

**Methods:** The research design was a cross-sectional descriptive research design. The instrument was divided to 2 section. The first was individual information. The second was interview about spiritual needs of cancer patients and spiritual supports need from nurses. These was developed from Highfield’s Spiritual Needs Scale (1992). It composed 3 concepts. One is the meaningful. Second is the hopeful and the last is the relationship. The sample was 91 cancer patients in every organ who take radiation treatment and admitted in the hospital.

**Results:** The results indicated that: 1. Most of them is Buddhism so they think about the life after death. Outcome that they made of good or bad. And they believed about birth, old, sick and death. These uncertainly is the core of Buddha. 2. The patient did not want to give pain or suffering when they had they want to take off by death. But when they think about their family or their loved which pull them to be alive.

**Conclusions:** In anything that they needs but the patient did not want helping or supporting from nurses. Because they look at the nurses are busy and they think someday when they go home they will do everything that they want by themself.

**22-274**

**Mapping The Psychosocial And Practical Support Needs Of Cancer Patients And Their Families In Western Australia.**

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**Objectives:** The diagnosis and treatment of cancer has a significant psychological impact on both the patient and their family. Cancer patients require access to a range of practical supports during the course of their illness, to facilitate recovery and improved health outcomes. This study aimed to map the psychological and practical support needs of Western Australian cancer patients, in metropolitan rural and remote areas. To date, no research has explored the unmet needs of cancer patients within Western Australia, and few studies have attempted to assess this on a population wide basis.
Methods: 1770 cancer patients identified through the Western Australian Cancer Registry with the Long Form Supportive Care Needs Survey (SCNS-LF59) were invited to participate. The SCNS-LF59 assesses the perceived needs in the domains of psychological, health system and information, physical and daily living, patient care and support and sexuality needs.

Results: A total of 829 participants returned the survey. Psychological needs were the highest unmet need, with 73.3% percent of the psychological domain items ranking in the top 15 needs. Other domains that were highlighted included fear of recurrence, fear for family and the sexuality domain (25.6%). The physical and daily living domain was also highlighted with 20% of the total sample indicating unmet need. Variations across tumour groups were noted.

Conclusions: The results of this study highlight that cancer patients in Western Australia have a number of psychological needs that are unmet. The results also illustrate the variations in unmet needs among tumour groups, for instance with prostate cancer patients and their needs for support relating to sexuality issues in addition to psychological support. Equally important the study highlights areas where needs are being met. The results of this study will be beneficial to assist develop services to suit the needs of different cancer populations.

22-275
Lusher Test As Screening Tool
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Clinics "Hypocrates", Administration, Rostov-on-Don, Russia

Objectives: In cancer patients who need rather palliative then supportive care routine psychometric assessment meets frequently some difficulties, so the simplest procedures are desirable. The aim of our work is to present initial experience of using Lusher color test in patients with far-advanced tumors.

Methods: 43 patients with generalized neoplasms (various nosological forms) were assessed with minimal, 8-color Lusher test. These colors were chosen with standard descending sequence.

Results: In 39 of 43 patients (90.7%) the emotional sphere was characterized with negative tendencies which were apparently prevailed: first positions were occupied with black, grey and brown colors. It suggested severe depressive disorders (in asthenic, hypochondric or agitated forms) and/or anxiety. On the contrary, basic colors in positive part of emotional range: green, red, blue – were suppressed. In 30 of these 39 patients marked psychological tension was associated with emotional disorders. Such tension was usually accompanied with helplessness, demoralization syndrome and other related signs. Autoaggressive responses were sometimes observed, such responses being rigid. There was a trend to emotional and behavioral avoidance instead of beneficial coping strategies. 3 patients with true religious beliefs had less apparent emotional disturbances.

Conclusions: Lusher test is the health professional administered tool with easy procedure. It suggests to consider this test as useful for mood state screening, especially in debilitated patients with generalized cancer. However, results from studies with larger number of patients are warranted.

23-276
Prevalence Of Pain, Depression, Asthenia And Insomnia And Their Impact On Health-Related Quality Of Life, In A Cohort Of Lung Advanced Cancers
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H. General Universitario de Valencia, Valencia, Spain
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H. Lluis Alcanyis, Xativa, Spain
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Objectives: Pain (P), depression (D), asthenia (A) and insomnia (I), alone or in combination, are some of the most important and invalidating cancer symptoms. But little is known about the relationship between the symptoms of this cluster, and its impact on health-related quality of life (HRQoL). This analysis has been carried out to better know the prevalence of this symptoms cluster and its impact on lung cancer HRQoL.

Methods: An observational and longitudinal multicentre study was carried out on a sample of cancer patients with lung cancer, any site and period of disease duration, receiving chemotherapy. Data were collected at inclusion and 3 months later. Sociodemographic data, key clinical indicators, as well as Pain, Depression, Asthenia and Insomnia complaints or diagnosis were collected. HRQoL was assessed by means of Nottingham Health Profile scale (a generic health measures of 22 items). Analysis were focused on baseline cross-sectional data.

Results: 63 patients were analyzed: 88.9 men, 60.1 (SD=8.4) years old, 2.09 (SD=0.72) years since diagnosis, 98.4% with metastasis. 88.9% presented at
least one of the symptom cluster under study: 31.7% a
symptom alone, 25.4% two symptoms, 31.8% three or
more symptoms in the cluster. 66.6% of patients reported
Pain, followed by 65.1% reporting Asthenia, 34.9%
Insomnia and 14.3% Depression.

<table>
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<th>variables</th>
<th>N(%)</th>
<th>NHP physical mean(SD)</th>
<th>p-value(1)</th>
<th>NHP psychol. mean(SD)</th>
<th>p-value (1)</th>
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<td>0 symptoms</td>
<td>7 (11.1)</td>
<td>18.2 (19.6)</td>
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<td>16 (25.4)</td>
<td>28.6 (27.6)</td>
<td></td>
<td>22.1 (24.1)</td>
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<td>≥3 symptoms</td>
<td>20 (31.8)</td>
<td>44.5 (30)</td>
<td></td>
<td>34.3 (28.5)</td>
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NHP physical $R_{\text{Spearman}}$  NHP psychological $R_{\text{Spearman}}$

Baseline Pain Intensity (Visual Analogue Scale) | 42 | 0.38 | 0.15 |
Baseline HADS depression | 9 | 0.79 | 0.92 |
Baseline FACT asthenia | 41 | 0.66 | 0.46 |
Baseline MOS-Sleep Insomnia | 22 | 0.42 | 0.87 |

(1) One-way ANOVA

Conclusions: In patients with lung advanced cancers, the
prevalence of the studied symptoms cluster is high
(≈88.9%). The more intensity of symptoms cluster, the
worse physical and psychological HRQoL assessed by
means of NHP scores. In the same way, the more
quantity of symptoms cluster, the worse physical
HRQoL. Supported by a grant from Amgen, S.A.

Objectives: We conducted this prospective study to
assess patients’ informed decision and examine its
impact on the change of health-related quality of life
(HRQoL) in patients receiving palliative chemotherapy
for solid cancers.

Methods: Patients were eligible if they had
histologically confirmed metastatic or recurrent cancer
and they would start 1st line palliative chemotherapy.
They were asked to complete the self-administered
questionnaires including demographic characteristics,
informed decision such as the insight for disease stage
and treatment aim, anxiety and depression, and HRQoL.
Anxiety and depression, and HRQoL were measured at
baseline and at 12 weeks after treatment using HADS and
EORTC QLQ-C30. We performed multivariate-adjusted
analyses in all HRQOL comparisons.

Results: One hundred patients were recruited and eighty
eight patients completed the HRQOL questionnaire and
fifty seven patients followed-up (follow-up rate, 64.8%).
Their median age was 57.4 years (range 24-78 years).
Most patients knew their disease (96%), but they were
only informed about the stage of disease (50%) and the
aim of anticancer treatment (58%). Overall, physical and
role functioning, and anxiety were significantly
decreased after treatment (respectively, $P=0.001$, 0.002,
0.006). Before treatment, insomnia and appetite loss
were more severe in patients who aware of their disease
stage compared to unaware, however overall QOL was
better in patients who aware of their disease stage
(clinical meaningful difference, 10 points or more). After
treatment, physical, role, emotional, and social
functioning, and overall QOL were better in patients who
aware of their disease stage. Regarding symptoms, most
symptoms (fatigue, pain, dyspnea, insomnia, appetite
loss, constipation, financial difficulties) were more
severe in patients unaware of their disease stage. Model-
based multiple regression analyses showed patients’
awareness of disease stage was independently predicts
increased role and cognitive functioning.

Conclusions: Korean patients receiving palliative
chemotherapy did not have informed well. But the
perception of the disease stage was helpful on improving
HRQOL.
Factors Associated With Weight Loss During Radiation Therapy In Patients With Stage I Or II Head And Neck Cancer
Isabelle Bairati, Alice Nourissat, François Meyer
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Objectives: Weight loss during cancer therapies might influence patients’ prognosis. The objective of this study was to identify factors associated with weight loss during radiation therapy (RT) among early stage head and neck cancer (HNC) patients.

Methods: This study was conducted as part of a phase III chemoprevention trial. A total of 540 patients with stage I or II HNC were randomized. Patients were weighted before and after RT. Weight loss during RT (in kg) was the outcome of interest. Tumour characteristics at baseline were noted and blood samples were collected. Many patients’ characteristics were assessed at baseline and again at the end of RT using validated instruments: performance status, life habits, quality of life, dietary intake and supplement use. Occurrence of acute adverse effects of RT was evaluated at the end of RT by radiation oncologists according to the RTOG criteria. Total dose of RT was recorded. Multivariate linear regression was used to identify factors independently associated with weight loss.

Results: The mean weight loss was 2.2 kg (SD=3.4). Patients with laryngeal cancer (p=0.0002), those with higher dietary energy intake during RT (p<0.0001), and those with better performance status during RT (p=0.0007) were less likely to experience important weight loss. Increased risk of weight loss was associated with stage II HNC (p=0.0003), higher weight at baseline (p<0.0001), and presence of dysphagia at baseline (p=0.0001). The severity of dysphagia during RT (p<0.0001) and the occurrence of digestive symptoms during RT (p<0.0001) were strongly associated with weight loss. This model explained 37% of the variance of weight loss.

Conclusions: These results show the importance of maintaining energy intakes in HNC patients during RT and of reducing the severity of adverse effects of RT.

Use Of A Comprehensive Geriatric Assessment Screen In The Ambulatory Medical Oncology Setting
Deborah Boyle
Banner Good Samaritan Medical Center, Nursing, Phoenix, USA

Objectives: While cancer is a disease of the elderly, there has been a paucity of attention paid to the special needs of the older adult. Comprehensive assessment is needed to determine early indications of functional, nutritional and psychosocial compromise as cancer therapies may induce considerable demands on the older patient. While comprehensive geriatric assessment (CGA) is a well accepted practice in general gerontology settings, it has not been introduced into oncologic settings of care. This presentation will address the use of a specialized CGA for older cancer patients and findings emanating from pilot testing of this novel tool.

Methods: Based on critique from oncology advanced practice nurses and evidence-based literature, the Comprehensive Onco-Geriatric Inventory Screen (COGIS) was devised using major components of the CGA. It is comprised of two parts. A patient report is completed prior to initial consultation. This reports collects data on social/living arrangements, nutritional status, distress, functional status and coping concerns. A professional component is completed by the oncology advanced practice nurse. This section determines the presence of co-morbidity, geriatric syndromes, caregiver concerns, pain, cognitive status and polypharmacy. Since a shorter version of the general CGA was required, the tool was created acknowledging the need for a thorough yet timely screen for a variety of issues.

Results: The COGIS has undergone pilot testing in seven medical oncology ambulatory practice settings. Users completed evaluations that queried the appropriateness of each tool component, timeliness, item inclusiveness, and practicality. After edits based on user feedback, the COGIS remains a 2-part initial screen having significant applicability for use in busy ambulatory medical oncology practice settings.

Conclusions: To ensure the provision of thorough, elder-sensitive care, a cancer-specific version of the CGA is needed. As a result of pilot testing, the COGIS has proven beneficial in augmenting existing assessment of new patients within medical oncology settings.

Laxative Use In Patients With Advanced Illness And Opioid-Induced Constipation Treated With Subcutaneous Methylnaltrexone
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Objectives: To report laxative use in patients with advanced illness and opioid-induced constipation (OIC) receiving subcutaneous (SC) methylnaltrexone or placebo stratified by laxation response in a double-blind phase 3 study.
Methods: Adults with advanced illness and OIC were randomly assigned to receive methylnaltrexone 0.15 mg/kg or placebo SC every other day for 2 weeks. Patients continued baseline laxative regimens during the study. The post hoc descriptive analyses of patients taking laxatives are reported by laxative class, treatment group, and laxation response.

Results: Baseline laxative use was comparable between treatment groups. Numerically fewer patients receiving methylnaltrexone than placebo reported using common laxatives during the study. Among all patients receiving double-blind methylnaltrexone (n=62), enemas were used by 15 (24.2%) patients, contact laxatives by 52 (83.9%), stool softeners by 26 (41.9%), magnesium compounds by 17 (27.4%), and osmotic agents by 20 (32.3%). Among placebo patients (n=71), enemas were used by 25 (35.2%) patients, contact laxatives by 66 (93.0%), stool softeners by 30 (42.3%), magnesium compounds by 32 (45.1%), and osmotic agents by 28 (39.4%). This study also examined usage by methylnaltrexone responders (n=19) and nonresponders (n=43). Among responders, enemas were used by 1 (5.3%) patient, contact laxatives by 15 (78.9%), stool softeners by 7 (36.8%), magnesium compounds by 6 (31.6%), and osmotic agents by 4 (21.1%). By comparison, in nonresponders, enemas were used by 14 (32.6%) patients, contact laxatives by 37 (86.0%), stool softeners by 19 (44.2%), magnesium compounds by 11 (25.6%), and osmotic agents by 16 (37.2%). Enema use was substantially reduced among methylnaltrexone responders vs patients on placebo (5.3% vs 35.2%, respectively). All methylnaltrexone responders had laxation within 4 hours for at least 4 of the 7 doses during the study.

Conclusions: SC methylnaltrexone-treated advanced illness patients with OIC had less use of some common types of laxatives, especially enemas, compared with placebo.

23-281
Symptom Clusters And Quality Of Life In Patients Receiving Treatment Of Cancer
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Objectives: To explore the prevalence of fatigue, pain, difficulty sleeping and depression in patients with cancer, and to examine the relationship of symptom cluster to quality of life (QoL) after adjusting for demographic and clinical factors.

Methods: This study used secondary data from a sample of 214 patients with head/neck (HN), breast, lung, colorectal (CR), gynecological (GYN) or other cancers receiving any type of active cancer treatment. Measuring instruments included Memorial Symptom Assessment Scale and Functional Assessment of Cancer Therapy-General.

Results: Fatigue, pain, difficulty sleeping and depression were found in about half of the patients, with fatigue being the most common symptom (59%). Fatigue (71%) and depression (56%) were most prevalent in HN cancer. Pain (68%) and difficulty sleeping (56%) were most common in lung cancer. Pain was the most severe (mean 2.3) (score range is 0 – 4, with higher scores representing severe symptom) and distress (mean 2.3) of the four symptoms. Significant relationships were found among the four symptoms (r = 0.34 – 0.57, p<0.01). The physical (20.5 ± 5.8), social (19.2 ± 4.1), functional (13.4 ± 6.5) (score range is 0 – 28, with lower scores representing poor QoL), and emotional health (17.4 ± 4.4) (score range is 0-24), as well as overall QoL (76 ± 17.2) (score range is 0-116) were moderately low. Patients with lung (mean 10 – 18.7) or HN (mean 12.1 – 19.6) cancer reported lower scores in all QoL subscales than those with other cancers (mean 13.9 – 21.9) (p<0.05). In multiple regression, patients with severe fatigue (β=-0.75, p=0.003), pain (β=-0.66, p=0.012), difficulty sleeping (β=-0.40, p=0.028) and depression (β=-0.44, p=0.021) was associated with poor emotional health, which explained 64% of variance in emotional health.

Conclusions: The symptom cluster of fatigue, pain, difficulty sleeping and depression are common and co-exist in different type of patients receiving treatment of cancer. Emotional QoL are predominately influenced by the symptom cluster.

23-282
The Effects Of Resistance Training On Quality Of Life In Cancer Survivors: A Systematic Literature Review And Meta-Analysis
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Objectives: Cancer and its' treatment can result in a range of symptoms detrimental to quality of life (QoL). Recent reviews have confirmed the benefits of general exercise to cancer survivors (e.g. Cramp and Daniel, 2008; Stevinson et al 2004) but little is know about the specific effects of resistance training. Therefore we carried out a systematic review and meta-analysis to evaluate the effect of resistance training upon QoL in cancer survivors.

Methods: Search strategy: MEDLINE (1966 to January 2009), CINAHL (1982 to January 2009), AMED (1985...
to January 2009), and EMBASE (1974 to January 2009) were searched using relevant key words. Reference lists of all studies identified for inclusion and relevant reviews were also searched. In addition, relevant journals were hand searched and experts in the field contacted. Selection criteria: Randomized controlled trials that investigated the specific effect of resistance exercise on QoL in adult cancer survivors were included. Data collection & analysis: Two review authors independently assessed the methodological quality of studies and extracted data based upon predefined criteria. A meta-analysis was performed for QoL using a random-effects model.

Results: Six studies were identified for inclusion. Two studies demonstrated a significantly beneficial effect of resistance training on QoL compared to usual care. A meta-analysis was used to combine the post test results. Post-test means +/− SD were available for all comparisons providing data for 278 participants who received an exercise intervention and 270 control participants. At the end of the intervention period exercise was statistically more effective than control (SMD -0.17, 95% CIs -0.34 to -0.00) demonstrating a marginal effect. Overall there was heterogeneity between studies in relation to tumor type, stage of therapy, type of cancer therapy and duration of the intervention.

Conclusions: Existing evidence suggests that strength training programs for cancer survivors are beneficial. Further studies are required to determine the optimal type, intensity and timing of resistance training.

23-283 Prospective, Randomized, Single-Blinded, Multicenter Phase II/III Study Of Auron Misheil Therapy (Amt) Vs. Placebo To Evaluate Clinical Benefit Response (CBR) And Effect On Quality Of Life In Patients (Pts) With Advanced Solid Tumors Klaus Diergarten1, Faiz Niazi1, Jens Soltau2, Ralph Lohrmann2, Juergen Scheele1, Joachim Dreves2

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Sanafontis Clinic, Freiburg, Germany

Objectives: CBR consists of pain response (pain intensity /analgesics consumption), Karnofsky performance status and body weight and is used as study endpoint and clinical measure for symptom improvement in patients with advanced cancers. AMT contains human insulin and chlorpheniramine in low therapeutic doses and aqueous camomile extract. Safety and efficacy of AMT was shown in phase-I- and -II-studies. Compassionate use patients reported an increase in quality of life (QoL), with better ability to perform daily activities, sometimes an increase in body weight and/or pain-reduction. Study AMT/P2CA/001 compares CBR-efficacy and safety of AMT with placebo in patients with advanced solid tumors refractory to standard therapy or for which there is no standard therapy. For these patients the impairment in quality of life is a major issue.

Methods: Pts were randomized to placebo or AMT (0.066 ml/kg body weight) twice daily i.m. Under certain conditions pts on placebo could switch to AMT in the open phase CBR was evaluated after 2 weeks of treatment with randomized AMT/placebo and after 2 weeks of open AMT, confirmed 4 weeks later. 1 week screening period for the assessment of the baseline CBR was necessary.

Results: 45 patients were evaluable in this first analysis for CBR at 2 and 6 weeks. 6/ 45 patients showed overall CBR response at week 2 and 6. All cases were provided by responders in the parameters determination of pain response and/or Karnofsky index. The general adverse event profile (related and not related events) reflects the advanced disease of the patients, and no relevant differences were observed between patient groups.

Conclusions: This study shows that CBR can be achieved with AMT after 2 respectively 6 weeks of treatment in advanced stage cancer patients and a clinically relevant number of patients seems to benefit by improvement of symptoms and quality of life.


Objectives: Analysis of pts needs is the base of pts satisfaction. The present analysis aims to identify the needs of our in-outpatients with breast cancer who received chemotherapy.

Methods: From September to November 2008, 134 pts with breast cancer who underwent chemotherapy were eligible for study. Eligibility criteria required age ≥ 18 yrs (median age of pts was 55 yrs), histologically proven breast cancer; at lest 1 completed cycles of neo-adjuvant or adjuvant or palliative chemotherapy. We administered the “Need Evaluation Questionnaire” NED ( validated by U.O. Psiconologia INT- Mi) to 125 pts after consent, 9 pts (7%) refused to answer items. . NED was built on 23 items in 7 domains of necessity: 1) information on diagnoses, prognoses, diagnostics tests and treatments (items 1-4); 2) relationship between pts and physicians or nurses (items 5-8), 3) nursing and supportive care (items 9 -13) 4) Hospital service (item 14); 5) economical aspects (items 15-16); 6) psychological, ethical, spiritual care (items 17,18,19,23); 7) relationship with relative.
NED makes a quantitative evaluation of necessity with simple questions. 96 (77%) pts completed questionnaire by their self.

**Results:** 93 % of pts completed NED questionnaire. More significant data were reported afterward and answers were allocated among the 7 domains: 1) more information about prognosis was required by 52 % of pts; 2) 90 % of pts thought that physicians embroiled them in therapeutic choices, but 36% of pts required information about their future and the quality of life. 96% of pts considered very good nursing care; 4) positive for all pts 5) 26% of pts required more informations about insurance, tickets 6) 13 and 14 % of pts required psychological or spiritual relationship; 7) women generally had support by relatives.

**Conclusions:** this analysis a shows that needs of our pts generally received responses, but answers also emphasized assurances on pts’ future.

23-285

**Navigation: Creating A National Agenda For Cancer Patient Navigation**

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**Objectives:** Funding has been made available for five years to implement the Canadian Strategy on Cancer Control, through the auspices of the Canadian Partnership Against Cancer. One of the eight action groups charged with specific mandates is the Cancer Journey Action Group. Its mandate is to provide leadership to change the focus of the cancer system so that patient, survivor and family member needs are better served. This presentation will highlight the overall plans for the Action Group in its move toward creating a person-centered cancer system, with a specific emphasis on navigation as a system intervention.

**Methods:** One of the key strategy plans to assist in achieving the vision of a person-centered care delivery system is Patient Navigation. This intervention can increase timely access to the full range of supportive care services required by patients and their families. Professional led, peer led, and virtual approaches to navigation have been initiated across the country.

**Results:** Cancer and its treatment have more than a physical impact. There are also psychosocial, spiritual and practical consequences. Patients and families need access to a wide range of services. Navigation through the complex cancer system is imperative to improve the patient experience but programs need to be implemented with specific objectives and clear parameters.

**Conclusions:** Research and evaluation on patient navigation is required to determine best models for particular settings. This work presents an excellent opportunity to influence the quality of psychosocial/supportive care.

23-286

**Improved Quality Of Life And Survival Prolongation By A Long-Term Supportive Treatment With Fermented Mistletoe (Viscum Album L.) Extract In Primary Non-Metastatic Colorectal Cancer**

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**Objectives:** Aim of the study was to prove safety and efficacy of a fermented mistletoe extract (Iscador®, ISC) in supportive care of post-surgical patients with primary colorectal cancer as compared to a parallel control group without ISC.

**Methods:** In a comparative, multicenter, non-interventional cohort study with parallel groups ISC was applied additionally to conventional adjuvant chemotherapy and/or radiotherapy (conv-th). The control group was treated with conv-th only. Unselected, standardized, anonymized data from medical records of patients treated between 1993 and 2002 who met the eligibility criteria were followed until last visit or death. As endpoints for Quality of Life the incidence of conv-th induced adverse drug reactions (ADR), persistence of tumor or conv-th related symptoms, Karnofsky index (KPS), and duration of hospitalization(s) were evaluated. Additionally, disease-free survival (DFS) was calculated. All endpoints were adjusted to confounders.

**Results:** 804 eligible patients (429 ISC and 375 control) from 26 centers were evaluated. ISC started mostly during conv-th (72.9%), with doses escalating from 0.01 mg to 20 mg as s.c. injections, 2-3 times weekly. The median follow-up time was 58 (ISC) vs. 51 months (control), median ISC duration was 52 months. The adjusted relative ADR risk was significantly lower in the ISC groups as compared to control: odds ratio, OR (95% CI) = 0.46 (0.28-0.77), p=0.003. Symptom persistence, KPS and duration of hospitalizations were all significantly better in the ISC group. Analysis of DFS showed significantly longer survival in the ISC groups. ISC was well tolerated.

**Conclusions:** The results show reliable safety and clinically relevant beneficial effects of ISC treatment.
The study was supported by an educational grant of the Society of Cancer Research, Arlesheim, Switzerland.

23-287
Supportive Care Needs In Advanced Cancer Patients: Experience In A Hospital-Based Palliative Radiotherapy Clinic
Corsita Garraway¹, Andrew Potter¹,², Andrea Bezjak¹,², Wilfred Levin¹,², Michael McLean¹,², Rebecca Wong¹,²
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Objectives: Referral for palliative radiotherapy may serve as an indicator of evolving symptom complexes in patients with advanced cancer. Patients might have unmet supportive care needs that require active intervention. This study was done to establish the frequency of supportive care needs among patients referred to our palliative radiation oncology program, and examine patient characteristics associated with an increased need for supportive care.

Methods: A prospective database is maintained for all patients referred to our program. This includes patient demographics, symptom profile and assessments of the adequacy of community support (for out-patients), and whether referrals are made from our clinic for additional supportive care services. This database serves as the source for our analysis.

Results: Between Apr 2006-Dec 2008, 712 patients were evaluated for supportive care needs. 85 (12%) were felt to have inadequate support. A total of 106 referrals were made for 90 patients: 35 home care, (nursing assistance), 36 palliative care (physician supervision), and 35 social/other services). These patients had significantly worse ECOG performance status (p=0.001), pain (p=0.007), and shorter clinician-assessed life expectancy (p<0.001). There were no significant differences in age, gender, location of primary cancer, the presence of brain metastases, the discipline of referring physician, the time from diagnosis to metastases nor the time from diagnosis of metastases to referral for palliative radiotherapy.

Conclusions: Assessing the adequacy of patient support is important to ensure timely referrals to preempt the situation where patients suddenly decompensate and have no help. Patients with poorest performance status, worst pain and decreased life expectancy had the greatest need for additional supports. These characteristics may assist community support providers to plan for optimal care delivery.

23-288
A Prospective Evaluation Of The Attitudes Of Patients, Physicians And Nurses Using A Computer-Assisted Quality Of Life Instrument (LCSS-QL) In A Large Multicenter Clinical Trial In Advanced Non-Small Cell Lung Cancer: Results From The Asia-Pacific QL Trial
Richard Gralla¹, Patricia Hollen², Sumitra Thongprasert¹, Hoon-Kyo Kim³, Te-Chun Hsia⁴, Shi Yuankai⁵
¹North Shore - LIJ Health System, Lake Success, USA, ²University of Virginia, Charlottesville, USA, ³Maharaj Nakorn Chiang Mai Hospital, Chiang Mai, Thailand, ⁴St. Vincent's Hospital, Suwon, Korea, ⁵China Medical University Hospital, Taichung, Taiwan, ⁶Chinese Academy of Medical Sciences, Beijing, China

Objectives: Many barriers to the assessment of health-related quality of life (QL) in practice and clinical trials have been identified. These include perceived lack of validated QL instruments and the time and resources required. One major aim of the Asia-Pacific QL Trial is to determine if conversion of a well-validated QL instrument (LCSS) into a computer-assisted format using an inexpensive pocket-pc enhances feasibility, provides immediate results, and helps overcome barriers. This analysis determines the acceptability and value of LCSS-QL as assessed by patients and healthcare professionals.

Methods: Patients receiving initial chemotherapy utilized the LCSS-QL as part of a clinical trial and completed a form evaluating their experiences. All received docetaxel-based chemotherapy (83% with cisplatin or carboplatin). Treating physicians and nurses administered the LCSS-QL and also completed an evaluation form assessing their views. The form evaluated: time required, satisfaction with the process, value of assessment, impact on communication, resource utilization.

Results: 242 patients have been treated and assessed by 31 physicians and 41 nurses in 8 Asian countries at 43 sites. Patient characteristics: Stage III/IV 23%/77%; median KPS 90%; 72% male; median age 58 years. Patients reported little computer experience. The table below gives the results from the categorical scales of the questionnaires concerning the LCSS-QL (not all individuals answered all questions).
The LCSS-QL was easy to use 93% 92%
It was acceptable to complete the LCSS at each visit 88%
QL evaluation aided communication 84% 92%
QL evaluation made the visit more difficult 2%
The effect of chemotherapy could be identified earlier 72%
QL evaluation could result in ordering fewer tests 75%
It helped in addressing QL and symptom issues 70%
The LCSS-QL could save time with patient visits 83%
QL evaluation increased satisfaction with the visit 88%

The LCSS-QL generally took <3 minutes to complete. Healthcare professionals had high computer skills and found the LCSS-QL easy to learn and use.

**Conclusions:** Patients and professionals found that using a validated QL instrument in a computerized format was easy, added value and satisfaction, while enhancing communication and QL awareness. Ongoing analyses are comparing results by country and with a similar evaluation in Canada for cross-cultural assessment. These results indicate that this QL evaluation method can be used in clinical trials and patient management to overcome barriers to QL assessment. Supported by sanofi-aventis

### Results:

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<th><strong>Initial Evaluation</strong> (baseline)</th>
<th><strong>Evaluation after therapy</strong> (n=22)</th>
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<tr>
<td><strong>Somatic Health</strong></td>
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<tr>
<td>Somatic performance</td>
<td>33.7±17.5</td>
<td>51.6±20.1</td>
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<tr>
<td>Somatic roles</td>
<td>9.3±19.8</td>
<td>77±43.8</td>
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<td>General health</td>
<td>33.5±18.8</td>
<td>57.1±16.9</td>
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<tr>
<td><strong>Mental Health</strong></td>
<td></td>
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<tr>
<td>Vitality</td>
<td>40.8±15</td>
<td>53.8±18.1</td>
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<tr>
<td>Social performance</td>
<td>49±30.1</td>
<td>73±20.1</td>
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<tr>
<td>Emotional roles</td>
<td>35.8±21</td>
<td>69.8±43</td>
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<tr>
<td>Psychological health</td>
<td>52.1±23</td>
<td>63±18</td>
<td>0.01</td>
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**Conclusions:** The treatment approach with cetuximab improved significantly the somatic and mental health of MCC patients compared to the quality of life before the initiation of cetuximab, as shown from the results of the study.

### 23-289

**Cetuximab And Quality Of Life In Patients Suffering From Metastatic Colorectal Cancer (MCC)**

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**Objectives:** The aim of the present study was the evaluation of the improvement of quality of life in MCC patients after receiving therapy with cetuximab, according to the scale Short Form-36 Health Survey (SF-36).

**Methods:** We studied 22 (15 men – 7 women) MCC patients, aged 25-81 years old (56.8±19.4) that received cetuximab. We evaluated the improvement in the quality of life (SF-36) in the first 12 months of the therapy compared with the initial evaluation. The scale SF-36 is an evaluation method of the level of health with 36 questions that concern the Somatic and Mental health of the patients.
Methods: Patients were previously untreated and received docetaxel-based regimens (83% with cisplatin or carboplatin) based on known response and survival results (Fossella, JCO 2003). Patients assessed every 3 weeks.

Results: 300 patients are entered to date, 243 evaluated. Repeated QL/PRO measures available on 91% through 3 chemotherapy cycles. Demographics: 77% Stage IV; 72% men; 67% adenocarcinoma; median age 58; KPS 90-100=66%, 70-80=34%. A 37% MR rate was achieved. QL feasibility: high patient and staff acceptability (43 sites, 8 countries). For all patients (5% as minimally important difference), after 3 cycles all 9 LCSS parameters were stable with improvement in overall QL and cough (> 5%, 7%). PRO effects were found rapidly (within 6 weeks of treatment) by chemotherapy response. Patients with MR had better symptom control than patients with progression (p<0.05 in 4 of 6 major symptoms after cycle 3). Total LCSS-QL score was better for patients with MR (p=.007) or SD (p=.03) compared with progression.

Conclusions: 1) The 91% compliance rate with QL assessment supports feasibility when using the computer-assisted LCSS-QL; 2) with docetaxel-based chemotherapy, MR is associated with better symptom control and QL improvement than SD or progression; 3) even with a minority (37%) having major response, QL and PRO parameters are stable or better for all patients by key decision points of 2 and 3 chemotherapy cycles. This study demonstrates that QL and PRO evaluation should influence treatment decisions. Supported by sanofi-aventis

23-291
Lung Cancer Patients’ Quality Of Life During Chemotherapy: A Comparison Of Patients And Their Partners’ Perceptions.
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Objectives: Quality of life (QoL) is a significant prognostic factor in lung cancer patients. In Greece partners play a substantial role during illness trajectory. The purpose of this study is the comparison of Greek patients’ and partners’ perceptions about patient’s QoL.

Methods: The sample consisted of chemotherapy naïve patients newly diagnosed with primary lung cancer and their partners (n=40), who consented to participate in the study. Patients and partners completed in the same day, the same measurement instruments in separate rooms. The measurement instruments completed at three different points, before (T0), in the middle (T1) and after (T2), chemotherapy course were: Quality of Life Patient Version Scale of the City of Hope and Partner Relationship Inventory.

Results: The majority of patients were married (97.5%), male (95%) with a mean age 60.3 years, and advanced (62.5%) and metastatic (59%) disease. Partners mean age was similar to patients (55.1 years). High attrition rate reduced sample couple size to 25 at T1 and 10 at T2. Partners underestimated patients’ total QoL (pT0,T1=0.003) at T0 and T1, while partners and patients estimations were not different (pT2>0.050) at T2. Partners’ physical (pT0=0.015, pT1=0.031), psychological (pT0=0.025, pT1=0.019) and social (pT0=0.017, pT1=0.004) well being were underestimated at T0 and T1 measurements, while spiritual well-being was underestimated (pT1=0.036) only at T1 by their partners. Multiple regression analysis identified that patients’ poor emotional satisfaction from their relationship (pT0=0.022) accounted for 17.1% of the difference between patients’ and partners’ estimations of patients’ total QoL at T0. Moreover poor patients’ emotional satisfaction, existence of metastases, patients’ knowledge of diagnosis and partners’ knowledge of metastases (pT1<0.010) accounted for 93.4% of that difference at T1.

Conclusions: Despite study limitations, these results are instrumental in assisting nurses and patients’ partners to recognize lung cancer patients’ QoL alterations, in order to care for them more effectively.

23-292
Financial Implications For Patients And Their Families Having Treatment For Head And Neck Cancer : Another Aspect Of Quality Of Life
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Objectives: Our aim is to obtain an understanding of the financial implications on patients and their families following head and neck cancer (HNC) treatment. This study is the first to provide data on the financial effects of HNC treatment on patients and the quality of life implications from these effects.

Methods: The study sample was taken from the HNC clinic at Freeman Hospital, Newcastle throughout one month in 2009. Patients were eligible if aged 21 to 70
years old and completed treatment for HNC in the past 6 to 18 months. The data were collected based on the self-administered questionnaires consisting of 3 sections - University of Washington Quality of Life (UW-QoL) questionnaire, Hospital Anxiety and Depression Scale (HADS), and a patients finance tool. Demographic data and the financial status of patients were collected and analysed on the background of quality of life to establish links between them.

**Results:** A significant number of patients became less satisfied with their financial status after HNC treatment. However, the older patients were relatively less affected. Overall, HNC treatment had a moderate or significant effect on their future financial status. Patient worries increased if they perceived greater change in future financial status. If all financial income sources were reduced, those who had larger pool of financial reserve generally fared better in health-related QoL and illness psychology.

**Conclusions:** Financial status is important to patients while receiving HNC treatment and anxiety about future finances is a real patient concern. The causative role of finance stability on long term bio-psychosocial well-being needs further investigation. Patients with dependants are relatively more affected by potential change in financial status due to implications on their partner and children. Further studies on HNC patients’ financial status are warranted to provide deeper understanding in this field.

**23-293**
**Terminal Symptoms At The Last 72 Hours In Cancer Patients**
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**Objectives:** Identifying symptoms (sy) at the end of life in cancer patients (pt) is important to predict the timing of termination. We studied the sy during their last 72 hours of life and the dying process.

**Methods:** Sy of 33 pt with ECOG performance status 3 or 4 who were admitted to Hospice or Cancer Ward were recorded daily. A 15-sy list which was chosen from the literatures were used (including pain, nausea/vomiting, etc.). Additional sy list including not eating, hepatic failure, cyanosis, want to going home, want to take a bath, start to eat after not eating which were suggested by experienced nurses or volunteers were used, too. Physician and nurse checked sy until the pt died. The dying process of each pt was censored from physician, nurse, volunteer & family, i.e., good (usual or comfortable) or bad (unusual or uncomfortable).

**Results:** There were 17 male and 16 female with median age 65. Three pt & another 3 pt died within 48 hours & 24 hours after start of study respectively. At 72 hours before dying, fatigue (general weakness) (100%) & sleepness (88%) were most common. And dyspnea (85%), urinary dysfunction (81%), pain (67%), restlessness (67%), noisy respiration (59%), fever (41%), & confusion (33%) were noted. Among additional sy list, not eating (96%), hypoxia (37%) and cyanosis (37%) were important sy. Good and bad death was recorded in 80% & in 20% respectively. The main cause of bad death was uncontrolled dyspnea.

**Conclusions:** Fatigue, not eating, sleepness, dyspnea and urinary dysfunction were most frequent sy at the last 72 hours of life in cancer pt, but were not specific to predict the timing of death. Majority of death was recorded good.

**23-294**
**Evaluation Of Health-Related Quality Of Life In A Group Of Thai Oral Cancer Patients**
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**Objectives:** Oral cancer and its treatment have debilitating effect on oral and other related organs functioning. The aims of this study were to develop a health-related quality of life questionnaire for Thai oral cancer patients and assess oral and other related organs dysfunction.

**Methods:** A modified University of Washington Quality of Life Questionnaire that had been translated into Thai language and evaluated by a panel of oral cancer experts was used to question 51 oral cancer patients prospectively. The Questionnaire consists of 2 parts. The first part is for evaluating the impact of oral cancer and has 12 items such as pain, appearance, activity, recreation, swallowing, chewing, speech, shoulder, taste, saliva, mood and anxiety. The second part of the questionnaire consists of general questions dealing with global health-related quality of life measure. We compared change in health-related quality of life from baseline (pre-treatment) with post-operative follow up (25-49 days after surgery) and post-radiotherapy/ follow up (25-60 days after radiotherapy).

**Results:** Thirty seven patients were men and 14 were women. The age range was 22-80 with an average age of 55.78. The most frequent site was the tongue (49%). 94.1% of patients had squamous cell carcinoma. At post-operative follow-up, oral cancer patients presented
significantly poorer indications of swallowing, chewing, speech, shoulder and saliva domains, however the pain domain was significantly better. At post-radiotherapy follow-up, oral cancer patients presented significantly poorer indications of swallowing, chewing, shoulder, taste and saliva domains but the pain domain was significantly better. Patients with large tumors presented significantly poorer indications of pain, appearance, activity, swallowing, chewing and speech.

Conclusions: The data show a significant difference in health-related quality of life between before and after treatment, tumor size and staging. Information presented in this study is useful when counseling patients and their families regarding the likely outcomes of treatment.

23-295
Treatment With A Soluble Activin Receptor Type Iib Prevents Androgen-Deprivation-Induced Effects On Muscle, Bone And Fat
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Objectives: Androgen deprivation therapy (ADT), used in the management of prostate cancer, leads to bone and lean tissue loss and increased adiposity. These effects increase risk of health problems and can negatively impact quality of life of these patients. Mediators of muscle, bone and fat growth signal, at least in part, through the activin receptor type IIB (ActRIIB). Inhibition of ActRIIB signaling results in increased lean and bone mass and decreased fat mass. To determine whether ActRIIB inhibition can offset ADT-induced changes in muscle, bone and fat, we tested the efficacy of RAP-031, a fusion protein comprised of a form of the ActRIIB extracellular domain fused to a murine Fc, in a mouse model of androgen deficiency.

Methods: Sham-operated (SHAM) and orchiectomized (ORX) mice were treated twice/week for 8 weeks with either vehicle (VEH) or 10mg/kg RAP-031 (RAP). NMR and microCT scans were used for body composition and bone microarchitecture determination.

Results: In SHAM mice, RAP-031 significantly increased lean tissue and bone mass while decreasing adipose mass compared to VEH. Relative to VEH-SHAM, VEH-ORX mice had 18.0% less lean tissue and 41.6% more fat at study completion. In contrast, RAP-ORX mice had comparable lean tissue and fat mass to the VEH-SHAM group and increased lean tissue mass and decreased fat mass compared to VEH-ORX groups (Lean: VEH-ORX: 15.59±0.26g, RAP-ORX: 19.78±0.26g, p<0.05; Fat: VEH-ORX: 7.12±0.53g, RAP-ORX: 4.57±0.26g, p<0.05). Proximal tibia microCT scans showed reduced trabecular bone volume fraction (BVF; -65.3%, p<0.001) and increased trabecular spacing (+104%, p<0.001) in the VEH-ORX group compared to VEH-SHAM controls. In contrast, RAP-ORX trabecular BVF was increased (+300%, p<0.001) and trabecular spacing decreased (-60%, p<0.001) relative to VEH-ORX mice.

Conclusions: These data support the hypothesis that ActRIIB inhibition can offset negative effects of ADT and have significant therapeutic benefits for ADT patients. This work was supported by Acceleron Pharma.

23-296
Communication Status, Quality Of Life And Their Relationships In Head And Neck Cancer Patients With Surgery In Taiwan
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Objectives: The purpose of this study was to examine communication status, quality of life and their relationship in Taiwanese head and neck cancer patients with surgery.

Methods: A cross-sectional survey was conducted to recruit oral cavity cancer patients and laryngeal cancer patients with surgery. Patients were assessed of their communication status and levels of quality of life. Background information was also assessed for further analysis. Patients were recruited from a head and neck outpatient clinic and an inpatient ward in a medical center in Northern Taiwan.

Results: A total of 102 eligible subjects were recruited. The results showed: (1) Majority of head and neck cancer patients had various levels of communication problems; (2) Patients with better communication ability had significantly better quality of life; (3) Selected physical symptoms, such as chewing disturbance, speech disturbance, and swallowing disturbance, were negatively correlated to patients’ quality of life and communication.

Conclusions: The results supported our research assumption that communication is one of the major problems related to head and neck cancer patients’ quality of life. Careful assess these patients’ level of communication abilities would be an important clinical task to help patients to have a better quality of life. Symptom related to communication should also be assessed. Supportive intervention should be further developed and tested to enhance these patients’ communication and quality of life.
**23-297**

**Chinese Translation And Clinical Correlates Of Reconstruction Module Post Operative Breast-Q**

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**Objectives:** The purposes of this study are 1). to validate the validity and reliability of the Chinese version and 2). to identify the impact of different types of reconstruction on the quality of life of the breast-reconstructed subjects.

**Methods:** Following the standardized translation - back translation procedure, a Chinese version of Breast-Q was established. Also, data collected from the 69 subjects were analyzed for the validity and reliability of Breast-Q and for the comparison between types of reconstruction.

**Results:** 1. The Chinese version of Breast-Q is valid and reliable. 2. Subjects under delayed reconstruction reported higher overall quality of life and the subscales as: trunk and abdominal symptoms, satisfaction of nipple appearance, and surgeons than those who received immediate reconstruction. 3. Quality of life for those who received autologous tissue reconstruction is superior to those who received implant reconstruction.

**Conclusions:** Translation and back-translation procedure is appropriate for transcultural assessment that makes international comparison possible. Also, type of reconstruction does affect the reported quality of life of breast cancer women. Providing certain information when patients are first diagnosed as breast cancer is necessary in clinics. Thus, the health personnel can help patients make an appropriate decision in regard to their life.

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**23-298**

**Health-Related Quality Of Life As An Outcome Predictor For Patients With Localized Head And Neck Carcinoma Treated With Radiation Therapy**

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**Objectives:** Several studies have shown that Health-related Quality of Life (HRQOL) parameters can be independent prognostic factors for cancer outcomes in patients with advanced or recurrent disease. The prognostic significance of HRQOL variables in localized cancer has not been established. The objective of the study was to assess whether HRQOL data collected prospectively for three years in patients with localized head and neck cancer (HNC) improves cancer outcome prediction beyond what is achieved by recognized prognostic factors.

**Methods:** All 540 patients with localized HNC, who participated in a randomized controlled trial, were requested to complete the EORTC QLQ-C30 at baseline, at the end of radiation therapy, and at 1, 6, 12, 24, and 36 months after the end of radiation therapy. Three outcomes were considered: 1) cancer recurrence, 2) incidence of a second primary cancer (SPC), 3) death. Follow-up time was counted from entry into the trial until the outcome of interest, death, loss to follow-up or administrative censoring at four years. Cox models were used to estimate the hazard ratios (HR) with their 95% confidence intervals (CI) for each of the three outcomes associated with a 10 point increment in each QLQ-C30 variable. All HRQOL variables were treated as time dependent variables. Stepwise multivariate Cox models were used to test whether HRQOL variables provided additional prognostic value over recognized predictors.

**Results:** After a median follow-up of 4.0 years, 109 recurrences, 77 SPC and 108 deaths were observed. No HRQOL variable was associated with cancer recurrence. Physical functioning was the only HRQOL variable associated with SPC: HR=0.84, CI: 0.76-0.93. Three HRQOL variables were associated with death: physical functioning (HR=0.71, CI: 0.64-0.78), cognitive functioning (HR=1.12, CI: 1.01-1.24), and pain (HR=1.11, CI: 1.03-1.19).

**Conclusions:** Our study indicates that prospective assessment of HRQOL, especially physical functioning, could improve outcome prediction for patients with localized HNC.

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**23-299**

**Evidence Of Genetic Association Between A Polymorphism In The Il6 Gene And Sleep Disturbance In Oncology Patients And Their Family Caregivers (Fcs)**

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**Objectives:** Recent evidence suggests that a significant proportion of both oncology patients and their FCS experience moderate to severe levels of sleep disturbance. However, little is known about the biological mechanisms that underlie the development of sleep disturbance. Purpose of this study was to identify whether genetic variations in IL-6 could impact levels of sleep disturbance in oncology patients and their FCS.

**Methods:** DNA was recovered from plasma archived from 253 patients and FCSs who participated in a descriptive longitudinal study of symptoms. The IL-6
(rs4719714) genotypes were collected by TaqMan Allelic Discrimination and the distribution of the polymorphism met Hardy-Weinberg expectations. Sleep disturbance was measured using the General Sleep Disturbance Scale. Differnces in severity of symptoms between the two genotype groups were evaluated using Independent Student’s t-tests.

Results: Mean age of the sample was 61.4 years; 46% were male, and 75% were Caucasian. IL-6 genotype frequencies were 63.9% common allele homozygotes (TT), 4.1% rare allele homozygotes (AA), and 32.0% heterozygotes (AT). No sex differences were found in genotype distribution. Common allele homozygotes for IL-6 reported significantly higher total sleep disturbance scores (p=.003), poorer sleep quality (.007), a higher number of mid-sleep awaking (p=.008), and higher levels of excessive daytime sleepiness (.02) at the initiation of radiation therapy than carriers of the rare allele (i.e., AT+AA). When differences in mean scores for these four sleep parameters were evaluated, the same differences were found between the two allele groups (all p <.03).

Conclusions: Results provide preliminary evidence of a genetic association between a prominent cytokine and levels of sleep disturbance in a sample of oncology patients and their FCs. Carriers of the IL-6 minor allele appear to have less sleep disturbance. Genotyping may identify high risk groups who warrant more targeted symptom management interventions.

23-300 Quality Of Life Data As Prognostic Factor Of The Survival In Cancer Patients: A Rapid And Systematic Review Of The Literature
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Objectives: To review literature on relationship between quality of life data and the length of survival in cancer patients.

Methods: A literature search was carried out using MEDLINE to assess existing knowledge on relationship between quality of life data as a prognostic factor and survival in cancer patients. The intention was to review all full publications in English language biomedical journals. The search strategy included the combination of keywords ‘cancer’, ‘prognostic’, ‘predictor’, ‘quality of life’, ‘patient reported-outcomes’ and ‘survival’ in titles of publications. The literature was also examined to ensure that the study used multivariate analyses. Pure psychological studies were excluded. The initial search was carried out twice in December 2008 and twice for a final check in early and late January 2009. A manual search also was performed for including possible additional papers.

Results: The findings are summarized under different headings including studies on heterogeneous sample of cancer patients, lung cancer, breast cancer, gastrointestinal cancers, colorectal cancer and other cancers. Except a few exceptions most studies found that quality of life data or some aspects of quality of life measures were significant independent predictors of survival duration. Global quality of life, functioning domains and symptom scores such as appetite loss, fatigue and pain individually or in combined were the most important factors that predicted the length of survival in cancer patients after adjusting for one or more demographic and known clinical prognostic factors.

Conclusions: Pretreatment quality of life data are appeared to be most reliable information that could help clinicians to establish prognostic criteria for treatment of their cancer patients. Indeed, conducting studies using valid instruments, applying sound methodology and adequate but not sophisticated multivariate statistical analyses adjusted for demographic characteristics and known clinical prognostic factors are recommended in order to yield more specific quality of life related prognostic variables for specific cancers.

23-301 Symptom Predictors Of Work Disruption In People Receiving Chemotherapy For Cancer
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Objectives: Cancer and its treatment can be disruptive to daily life including the ability to continue work. Maintaining work is critical to financial security, health insurance and personal identity as well as workforce productivity. The purpose of this study was to monitor the presence and severity of 10 common symptoms (pain, fatigue, nausea/vomiting, sore mouth, fever, diarrhea, constipation, depressed mood and anxiety) and to identify symptom predictors of work disruption.

Methods: Fifty-five participants responded during chemotherapy cycles 2 and 3 with daily symptom reports rating the presence and the severity (1-10 scale) of each symptom, whether it was a work day and if they worked.

Results: A variety of cancer diagnoses, treatment protocols, ages, incomes and educational levels were represented. Eight-five percent worked full-time, 15% part-time. The average participant was a 50 year old woman with breast cancer, working full-time with an income of $50,000. The most commonly reported symptoms were fatigue, pain and insomnia yet all 10
symptoms were represented. The mean severity ranged from 2.8 to 4.2; 4.2 was also the mode. There were 1358 possible work days reported by participants with participants unable to work 32% of those days. Generalized estimated equations were used with a 15 variable model (demographics and symptoms) to determine predictors of work disruption. The model yielded a two variable solution which included nausea/vomiting (OR=1.16, p=.004) and fatigue (OR=1.14, p=.016).

**Conclusions:** Findings indicate that people being treated with chemotherapy continue to work in the presence of unrelieved symptoms. In spite of this, they miss work nearly one-third of the time. Nausea/vomiting and fatigue are the symptoms most likely present when work is missed. Unrelieved symptoms significantly impact the work life of cancer patients. Further study is needed to investigate the relationship of symptom patterns and symptom clusters to work disruption and productivity while at work.

**23-302**

**Usefulness Of The Eastern Cooperative Oncology Group (ECOG) Score In Patients Receiving Day Chemotherapy In A Resource Strained Setting.**

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**Objectives:** The Eastern Cooperative Oncology Group (ECOG) score is widely used to determine eligibility for clinical trials and to monitor disease progress. The authors used this tool to determine the usefulness of ECOG performance scores in outpatient chemotherapy setting. There is very little data on the use of ECOG in resource poor countries Objective: To determine the usefulness and the factors influencing ECOG performance status tool in patients receiving day chemotherapy

**Methods:** All patients receiving day chemotherapy have their performance status assessed on every visit using the Eastern Cooperative Oncology Group (ECOG) score scale. Data was collected retrospectively from patients records for 30 randomly selected patients on different treatment protocols for various malignancies. All patients were surveyed in their third cycle of treatment. Data was coded and analyzed using SPSS for Windows.

**Results:** Poor ECOG scores were noted in older patients. The treatment protocol did not seem to have any influence on the ECOG performance status though presence of co-morbidities had a negative effect on the ECOG scores.

**Conclusions:** The Eastern Cooperative Oncology Group (ECOG) score is a useful, simple, cost effective tool to monitor how patients performance and quality is affected by chemotherapy. It can be incorporated into existing patients assessment forms.

**23-303**

**Contribution Of QoL Questionnaires For Doctor-Patient Interaction. Daily Clinical Practice: The Doctors’ Perspective**

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**Objectives:** We developed and validate an automated method for measuring QoL, using the QLQ-C30 and its modules. QoL data was processed by the Rasch model in order to elaborate a report for the doctor before the appointment. This way, the doctor has access to a QoL report, which includes besides patients’ QoL, their evolution, allowing the doctor to use this information for clinical decisions. The aim of this research is to study this tool’s utility in oncological clinical practice.

**Methods:** Initially the study will include 4 oncologists and 30 patients per oncologist, in a total of 120 patients. They will answer the QoL questionnaire minutes before seeing the doctor and those results will be immediately sent to the doctor in a form of a graphic report. At every 15 patients we will ask the doctor to answer a questionnaire assessing the utility of this information in the medical appointment.

**Results:** All the doctors found the QoL report very useful and used it in the medical appointment. The main advantages included: pointing out problems that were never brought up by the patient, but when asked by the doctor the problem related by the QoL questionnaire was confirmed; some symptoms that were difficult to explain by the patient were also confirmed; symptoms and functioning presented in a chart helped doctors to detect changes across time.

**Conclusions:** The QoL information given to the clinician before the medical appointment seems to be an excellent aid to decision making and allows to bring about the problem-issues, making the questionnaire a useful tool. This method has proven to be valid in oncology setting and useful for monitoring the patients’ Quality of Life in daily practice, in real time, helping the doctor on decision making.
23-304
Qol Information System Of The Oncological Patient:
Comparison Of The Traditional Paper Data
Collection Versus Electronic Version: Using A Report
To The Doctor
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Ferreira4,5, Francisco Pimentel2,3,4
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Feira, Portugal, 2 University of Aveiro, Health Sciences,
Aveiro, Portugal, 3 Aveiro Hospital, Aveiro, Portugal,
4 Center of Health Studies & Research, Coimbra,
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Coimbra, Portugal

Objectives: Computerized technologies offer the
possibility of collecting QoL data in a matter of minutes.
We aim to validate the electronic collection of QoL data
in the clinical daily practice, using the EORTC QLQ-
C30 in real time, and to compare the traditional paper
method and the electronic touchscreen version. We also
aim to achieve patients’ preference and acceptance about
these two ways of administration.

Methods: 200 cancer patients filled the paper and
computer version of the EORTC QLQ-C30 with 1 hour
interval. The first 100 patients did paper than computer,
the other 100 did the opposite. Electronic collection used
a computer with touch-screen technology which allowed
patients to answer alone, just like they did on paper.

Results: There were no statistical significant differences
found between paper and computer questionnaires. There
was a high correlation between answers given in both
methods. The highest was for the subscale diarrhea
(r=0.92) and physical functioning (r=0.90). 58% of the
patients preferred the electronic version and 5.5% had no
preference.

Conclusions: The electronic version of the QoL
questionnaire has similar results to the paper version and
it is well accepted and tolerated by all patients included
in the study, even people with no experience with
computers and older patients.

23-305
Development Of Software For Qol Data Collection:
Onqol
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Aveiro, Portugal, 3 Aveiro Hospital, Aveiro, Portugal,
4 Center of Health Studies & Research, Coimbra,
Portugal, 5 Faculty of Economics, University of Coimbra,
Coimbra, Portugal, 6 iUZ Technologies, Aveiro, Portugal

Objectives: To develop a tool that allows collection of
QoL data and printing the results of cancer patients in
clinical practice.

Methods: OnQoL road map was organized in 4 (four)
integrated steps: a) Data acquisition; b) Results’
validation; c) Information processing and Reporting.
Each took from 4 to 6 weeks and had a special set of
tasks in order to fulfill the goal intended: 1- Requirements
Analysis (RA); 2- Requirements Specification (RS); 3-
Architecture Design (AD); 4- Development and Testing
(DT1); 5- Deployment and Training (DT2). They were
repeated in each iteration. The purpose of 1(RA) was to
identify and extract features for OnQoL information
system; 2(RS) was to specify how the intended features
should be implemented and how the end users could use
them in their daily professional activities; 3(AD) was
technically design how the information system should be
developed for correct requirements affordance; in 4(DT1)
programmers, database architects and human computer
interaction designers brought their skills in order to
develop and test the information system; in 5(DT2)
OnQoL was released for the end users.

Results: At the end of the 4 iterations there was a mature
version 1.0 of an information system that respects
requirements and constraints identified, with large
impact in oncology patients and health care
professionals’ day to day routines. An electronic version
of the EORTC QLQ-C30 was developed. The original
paper format was maintained: same instructions, same
possibilities of response, possibility of changing an
answer at any time and go back to check one or more
answers given. All this is done with touch-screen
technology (pen-touch).

Conclusions: OnQoL allows QoL data collection
through laptop computers with touch-screen technology.
Answers are automatically stored in a database base and
can be analysed using pre-determined statistical models,
creating automatically, the QoL results’ reports.

23-306
The Association Between Age And Gender With
Health Related Quality Of Life For Cancer Patients
Stratified By Disease Severity: A Meta-Analysis Of
Randomized Controlled Trials.
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Reeve4, Madeleine King5, Andrew Bottomley1
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Toronto, Canada, 4 National Cancer Institute, NIH,
Bethesda, USA, 5 University of Sydney, Psycho-oncology
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Objectives: The objective of this analysis was to
investigate the influence of age and gender on Health
Related Quality of Life (HRQOL) scores, as evaluated by the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30, in a subset of metastatic and non-metastatic cancer patients.

**Methods:** Pre-treatment HRQOL was measured in closed EORTC Randomized Controlled Trials on a set of 15 EORTC QLQ-C30 scales; Global health status (QL), Physical functioning (PF), Role functioning (RF), Emotional functioning (EF), Cognitive functioning (CF), Social functioning (SF), Fatigue (FA), Nausea and Vomiting (NV), Pain (PA), Dyspnea (DY), Insomnia (SL), Appetite loss (AP), Constipation (CO), Diarrhea (DI) and Financial Difficulties (FI). For each scale, a linear mixed model was fitted for metastatic and non-metastatic cancer patients to investigate the significance (p<.05) of age (<40, 40-49, 50-59, 60-69, 70-79, =>80) and gender (men vs women) after correction for country and cancer site.

**Results:** The sample included 6,862 patients from 15 countries over 11 cancer sites. Age was significant in non metastatic patients for PF, RF, CO, FI (all p’s < .02) and in metastatic patients for SF, PA, SL and FI (all p’s < .001). Older people reported, except for NV, higher level of symptoms. For the functional scales a constant pattern was found across age categories. Gender was significant in non metastatic patients for QL, SF, PF, RF, CF, FA, NV, PA, SL, AP, CO (all p’s ≤ 0.001) and in metastatic patients for PF, CF, FA, NV, AP, DI and FI (all p’s < .04). Except for DY, women reported higher level of symptoms and a lower functioning and global health status compared to men.

**Conclusions:** Age and gender are strongly linked with HRQOL status of cancer patients, but the relationship depends on the disease stage. Our large sample supports HRQOL status of cancer patients, but the relationship depends on the disease stage. Quality of life (QoL) is considered an important treatment outcome when the treatment intent is not curative but palliative. Exercise has been shown to improve physical performance and QOL in cancer patients undergoing chemotherapy. However, only a few studies have included lung cancer patients NSCLC (III-IV) and SCLC (ED). The aim of this study is to examine the effect of a six-week (minimum) combined supervised and home-based exercise intervention for lung cancer patients (NSCLC (III-IV) and SCLC (ED)) undergoing chemotherapy.

**Methods:** The study design as a prospective, explorative and descriptive interventions study which includes men and women diagnosed with NSCLC (III-IV) and SCLC (ED). (n=25) The supervised intervention comprised of cardiovascular and heavy resistance training and relaxation training. The home-based training consisted of gait training, respiration and relaxation training. Repeated assessments were conducted at baseline and after 6 weeks and included physiological tests (IRM, VO2Max, FEV1), questionnaires FACT-L, EORTC LC and HAD.

**Results:** The preliminary data from this study will be presented (QOL and VO2max).

**Conclusions:** The results of this study will whether the effects (QOL and VO2max) are positive or negative provide new knowledge about how lung cancer patients (NSCLC (III-IV) and SCLC (ED)) adapt a combined supervised and home-based exercise intervention.

23-308
**Results Of A Web-Based Study In 1072 Patients With Breast Cancer To Identify Issues Of Importance In Health-Related Quality Of Life.**

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**Objectives:** Patient involvement in establishing content validity is critical for quality of life instrument development. Validated quality of life instruments aid in evaluating the effectiveness of interventions and in assuring that appropriate goals are met. The conceptual model for the new health-related quality of life instrument, the Breast Cancer Symptom Scale (BCSS) focuses on areas of importance for patients (Hollen, Supp Care Ca 1994).

**Methods:** The established patient base of the web-based NexCura information resource was used to survey registered patients with breast cancer. Patients ranked 21 issues, including general, physical, functional, psychosocial and summative items, on a 5-point scale of importance. 1072 patients (median age 53, 63% stage I, 43% > 2 years since diagnosis) completed the anonymous web-conducted survey. Demographic factors...
used in stratification included disease stage, age, menopausal status, time since diagnosis, prior/current treatment with surgery, radiation therapy, chemotherapy, hormonal, targeted, and complementary alternative medicine approaches.

Results: Results shown indicate the percent of patients choosing the top category (very important) and the top 2 importance categories. The nine highest ranked items are listed below. The five lowest ranked items dealt with appetite, breast-specific issues, hot flashes and sexuality. There were some differences noted by breast cancer subsets (newly diagnosed, on treatment, NED, hormonal or non-hormonal treatment, metastatic disease, survivors) when compared with the whole group.

<table>
<thead>
<tr>
<th>Item</th>
<th>Very Important</th>
<th>Very Important + Important</th>
</tr>
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<tbody>
<tr>
<td>Good QL</td>
<td>82%</td>
<td>99%</td>
</tr>
<tr>
<td>Maintaining independence</td>
<td>75%</td>
<td>97%</td>
</tr>
<tr>
<td>Able to sleep</td>
<td>69%</td>
<td>97%</td>
</tr>
<tr>
<td>Able to concentrate</td>
<td>65%</td>
<td>97%</td>
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<tr>
<td>Perform normal activities</td>
<td>62%</td>
<td>97%</td>
</tr>
<tr>
<td>Being fatigued</td>
<td>61%</td>
<td>95%</td>
</tr>
<tr>
<td>Having depression</td>
<td>51%</td>
<td>85%</td>
</tr>
<tr>
<td>Being anxious</td>
<td>47%</td>
<td>85%</td>
</tr>
<tr>
<td>Having pain</td>
<td>46%</td>
<td>80%</td>
</tr>
</tbody>
</table>

Conclusions: This study, representing one of the largest surveys of concerns expressed by patients with breast cancer, gives strong support for content validity for the BCSS. Additionally it provides data on which to base separate QL instruments for specific breast cancer settings.

23-309
Sleep Disorders In Patients With Cancer
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Objectives: Sleep disorders occur in about 12% to 25% of the general population and are even more frequent in cancer patients. This problem has many potential consequences on physical and emotional status. In this study we investigate the prevalence of sleep disturbances in cancer patients and their behaviour regarding the referral of this symptom.

Methods: Consecutive patients from the Day Hospital Unit in 3 months time are interviewed, if fulfilling the inclusion criteria (Age: 18-80 years old; Performance Status: ECOG 0-2; No psychiatric disorder; Informed consent). Questionnaires used are: the Pittsburgh Sleep Quality Index (PSQI); and the EORTC QLQ-C30 for Quality of Life. A semistructured clinical interview focuses on patients' behaviors in referral and treating this symptom.

Results: Preliminary descriptive data reveal 46 patients, 68% women, aged 25 to 80 years and all undergoing a chemotherapy treatment. Answers to the sleep item of the EORTC (Have you had trouble sleeping?) were: no (47%), a bit (22%), a lot (20%), very much (11%). Subjective sleep quality, a PSQI subscale, was considered: very good (13%), quite good (56%), quite bad (24%), very bad (7%). 40% of poor sleepers did not ask to any doctor to solve their problem, because: they don’t want to assume medications; don’t consider sleep as a priority; don’t feel sleepy during the day; believe that the problem could stop by itself. 33% of patients who were prescribed a medication, did not assume it.

Conclusions: The study is ongoing, more in depth statistical analyses will be carried out. Preliminary data reveal that 31% of patients interviewed have some trouble sleeping. Despite the presence of this symptom, less than half of the patients refer the problem during medical visits. Moreover, when a medication is prescribed, a third of patients don’t assume it. Thus, insomnia is an under-referred and undertreated symptom in cancer patients.

23-310
A Survey To Identify Unwanted Side-Effects In Patients Receiving Radiotherapy And Concomitant Weekly Cisplatin. A Multinational Collaborative Study
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Objectives: The purpose of the study is to prospectively assess unwanted side-effects induced by radiotherapy and concomitant weekly cisplatin. Radiotherapy and concomitant chemotherapy has increased the therapeutic effect in some cancers, but only sparse attention has been paid to the increase or change in side-effects induced by combination therapies. Advances in radiotherapy techniques have optimized tumour control while
minimizing dose delivery to normal tissue, thereby potentially decreasing unwanted side-effects. However, a large proportion of patients still suffer from various side-effects, such as nausea, vomiting and mucositis, which are aggravated by the addition of concomitant chemotherapy.

Methods: A multinational survey with five active study sites. The study population consists of patients with a diagnosis of cervical cancer, vulval cancer or head and neck cancer. Eligible are adult patients, scheduled to receive at least 15 fractions of radiotherapy and 3 doses of weekly cisplatin, who are radiotherapy and chemotherapy naïve. Patients complete a questionnaire prior to anti-cancer treatment and again after the third dose of cisplatin. The questionnaire consists of 57 items, focussing on physical and non-physical items. Patients are asked to rank the five most severe symptoms according to severity. Symptom ranking will be used to assign each symptom an overall score. Symptom scores will be ranked and the top ten symptoms regarded by patients as most severe will be listed. A total of 200 patients will be enrolled.

Results: Currently ten patients are enrolled. Based on the estimated accrual rate, results from approximately 100 patients will be presented at the meeting.

Conclusions: There is a need for more insight into the side-effects induced by radiotherapy and concomitant cisplatin-based chemotherapy in order to provide optimal supportive care for these patients.

23-311
Improvement Of Pain Control And Quality Of Life With Erlotinib Based Chemotherapy In Patients With Metastatic Pancreatic Cancer
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Objectives: Pancreatic cancer represents 2% of all cancers in the 4th leading cause of cancer-related deaths worldwide. Patients with unresectable and metastatic pancreatic adenocarcinoma had a median survival no longer than 2 months. This is a treatment challenge due to poor outcomes with current treatment modalities.

Methods: Chemotherapy naïve patients with histologically confirmed unresectable pancreatic cancer and documented extrapancreatic metastases, received docetaxel 75mg/m² on day 1, gemcitabine 1250mg/m² on day 1 and daily erlotinib 100mg p.os. continuously, in a biweekly schedule cycle. Patients were monitored every 4 cycles with CT scans and monthly serum CA19-9 measurements.

Results: 25 patients (14 males, 11 females, median age 71 years, range 41-80, ECOG PS: 0-2) were enrolled; 23 were eligible for the study. 10 patients remain alive and undergoing the study treatment. Patients received a total of 146 cycles with a median of 8.33 cycles (2-22). 13 patients died due to disease progression. Fatigue had 9/23 patients (36%), cumulative fluid retention edema had 11/203 patients (44%) (docetaxel-related that resolved with diuretics and corticosteroids). Onycholyshis 10/23 (40%). Skin toxicity (rash) 15/23 patients (60%). Nausea and vomiting 4/23 (16%). 10/23 patients (42%) had improvement in their pain control and stop to take analgesics after a mean of 6 cycles of chemotherapy. 9/23 patients (39.1%) had amelioration of their performance status. 1 patient (4.3%) achieved CR, 3 (13%) PR and 4 (17.3%) showed stabilization in measurement disease. The median survival in all patients and those still alive is 5.5 and 12.5 months respectively.

Conclusions: Biweekly chemotherapy with docetaxel, gemcitabine and daily erlotinib is effective for pain control and amelioration of the quality of life in patients with metastatic pancreatic cancer and offered a median survival of 5.3 and 12.5 months (in the survivors) and a reduction >50% in the CA19-9 in 50% of the patients.

23-312
Economics/Quality Of Life In Gastrointestinal-Cancer Patients In Resource-Poor-Settings-Initiatives By Community-Cancer-Ngo In India.
Pramod Sankpal, Vaishali Sankpal, Rawandale Nirmal
Health Alert Organization of India, [NGO], Community medicine, Dhule, India

Objectives: Highly consumed-Crude [filter-less] tobacco alongwith spicy-food increase incidence of Gastrointestinal-cancer in rural/tribal India. Access-to-drugs, Economic-constraint, Quality of life (QoL) in Gastrointestinal-cancer poorly studied in developing nations.

Two Tier-project in 12 villages of rural/tribal India. To Evaluate QOL/survival in patients after treatment in city-hospitals. NGO-volunteers assessed questionnaire replies from patients about food/dietary habits, funds available for chemotherapy, social/family support, mental-condition, functional-abilities. Our Cancer-NGO took initiatives in rural/tribal-India to help treatment-support-services on Gastrointestinal-cancer in since-2004.
**Methods:** Supportive care programs are virtually nonexistent in India, our N.G.O. took this initiative. We motivated 82 patients, M-50 F-32. 42% low on QoL, 15% depression, 43% rehabilitation, 21 turned to quacks/faith-healers for solace. Preliminary analysis suggests correlation between follow-up facilities, counseling/community support with baseline QOL by Kaplan Myer-survival-curve.

**Results:** Tobacco+spicy-food+alcohol correlate with Ca incidence. 75% had Upper GI-cancer, 24% colonic-cancer, 18% hepatic cancer. Depression had negative impact on QOL. Patients communities need facilities for psychological/rehabilitation. 3 Community out-reach programs initiated for affordable-nursing-care at home. Poor access to therapy worsened QOL in 80%. We advocate state-level planning on this issue. 70% had colostomy. Our NGO-Cancer-care-module in various stages of functioning shown graphically at MASCC 2009 Rome Symposium.

**Conclusions:** Colostomy badly affects social-life & work-output. Further initiatives needed for establishing follow-up-centers & identify specific needs of rural/tribal population. Lack of rehabilitation support causes poor Rx-outcome. Community NGO's pivotal role for quality treatment with Psychosocial/counseling. MASCC like organizations must propagate oncology-CME's in developing nations to overcome these barriers. Economics of Cancer-therapeutics must be high on agenda of such specialized supportive-care cancer-conferences.

Our-NGO Recommendation: We N.G.O. participants at MASCC 2009 Rome Symposium must work with senior-researchers from USA-Europe towards goal of “Access to expertise in supportive-care for Developing nations”. WHO/MASCC need to formulate policy on this burning-issue at Satellite sessions at Rome symposium.

**23-314**

**Fermented Mistletoe (Viscum Album L.) Extract From Oak Tree As Supportive Treatment Improves Quality Of Life In Patients With Pancreatic Cancer Of Any Stage**

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**Objectives:** To evaluate safety and efficacy of supportive treatment with fermented mistletoe extract from oak tree, Iscador-Qu (ISC-Qu) on quality of life and survival.

**Methods:** A cohort of patients received ISC-Qu additionally to conventional adjuvant chemo- and/or radiotherapy (conv-th) - ISC-Qu group - or conv-th alone - control group - in a multicenter, comparative, non-interventional cohort study with parallel groups. Unselected, standardized, anonymized data from medical records meeting the eligibility criteria were followed until last visit or death. As endpoints for QoL, conv-th induced ADR, symptom persistence, Karnofsky index (KPS), and duration of hospitalizations were evaluated. Additionally, overall survival was computed. All endpoints were adjusted to confounders.
Results: 270 patients (75 ISC-Qu/195 control) from 17 oncological centers were evaluated. The treatment with ISC-Qu started mostly (75%) during the conv-th (mainly with gemcitabine) and usually lasted until last visit or death. The period of aftercare was median 20.3 (test group) and 10.1 months (control). ISC-Qu was applied by sequential dose escalation from 0.01 mg up to 20 mg, 2-3 injections per week (s.c.). Efficacy: The number of ADR to conv-th (odds ratio, OR = 0.20, p = 0.006, risk reduction 80%) and the estimated risk for disease or therapy related symptom persistence were significantly reduced in the test group with ISC-Qu. There was also a significant and relevant prolongation of overall survival: hazard ratio, HR (95% CI) = 0.35 (0.21-0.58), p <0.001; estimated relative risk reduction = 65%. Safety: Only 14.7% of the patients developed local ADR to ISC-Qu, there was no life-threatening ADR.

Conclusions: The results show reliable safety and an important effect of supportive ISC-Qu treatment on QoL and overall survival in patients with pancreatic cancer of any stage. The present study was supported by an educational grant from the Society of Cancer Research Arlesheim, Switzerland.

23-315
Correct, A Web-Based, Observational Study, Shows That Darbepoetin Alfa Is Effective In Treating Chemotherapy-Induced Anaemia and Improves QoL in Patients With Non-Myeloid Malignancies
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Objectives: Clinical studies have shown that darbepoetin alfa (DA) therapy is effective in treating chemotherapy-induced anaemia in patients with non-myeloid cancer, resulting in improved haemoglobin (Hb) levels, reduced transfusion requirements and better quality of life (QoL). However, data regarding these parameters in daily clinical practice are lacking.

Methods: This prospective, multicenter observational study evaluated the efficacy and safety of DA in treating anaemia in chemotherapy-receiving patients with non-myeloid malignancies. A web-based registry was used to collect data on tumour type and stage, previous and current therapies, Hb and iron levels, transfusions, adverse drug events, and QoL.

Results: Of the 2043 patients that received DA, 28% had breast, 11% colorectal, 11% lung and 7% ovarian cancer. Treatment objectives for DA included prevention of blood transfusions (82%), fatigue (65%) and prevention of an Hb decrease (63%). Mean (SD) Hb levels increased from 9.7±0.9 g/dL at baseline to 11.1±1.5 g/dL at the end of the correction phase (p<0.0001). 54% of patients reached Hb>11 g/dL by end of the observation time. 30% of patients received blood transfusions, and 25% received oral and/or intravenous iron supplementation. QoL improved for 46% of patients, was unchanged for 37% of patients, and worsened for 11% of patients, as per physicians’ assessments in an ordinal scale. From baseline to end of the correction phase, median FACIT-F scores improved from 95.3 (range 17.5-158) to 104.5 (range 22-158) (p<0.0001), and median LASA scores from 48 (range 0-100) to 38 (range 0-100) (p=0.0001). Darbepoetin alfa treatment was generally well tolerated. The incidence of adverse drug events was <1% in most categories. Severe thromboembolic events were reported for 0.49% of the patients.

Conclusions: Darbepoetin alfa treatment was well tolerated, efficacious for treating CIA and improved patient subjective QoL in daily clinical practice. This observational study was conducted by Amgen GmbH.

23-316
Life Satisfaction in Young Adults Ten Years After Hematopoietic Cell Transplantation Performed For Childhood Hemato-Oncological Diseases: A Case-Matched Control Study
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Objectives: Patients undergoing hematopoietic cell transplantation (HCT) should be investigated for late physical deterioration and psychological stress which could impair quality of life (QOL). The current pilot study assessed a set of QoL items which could elucidate the concept of life satisfaction (LS) years after HCT.

Methods: From March to December 2005 a subset of 36 patients (29 males), who underwent HCT (32 allogeneic, 4 autologous) for childhood hemato-oncological diseases at least ten years ago, was included in the study. A questionnaire including a modified Satisfaction with Life Scale for Bone Marrow Transplantation was administered both to the patients and to the controls (60 subjects) after obtaining an informed consent. Five domains, each containing two to 10 items for a total of 30 questions, were assessed. The domains were as follows: education, employment, leisure time, social
relationship and perception of physical status. Domains ratings, when applicable, were made on the basis of four-point scale. We assumed that higher scores (4 and 3) indicated the greatest LS. To investigate the association between some domains and the probability of LS, we performed the logistic procedure by the method of maximum likelihood. Predictive factors of LS adjusted for age (as continuous variable) were evaluated.

**Results:** Final analysis showed a statistical significative advantage for the attainment of higher LS in young adults who experienced a previous HCT (p=0.03 at multivariate analysis) with odds to be satisfied 7.127 times more than controls.

**Conclusions:** The use of well-validated questionnaire on LS and the comparison with age and gender-standardized reference data enabled us to find out a relatively optimistic information about a perspective of LS in adolescents survivors years after HCT.

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**23-317**
**Working Against The Odds: Challenges Facing The Health Care Providers In The Provision Of Supportive Oncology Care In Western Kenya Region**

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**Objectives:** This paper aims to highlight on:
- The knowledge, attitude and practice of the healthcare providers in the provision of supportive oncology services
- Obstacles and limitations in the provision of quality oncology care

**Methods:** Cross sectional study carried out in 6 health institutions in Western Kenya Region

**Results:** Most healthcare providers in this region do not have adequate knowledge and skills as well as displaying negative attitudes towards cancer patients and the care givers. There is limited access to chemotherapeutic agents and narcotic analgesics not mentioning total lack of radiotherapy services. Stigma, discrimination and lack of administrative support posses a major challenge to the healthcare providers especially those providing palliative care. Despite all these, 30% of the patients are able to resume activities, 20% of healthcare workers display some change in attitude and know about that something can be done about their condition despite their limitations. Lack of narcotic analgesics, chemotherapeutic agents and radiotherapy is a major hindrance in the provision of quality services

**Conclusions:** Sufficient supply of narcotic analgesics is mandatory in the provision of quality supportive care. There is an urgent need to increase training and awareness among the health care providers to achieve quality supportive care. Need for capacity building through collaboration in order to acquire radiotherapy facilities. Some of the patients (image attached) can benefit from palliative radiotherapy but instead, go through lots of stigma and humiliation.

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**23-318**
**The Multidimensionality Of Spiritual Wellbeing: Meaning, Peace, And Faith And Their Association With Quality Of Life And Coping In An Oncological Population**

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**Objectives:** This study explored associations between the newly proposed three-factor structure of the 12-item FACIT-Sp Spiritual Wellbeing Scale (Meaning, Peace, and Faith), quality of life (QoL), and coping in an Australian oncology population.

**Methods:** Four-hundred-and-ninety consecutive cancer patients with mixed diagnoses completed the Functional Assessment of Chronic Illness Therapy – Spiritual Well-Being (FACIT-Sp) and the Mental Adjustment to Cancer (MAC) scale.

**Results:** Analyses assessed whether each of the three individual factors of Spiritual Wellbeing were significantly associated with QoL (FACT-G Total) after controlling for the other two factors. Hierarchical multiple regressions revealed that Meaning accounted for 7.3% (R² Change) of the variance on QoL after
patients and their families. The primary objective of this study is to identify and describe the psychosocial characteristics of patients referred to the CNR program social worker.

Methods: A retrospective data review of 70 patients referred to the CNR program social worker from February 21, 2007 – December 31, 2008, describes the patients’ risk factors, priority needs, severity of problems, and ability to cope.

Results: Our findings show that the majority of patients referred to the social worker have moderate to severe psychosocial problems when classified by the Person-In-Environment (PIE) standardized instrument for social functioning problems. Findings indicate the types of patients which may benefit most from the CNR program.

Conclusions: The social worker makes an important contribution to the CNR program's understanding of the patient's environmental context. Follow-up research will address the impact of social worker interventions on the psychosocial needs of patients, particularly with regard to coping ability and severity of problems.

24-320
National Cancer Institute Of Bari: Our Early Experience In Cancer Survivorship Work In Progress
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Objectives: In Italy the Cancer Survivors (C.S.) are about 1.709,000, 2.5% of the whole population with an increasing forecast to 2010 of 1.250.000 (3.3%). For this reason the National Cancer Institute of Bari wanted to identify qualitatively the needs and concerns of a sample of C.S. Indeed we know the cancer diagnosis can lead to impairment in multiple areas of psychosocial well-being: physical, social and emotional functioning.

Methods: A sample of 60 C.S. (≥18 age, male and female, ≥5 years from diagnosis, disease free) were interviewed on the phone by the Nurses, about a wide variety of psychosocial concerns and needs related to:
coping with side-effects; dealing with self-concept change; stress and adjustment reactions; management of their own unhelpful beliefs, expectations and emotions; and issues with survival and post-traumatic growth.

**Results:** Telephonic consultation was an effective way of identifying concerns and needs of C.S. and of describing both the Quality of Life experienced by C.S., and the factors that promoted their adaptation. The interviewed C.S. (93% women and 7% men) shown the following problems. State of Mind: 70% anxiety; 12% quietness; 9% denial; 9% indifference. Physical issues: 24.3% pain; 12% lymphedema. Dealing with self-concept change: 34.1% difficulty in touch himself; 29.2% difficulty in showing himself; 26.8% difficulty to look in the mirror himself. Relationship: 49% reinforced relationship; 7.3% partner considered as a stranger.

**Conclusions:** This preliminary study allowed the identification of many problems which affected C.S. Findings showed a new scenario, less known until now. C.S., Persons cured of cancer but still dealing with long-term and late effects of cancer and its therapy, represent a wide field of interest for nursing, to give relief and support to the different needs and concerns which impact their QoL. The Nurses can resolve many of the problems resulting in C.S. feel alone without physical and emotional support.

**24-322**

**Music Perception And Self-Reported Memory In Breast Cancer Survivors**

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**Objectives:** A variety of chemotherapy agents have ototoxic effects that can decrease both high and low frequency hearing. Several studies have shown that chemotherapy may also induce cognitive impairments such as decreased information processing speed, motor function, verbal memory, visuospatial skill, and visual memory. It is unclear whether reports of qualitatively different and negative musical listening experiences in cancer patients who have received chemotherapy are due specifically to the ototoxic effects or to more general neurotoxic effects. Finally, it is also unclear whether such changes in music perception are domain-specific (i.e., limited to music) or domain-general (i.e. cognition). The purpose of this study is to describe the relationships between the results of auditory-based perception tests and self-reported memory in breast cancer survivors who have received adjuvant cancer treatment and age-matched healthy controls.

**Methods:** Breast Cancer Survivors (BCS) and age-matched Healthy Controls (HC) completed audiometric testing and the Montreal Battery of Evaluation of Amusia to determine hearing thresholds, pitch perception, rhythm perception, and melodic memory. Participants also completed the Squire Memory Self-report Scale.

**Results:** The groups (BCS & HC) were similar in years of education, hearing PTA, race/ethnicity, and marital status. There was a moderate, negative correlation between hearing and the scores on the auditory perception tests. There were no significant differences in self-reported memory or perception tests between the two groups. Correlations between scores on working memory and music perception were significant for HC., but not for BCS.

**Conclusions:** Although BCS and HC received very similar scores on tests of working memory and music perception, their processing of such information differs dramatically, as revealed by significant correlations between the two tasks for healthy controls but not for breast cancer survivors. This project is sponsored by the Walther Cancer Foundation & the IU Signature Center for Advanced Studies in Hearing, Perception and Language. Indianapolis, IN.

**24-323**

**Should All Patients Be Enrolled In A Cancer Rehabilitation Program**

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**Objectives:** McGill Cancer Nutrition and Rehabilitation (CNR) program consists of physician, nurses, physiotherapist, occupational therapist, dietician, psychologist and social worker. The global objective of the CNR program is, through an interdisciplinary approach, to empower individuals who are experiencing loss of function, fatigue, malnutrition, psychological distress, and other symptoms as a result of cancer or its treatment to improve their own quality of life. The McGill CNR program developed as a result of the ever-increasing demand for a focus on addressing individual cancer patients and their needs, as well as on achieving optimal tumor-related outcomes. **Objectives:** To analyze the effect of interdisciplinary 8-week rehabilitation program on the functional outcomes of patients with advanced cancer.
Methods: Seventy-five patients were entered to 8 week interdisciplinary cancer rehabilitation program. Edmonton Symptom assessment Score (ESAS), Patient Generated Subjective Global Assessment (PG-SGA), Distress thermometer (DT) and Simmonds Functional Assessment Tool (SFAT) were used to assess all patients prior to and following an 8-week. A paired t-test comparing patients pre and posttest scores was used.

Results: Thirty eight male and 37 female participants, with ages ranging from 25 to 80, and diagnosis of one of the following cancers: breast (19%), hematologic (16%), hepatobiliary (15%), gastro-esophageal (15%), lung (10%), head and neck (6%), ovarian (6%), colorectal (5%), bladder (4%), CNS lymphoma (3%) and sarcoma (1%). patients’ was used, there was a significant improvement after an 8-week cancer rehabilitation program in sleep (p= <0.01), quality of life (p= 0.04), pain (p= <0.01), strength (p= <0.01), nausea(p= <0.01), sleepiness (p= <0.01), shortness of breath (p=0.02), depression (p= <0.01), nervousness (p= <0.01), distress thermometer (p= <0.01) and total PG-SGA score(p= <0.01).

Conclusions: We suggest that participation in a cancer rehabilitation program is beneficial to patients. This is supported by the significant differences in the observed pre and post program measurements.

24-324
Analysis Of Patient And Physician Expectations For Cancer Survivorship Care
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Objectives: Concerns have been raised about the lack of clarity surrounding physician roles during the cancer survivorship care process, and that this may contribute to sub-optimal qualities in care. Our aim was to compare expectations for cancer survivorship care between patients and their physicians and between primary care providers (PCPs) and oncologists.

Methods: Cancer survivors and their physicians were surveyed to evaluate for expectations regarding physician participation in primary cancer follow-up, screening for other cancers, general preventive health, and management of co-morbidities. Responses were graded on a Likert scale and compared among patients, PCPs and oncologists.

Results: Of 992 eligible survivors and 607 physicians surveyed, 535 (54%) and 378 (62%) were evaluable, respectively. Among physician respondents, 255 (67%) were PCPs and 123 (33%) were oncologists. Comparing patients with their oncologists, expectations were highly discrepant for screening for cancers other than the index one (agreement rate 29%), with patients anticipating significantly more oncologist involvement. Between patients and their PCPs, expectations were most incongruent for primary cancer follow-up (agreement rate 35%), with PCPs indicating they should contribute a much greater part to this aspect of care. Expectations between patients and their PCPs were generally more concordant than between patients and their oncologists. PCPs and oncologists showed high discordances in perceptions of their own roles for primary cancer follow-up, cancer screening, and general preventive health (agreement rates 3%, 44%, and 51%, respectively). In the case of primary cancer follow-up, both PCPs and oncologists indicated they should carry substantial responsibility for this task.

Conclusions: Patients and physicians have discordant expectations with respect to the roles of PCPs and oncologists in cancer survivorship care. Uncertainties around physician roles and responsibilities can lead to deficiencies in care or duplications of services, supporting the need to make formal survivorship care planning a standard component in cancer management.

24-325
Determinants Of Disablement In Patients With Metastatic Lung Cancer
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Objectives: Functional decline occurs inevitably among patients with stage IV lung cancer yet understanding of the timecourse and precipitants of disablement remain limited. Characterization of the trajectory of disablement and related factors will allow for the development of rehabilitation care delivery models geared toward functional preservation.

Methods: 300 patients with Stage IV lung cancer were recruited by telephone from a larger cohort prospectively followed through the Mayo Clinic Lung Cancer Epidemiology and Quality of Life Study. Patient report data was collected via telephone at baseline and every 4 weeks thereafter until death or elective study withdrawal. Outcomes included the mobility and daily activities domains of the Ambulatory Post Acute Care Computer Adaptive Test (AM PAC CAT) (an IRT-based, extensively validated functional metric) and 11-point symptom numerical rating scales (NRS) of (pain average/worse, dyspnea, fatigue, and psychological distress). Demographic and disease-related data were abstracted from the Mayo Clinic electronic medical
record. General estimating equations (GEE) were utilized to identify disease- and symptom-related variables associated with changes in AM PAC CAT scores.

**Results:** AM PAC CAT mobility and daily activities scores remained at low but stable levels until 2 months prior to death at which time a statistically significant decline was detected in GEE models. Reduced AM PAC CAT scores were associated with increased NRS fatigue, dyspnea and pain scores. Interaction terms between symptom NRS scores were significant in GEE models. Cancer-related factors including bone and brain metastases, receipt of chemotherapy and radiation therapy, and serologic abnormalities were not significant in GEE models.

**Conclusions:** Patients with stage IV lung cancer have stably diminished function until 2 months prior to death when increasing symptom burden appears to precipitate functional decline.

**24-326**

Behavior Patterns In Breast Cancer Supportive Care  
Eugeny Demin  
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**Objectives:** At least in Russia cancer is still a behavioral experience for patients, their relatives and professionals. The following important questions arise each time when cancer sufferers are seen in their relationships with others: *why do individuals, facing any malignancy, encounter unfriendly and sometimes opposed attitudes?* *why is shock a more intense reaction in cancer than in heart disease where mortality is much higher?* *what prevents people from coping?* *what would help both patients and healthy people to cope better?* *what helps, when there is no guarantee of avoiding cancer, to encourage real participation in positive solutions?*

**Methods:** To settle the behavior patterns we conducted a big study and summarized women’s considerations about their feelings regarding breast cancer. A special questionnaire was used in over 100 affected and healthy women. It was essential to discover some particular behavioral peculiarities in cancer management.

**Results:** Precisely professionals remained the most conservative in terms of skills to communicate both with healthy people and cancer patients. The majority of information about cancer coming from mass media was more of horror. No constructive idea for women to be responsible for their own health was found in it. Patients’ close relatives did not know what type of behavior was required in order to be supportive as much as necessary. Nobody had taught them how to interact. However carefully selected and trained volunteers - the former breast cancer patients - proved to be beneficial in their assistance to today’s sufferers.

**Conclusions:** For everybody cancer is the beginning of a long trip into the world of painful hesitations. In the meantime there are a lot of positive ways to decide these difficult behavioral problems. Nothing special is needed except a wish of the society to be aware that health behavior in cancer means not only curable medical therapy.

**24-327**

The Role Of Exercise In Cancer Rehabilitation Across The UK: A Survey Of Physiotherapists In Oncology And Palliative Care  
Caroline Donnelly¹, Andrea Lowe-Strong¹, Jane Rankin², Anna Campbell ³, Jim Allen ¹, Jacqueline Gracey⁴  
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**Objectives:** There is a growing body of evidence supporting the use of exercise within the cancer population. However, very little is known about the level of exercise service provision currently available to the cancer population. This study aimed to ascertain physiotherapists’ knowledge of the exercise services currently available to their cancer patients within the UK, and to determine their opinions regarding future exercise provisions.

**Methods:** Ethical approval for an anonymous, census survey was granted and a postal questionnaire was distributed in June 2007 to 368 practising physiotherapist members of the Association of Chartered Physiotherapists in Oncology and Palliative Care, a special interest group of the UK professional body, the Chartered Society of Physiotherapy.

**Results:** A valid response rate of 65% (223) was achieved. The majority of the sample were working in palliative care settings including hospices (53%) and community palliative care teams (34%), with twenty-five percent employed in oncology settings. Individual exercise counselling (62%) and information resources on exercise (50%) were the only two exercise services that were commonly identified as being available to cancer patients. Relating to this the majority of therapists (77%) agreed there is a need to improve the exercise services available to cancer patients in their area. Therapists showed most support for the provision of supervised group programmes post treatment (60%) and community based exercise programme (59%).
Conclusions: The majority of therapists agree there is a need to improve exercise services for cancer patients, indeed findings show there is a significant discrepancy in the services physiotherapists identified as being currently available compared to their opinions on what should be made available. Therapists show most support for supervised exercise programmes during and following treatment, therefore outlining the need for further research to investigate the effectiveness of supervised exercise programmes with a range of cancer populations during all stages of disease.

24-328
Educating Health Care Teams In Survivorship Care Improves Quality Of Life
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Objectives: Cancer survivors are close to 13 million strong. One in every 7 survivors received their cancer diagnosis more than 20 years ago. Educating health care teams in survivorship care can lead to institutional changes and improved quality of care for survivors.

Methods: Survivorship Education for Quality Cancer Care is an NCI funded 3 day educational program that provides 4 yearly training sessions for multidisciplinary teams designed to promote institutional changes in survivorship care. Based on the recommendations of the Institute of Medicine report and built around adult learning principles and the 4 domains of quality of life this program follows 3 goals developed by each team and evaluated at 6, 12 and 18 months post course along with institutional evaluations to identify changes in institutions philosophy and practice.

Results: To date 155 teams have been trained in survivorship care essentials. At 18 months, year one had seventy-seven percent follow up and achieved 81% of their goals. Year 2 at 12 month follow up had 66% followed up and achieved 69% of their goals. Year 3 team follow up at 6 months has shown 94% follow up and achieved 52% of their goals. Institutional Assessments from baseline to 12 months for Year 1 and Year 2 has shown significant changes in 7 standards of care.

Conclusions: Completing this educational program improved survivorship care in the participating institutions. Goal driven planning and program building helped motivate teams to reach their goals and changed the quality of care cancer survivors received in these institutions. Educating health care professionals to meet those needs is the first step in developing successful programs for the future.

Funding source: NCI R25 CA 107109 Survivorship Education for Quality Cancer Care

24-329
Dyspepsia Symptoms Are Not Explained By Abnormal Gastric Myoelectrical Activities
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Objectives: The objective of this study is to explore the correlation between dyspepsia symptoms (DS) and gastric myoelectrical activity (GMA) in patients with cancer.

Methods: Forty four patients (pts) diagnosed with cancer were enrolled prospectively. An electrogastrography (EGG) to measure AMG was performed 30 min pre-prandial and 30 min after ingestion of 500 ml water. EGG measurements are recorded by electrodes positioned externally on the abdominal wall. The EGG results were regrouped in 5 categories: normal, bradygastria, tachygastria, mixed and gastric outlet obstruction. All patients completed the dyspepsia symptom severity index (DSSI) to assess DS.

Results: The EGG results are: only 5 pts (11%) had normal EGG and the frequency of abnormal tests was as follow: 3 (7%) bradygastria; 15 (34%) tachygastria; 20 (46%) mixed, and 1 (2%) gastric outlet obstruction. The intensities of DS between each group of pts classified by their EGG results were not significantly different even for pts with normal EGG.

Conclusions: The majority of patients with cancer present abnormal GMA and experience a wide spectrum of DS. However, symptoms could not be explained by the EGG characteristics. Further studies are needed to better understand the pathophysiology of DS.

24-330
Are There Gender Differences In The Work Ability Of Cancer Survivors? A Nocwo Study
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Objectives: The aim of this study is to investigate gender differences concerning work ability in working
cancer survivors (CSs), and compared the findings to those of matched population-based controls.

**Methods:** A mailed questionnaire was completed by 446 Norwegian CSs (269 breast cancer, 166 testicular, and 54 prostate cancer) with good prognosis 2-6 years after primary treatment, and 588 controls (319 females and 269 males) (NORM). Overall current work ability (OCWA) was primary outcome measure, but ten indices of work ability were also studied.

**Results:** The overall mean OCWA score was high in both CSs and NORM. The mean OCWA score was similar between male and female CSs, but males showed clinically significant better scores on three out of 10 work ability indices. Male CSs had a similar mean OCWA score as NORM, but showed significantly poorer scores on two out of 10 indices compared to NORM. Female CSs had significantly lower mean OCWA score and poorer scores on two indices compared to NORM. The gender difference between the mean OCWA scores was similar in males, but higher in females. Physical and mental indices explained most of the variance in OCWA, whereas being a cancer survivor only made a small contribution.

**Conclusions:** The overall work ability of CSs was high, and was similar in male CSs and NORM, but lower in female CSs than in their NORM. CSs with reduced low mental and physical work ability should be identified, and have thorough medical work-up and eventual rehabilitation in order to improve their work ability.

**Discussion and Perspectives:** Development and implementation of support groups/network for anal cancer survivors may be an important source of recognition, which may help patients to cope with long term disabilities and enabling the individual to maintain an active, working and social life, as desired. We specifically discuss whether and how the possibility of participating in meetings with other anal cancer patients and health professionals may help survivors of anal cancer to resist and to manage potentially complex stressors encountered in the recovery from the disease.

24-331
**Building Sources Of Recognition - The Impact Of Network Meetings In The Rehabilitation Of Anal Cancer Survivors**

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**Objectives:** Anal cancer is a rare disease within the cancer spectrum. Long-term disabilities are notable and place increased demands on rehabilitation. However anal cancer appears to lack attention and deserved recognition from professional and social services, which in itself may lead to mistrust and devaluation of the individual seeking support. Own recently published study based on interviews with anal cancer survivors (n=16, 11 women and 5 men; average age 52 years) revealed two concepts, modesty and recognition, which describe the essence of the lived experience of anal cancer, and which each appear to be important resistance resources. While modesty is regarded as an enforced and necessary competence developed and mastered by the individual, recognition refers to a desired, but often lacking, resource in the individual’s interaction with health authorities and relatives. Aim: The objective of this study was to describe the process of developing and implementing information networks for anal cancer patients and their relatives.

**Methods:** The study reports on the development, realization and evaluation of networks designed for survivors of anal cancer. The initiative consisted of meetings for anal cancer patients and their relatives. Themes included management of long-term disabilities related specifically to anal cancer and how to seek professional support to ensure both physical and psychosocial.

**Results:** Preliminary results will be presented.

**Conclusions:** Discussion and Perspectives: Development and implementation of support groups/network for anal cancer survivors may be an important source of recognition, which may help patients to cope with long term disabilities and enabling the individual to maintain an active, working and social life, as desired. We specifically discuss whether and how the possibility of participating in meetings with other anal cancer patients and health professionals may help survivors of anal cancer to resist and to manage potentially complex stressors encountered in the recovery from the disease.

24-332
**Surviving Cancer. Physical Problems At Rehabilitation: Need For Physiotherapy**

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**Objectives:** Purpose: Identification, quantification and evaluation of cancer patient's physical problems after completion of treatment. Relevance: There is a scarcity, or total lack, of information regarding these problems months and years after treatment. Participants: All 624 patients attending to residential rehabilitation stay at Rehabilitation Centre Dallund (rcD) in 2005 are included in this study. 85% of the participants are women and 52% had had a cancer mamma diagnose.

**Methods:** Prior to their stay at rcD, each patient receives a set of questions including a question about side effects. They also receive the Dallund Scale, which is a structured one page questionnaire qualified to disclose the patients' need of rehabilitation. The scale contains the possibility of checking 64 different late effects (practical, work- or family related, psychological or spiritual factors). Dallund's physiotherapist systematically records information on the most common questions and problems during the course.
Results: When answering the open questionnaire in 2005, 607 patients present 2, 145 statements, 40% relating to muscle, joint or bone problems, and 6% reflecting problems with their scars. Of the 617 patients answering the Dallund Scale 2005, 38% have problems with muscular strength, 39% have muscle or joint pain, while 21% have problems with scar tissue. 172 patients consulted the physiotherapist at Dallund. The most common question asked was: "What am I allowed to do? / What should I do?" (48%). Of 108 patients diagnosed with breast cancer, 33% had problems with mobility, 43% with scar tissue, 30% with lymphoedema, 24% have nerve pains and 33% presented muscle- or joint pain.

Conclusions: Physical activity must be an essential part of the rehabilitation process both during the stay at the hospital and during rehabilitation. Implications: Physiotherapists must place increased focus on cancer patients' problems both during their education and thereafter work with treatment and rehabilitation.

24-333
The Effect Of A Multimodal Intervention On Treatment-Related Symptoms In Patients Undergoing Hematopoietic Stem Cell Transplantation: A Randomized Controlled Trial
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Objectives: Studies applying exercise, relaxation training and psychoeducation have each indicated to have a positive impact on physical performance and/or psychological factors in patients diagnosed with cancer. We explored the longitudinal effect of a combination of these interventions on treatment-related symptoms in patients undergoing myeloablative allogeneic hematopoietic stem cell transplantation (allo-HSCT).

Methods: 42 patients (18-65 years) were randomized either to an intervention or a control group. The intervention group received standard treatment and care; and a supervised 4-6 week, structured exercise program, progressive relaxation and psychoeducation during hospitalization, 1 hr. 5 days/wk. The control group received standard treatment, care and psychotherapy. A twenty four item symptom assessment questionnaire was completed weekly during hospitalization, 3 and 6 months after allo-HCST. Through Principal Component Analysis (PCA) with Varimax Rotation, individual symptoms were grouped into five symptom clusters: mucositis, cognitive, gastrointestinal, affective and functional symptom clusters.

Results: Subsequent General Estimate Equation (GEE) analysis revealed similar longitudinal patterns of intensity in all symptom clusters for intervention and control groups, but in the intervention group there was an overall significant reduction (p<0.05) in symptom intensity over time for all clusters except the affective symptom cluster.

Conclusions: This study provides beginning evidence for the efficacy of an exercise-based multimodal intervention in reducing the intensity of a spectrum of symptoms in this small sample of patients undergoing allo-HSCT. Understanding the patterns of symptom clusters during allo-HSCT can assist in the development of important strategies in prevention and treatment.

24-334
History Of Major Depressive Disorder Predicts Poorer Quality Of Life Outcomes In Women With Breast Cancer
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Objectives: Previous studies have shown that cancer patients with current major depressive disorder (MDD) experience poorer quality of life. However, it is unknown whether patients with a past history of MDD are also at risk for poorer outcomes. The purpose of the current study was to examine past history of MDD as a predictor of quality of life during adjuvant treatment and early survivorship in women with breast cancer.

Methods: Participants were 414 women (mean age = 55 years, range 21-82) diagnosed with Stage 0, I, or II breast cancer and treated with chemotherapy and/or radiotherapy. Past history of MDD and current MDD were assessed with the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) before initiation of adjuvant treatment; quality of life was assessed with the Medical Outcomes Study Short Form – 36 (SF-36) prior to initiation of adjuvant treatment, at the completion of adjuvant treatment, and at six months post-treatment. Mixed models analyses were used to examine change in quality of life over time by past history of MDD, controlling for current MDD.

Results: Seventy-five participants (18%) met criteria for past history of MDD. Significant (p <.05) main effects were found, showing that patients with a past history of MDD reported worse physical functioning and physical role functioning. Past history of MDD also interacted
significantly (p < .05) with time; patients with a past history of MDD displayed worse mental health over time, while patients without a past history of MDD displayed improved mental health over time.

**Conclusions:** Independent of current MDD, past history of MDD predicts poorer physical and mental health in breast cancer patients during adjuvant treatment and early survivorship. Findings suggest that assessment of both past history of MDD and current MDD should be part of routine psychosocial screening.

**24-335**
The Reason For Failure Of Participation In Physical Therapy (Pt) And Occupational Therapy (Ot) During Cancer Inpatient Rehabilitation And The Effect Of A Simple Intervention.

Benedict Konzen
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**Objectives:** To evaluate the reasons for failure of therapy participation in cancer patients and to evaluate if a simple intervention would improve therapy participation.

**Methods:** The research was conducted on a cancer rehabilitation inpatient unit. Physical and occupational therapists recorded the patient’s therapy participation in 15 minute incremental units consecutively prior and post intervention. When a patient was not able to participate in a therapy unit, we called it missing unit, one of the following reasons was recorded for each missing unit: interruption by health care personnel, interruption secondary to a diagnostic procedure, a medical condition precluding participation in therapy; or lastly, an emotional event. Placement of a “Do not interrupt, therapy in session” outside of the patient’s room during therapy was the intervention. The percentage of missing units is compared pre and post intervention using X^2.

**Results:** Total PT and OT units recorded pre-intervention were 428 each. Total PT and OT units recorded post-intervention were 1084 and 1088, respectively. Thirteen percent of OT and 17% of PT units were missing pre-intervention. For OT missing units, 18% (10/57) were due interruption by health care personnel, 28% (16/57) due to a diagnostic procedure, 47% (27/57) due to medical condition, and 7% (4/57) due to emotional event. For PT missing units, 21% (15/71) were due interruption by health care personnel, 20% (14/71) due to a diagnostic procedure, 51% (36/71) due to medical condition, and 8% (6/71) due to emotional event. Post-intervention, there was significantly less (9.4%) missing OT units (p=0.02), and the improvement were due to significant less (10%) interruption from health care personnel.

**Conclusions:** Most interruptions on cancer patients’ rehabilitation therapy units were due to medical reasons, which confirmed the medical acuity of cancer rehabilitation patients. Simple intervention may improve therapy participation caused by interruption from health care personnel.

**24-336**
The Use Of The Modified Champs To Measure Changes In Physical Activity Following An 8 Week Cancer Nutrition Rehabilitation Program.

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**Objectives:** There were in excess of 850 000 cancer survivors in Canada in 2004, comprising 2.7% of the overall population. In 2006, a cancer nutrition and rehabilitation program (CNRP) was developed at the McGill University Health Center to address some of the needs of these patients. One of the goals of the CNRP is to improve the physical activity of cancer survivors regardless of diagnosis or stage of disease. The objective of the study was to measure the effectiveness of an 8 week CNRP to increase physical activity of cancer survivors.

**Methods:** The Community Healthy Activities Model Program for Seniors (CHAMPS), a self-report physical activity questionnaire designed for seniors, was modified to measure change in physical activity of cancer survivors enrolled in the CNRP. A modified CHAMPS was administered to 22 patients with a cancer diagnosis enrolled in the CNRP before and after an 8 week program. Patients received regular interventions from an interdisciplinary team.

**Results:** There was a trend in increase of overall activities (METS; before 101.8 ± 38.8 and after 115.3 ± 49.4, p=0.095), light and moderate activities, and significant increase in heavy activities (p<0.05). This increment in the level of activities was seen mainly in men of all ages.

**Conclusions:** Participation in an 8 week CNRP increases the level of physical activity of male cancer survivors. The modified CHAMPS could be used to measure the change in levels of physical activity in a cancer population.
Adult Radiation Late Effects Clinic (Arlec) - Serving The Needs Of Survivors
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¹Princess Margaret Hospital, Radiation Oncology, Toronto, Canada, ²Toronto General Hospital, Hyperbaric Medicine Unit, Toronto, Canada

Objectives: Success in treating cancer patients translates into longer life and opportunity for late effects to manifest. Management of toxicity is often a secondary consideration when disease free survival is the main endpoint. An ARLEC was set up to address this imbalance. The referral patterns have been analysed.

Methods: In 2000, ARLEC was established. Patients deemed to have radiation late effects (RLE) were seen on referral. Patients were seen at a weekly clinic by a team of oncologist and clinical nurse. They were assessed, treated and/or referred to different services as appropriate. The follow up was dependent on the clinical picture and response.

Results: Over 8 years, 380 new patients were seen. Seventy percent of referrals came from radiation oncologists, and 15% were from other institutions. Median time from completion of radiation therapy to clinic attendance was 26 months (range 1 – 720). All major tumor sites were represented with a broad range of presenting problems, mostly EORTC CTC v. 3.0 grade 2 (54%) at first assessment (Table). Mean clinic follow up time was 7 months (0-72).

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Conclusions: ARLEC catered for all toxicity grades and allowed long term survivors, patients who were no longer under regular review, to be assessed by a team with interest and expertise in the management of RLE. This specialized clinic allows time to adequately investigate and discuss the issues and provide interventions when available. ARLEC is unique in Canada and serves to validate patients who have concerns with symptoms that impact on their physical, sexual and social function.

Worldwide And European Use Of Internet-Based Survivorship Care Plans
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Objectives: Development of survivorship care plans (SCP) is encouraged to improve communication regarding longterm healthcare needs of cancer survivors. This report evaluates worldwide and European utilization of the first Internet-based SCP.

Methods: A program for creation of SCP, OncoLife, is accessible through www.oncolink.org, a cancer information website based at the University of Pennsylvania, serving over 3.9 million pages/ month to 385,000 unique IP addresses. Users responding to queries regarding demographics, diagnosis, and treatment receive comprehensive guidelines addressing late toxicity, second malignancy, fertility, and tumor recurrence. Data maintenance is anonymous, secure, and IRB approved.

Results: From 5/07-2/09, 4460 individuals utilized OncoLife, and US residents represented 89%. Of non-US users, 14% were European. Median diagnosis age of US users was 50, and median current age 53, compared to 48 and 50, respectively, for non-US users (p = NS). Primary cancer diagnosis was breast in US, non-US, and European user populations (46%, 39%, 35%, respectively), followed by hematologic (13%) and gastrointestinal among US, gastrointestinal (16%) and hematologic (12%) among non-US, and gastrointestinal (20%) and gynecologic (12%) among European users (p = NS). US survivors reported having undergone surgery (84%), chemotherapy (81%), and radiotherapy (60%), similar to 80%, 73%, and 52%, respectively, of non-US users. European users appeared more likely to have received chemotherapy (91%), and equally likely to have undergone surgery (76%) and radiotherapy (50%). European survivors appeared less likely to have received survivorship information previously than non-European (6% vs. 12%, p = 0.041).

Conclusions: Although the majority of cancer survivors using this tool are US residents, non-US survivors represent an important subset willing to use the Internet to create SCP. Breast cancer is the most common diagnosis among users worldwide. Survivors appear equally likely to receive cancer treatments regardless of residency; most have not received prior survivorship
Are Primary Care Physicians Ready To Care For Cancer Survivors? Results Of A Survey On Lasting Health Effects Of Chemotherapy.

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Objectives: Chemotherapy, one of the cornerstones in winning the battle against cancer, has lasting health effects that require medical attention. Objective: Describe primary care physicians’ perception of their own knowledge and comfort level ascertaining and managing lasting effects of chemotherapy in cancer survivors, and their preferences for further Continuing Medical Education (CME) in this area.


Results: The response rate was 27.4% and most responses were received by fax (61.2%). From 128 eligible respondents (mean of 19.4 years from last post-graduate training), 64.0% reported they were unfamiliar with the topic, 75.0% were uncomfortable with screening practices, and 73.7% were uncomfortable with management strategies of these complications. “Complexity of chemotherapy agents and their lasting effects” was the most significant barrier reported, and “Lack of time during patient encounters” the least significant barrier. Only 17.6% responded that they had ever been offered any CME opportunity on screening and management of lasting effects of chemotherapy, however 85.6% stated that they would attend such CME if offered. “Lecture format in conferences” (63.4%) and “Printed educational materials by mail” (44.6%) were the preferred methods of CME. Most physicians (81.6%) reported that it would be helpful to receive advice/guidelines from oncologists.

Conclusions: Most primary care physicians felt they were unfamiliar with lasting effects of chemotherapy, and reported lack of opportunities for training. These findings underscore the need for additional medical education in this area so that gains achieved in cancer survival are not offset by loss in quality of life, comorbidities, and premature mortality from the same treatment used to save patients’ lives.

Lymphoedema Secondary To Breast Cancer: A Randomised Controlled Trial Of Low Level Laser Therapy (Lllt)

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Objectives: Background and purpose: Lymphoedema secondary to breast cancer has physical and emotional consequences for the individual sufferer. Over the last 15 years the main approaches to treatment of lymphoedema have been education and exercise, compression hosiery or bandaging, massage and drug therapy. More recently the use of low level laser therapy (LLLT) has been instigated. This paper describes a randomised controlled trial of LLLT for the treatment of lymphoedema secondary to breast cancer. The primary outcome of the study was to determine whether LLLT is as effective as standard lymphoedema treatment.

Methods: Methods: The study involved recruiting one hundred and forty eight women who had either mild or moderate lymphoedema. Participants were randomly allocated to either the standard treatment group or the low level laser therapy treatment group. Participants in the experimental groups received two weeks of LLLT treatment. Measures included limb circumference, and bioelectrical impedence data.

Results: Results: Women in the mild laser group experienced a sustained reduction in lymphoedema compared to baseline, while the standard treatment group experienced a sustained increase (p <0.01). For women with moderate lymphoedema, both groups showed a reduction in lymphoedema; however the standard treatment group indicated that standard treatment was uncomfortable, time consuming, restrictive of movement and detrimental to activities of daily living.

Conclusions: Conclusion: Women with mild lymphoedema may benefit from application of laser treatment as the laser group in the study showed a response to treatment (reduction) opposite to the response of those who received standard treatment (increase) in size of lymphoedema. Laser appears to be a viable option to standard treatment for women with moderate lymphoedema, as the same result is achieved.
(reduction in size of lymphoedema) without the discomfort and inconvenience of standard treatment.

25-341
Cost Analysis For The Treatment Of Sorafenib-Induced Dermatologic Toxicities
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Objectives: Toxicities due to sorafenib are noteworthy due to their high frequency and impact on quality of life and the importance of managing the toxicity in order to minimize disruption of therapy. This study evaluates costs associated with managing dermatologic toxicity caused by the multikinase inhibitor sorafenib in the treatment of cancer patients referred to a dermatology-based program in oncology, the SERIES (Skin and Eye Reactions to Inhibitors of EGFR and kinases) clinic.

Methods: Medical records for 14 cancer patients receiving sorafenib between November 2005 and January 2008 were reviewed to evaluate the cost of toxicity management (including medications and supplies, clinic visits, and laboratory as well as diagnostic costs). Prescription costs were determined by using the Average Wholesale Price (AWP) and 0.4 multiplier in order to approximate Medicare Part D prescription plan pricing. Clinic visit costs, including procedures, were obtained from the Medicare Physician Fee Schedule for outpatient services.

Results: All patients who received sorafenib developed HFSR in addition to rash (57% of patients), mucositis (29%), pruritus (21%), alopecia (21%) and xerosis (14%). Other cutaneous reactions included dermatitis (14%), seborrheic dermatitis (14%), urticaria (7%) and stomatitis (7%). Upon presentation, 36% of patients presented with Grade 3 skin toxicity, 43% presented with Grade 2, and the remaining 21% presented with Grade 1 per CTCAE v.3.0 criteria. Median cost per patient to treat dermatologic toxicity was $2609. Median cost for medications and supplies was $1631. Median cost for clinic visits was $796. Clinic visit costs do not include mean laboratory and diagnostic fees of $330.

Conclusions: Dermatologic toxicities have a significant and expected financial impact in the management of patients treated with sorafenib. Increased awareness and treatment of these events are needed to decrease interruption of sorafenib therapy in order to improve patient outcomes and decrease health care costs.

25-342
A Pilot Study To Evaluate An Algorithm To Manage Egfr Inhibitors Associated Cutaneous Toxicities
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Objectives: Currently, there is a lack of standardized recommendation to manage cutaneous toxicities induced by EGFR inhibitors. In view of this, we have proposed a treatment algorithm (Table 1) based on evidence available in the literature. This study evaluates the feasibility of this algorithm to reduce cutaneous toxicities induced by EGFR inhibitors.

Methods: Adult cancer patients receiving EGFR inhibitors from June 2007 to December 2008 at National Cancer Centre Singapore were included. Patients are evaluated and followed up by clinical pharmacists at the outpatient treatment unit. Cutaneous toxicities, including rash, dry skin and skin pruritis, were graded utilizing the National Cancer Institute Common Toxicity Criteria (NCI-CTCAE) Version 3.0. Pre-treatment evaluations, including severity and number of areas of cutaneous toxicities, were compared to post-treatment evaluations using two-tailed paired t-test.

Results: Forty-two patients (20 male and 22 female) were evaluated within the time period. Majority of the patients were Singaporean Chinese (88%). Patients were prescribed with gefitinib (52.3%), cetuximab (42.9%) and erlotinib (4.8%). Twenty patients were offered interventions and followed up (3-62 days) according to treatment algorithm. When compared the severity of rash, the grade of rash reduced from 1.15 to 0.80 (p=0.015), the grade of dry skin reduced from 1.30 to 0.70 (p=0.004) and the grade of skin pruritis reduced reduced from 0.80 to 0.55 (p=0.096). In terms of number of areas where cutaneous side effects were involved, number of areas of rash reduced from 1.30 to 1.15 (p=0.419), number of area of dry skin reduced from 1.00 to 0.85 (p=0.419) and number of areas with skin pruritis reduced from 0.9 to 0.65 (p=0.234).

Conclusions: A standardized protocol to manage EGFR induced skin toxicities was developed and has proven to reduce the severity of cutaneous toxicities induced by EGFR inhibitors.
Table 1: Treatment Algorithm

<table>
<thead>
<tr>
<th>Toxicity Severity (per CTCAE guideline)</th>
<th>Rash Care</th>
<th>Dry Skin</th>
<th>Pruritis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1: Clindamycin 2% gel</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Grade 2: Clindamycin 2% gel</td>
<td>Doxycycline 100 mg PO BID</td>
<td>Moisturizers (any brand) +/- Oatmeal lotions</td>
<td>Hydroxyzine 10 mg PO TID PRN</td>
</tr>
<tr>
<td>Grade 3: Clindamycin 2% gel</td>
<td>Doxycycline 100 mg PO BID</td>
<td>Recomended dose reduction of offending agent (per package insert)</td>
<td>Moisturizers (any brand) +/- Oatmeal lotions</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Refer to further workup</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

25-343
Dermatologic Infections Complicating Epidermal Growth Factor Receptor Inhibitor (Egfr) Therapy In Colorectal Cancer Patients
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Objectives: Epidermal growth factor receptor inhibitors (EGFRIs) are effective for treating malignancies including colorectal cancer. Despite their benefits, dermatologic toxicities are reported to affect 75-87% of those treated. Dermatotoxicities impact quality of life and can also lead to dose modification, thereby affecting tumor response. This study investigates the prevalence of infections complicating dermatotoxicities in patients with colorectal cancer on EGFRIs.

Methods: Retrospective chart review methods were employed to analyze 68 colorectal cancer patients treated in the SERIES (Skin and Eye Reactions to Inhibitors of EGFR and Kinas) clinic. Cultures, biopsies, and viral stains were analyzed for pathogens and sensitivities. Selection criteria included patients treated with cetuximab or panitumumab at time of referral. Selection was limited to initial patients and their follow up visits in the time frame of August 2007 to June 2008.

Results: Thirty-two (47%) of the 68 colorectal cancer patients had evidence of infection at sites of dermatologic toxicity. Twenty five (36.8%) patients were positive for bacterial infection. Five of these 25 patients had concomitant fungal or viral infection. Eighteen (26.5%) patients cultured positive for Staphylococcus aureus. Of the patients with Staphylococcus aureus infections, 2 (2.9%) had tetracycline-resistant Staphylococcus aureus, 3 (4.4%) had Methicillin-resistant Staphylococcus aureus (MRSA), and 3 (4.4%) had tetracycline-resistant MRSA. Seventeen of the 25 bacterial infections were localized to the seborrheic region. Four (5.9%) patients had fungal infections alone and 2 (2.9%) had viral infections alone. One (1.5%) patient had concomitant fungal and viral infections. All of the infected patients were followed to clinical resolution.

Conclusions: The data suggests that colorectal cancer patients treated with EGFRIs have a high prevalence of cutaneous infections; primarily with secondary bacterial sources. Prompt recognition and management of these infections is vital to maintain consistent antineoplastic dose therapy, quality of life, and dermatologic health in colorectal cancer patients treated with EGFRIs.

25-344
Unanticipated Dermatologic Toxicities From Anti-Cancer Therapies: Survivors Perspectives
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Objectives: Improvements in oncologic therapies have resulted in increased survival across numerous malignancies, shifting attention to other aspects of the cancer experience. In particular, the impact of treatment-related dermatotoxicities has gained considerable attention due to their prevalence and possible effect on clinical outcome such as inappropriate treatment delay or discontinuation.

Methods: This study examined the results from quantitative grading of anticipated and unanticipated dermatotoxicities before and after the treatments by cancer survivors. Dermatologic side effects were assessed using a questionnaire developed by the CancerCare® Network. Patients retrospectively rated their level of concern about toxicities prior to and after therapy completion. In addition, specific dermatologic toxicities were also listed for participants to designate which were particularly damaging or caused a negative impact on quality of life.

Results: A total of 379 participants from 6 survivor groups: breast (n=250), ovarian (n=27), lung (n=23), colorectal (n=15), genitourinary (n=23), and other cancers (n=45) responded to the survey. The survey highlighted that skin irritation and dry skin were fairly minor concerns among patients prior to treatment. However, after having undergone treatment there was an increase, with 79% and 80% of patients reporting that
they were concerned about dry skin and skin irritation, respectively (p<0.001); most of whom reported that skin irritation (83%) and dry skin (80%) had a negative impact. When asked which toxicity was particularly damaging or caused a negative effect, 232 (63%) listed dryness, followed by nail problems (n=188, 51%) and itching (n=133, 36%). The majority of responders (n=247, 67%) felt that dermatologic toxicities were worse than their initial beliefs.

Conclusions: These findings underscore the importance of counseling patients on all potential toxicities, particularly dermatologic side effects prior to their cancer therapies. These efforts have the ultimate goal of maximizing quality of life and ensuring consistent dosing and improved clinical outcome.

25-345
The Effect Of Skin Toxicity (Rash) On Outcomes In Two Trials Of Erlotinib-Based Therapy In Pancreatic Cancer.
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Objectives: Rash, a common EGFR inhibitor toxicity, correlates with erlotinib (E) efficacy in multiple tumor types (Wacker 2007). E plus gemcitabine (G), improves survival (OS) in metastatic PanCa compared to G alone (PA3 – Moore 2007). The addition of bevacizumab (B) to GE provides no difference in OS compared to GE. (AVITA -Vervenne 2008) in PanCa.

Methods: Retrospective analyses were performed on two randomized trials (PA3 and AVITA) to examine the effect of survival by presence of rash vs no rash and by grade of rash.

Results: In PA3, rash incidence was higher with GE vs G (69% vs 30%) with a median onset of 10 days. OS was significantly improved in patients (pts) with rash in the GE arm (HR=0.59, p<0.001 median OS 7.4 vs 5 mos). No difference was evident in the G alone arm (HR 0.85,p=0.26 median OS 3.4 vs 5.9 mos). Pts with ≥ G2 rash derived further benefit with a median OS of GE 10.7 vs G 7.0 mos (p=0.02). In AVITA, rash incidence was slightly higher with GE-B 49% vs compared to GE, 44%. A trend for longer OS with increased grade of rash was seen in both arms (HR=0.54, p<0.0001), median OS: G0 vs G1 vs ≥G2 (4.3 vs 7.1 vs 8.3 mos). There was no difference in OS between arms for rash grade, consistent with overall study results.

Conclusions: These results highlight a correlation between rash grade and outcome in advanced PanCa patients treated with erlotinib and suggest the need for a comprehensive skin toxicity management program to ensure patient adherence. Ongoing studies (eg: RACHEL) are prospectively investigating the relationship between rash and efficacy in PanCa.

26-346
Epoetin Beta Treatment In Patients With Cancer Chemotherapy Induced Anaemia: The Impact Of Initial Haemoglobin And Target Haemoglobin Levels On Survival, Tumour Progression And Thromboembolic Events
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Objectives: Epoetin beta (NeoRecormon®) is used to treat patients with cancer undergoing chemotherapy to alleviate the symptoms of anaemia, reduce the risk of blood transfusions and improve Quality of Life (QoL). The objective of this analysis was to evaluate the impact of therapy at different Hb initiation levels and to different target Hb levels on overall survival, tumour progression and thromboembolic events (TEE).

Methods: A meta-analysis of all 12 randomised, controlled studies of epoetin beta was performed. An analysis of risk factors predisposing patients to TEEs under epoetin beta therapy was also performed. A total of 2,297 patients were included in the analysis.

Results: Analyses based on various Hb initiation levels indicate no negative impact on survival (HR 0.99; 95% CI 0.70, 1.40) and a favourable impact on disease progression (HR 0.73; 95% CI 0.57, 0.94) when epoetin beta was used within its licensed indication (Hb initiation ≤10 g/dL) or the EORTC recommended level of 11 g/dL. An increased risk of TEEs is seen for all Hb initiation level strata and a negative impact on survival is seen when initiating epoetin beta therapy at Hb levels >11 g/dL. We observe no association between high target Hb levels (≥13 g/dL) and an increased risk of mortality, disease progression or TEEs with epoetin beta compared with control.

Conclusions: The results of this analysis indicate that epoetin beta therapy has no negative impact on survival or tumour progression when initiated at Hb levels up to 11 g/dL. Furthermore there is no evidence to suggest that high Hb values achieved during epoetin beta therapy are associated with an increased mortality, disease progression or TEE rate. Supported by F. Hoffmann-La Roche Ltd. KEYWORDS: Anaemia, epoetin beta
Using A Multidisciplinary Team Approach To Perform Multidimensional Assessment Of Patients With Brain Metastases
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Objectives: We propose to perform multidimensional assessment of patients with brain metastases in the context of a new multidisciplinary Rapid Access Palliative Radiotherapy Program (RAPRP) Brain Metastases Clinic at the Cross Cancer Institute (CCI) in Edmonton, Alberta, Canada.

Methods: The proposed RAPRP Brain Metastases Clinic will streamline patient referral, consultation, and treatment with radiotherapy. Patients will be assessed using patient-reported questionnaires and physician-reported measures, performed at initial consultation and 1 and 4 weeks later by telephone follow-up. Involved multidisciplinary (MDT) members will include health care providers from Radiation Oncology, Nursing, Radiation Therapy, Pharmacy, Social Work, Occupational Therapy, and Clinical Nutrition.

Results: All patient information will be captured in a prospective ethics-approved database. We hope to show that this innovative MDT approach is feasible, will result in useful and acceptable recommendations and interventions by MDT members, will improve CCI referrals for stereotactic radiosurgery, and will facilitate patient accrual to clinical trials. The information collected will form a complete, holistic picture of the challenges faced by patients and their families, symptom burden and quality of life, the success of treatment with radiation, resource utilization, and patient care needs.

Conclusions: Our MDT approach and multidimensional assessment may suggest a new standard for routine assessment of brain metastases patients. It will serve as pilot data to inform future therapeutic intervention trials. Our approach will benefit involved healthcare professionals by encouraging collaboration and information sharing. The clinic will be an educational opportunity for medical students, residents, and health care trainees from other disciplines. It will also further research in brain metastases by assisting in the accrual of patients to clinical trials. If successful, the RAPRP Brain Metastases Clinic will be continued indefinitely, providing MDT-based supportive care and reporting our outcomes in a prospective manner.

Polymorphisms Of The Dna Base Excision Repair Gene Mutyh In Head And Neck Cancer
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Objectives: Head and neck squamous cell carcinomas (HNSCC) comprise about 6% of all malignant neoplasms. The major risk factors of HNSCC are smoking and alcohol consumption. Genetic polymorphisms of DNA repair enzymes may lead to genetic instability and carcinogenesis. MUTYH gene encodes a DNA glycosylase that can initiate the base excision repair (BER) pathway and prevent G:C > T:A transversion by excising adenine mispaired with 8-hydroxyguanine produced by reactive oxygen species (ROS). We performed a case-control study to test the association between polymorphism in the MUTYH gene Tyr165Cys and head and neck cancer risk progression.

Methods: Genotypes were determined in DNA from peripheral blood lymphocytes of 193 patients (among them 97 subjects with precancerous hyperplastic laryngeal lesions and 96 subjects with head and neck cancer) and 140 age, sex and ethnic-matched cancer-free healthy individuals.

Results: We found an association between head and neck cancer risk and the Tyr165Tyr variant of the MUTYH gene (OR 2.18; 95% CI 1.19-3.97). For Tyr165Tyr genotype we also observed positive correlation with cancer progression assessed by tumor size (OR 4.56; 95% CI 1.60-12.95). We did not observe any correlation between Tyr165Cys polymorphism of MUTYH gene and precancerous hyperplastic laryngeal lesions risk.

Conclusions: The Tyr165Tyr polymorphic variant of the MUTYH gene may be associated with head and neck cancer in Polish population.

Development And Problems Of Palliative Care In Albania
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Objectives: The goal is to present the development, problems of Palliative Care and the efforts of palliative care workers in Albania.
care teams operating in Albania to include this service in the governmental policies.

**Methods:** In this study are described the work and efforts of three palliative care teams in Albania as well as the National Albanian Association for Palliative Care on the development of palliative care, its inclusion in the curricula of Nursing and Medicine faculty, raising awareness of governmental healthcare structures to support this service and increase availability of opioids and other drugs frequently used in terminal care.

**Results:** Ø Meetings with Ministry of Health, parliamentary members, journals and donators. Ø Palliative care doctors are eligible to prescribe opioids without limit doses. Ø Inclusion of palliative care subject in the curricula of Nursing Faculty Ø Preparation of drugs most commonly used for patients with incurable illness in terminal stage Ø Continues trainings on palliative care with health professionals Ø Trainings with health professionals, doctors and nurses from other cities aiming the setting of other palliative care teams in such areas.

**Conclusions:** Further development of Palliative Care, despite its difficulties and problems, is supported by governmental institutions.
Conclusions: Our results suggest that capecitabine may evoke a pronounced cyto- and genotoxic effect in head and neck cancer cells, whereas it may not induce such effects in normal cells, which justifies further research on the suitability of CAP in head and neck cancer therapy.

26-353
Effect Of Cpp-Acp Paste And Artificial Saliva On Hardness Of Intact Enamel Eroded By A Cola Drink: An In Vitro Study.
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Objectives: The present study aimed to evaluate prevention effect of Casein Phosphopeptide-Amorphous Calcium Phosphate paste and artificial saliva on hardness of intact enamel eroded by a Cola drink.

Methods: Ten extracted human premolars were embedded in acrylic resin and positioned on the testing platform. The baseline nanohardness measurements (10 indentations on the buccal surface of each specimen) were conducted by Berkovich indenter using an Ultra-micro Indentation System (Fischer-Cripps Laboratories Pty Ltd, Australia) with a maximum force of 450 mN. For the experimental group, 5 specimens by randomization were applied with CPP-ACP paste (Toothmousse, GC Asia Dental, Japan) according to the manufacturer’s instruction and stored in artificial saliva (37 degree Celsius) for 1 hour. Another 5 specimens were stored in artificial saliva for 1 hour as control. Simulated demineralization process alternatively immersed each specimen in the Cola drink (Thai Namthip Co.Ltd, Thailand) for 5 seconds and the artificial saliva (Chulalongkorn University, Thailand) for another 5 seconds for 10 cycles. Three demineralization processes were conducted with a waiting period (storage of specimens in the artificial saliva for 6 hours) between each process. The demineralized nanohardness measurements were repeated on the same area of each specimen after the whole demineralization process.

Results: The baseline and demineralized nanohardness in GPa were 4.42 ± 0.38 and 4.00 ± 0.43 for the experimental group and 4.26 ± 0.41 and 3.71 ± 0.89 for the control respectively. The experimental group showed less reduction of enamel hardness than the control group after the demineralization process. However, the enamel hardness decreased significantly in both groups (paired Student t-test, p<0.05).

Conclusions: The CPP-ACP paste and artificial saliva cannot prevent the reduction of enamel hardness eroded by a Cola drink in vitro.