

Journal of Oncology Pharmacy Practice

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J Oncol Pharm Pract 2010 16: 5
DOI: 10.1177/1078155209356733

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Abstracts

Platform Presentations

P1

Comparison of ondansetron versus palonosetron in chemotherapy-induced nausea and vomiting for patients receiving intraperitoneal cisplatin chemotherapy: a retrospective analysis on the use of healthcare resources
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Objective: To analyze the differences between ondansetron and palonosetron in healthcare resource use (i.e., inpatient/outpatient encounters) among patients receiving intraperitoneal cisplatin.

Method: A medical record review was performed. Intraperitoneal cisplatin administrations for gynecological cancers from January to June 2006 and from October 2007 to June 2008 were stratified into two groups based on serotonin-receptor antagonist used. The occurrence of chemotherapy-induced nausea and vomiting (CINV)-related hospital readmissions, emergency department (ED) visits, and outpatient encounters occurring within 7 days after cisplatin was compared. CINV-related resource use was defined as events associated with dehydration, hypovolemia, nausea/vomiting, hypokalemia, constipation, shortness of breath, or syncope/collapse.

Results: Ondansetron and palonosetron were used in 39 and 89 cisplatin administrations, respectively. The baseline characteristics were similar between the two groups with mean age of 59 years and ovarian cancer being the most common cancer. Length of stay was approximately 2 days. Palonosetron was always administered as a single-day therapy while 1, 2, and 3 days of ondansetron were administered in 25%, 61%, and 14% of cycles, respectively. A trend towards more CINV-related hospitalizations with ondansetron compared to palonosetron was observed (5.1% vs. 0%, $p=0.09$) with no significant difference in CINV-related ED or outpatient encounters.

Conclusions: Palonosetron was associated with a trend to a lower risk of CINV-related hospital readmission than ondansetron in patients receiving

intraperitoneal cisplatin for gynecological cancers. The duration of ondansetron therapy was not optimal with 25% of patients receiving only 1 day of therapy. These findings need to be confirmed in prospective, randomized trials.

P2

An evaluation of myelosuppression in obese patients with a capped BSA
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Objective: The primary objective of this study is to evaluate the incidence of grade 3/4 myelosuppression in capped obese versus nonobese patients.

Methods: This was a retrospective chart review of data collected from January 1, 2000 to September 30, 2008. Patients included obese (BMI > 30 kg/m²) and nonobese (BMI < 25 kg/m²) with lung, colorectal, and hormone refractory prostate cancer. Obese patient's chemotherapy doses were capped at a BSA of 2.2 m². Patients were eligible if they were receiving their first cycle of chemotherapy. Patients were excluded if they received concurrent or recent radiation to their pelvis.

Results: A total of 285 patients were included in this analysis, 41 patients were obese and 244 patients were nonobese. The patients consisted of 74.4% lung cancer, 23.2% colorectal cancer, and 2.4% had prostate cancer. Baseline characteristics were similar between both groups with a median of four cycles of chemotherapy. Incidence of grade 3/4 hematologic toxicities were lower in the obese group 29.3% in comparison to the nonobese group 40.2% ($p=0.493$). Similarly, the incidence of grade 3/4 nonhematologic toxicities were lower in the obese group 17.1% versus the nonobese group 20.5% ($p=0.613$).

Conclusions: Capping the dose of chemotherapy shows an overall reduced risk of toxicity, suggesting that there may be room to increase the dose cap above 2.2 m² as is commonly practiced.

P3

Palonosetron uniquely inhibits substance P-mediated responses *in vitro* and *in vivo*

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Objective: To determine if palonosetron differentially inhibited NK-1/5-HT₃ crosstalk, this could help explain its unique efficacy profile in delayed emesis.

Methods: *In vitro*: NG108-15 cells were pre-incubated with palonosetron, granisetron, or ondansetron. Subsequently, antagonists were removed and the effect on serotonin enhancement of SP-induced calcium release was measured. *In vivo*: Rats were treated with palonosetron, granisetron, or ondansetron. Single neuronal recordings of nodose ganglia expressing both NK-1 and 5HT₃ receptors were collected following stimulation with SP.

Results: *In vitro*: Serotonin enhanced SP-induced calcium ion release in NG108-15 cells. Palonosetron but not ondansetron or granisetron inhibited the serotonin enhancement of the SP response. *In vivo*: Neuronal responses to SP were significantly enhanced in the presence of cisplatin. Palonosetron, but not ondansetron or granisetron, dose-dependently inhibited the cisplatin-induced SP enhancement. This inhibition was observed when palonosetron was administered 30 min before or 5 or 10 h after cisplatin administration.

Conclusion: For the first time, we have shown that palonosetron, but not ondansetron and granisetron, inhibits SP-induced calcium ion release *in vitro* and SP-induced neuronal responses *in vivo*. The results may help explain the unique efficacy observed with palonosetron in delayed CINV in the clinic.

P4

Dosing patterns, hematologic outcomes, and costs of erythropoiesis-stimulating agents (ESAs) in chemotherapy-treated cancer patients initiated on FDA-approved fixed ESA dosing: real world data from the D.O.S.E. registry

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Objectives: Data from the D.O.S.E. registry, an ongoing US study of ESA-treated CIA patients, were analyzed for ESA dosing patterns, hematologic, and economic outcomes in patients initiated with epoetin alfa (EPO) 40,000 Units or darbepoetin alfa (DARB) 500 mcg (FDA-approved fixed initial doses).

Methods: Adult cancer chemotherapy patients receiving ≥ 2 treatments with the same ESA between January 2006 and May 2009 were identified. Patients exposed to both ESAs were excluded. Outcomes included transfusions, blood utilization, office visits and Hb determinations, cumulative ESA dose, and cost (using 5/2009WAC (EPO \$14.44/1000 Units, DARB \$4.94/mcg)).

Results: 540 patients (420 EPO, 120 DARB) from 44 sites were included. Baseline characteristics were similar among groups, except a lower proportion of the EPO-treated group received iron supplementation (EPO 11%, DARB 20%, $p = 0.02$). Mean administered dose was 42,000 Units for EPO and 488 mcg for DARB. Proportion of patients requiring transfusion after Day 28 was lower in the EPO group (EPO 14%, DARB 22%, $p = 0.03$) as was blood utilization (mean units/study patient: EPO 0.4, DARB 0.7, $p = 0.02$). Office visits were lower among EPO-treated patients (EPO 6.7, DARB 8.1 visits, $p < 0.005$), but Hb determinations were higher (EPO 7.7, DARB 5.9, $p < 0.001$). Cumulative dose (associated ESA cost) was 295,058 Units (\$4261) for EPO and 1750 mcg (\$8643) for DARB ($p < 0.0001$ for cost).

Conclusions: Among cancer chemotherapy patients initiated with fixed ESA doses, EPO patients experienced significantly lower transfusion frequency, blood utilization, and office visits than DARB patients, but more Hb determinations. DARB cost was twice that for EPO, an effective 103% price premium.

Poster Presentations

Translational/Basic Sciences

1

Comparative Schild plot analyses of 5-HT₃ receptor antagonists: palonosetron exhibits unique profile

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Objective: The objective of this work was to determine if palonosetron displays unique molecular interactions with the 5-HT₃ receptor that could provide a scientific rationale for observed clinical efficacy differences.

Method: Previously, using binding studies we showed that palonosetron exhibits allosteric binding and positive cooperativity to the 5-HT₃ receptor in contrast to ondansetron and granisetron, which exhibit simple bimolecular binding. The present work further details this difference by monitoring receptor function as measured by calcium ion influx.

Results: Binding constant (K_d) values for ondansetron, granisetron, and palonosetron obtained from Schild plots were 6.7 ± 1.4 , 1.2 ± 0.1 , and 0.054 ± 0.007 nM, respectively. The slope of the Schild plots for ondansetron and granisetron were -1.04 ± 0.02 and -1.08 ± 0.05 , respectively. These values were not significantly different from 1.00. Further, each plot exhibited similar x and y intercepts. In contrast, the slope of the Schild plot when using palonosetron was significantly different from 1.00 (-1.39 ± 0.06 , $p < 0.001$) and the x and y intercepts were significantly different from each other.

Conclusion: The results suggest that palonosetron's interaction with the 5-HT₃ receptor is more complex than a simple competitive interaction and is in accord with our earlier results from mode of binding studies that indicate palonosetron is an allosteric modifier that induces positive cooperativity.

Clinical Sciences

2

Spontaneous regression of erlotinib-induced papulopustular rash: need for new management approach?

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Objectives: The objectives of this study are to document the presence of spontaneous regression of rash, examine current approaches to rash management and determine its effect on disease outcome.

Methods: Patients with diagnosis of lung or pancreatic cancer were screened. Retrospective chart reviews were conducted in patients who received erlotinib 100–150 mg PO daily. The time course of the EGFR-induced skin rash, the dosing regimen of the EGFR, and the intervention management were examined.

Results: A total of 152 medical charts were screened with 11 eligible patients. Five patients exhibited spontaneous regression of rash up to 14 months follow-up. Six were not evaluable because the erlotinib dose was modified. Patients who experienced spontaneous regression of rash trended towards longer time to disease progression.

Conclusion: This review confirmed the occurrence of spontaneous regression of papulopustular rash in patients who received erlotinib. Prospective observational study is needed to better document the time course of these skin rashes. Practitioners should be made aware of the potential difference between EGFR Mab and TKIs-induced skin rash to determine if different management approaches should be considered.

3

Safety and efficacy of pegfilgrastim 6 mg versus 3 mg once-per-chemotherapy-cycle dosing: a retrospective analysis

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Objective: This preliminary retrospective analysis evaluated pooled data for patients who received pegfilgrastim doses equivalent to 3 or 6 mg.

Methods: Five studies were included; patients were randomized to receive pegfilgrastim 30, 60, 100, or 300 mcg/kg. The equivalent fixed-dose levels were calculated as dose level (mcg/kg) times baseline weight. Patients were categorized into two dose-groups: ~3 mg-‘half-dose’ (2.5 to <3.5 mg) and ~6 mg-‘full-dose’ (5.5 to <6.5 mg). Efficacy and safety endpoints included incidence of FN and any grade bone pain, respectively, in chemotherapy cycle 1.

Results: Of the 557 enrolled patients, 22 received the ~3 mg-‘half-dose’ and 66 received the ~6 mg-‘full-dose’. Incidence of FN (95% CI) was numerically higher in the ~3 mg-dose group [18.2% (5.2–40.3)] than the ~6 mg-dose group [10.6% (4.4–20.6)]. Incidence of bone pain (95% CI) was similar in the two treatment arms; 45.5% (24.4–67.8) and 37.9% (26.2–50.7), respectively.

Conclusions: These results suggest that reducing the recommended dose of pegfilgrastim may lead to increased risk of FN and is unlikely to decrease the overall incidence of bone pain in cancer patients.

4

Utilization of evidence-based assessment to develop warfarin protocol for management of venous thromboembolism in oncology patients at an oncology medical office

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Objective: Use evidence-based approach to design an anticoagulation protocol for oncology patients to improve INR control, prevent significant bleeding and recurrent thrombosis.

Methods: Literature review to identify potential risk factors. Patients with active malignancy and receiving warfarin full anticoagulation therapy were examined using retrospective chart review to capture presence of risk factors, incidence of bleeding, recurrent VTE, and poor INR control. Fisher’s exact test, logistic regression, and one-way ANOVA were used to evaluate the associations between various potential risk factors and outcomes.

Results: One hundred and forty patients were screened and 30 subjects were eligible. Most risk factors (i.e., catheter, growth factors, type of chemotherapy, co-morbidities, smoking, and use of alcohol) did not show association with adverse events. The presence of malabsorption demonstrated positive association with bleeding ($P=0.04$) and overall risk of adverse events ($P=0.06$).

Conclusion: Based on the results obtained in this evaluation, a specially designed anticoagulation protocol for oncology patients with VTE may not be warranted. The use of low dose oral vitamin K supplement in cancer patients with malabsorption can be explored to improve anticoagulation therapy.

5

Efficacy of iron repletion without erythropoiesis-stimulating agent in patients with chemotherapy-induced anemia

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Objective: To evaluate the response to parenteral iron therapy in patients receiving chemotherapy who did not receive an erythropoiesis-stimulating agent.

Method: Data were collected through retrospective chart review. Patients receiving chemotherapy who received at least one dose of intravenous iron from January to December of 2008 were included. Data collected included baseline demographics, baseline hemoglobin, serum ferritin, transferrin saturation, change in hemoglobin at weeks 4, 8, and 12, and the incidence of PRBC transfusion. The primary endpoint

was the percentage of patients receiving PRBC transfusion. Secondary endpoints included average change in hemoglobin response and the percentage of patients with a hematopoietic response

Results: A total of 68 patients were evaluated. The baseline hemoglobin was 10.1 g/dL. The baseline ferritin and transferrin saturation were 204.1 ng/mL and 12.9%, respectively. The percentage of patients requiring RBC transfusions was 16.2%. The average hemoglobin at 12 weeks was 10.9 g/dL and the average increase in hemoglobin at 12 weeks was 0.79 g/dL. The percentage of patients achieving a hematopoietic response was 32.3%.

Conclusion: Intravenous iron repletion has been shown to augment response to ESAs in chemotherapy-induced anemia. Prior trials have shown that the percentage of patients who achieved a hematopoietic response with ESA alone versus those who received IV iron plus an ESA was 61% and 68%, respectively. Given the recent decrease in use of ESAs, our study shows that parenteral iron monotherapy may decrease transfusion rates and decrease the level of anemia in patients receiving chemotherapy. Further studies evaluating this prospectively are warranted.

6

Evaluation of palonosetron utilization in a large ambulatory cancer center

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Objectives: The purpose of this analysis is to quantify and characterize palonosetron usage at our center. A secondary objective is to use our findings to develop cost-effective guidelines.

Methods: A retrospective analysis of palonosetron utilization was conducted over a 3-month period. Special attention was paid to the antiemetic regimen employed in both the acute and delayed setting prior to initiating palonosetron. Data was collected from electronic MARs, pharmacy records, and drug utilization reports.

Results: Fifty-nine patients received palonosetron for a total of 149 doses. Palonosetron was administered

cycle 1 in 31% ($n=18$) of patients and initiated concurrently with aprepitant in 78% ($n=14$) of patients. Palonosetron was initiated after cycle 1 in 69% ($n=41$) of patients and used in combination with aprepitant in 68% ($n=28$) of these patients. Approximately, 50% of patients received adequate corticosteroids cycle before palonosetron was initiated. The most common chemotherapy regimens identified contained carboplatin, cisplatin, or doxorubicin/ cyclophosphamide.

Conclusion: Palonosetron use was quantified and characterized. Opportunities exist for improving antiemesis management by optimizing corticosteroid use through education. This data will be used to develop cost-effective guidelines.

7

Fluorouracil surface contamination study

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Objectives: Fluorouracil was targeted for examination by our safety team. A study was designed to determine the feasibility of using UV-HPLC and an appropriate cleaning formula to extract and identify the extent of fluorouracil on work surfaces in the chemotherapy preparation areas. A spill recently occurred in the delivery space and this area was compared to work areas within the preparation room.

Methods: A method was developed and validated for limits of detection using a linearity model. Three test areas where the vials are handled were marked off. A low-residue wipe was used with 0.1N NaOH. A test wipe was spiked with 0.01 mL fluorouracil as a blinded control. The test cloths were then soaked in water, filtered, and solution concentrated with a roto-evaporator to a 2 mL chromatography sample. Tests were conducted in triplicate and compared against a standard curve.

Results: Validation analysis showed that the limits of detection at 10^{-7} mg/mL. The tests showed that the floor area where deliveries were made had lowest concentration of drug present. The second highest was on the floor directly in front of BSC. The highest

concentration of fluorouracil was found on counter area below where the drug is unpacked from delivery bin.

Conclusions: This study demonstrated the need for improving safety of handling chemotherapy vials. The drug was found in highest concentrations where no direct spills have occurred, indicating drug is present on the outside of the container. Further tests are needed to validate cleaning methods and solutions.

8

An outpatient oncology treatment center approach to enhancing continuity of care related to dispensing oral chemotherapeutic agents

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Objectives: To improve overall patient satisfaction, enhance continuity of care, and provide comprehensive services to our oncology patients, the Kellogg Cancer Care Centers (KCCC) opened a Point of Care Pharmacy (POC) with involvement from the multiple disciplinary staff.

Method: An initial survey was performed prior to opening of the KCCC POC pharmacy to gauge patient access and understanding of these medications as well as to determine overall satisfaction with their current dispensing pharmacy.

Results: Of the 45 patients surveyed, 37% said they were not counseled or educated on their new medications and only 15% were contacted by the pharmacy staff for follow up to check adherence or monitor for adverse effects. Overall, the respondents' average patient satisfaction scores for their current pharmacy were 3.8, based on a 5-point scale.

Conclusions: The KCCC POC pharmacy opened in August 2009 and is staffed by an oncology-trained clinical pharmacist with previous community practice experience. The pharmacy provides intensive medication counseling and education, adherence monitoring, assistance in side-effect management, patient financial assistance when necessary, and intervention documentation. The new pharmacy has filled over 400 prescriptions, which necessitated

pharmacy intervention on numerous patient treatment plans. Initial patient and staff satisfaction has been extremely positive and a formal follow-up survey will ensue.

9

Evaluation of the use of plerixafor at a large national cancer center

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Objectives: The purpose of this evaluation is to characterize the use of plerixafor at a large national cancer center, and to determine if appropriate patient evaluation and administration are occurring.

Method: All adult patients administered at least one dose of commercial plerixafor from January 1, 2009 to October 1, 2009 were evaluated. Patients on plerixafor from June 1, 2009 to September 30, 2009 were compared to all patients who were mobilized for stem cell collection and diagnosed with multiple myeloma (MM) or lymphoma during that time.

Results: There were 48 patients who received 96 infusions. Diagnosis included: NHL (66%), Hodgkins (18%), MM (12%), CLL (2%), testicular (2%). Plerixafor was used first-line in 38 patients (79%), of those 84% met collection target during first attempt. Full evaluation and correct dosing (related to CD34+ count and CrCl) occurred in approximately 82% of patients. Average CD34+ count was 8.49 (range 0-32.5; SD = 7.76). Inappropriate use, defined as doses wasted or given when not needed, occurred in 12.5% of patients. Overall, there is a trend towards increased use in lymphoma patients vs. MM 30.8% vs. 12.2%, $p = 0.068$, respectively and a trend towards increased use in lymphoma vs. MM patients in nonchemotherapy mobilizations, 53.3% vs. 26.7%, ($p = 0.118$), respectively.

Conclusion: Plerixafor can be important in the mobilization of stem cells, prior to transplant. However, it is a high-cost drug and more defined guidelines may help to evaluate and select appropriate patients for use, and subsequently reduce the number of inappropriate dispenses.

10

Description of oncology patient characteristics and cost analysis associated with the administration of rasburicase in a pediatric academic teaching hospital

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Objectives: The primary objective of this study was to assess the current prescribing practices of rasburicase.

Methods: A retrospective review of patient charts was conducted, beginning September 1, 2002 until April 28, 2009. Patient characteristics were collected including concomitant administration of allopurinol and diuretics, alkalization of urine, and need for hemodialysis.

Results: Thirty-six cases were included in the analysis. Seventy-two doses were administered with repeat doses in 18 cases with an average of three rasburicase doses per case (range 2–6 doses; average dose 0.18 mg/kg/dose). The average length of hospitalization was 24 days (range 3–171 days). The most common diagnosis was acute leukemia (25 cases) followed by lymphoma (8 cases). Six cases were diagnosed with relapsed disease. Allopurinol, diuretics, and alkalization of the urine were utilized in 26, 21, and 20 cases, respectively. Hemodialysis was initiated in three cases for indications other than hyperuricemia.

Conclusions: The majority of patients received rasburicase for elevated plasma uric acid levels in association with high tumor burden and/or additional electrolyte derangements. Due to the cost differential associated with the use of rasburicase, a guideline will be developed to stratify patients at high risk for tumor lysis syndrome and provide criteria for the appropriate use of rasburicase.

11

Dosing trends over time of epoetin alfa (EPO) and darbepoetin alfa (DARB) in cancer patients (pts) with chemotherapy-induced anemia (CIA): results from a prospective observational study

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Objective: Evaluation of ESA dosing trends over time is of interest to healthcare providers given the 2006 FDA-approval of DARB 500 mcg Q3W and the 2007 CMS NCD.

Methods: Data were analyzed (January 1, 2004 to May 8, 2009) from the D.O.S.E. registry, an ongoing US study of ESA-treated CIA pts. Chemotherapy pts ≥ 18 years old with ≥ 1 EPO or DARB treatment were included. Pts receiving both ESAs, with ESRD or MDS were excluded. Data from 2007, when NCD was announced, were excluded.

Results: 1662 pts (694 EPO, 968 DARB) from 65 sites were included. 8487 ESA doses were administered (EPO 3660, DARB 3638 (2004–2006) and EPO 695, DARB 494 (2008–2009)). EPO 40,000U and DARB 200 mcg were predominantly administered during 2004–2006, and during 2008–2009, EPO 40,000U and DARB 500 mcg were most common. Proportion of pts initiated with EPO doses $>40,000$ U decreased from 12.5% (2004–2006) to 3.4% (2008–2009). Proportion of all administered EPO doses $>40,000$ U decreased from 28.3% to 11.9%; mean[SD] EPO dose administered for all injections reduced 12.7% (46,556[15,997]U to 40,620[9676]U) during the same periods. Proportion of pts initiated with DARB doses >200 mcg increased from 23.9% (2004–2006) to 65.6% (2008–2009), as did proportion of all DARB administered doses (27.9% and 55.9%, respectively). Mean[SD] administered DARB dose for all injections was 242[100]mcg in 2004–2006 and 293[151]mcg in 2008–2009, an increase of 21.1%.

Conclusions: Fewer pts were initiated on EPO doses $>40,000$ U over time, with an associated decrease in mean EPO doses administered. In contrast, the proportion of pts initiated with DARB >200 mcg increased over time with an increase in mean DARB administered dose.

Process Improvement/ Pharmacoeconomics

12

Identification of intravenous chemotherapy wastage and implementation of a monitoring and management program resulting in significant cost savings

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Objectives: The objective of this study was to implement a monitoring and management program to minimize chemotherapy wastage and optimize cost savings for the pharmacy department.

Methods: Documentation of chemotherapy wastage over a 2-month period in 2005 and 2007 was conducted through a wastage monitoring log that captured the date of wastage, drug specific information, and reason for wastage. A chemotherapy management program was implemented based on the findings. In 2006, delayed preparation of expensive chemotherapies, specifically monoclonal antibodies (i.e., bevacizumab, rituximab, etc.), was implemented. In 2008, additional expensive chemotherapies were added to the list for delayed preparation. Descriptive statistics were utilized to analyze the data.

Results: A total of 143 chemotherapy doses were wasted over 2 months in 2005. The most frequently wasted drugs were bevacizumab, docetaxel, gemcitabine, oxaliplatin, and rituximab. The total cost of wastage was ~\$90,400, extrapolating to over \$500,000 annually. Monitoring of wastage over 2 months again in 2007 identified 61 chemotherapy doses wasted, similar to those drugs wasted in 2005. The total cost of wastage was ~\$42,000, extrapolating to \$250,000 annually. The continued chemotherapy wastage resulted in approval of one FTE hematology/oncology clinical pharmacy specialist. The chemotherapy ordering oversight provided by this new position resulted in reductions in chemotherapy wastage over two months in 2008 to \$15, extrapolating to \$90 annually.

Conclusions: Identification of significant chemotherapy wastage and implementation of delayed preparation and hematology/oncology clinical pharmacist oversight has resulted in negligible amounts of chemotherapy wastage, significant cost savings, and reductions in chemotherapy errors.

13

Summary of the detection of docetaxel and paclitaxel exposures in the work environment using ChemoGLOTM

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Objective: To evaluate if ChemoGLOTM accurately quantifies trace amounts of docetaxel and paclitaxel in the work environment.

Methods: ChemoGLOTM kits were sent to three healthcare institutions to evaluate (1ft × 1ft) areas for docetaxel and paclitaxel. Each kit contained swabs, wiping solution, vials, and other materials. Wiping solution was used to wet the surface and then the two swabs were used to wipe the surface horizontally and vertically. Docetaxel and paclitaxel concentration were determined by LC-MS/MS.

Results: Docetaxel and paclitaxel concentrations were linear and quantifiable from 1 ng/mL/ft² to 1000 ng/mL/ft². Twenty test areas were sampled. The mean ± SD (range) of docetaxel concentrations detected: 161.0 ± 282.7 ng/mL/ft² (1.4–847.7 ng/mL/ft²). The mean ± SD (range) of paclitaxel concentrations detected: 400 ± 508 ng/mL/ft² (17.1–1,530.9 ng/mL/ft²).

Conclusions: No relationship between detection of docetaxel and paclitaxel at each wiped area exists. Docetaxel and paclitaxel detected by ChemoGLOTM were within range of cytotoxic exposures for cancer cells. Detected exposures are similar to plasma exposures of docetaxel and paclitaxel in patients

associated with toxicity. The relationship between detected exposures and resulting exposures in staff and associated side-effects are unknown. Risks associated with chemotherapy contamination exist, thus it is important for organizations to reduce these risks. ChemoGLOTM can readily and easily assess exposure levels of docetaxel and paclitaxel in work environments.

14

Standardization of the pediatric chemotherapy process: a patient safety initiative

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Objectives: Develop and implement standardize order sets consisting of pre-printed chemotherapy order forms, pre-printed medication administration record and a pre-printed pharmacy dispensing record that corresponds to COG treatment protocols.

Methods: A Chemo Medication Safe Practice Team, consisting of an oncology specialist pharmacist, a protocol specialist pharmacist, four pediatric oncology nurses, and four pediatric oncologists was formed to review and approve COG protocol specific pre-printed order forms and corresponding MAR. A pharmacy chemotherapy dispensing record, the triple check form, was also developed to reflect the protocol for a complete plan of care.

Results: Prior to the introduction of standardize pediatric order sets, many handwritten chemotherapy orders were problematic requiring multiple pharmacy interventions. After the introduction of the pre-printed forms, there has been a 93% reduction in chemotherapy transcribing and calculations errors.

Conclusions: Standardized pediatric chemotherapy forms improved safety by creating a consistent and streamlined method of ordering COG regimens/protocols. Outcomes of this process include: improved efficacy and accuracy in writing, checking, interpreting, and entering chemotherapy orders; decreased pharmacy chemotherapy preparation turn-around times; increased nursing chemotherapy administration efficiency; shortened length of stay/throughput times for pediatric patients and their families.

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Cost-benefit analysis of a darbepoetin alfa administration order form at a private oncology practice

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Objectives: To examine the impact of cost avoidance from the implementation of a darbepoetin alfa (EPO) Administration Order Form (AAOF) at a private oncology practice to reinforce compliance with the 2007 guidelines of the Centers of Medicare & Medicaid Services (CMS).

Method: Patients who received EPO for chemotherapy-induced anemia from May 1, 2008 to February 28, 2009 following the implementation of the AAOF were screened. Retrospective chart reviews to collect: patient demographics, renal function, hemoglobin, and hematocrit levels before chemotherapy and during EPO treatment period, date of last dose of chemotherapy, initial and maintenance doses of EPO, dosing frequency, and duration of therapy of EPO. Cost analysis to determine the projected reimbursement loss due to noncompliance to CMS guidelines. Comparative assessments were performed using data prior to and after implementation of AAOF.

Results: Fifty-three out of 223 patients screened were enrolled. Median age = 67 years, median BMI = 25.1 kg/m², female (66%), with breast cancer (35.8%) the most common. Inappropriate documentation of AAOF = 35.8% (19/53). Comparative noncompliance assessment using Z proportion test showed statistically significant ($p < 0.0001$) in initial weight-based dose and dose frequency before and after implementation of AAOF which is confirmed using c2 association test. The number of inappropriate dose adjustments appeared to have reduced. Cost benefit analysis showed approximately \$72,611 annual cost avoidance.

Conclusion: Implementation of AAOF has statistically improved the compliance of EPO use according to the CMS guidelines resulting in cost avoidance. Additional staff education may further improve the effectiveness of the AAOF.

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Evaluation of elastomeric and electronic medication pumps at an outpatient cancer center*George Carro; Abigail Harper; Jessica Lawton*

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Objectives: The objective of this study was to evaluate ambulatory electronic pumps versus nonelectronic elastomeric infusion devices for continuous infusion chemotherapy in an outpatient cancer center.

Methods: Cost comparison was completed relative to four factors: economic outcomes, efficiency, customer loyalty, and safety.

Results: Cost comparison between an electronic pump and two different elastomeric devices (Baxter infusors and Grifols Dosi-fuser) showed a \$20,000 annual savings with the elastomeric devices due to decreased equipment costs. The maximum savings were seen with the Dosi-fuser. The evaluation revealed a more efficient workflow and significant reduction in time and resources by utilizing the elastomeric pumps, resulting in an additional annual cost savings of \$25,000. Patients preferred the elastomeric device to the electronic pump for the following reasons: lighter, more convenient, quieter, and more discreet. Pharmacy preferred the elastomeric device because it decreased preparation time, storage space, and documentation because they do not require pump tracking, batteries, calibration, or maintenance. Pharmacy preferred the Dosi-fuser because only one size pump is required for most patients' doses. Multi-disciplinary oncology staff preferred the elastomeric device due to simplified patient education and decreased after hour calls. The elastomeric pumps also proved to have fewer malfunctions, which require multi-disciplinary intervention and result in suboptimal patient care. Elastomerics provide an increased safety measure by eliminating the potential of programming errors associated with the electronic pumps.

Conclusion: The pump evaluation project resulted in the practice change to elastomeric pumps, which afforded the cancer program cost savings, more efficient workflow, increased customer loyalty, and safety.

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Use of an automated compounding device to extend beyond use dating of pharmaceuticals from single-dose vials*Ryan Forrey; Dana Harms; Deborah Day-VanLone*

The Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University, Columbus, OH, USA

Objective: The objective of this study was to determine if automated compounding technology could decrease waste of medications while maintaining compliance with USP <797>.

Methods: Two outpatient pharmacies were selected to participate based on volume and specific pharmaceuticals commonly used. Four drugs were studied: rituximab, cetuximab, gemcitabine, and oxaliplatin. Over 7 weeks from April to May 2009, the Gri-fill® System 3.0 (Grifols, USA) automated compounding device was used to save the remaining drug from the selected SDVs after 6 h of use. Technicians recorded volume saved from each vial.

Results: The annualized savings for the limited subset of drugs and sites was \$111,532, or approximately 10% of the total waste estimated in the 2008 study. The average savings per vial was: \$233.20 for rituximab, \$255.55 for cetuximab, \$211.50 for gemcitabine, and \$535.90 for oxaliplatin.

Conclusion: Compounding technology to allow sterile transfers, such as the Gri-fill® System 3.0 can decrease the amount of pharmaceutical wastage and maintain compliance with USP <797>.

Trainee Research

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Fluoroquinolone prophylaxis in adult acute myeloid leukemia (AML) patients undergoing consolidation chemotherapy*Karissa Kusick; Jun-Yen Yeh; Marc Earl*

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Objective: Determine the rate of hospital admissions due to neutropenic fever in AML patients who received bacterial prophylaxis compared to those

who did not receive prophylaxis after high-dose cytarabine (HIDAC).

Methods: This study was conducted by a noninterventional, retrospective chart review. Patients were included if they met the following criteria: a diagnosis of AML between January 1997 and December 2008, age ≥ 18 , and received HIDAC chemotherapy regimen (six doses) for consolidation phase treatment. Patients were excluded if they were not discharged from the hospital after consolidation chemotherapy or if they were receiving antibacterial prophylaxis with any antibiotic other than a fluoroquinolone. Data were collected from the medical record that included basic demographics, drug, laboratory, and microbiology information. Study data were entered into a Microsoft Access database and analyzed with descriptive statistics for the primary and secondary outcomes.

Results: Patients receiving fluoroquinolone prophylaxis had a 31% absolute reduction in hospital admissions due to neutropenic fever compared to the historical control group (50.7% vs. 84%; $p < 0.001$). Patients in the treatment group also had a shorter average hospital length of stay compared to the control group (7.9 days vs. 10.5 days; $p = 0.007$) and fewer hospital days per chemotherapy cycle (4.2 days vs. 8.9 days; $p < 0.001$). A 19% reduction in the incidence of blood stream infections was observed in the treatment group compared to the control group (23% vs. 42%; $p = 0.009$).

Conclusion: Microbiology outcomes demonstrated a reduction in the incidence of blood stream infections in the treatment group compared to the control group; however, patients receiving fluoroquinolones had a statistical significant increase in developing resistant Gram-negative and Gram-positive infections.

Encore Presentations

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Multidisciplinary use of oncology pharmacist-generated medication calendars

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Objective: To create an individualized medication calendar for all oncology patients.

Methods: In 2003, the oncology pharmacists developed an individualized medication calendar program to help parents manage their child's medications and to overcome some challenges that exist during patient counseling sessions. The medication calendars allow the pharmacists to effectively educate the patient/parent regarding complex administration instructions of high alert chemotherapy as well as supportive care medications.

Results: Multidisciplinary uses, including: (1) pharmacists, nurses, and physicians (e.g., medication reconciliation upon ER visits, clinic visits, or inpatient admissions; as a compliance tool; medication counseling and discharge planning; (2) clinical research associates (e.g., store completed and signed medication calendars for both study and nonstudy patients; use the medication calendars as a record of home medication administration; and by (3) parents (e.g., document doses of medications on the medication calendar; keep track of symptoms of pain, constipation, or fever; help parents answer medication-related questions from health-care professionals).

Conclusion: Patients/parents find pharmacy-generated medication calendars extremely helpful to visualize and understand complex medication administration instructions. This tool increases safety around the administration of high alert medications to pediatric patients at home.

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Bendamustine demonstrates an acceptable long-term safety profile in patients with rituximab-refractory non-Hodgkin's lymphoma: a pooled analysis

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Objective: Data from two studies were pooled to examine bendamustine's safety in rituximab-refractory indolent non-Hodgkin's lymphoma (NHL).

Methods: Bendamustine 120 mg/m² was administered IV on D 1, 2 every 21 days for 6–8 cycles.

Results: One hundred and seventy-six patients (median 61 years; 81% stage III/IV) were enrolled. Ninety-four (53%) patients received ≥ 6 cycles of bendamustine. Median follow-up was 17 (11.5–24) months. Dose reduction and delay occurred in 14% and 18% of cycles, respectively. Adverse events (AEs), mostly grade 1/2, were nausea (75%), fatigue (57%), vomiting (40%), and diarrhea (37%). Ninety-seven percent of patients received antiemetics. Grade 3/4 neutropenia, thrombocytopenia, and anemia occurred in 58%, 25%, and 11%, respectively. Median time to neutrophil and platelet nadir was 21 (1–86) days. Corresponding recovery times were 8 days (2–62) and 14 days (3–63). Growth factors or blood products were used in 33% of cycles; 49% of patients received no growth-factor support. Fifty opportunistic infections occurred in 48 patients, including herpes zoster (HZ) (18), herpes simplex (7), candidiasis (16), cytomegaloviral infection (5), pneumocystis jiroveci pneumonia (2), atypical mycobacterial infection (1), and tuberculosis (1). HZ reactivation tended to increase with prior purine analog exposure (13% vs. 8%). Prophylactic antivirals given to 18 patients prevented HZ outbreaks; an 11% incidence was observed without prophylaxis. Grade 3/4 AE incidence was higher in pts >60 years. Second malignancies occurred in six patients: 3 MDS, 1 CMML, 1 squamous cell carcinoma, and 1 AML.

Conclusions: Bendamustine's manageable safety profile supports its use in rituximab-refractory patients with indolent NHL.

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The efficacy of aprepitant added to ondansetron and dexamethasone for prevention of chemotherapy induced nausea and vomiting (CINV) during autologous hematopoietic stem cell transplantation (aHSCT)

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Objectives: To evaluate the outcomes of ondansetron and dexamethasone compared with aprepitant, ondansetron, and dexamethasone in patients undergoing aHSCT, with BEAM or melphalan conditioning.

Methods: Patients were randomized to receive either ondansetron and dexamethasone on the days of chemotherapy followed by 3 days of dexamethasone (OD) or OD combined with aprepitant 125 mg on the first day of conditioning, followed by aprepitant 80 mg daily until day 0 (AOD). Rescue antiemetics were allowed. Acute phase was defined as each 24-h period of chemotherapy. Delayed phase was defined as the 5 days (0–120 h) following the last dose of chemotherapy. Complete response (CR) was defined as no emesis or rescue antiemetics in a 24-h period. Major response (MaR) was defined as 1 episode of emesis or the need for rescue antiemetics in a 24-h period.

Results: Twenty-four patients were randomized to each arm. Age, gender, prior history of CINV, and conditioning regimen were similar between OD and AOD. There were no significant differences between OD vs. AOD in the rates of acute (25% vs. 25%; $p = \text{NS}$) nausea, CR (62.5% vs. 75%; $p = \text{NS}$), and MaR (37.5% vs. 25%; $p = \text{NS}$). Delayed nausea (87.5% vs. 87.5%; $p = \text{NS}$), CR (8.3% vs. 16.7%; $p = \text{NS}$), and MaR (62.5% vs. 66.7%; $p = \text{NS}$) rates were similar. The most common toxicities reported were nausea, hypophosphatemia, anorexia, and infection.

Conclusion: Although the CR rates for acute and delayed emesis were greater in AOD, the addition of aprepitant did not significantly improve CINV control in this small autologous HSCT population.

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Evaluation of two closed system transfer devices in an Outpatient Community cancer center

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Objectives: To compare the protective efficacy of the Phaseal CSTD to the ICU Medical CSTD against occupational exposure to antineoplastic agents during the admixture process in pharmacy as well as the handling and administration of these infusions in the nursing units.

Methods: The study duration was 4 weeks comprising two phases of 14 days for each system with routine decontamination with surface safe. The chemicals investigated were 5-Fluorouracil, cyclophosphamide, methotrexate, and platinum agents.

Results: Twenty-two percent of the Phaseal trial samples demonstrated lower levels of surface contamination. Forty-four percent of the ICU trial samples showed lower levels of contamination. Thirty-three percent of samples from both systems showed product equivalence. In the treatment areas the terminal Phaseal injector was not consistently utilized but the complete ICU medical system was utilized contributing to 70% lower levels of exposure to the hazardous chemicals analyzed in the study.

Conclusions: The blinded evaluation of both Phaseal and ICU Medical CSTD using blinded controlled admixtures demonstrated that the products are generally equivalent with nondetectable levels for 5-Fluorouracil, cyclophosphamide, and methotrexate (p -values 0.08-0.14). Cyclophosphamide and platinum agents were detected most often. In the pharmacy both CSTD when used in combination with daily surface safe treatment provided equivalent control of surface contamination.