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INSIDE

Evaluating the Effectiveness of the Discharge Process

Seattle Cancer Care Alliance Discharge Medication Study in Hematopoietic Stem Cell Transplant (HSCT) and General Oncology Patients

Terri Cunningham MSN, RN, AOCN
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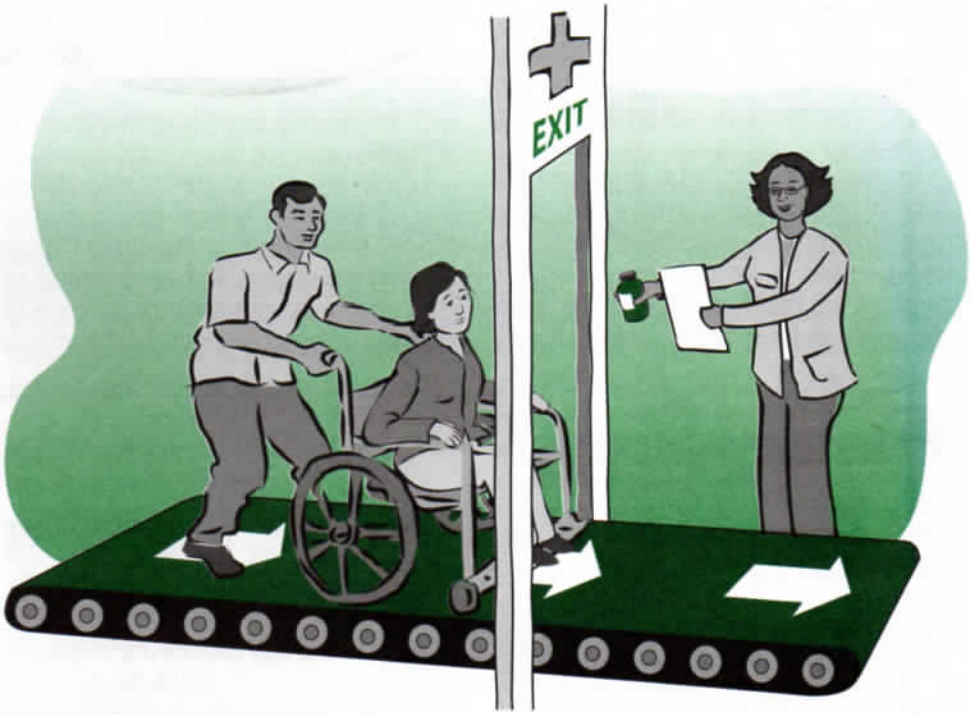
Many patients receiving their cancer care at the Seattle Cancer Care Alliance (SCCA) will have that care delivered in more than one location; the University of Washington Medical Center (UWMC), Children's Hospital and Regional Medical Center (CHRMC) and/or the SCCA Ambulatory Clinic.

The Pan Alliance Nurse Practice Committee (PANPC) was established in an effort to support patients as they move from one location of care to another. The work the PANPC undertakes focuses primarily on establishing consistent patient care practices so that nursing care is similar regardless of what campus delivers the care and facilitating seamless care delivery systems to support communication of patient needs as the patient moves from one location to another. This committee is comprised of staff nurses and clinical nurse specialists representing each of the patient care areas on the three campuses as well as a faculty member from the University of Washington School of Nursing.

As members discussed where the committee should focus its efforts, particularly in the area of facilitating seamless care, a common theme emerged. Committee members felt systems to support communication of patient status and/or needs when patients transition or move from the inpatient to the outpatient setting could be improved. Members also identified concerns about patients' understanding of their discharge medications and patients' accuracy in taking prescribed medications at home.

A literature review was conducted to identify interventions that promote successful discharges or transitions. While the literature available on the subject of transitions was limited, two types of interventions studied were found to be effective, use of discharge planning personnel (Mancher, 2001; Chielens & Herrick, 1990) and providing patients with hand-held records (McGough and Ladd, 1999).



Prior to implementing any type of new strategy, we conducted a study to obtain baseline information on the following questions:

1. How well do patients understand

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PRESIDENT'S MESSAGE

Getting to Know You... Getting to Know Us

Barbara Otto

Barbara Otto NSN, CNRN, OCN
PSONS President

It's hard to believe that my term as PSONS President is almost finished. I feel as if I'm just really getting to know more about our members, and hopefully, helping you get to know more about our chapter. Sitting at the table at a recent board meeting, listening to the committee reports, discussions, and plans, I couldn't help but be proud of the work the board of directors has done on behalf of the chapter - past, present, and future. I'd like to tell you a bit about some of that work.

PSONS is one of the largest ONS chapters - both in size and geography - and with that size comes challenges. One of the challenges is getting timely information to such a large and diverse group of people. Another is getting those people to feel a part of the organization. A third is developing chapter activities that can positively impact on our multiple communities.

In an effort to keep members informed of chapter activities and facilitate chapter business, PSONS is broadening its use of the technology that has become so valuable in our daily lives. Since online registration for the symposium was so well received last year, we plan to implement it again this year and hope to expand the activity to include it as an option for membership renewal.

We'd like to have the chapter website be the first place you refer to when planning your continuing education or have questions regarding legislative/advocacy issues or community events and activities. To that end, our Communications Committee is revising and updating web pages, making them even more user-friendly and relevant. In keeping with the practices of our parent organization, the Oncology Nursing Society (ONS), we've begun sending regular monthly emails to members as yet another way to keep them informed of not only educational offerings and legislative issues, but community and member news, and meeting minutes. For those of you who prefer the print medium, we, of course, will continue to publish our award-winning quarterly newsletter and specific mailings as in the past.

I think you would agree that continuing education is one of our strengths. PSONS consistently provides educational sessions, classes, and symposiums of high caliber at reasonable or no costs to members (just check out the Education page on the website!). In an effort to broaden that effort, PSONS has begun collaboration with the local Infusion Nurses Society (INS). This collaboration will involve joint educational offerings and invitations to and reduced registration for members to each other's meetings and symposiums. The goal is to offer an ever wider range of topics at more varied locations.

Community outreach to such a large geographic region can be challenging. Individual members have always been active in planning and participating in outreach efforts. How and where should the chapter focus its efforts? One way is through the food drive for Northwest Harvest that will take place during our annual symposium in March. Another

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EDITORS' NOTES

Cathy Goetsch MSN, ARNP, AOCNP
Janice Gibson RN, MSN, OCN
Co-Editors

This issue is is ecclectic in topic and content. This reflects the variety of our member interests and expertice. One highlight is a profile of our hard working treasurer Michealle Wetteland. Terri Cunningham and her colleagues share research results from a study funded through PSONS. Once again, updates on new cancer drugs and new indications are included to help us keep abreast in the recent avalanche of FDA approvals. Judy Petersen has provided a summary of her ASCO poster. Survivorship assistance sponsored by a Lance Armstrong Foundation grant is the focus of our Community Crossings. Announcements of upcoming events are also featured, including our beloved spring PSONS cancer nursing symposium.

As you read through this issue, we hope that you find something of interest. If there is a topic that you would like to see addressed or you would like to write, we are always looking for contributors. Also, we are in need of another co-editor as of March. Please contact Judy Petersen, Communications chair, if you are interested. Contact information for the editors and for Judy are on page 13 of this issue.

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Discharge Process: Study Conducted on HSCT and General Oncology Patients

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discharge medication teaching and are they able to follow their instructions and take their medication as prescribed after discharge?

2. Do ambulatory care nurses receiving discharged patients back into their settings have access to and knowledge of prescribed discharge medications?

Study Design

In order to answer these questions we designed a longitudinal, descriptive study which was reviewed and approved by the IRB. Hematopoietic stem cell transplant (HSCT) and general oncology patients who were admitted to the inpatient areas at the UWMC orCHRMC and received chemotherapy were eligible for the study.

Patients who were enrolled in the study were interviewed (in person or over the phone) by study personnel within three days of their discharge. The patient and/or caregiver were asked to retrieve the discharge medication instruction sheet they were given prior to discharge. Patients and/or caregivers were then asked to report the name, dose, frequency, route, and why they were taking each of the medications they were taking at home. Study participants were also asked which member(s) of the healthcare team provided discharge medication teaching and how satisfied they were the teaching provided.

Study personnel then identified the first nurse that the discharged patient saw in the ambulatory clinic. If the clinic nurse agreed to participate in the study, they were interviewed and asked the following questions: "Did you know this patient's discharge medications?" If yes, "What resource did you use in order to know what the discharge medications were?" (e.g. medical record, patient instruction sheet, the patient, etc.).

If the clinic nurse stated they did not know the patient's discharge medications, "Could you please provide more information about that?" (e.g. they did not know where to look, they did not know the patient had been admitted and discharged from the hospital, etc.). Clinic nurses were also asked "Is reviewing a patient's current medications a part of your nursing assessment?"

Study Findings

HSCT and general oncology patients and clinic nurses were enrolled at UWMC, CHRMC, and the SCCA Ambula-tory Clinic between August and November of 2005. Study findings from UWMC and SCCA Ambulatory Clinic will be reported. 53 adult patients were enrolled, 27 HSCT patients and 26 general oncology patients. Mean age of enrolled patients was 47.8 yrs

(range 20-83 yrs.), 30 men and 23 women were enrolled, and average number of medications at discharge for HSCT patients was 17 and for general oncology patients was seven. The number of days between discharge from the hospital and first appointment at the outpatient clinic was 0-2 days for HSCT patients and 0-19 days (mean of 5 days) for general oncology patients.

Of the 53 patients enrolled, 36 (68%) of the patients were interviewed. These interviews were with the patient only (17), caregiver only (6), or both the patient and the caregiver (13). When patients/caregivers were asked to retrieve discharge medication instructions, 76% of HSCT patients/caregivers remembered receiving written instructions and 56% of general oncology patients remembered receiving written instructions. Nurses and pharmacists were the healthcare providers who most commonly provided discharge teaching about medications.

Study personnel compared three sources for congruency of information about patient's discharge medications; the discharge orders written by the MD, the written discharge medication instructions provided by the nurse, and patient report of their discharge medications elicited during the patient interview. Among the 36 patients who were interviewed these three sources never matched. An unexpected finding was that the nursing instructions about discharge medications matched the discharge orders only 41% of the time.

The types of discrepancies found when matching the three sources (discharge order, written discharge instructions, and patient report) were: a drug name did not appear on all three lists (78%), drug dose did not appear on all three lists (72%), and drug frequency (the exact timing of prescribed medications including drugs ordered "prn") was not the same on all three sources 92% of the time.

While we were very stringent about what was interpreted as "a match", we found that most discrepancies were minor (e.g. discrepancy found in report of "as needed" medications that patient was not taking). Among the 36 patients who were interviewed, there was only one instance where study personnel needed to contact clinic staff to alert them of a dangerous medication discrepancy discovered during the patient interview.

While it was felt that most of the discrepancies were minor, the major discrepancies were: patient reported a wrong dose of a drug or did not report a dose (n=16, 44%), patient reported taking a medication that was not on the discharge order (n=8, 22%), patient reported they were not taking a medication (including "prn" medication) that was ordered (n=18, 50%), or the discharge instruction sheet provided to the patient did not include any information about medications (n=5, 9%). While there were frequent discrepancies in patients' report of drug name, dose, and frequency, the majority of patients (70%) understood the reason they are taking their medications.

Study personnel interviewed the first nurse that the patient saw in the ambulatory clinic (n=36). HSCT patients primarily saw a team or clinic nurse (n=22) and general oncology patients primarily saw an infusion room nurse (n=13).

Nurses were asked if they knew the patients discharge medications. HSCT Team nurses knew patients discharge medications 100% of the time and reviewing patients' current medications was consistently (100%) a part of their nursing practice. Infusion room nurses less frequently knew what the patients discharge medications were (23%) or reviewed a patients current medications as a part of their practice (31%).

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Discharge Process: Mostly Minor Discrepancies Found in Survey

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Conclusions and Recommendations

The findings of this study provide insight into both areas of strength and weakness in our patient education approach and systems to support oncology patients after discharge. Clearly, improvements can be made in the accuracy of the written instructions that patients receive. In discussing study findings with the inpatient staff we found that there were several obstacles that interfered with accurate discharge instructions, for example; last minute additions to the list of discharge medications added after patient instructions were created, computer systems used to create patient education tools are difficult to use, and while multiple providers share in the discharge teaching process, no one provider has been identified as responsible. We also found that due to organizational requirements, there were many locations where discharge medications could potentially be documented. Even with discharge medication information available in multiple locations, many staff in the outpatient areas had difficulty locating discharge medication information (e.g. our pharmacists provided excellent discharge medication sheets to HSCT patients, but these documents were not available to any other provider).

A JCAHO patient safety goal for 2006 involved medication reconciliation. This goal specifies that organizations must maintain a list of patients' current medications and communicate the list of current medications to the next provider of care. The findings of our study certainly highlight the importance of this safety goal.

Organizational improvements that have been established to meet the requirements of this patient safety goal have also addressed the problems we identified in the study. One of these improvements is maintaining a list of patients' current medications (this includes medications ordered at discharge) in a specified location of the computerized medical record.

This location is easily accessible to staff in both the inpatient and the outpatient settings. Another improvement from the medication reconciliation process included outlining the role of nurses, pharmacists, and MDs in maintaining an accurate list of patients' current medications, reconciling medications ordered at discharge with medications taken at home prior to the hospitalization, and the provider responsible for creating discharge medication instruction sheet.

While providing accurate patient instructions is essential, we also felt that follow-up after discharge was important, particularly for patients with complex needs. We found that follow-up after discharge from the hospital for HSCT patients provided an important safety net, especially for this group of patients who, on average, take 17 different types of medications. These patients were seen within 2 days of discharge (usually the next day) and a nurse would review medications with them at this clinic visit.

In contrast, general oncology patients were seen anywhere from day of to 19 days after discharge, and nursing staff generally did not review all of the patients discharge medications with them. While RN staff did not review all of the patients' medications, they indicated that their primary role was to evaluate the types of side effects that the patient was experiencing and ensure that patients had medications to address the side effects and provided patient education on side effect management. We felt this was the appropriate role for the infusion room nurses and do not plan to make any changes in their responsibility for review of medications.

We do believe that some of the general oncology patients would benefit from more immediate follow-up after discharge (e.g. patients discharged after first cycle of chemotherapy) and plan to look at the feasibility of phone follow-up after discharge.

We would like to thank PSONS for providing a research dissemination grant that was used to support travel costs so these study findings could be presented at a podium session of the 2006 ONS Congress, Boston.

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President's Message: Get to Know Your Fellow PSONS Members

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area is to provide cancer awareness and education to underserved communities. As a result of work with the Washington Comprehensive Cancer Control Plan (WCCCP), the chapter recently learned of an opportunity to work with regional coalitions of Native American tribes to provide these services. More information on this will follow as a plan is developed. There are other avenues to explore as well, such as cancer awareness/education at sports events. Please pass on any thoughts or ideas, as this becomes a chapter priority.

Now, a question. How well do you know your fellow members? PSONS is comprised of nurses in varied roles from direct patient care to business and administration, education, and research. It may be surprising to you to know the professional activities and accomplishments of your peers. The chapter and individual members are involved with local, state, and national professional, legislative, and advocacy groups: WCCCP; the ONS Board of Directors, Steering Council, State Health Policy Liaison, committees, and Special Interest Groups (SIGs); Susan G. Komen Foundation; and American Cancer Society are but a few. PSONS members have published and presented in journals and meetings across the country. Help us celebrate these accomplishments! Let us know news that we can include in our electronic and print publications.

PSONS wants to be of value to its members. In order to do that, it needs to get to know them and have them get to know the chapter. Hopefully, we've provided you with opportunities to do just that. The only way for PSONS to grow and develop is through its members.

Look forward to seeing you at Symposium!

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Puget Sound Chapter of the Oncology Nursing Society

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Influence of Tumor Type, Disease Status, and Patient Age on Self-Reported Interest Regarding Participation in Cancer Clinical Trials

by Judy Petersen RN, MN
and Robert Montgomery

Why do patients decide to enter a clinical trial? Which patients are more likely to participate? There is limited information available regarding the reasons cancer patients decide to enter clinical trials.

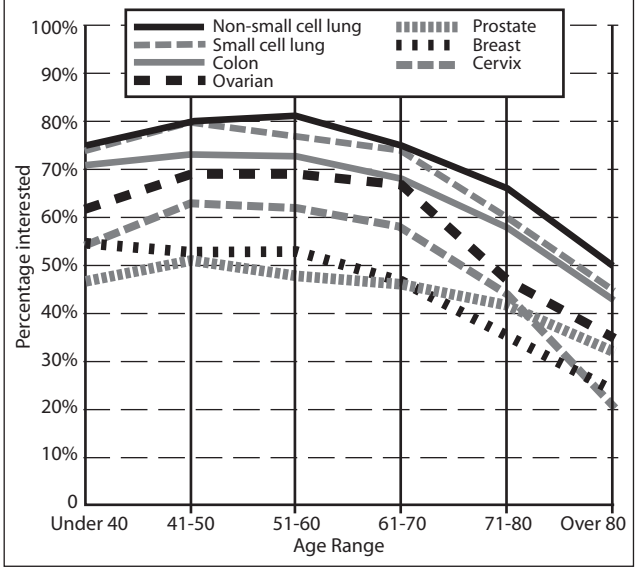
To investigate this issue, aggregate responses to the question, Are you interested in learning about clinical trials? obtained from >115,000 cancer patients (or their families) who entered data into one of several proprietary decision-support tools embedded within approximately 100 well-established cancer-related Internet sites were analyzed.

The percentage of patients (or their families) who expressed interest in learning about clinical trials ranged from as low as 21% (endometrial and cervix cancer patients >80 years of age; n = 178) to as high as 85% (recurrent ovarian cancer patients, age 51-60; n = 842). Patients >80 years of age, regardless of sex, tumor type, or status of disease, were considerably less likely to be interested in clinical trial information than younger individuals.

Whereas there were no differences between males and females in their desire to obtain information, patients with self-declared more serious conditions (e.g., metastatic breast cancer, recurrent prostate cancer), and those with specific cancers having a widely recognized poor prognosis (e.g., nonsmall cell lung cancer), were more likely to request study information. In the current evaluation of a large database of individuals who elected to participate in 1 of several cancer-related decision-support programs, major differences in self-expressed interest in obtaining information regarding clinical trials was observed.

Particularly notable was the reduced desire to gather such information among the very elderly, and the increased interest by patients with the most serious cancer-related conditions.

Influence of Age on the Percentage of Newly Diagnosed Patients Who Responded They "Would Be Interested in Learning About Clinical Trials"



FDA Approves New Cancer Drugs and New Indications for Existing Agents

Gemcitabine

On July 14, 2006, the U. S. Food and Drug Administration granted approval to gemcitabine(Gemzar® , Eli Lilly and Company) in combination with carboplatin for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy. The approval was based on a single multicenter, international, open-label, randomized trial enrolling 356 ovarian cancer patients whose disease had relapsed at least 6 months after first-line platinum-based therapy. Patients were randomized to receive either gemcitabine® 1000 mg/ m2 on days 1 and 8 of a 21-day cycle plus carboplatin (AUC 4) administered on day 1 of each cycle (GC) or to receive carboplatin (AUC 5) administered on day 1 of each 21-day cycle (C).

One hundred seventy-eight patients received GC and 178 patients received C. Patients were comparable for age, baseline ECOG performance status, platinum-free interval, and first-line therapy regimen. GC treatment resulted in a significant improvement in progression-free survival (PFS). Median PFS was 8.6 months for GC-treated patients and 5.8 months for C-treated patients [log rank p=0.0038; hazard ratio 0.72 (95%, C.I. 0.57, 0.90)]. A significant improvement in the investigator-assessed overall response rate was demonstrated for the addition of gemcitabine to carboplatin (47% versus 31%, p=0.0016), but not in the independently reviewed response rate that excluded sonography or physical exam findings (46% versus 36%, p=0.11).

Approximately 75% of patients in each arm received post-study chemotherapy, including 13 of 120 patients on the C treatment arm for whom post-progression chemotherapy drugs were known and who received gemcitabine after progression. No significant difference in overall survival was observed. The median survival was 18.0 months for GC-treated patients compared to 17.3 months for those receiving single-agent carboplatin [p=0.8977, hazard ratio 0.98 (95% C.I. 0.78, 1.24)].

Hematologic toxicity was the most frequent adverse event. Grade 4 (CTC) neutropenia, anemia and thrombocytopenia occurred in 29%, 6% and 5%, respectively, of patients receiving GC compared to 1%, 2%, and 1% of those receiving single-agent carboplatin. Red blood cell and platelet transfusions were more common in GC-treated patients.Grade 3 neurosensory toxicity was observed in 1% receiving GC and 2% of C-treated patients.

Pegaspargase

On July 24, 2006, the U.S. Food and Drug Administration granted approval to pegaspargase (Oncaspar®, Enzon Pharmaceuticals, Inc) for the first-line treatment of patients with acute lymphoblastic leukemia (ALL) as a component of a multi-agent chemotherapy regimen. Oncaspar® was previously approved in February, 1994 for the treatment of patients with ALL who were hypersensitive to native forms of L-asparaginase. Asparaginase exerts selective anti-leukemia activity by depletion of serum asparagine. The current approval is based on similar sustained reductions of serum asparagine concentrations in patients receiving an Oncaspar® -containing regimen compared to patients receiving a native E. coli L-asparaginase-containing regimen. Due to the longer half-life of Oncaspar®, similar anti-leukemic activity was achieved with a single Oncaspar® dose compared to 6-9 doses of native E. coli asparaginase.

The trial (Children's Oncology Group Study 1962) supporting this new indication was an open-label, randomized, multi-center clinical trial that enrolled 118 children (ages 1-9 years) with previously untreated, standard risk ALL. Treatment consisted of a 4-week induction phase (IP) and two 8-week delayed intensification (DI) phases. All patients received multi-agent chemo-therapy regimen consisting of intrathecal cytosine arabinoside and systemic therapy with vincristine, prednisone, and methotrexate with either native E. coli asparaginase or Oncaspar during IP and intrathecal methotrexate and systemic therapy with mercaptopurine and either native E. coli asparaginase or Oncaspar® during both DI phases. Oncaspar® was administered intramuscularly at 2,500 IU/m2 on day 3 of the 4-week induction phase and on day 3 of each of two 8-week DI phases. Native E. coli L-asparaginase was administered intra-

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muscularly at 6,000 IU/m2 three times weekly for 9 doses during induction and for 6 doses during each DI phase.

The two study arms were balanced for most major prognostic factors; however, patients allocated to receive the native E. coli asparaginase-containing chemotherapy had a higher percentage of children ages 1-2 years (34% vs. 19%), with platelet counts <50,000 cells/µl (51% vs. 34%), and with equivocal CNS involvement (15% vs. 7%). The study demonstrated similar mean asparagine concentrations between the two study arms at multiple time-points during all treatment phases. Event-free survival (time from randomization to either death, induction failure, relapse at any site, or start of new cancer treatment) was assessed in all patients. With a median follow-up of 3.2 years, the 3-year event-free survival rates were approximately 80% in both arms.

The most serious, sometimes fatal, Oncaspar® toxicities were anaphylaxis, other serious allergic reactions, thrombosis (including sagittal sinus thrombosis), pancreatitis, glucose intolerance, and coagulopathy. The most common adverse events were allergic reactions (including anaphylaxis), hyperglycemia, pancreatitis, central nervous system thrombosis, coagulopathy, hyperbilirubinemia, and elevated transaminases. Oncaspar® is one of the first FDA approved products to provide prescription information in the new format for prescription drug package inserts. This new format is designed to provide health care professionals and patients with a more concise and clearer presentation of prescribing information.

Full prescribing information in this new format including clinical trial information, safety, dosing, drug-drug interaction and contraindications is available at www.fda.gov/cder/foi/label/2006/103411s5052lbl.pdf.

Changes in the Neumega Package Insert Include Ventricular Arrhythmic and Ophthalmologic Adverse Events

Neumega® (Oprelvekin) was approved in November, 1997 for use in adults with nonmyeloid malignancies who are at high risk for severe thrombocytopenia due to myelosuppressive chemotherapy. Neumega® is indicated for the prevention of severe thrombocytopenia and for the reduction in the proportion of patients requiring platelet transfusions. Neumega® is not indicated for use in children or in patients receiving myeloablative chemotherapy. New adverse event information from post-marketing reports has been added to the Neumega® prescription information. The following statements have been added to the WARNINGS section: "In the post-marketing setting, ventricular arrhythmias have been reported, generally occurring within two to seven days of initiation of treatment. Changes in visual acuity and/or visual field defects ranging from blurred vision to blindness can occur in patients with papilledema taking Neumega® ."

The post-marketing reports of the ADVERSE REACTIONS sections has been revised and reformatted to include reports of optic neuropathy and ventricular arrthymias. In addition to incorporating the new adverse event information into product labeling, Wyeth Pharmaceuticals Inc. (Philadelphia, Pennsylvania) has committed to an evaluation of the effects of Neumega on the QT interval. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions, and contraindications is available at www.fda.gov/cder/foi/label/2006/103694s5065lbl.pdf

Imatinib mesylate

On September 27, 2006, the U. S. Food and Drug Administration granted accelerated approval to imatinib mesylate (Gleevec®, Novartis Pharmaceuticals) as a single agent for the treatment of pediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML). Approval is based upon the induction of both hematologic and cytogenetic responses.

A total of 51 pediatric patients with newly diagnosed and untreated chronic phase CML were enrolled in an open-label, multi-center, single arm phase 2 trial. Patients were treated with Gleevec 340 mg/ m2/day. Complete hematologic response (CHR) was observed in 78% of evaluable pediatric patients after 8 weeks of therapy. The complete cytogenetic response rate (CCyR) was 65%, comparable to the results observed in adult CML patients. The partial cytogenetic response (PCyR) rate was 16%. The majority of evaluable patients who achieved a CCyR developed the CCyR between months 3 and 10 (median time to response 6.74 months). Estimated 12 month survival was 98% and estimated 24 month survival was 84%.

Imatinib generally was well tolerated. Grade 3 or 4 toxicities were primarily hematologic. Non-hematological grade 3 or 4 toxicities included allergic reaction/hyper-sensitivity, avascular osteonecrosis, and desquamating rash. No deaths occurred on study therapy. Only one patient discontinued study drug due to suspected study drug-related AEs (elevated AST/ALT). Muscle cramps were reported sporadically during the study and there were no episodes of GI hemorrhage. No new safety concerns were raised. A required phase 4 commitment is to continue follow-up of pediatric patients with Ph+ CML treated in the Phase 2 study to obtain long-duration safety and efficacy data.

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions, and contraindications is available at www.fda.gov/cder/foi/label/2006/021588s016lbl.pdf.

Panitumumab

On September 27, 2006, the U.S. Food and Drug Administration granted approval to panitumumab (Vectibix™, Amgen, Inc) for the treatment of patients with EGFR-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.
The approval is based on the results of a single, open-label, randomized, multinational study that enrolled 463 patients with metastatic colorectal cancer. Patients were randomized to either best supportive care (BSC) alone or BSC plus panitumumab, 6 mg/kg intravenously, every other week. All patients were required to have progressed following one or more chemotherapy regimens containing a fluoropyrimidine, irinotecan, and oxaliplatin. Confirmation of eli-

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gibility (disease progression following an adequate course of treatment) was verified for 75% of the patients based on review of source documents by an external committee masked to treatment assignment.

The progression and response evaluations were based upon review of radiographs and other source documents by the same independent review group. The mean PFS was 96 days for patients receiving panitumumab and 60 days for patients receiving BSC alone however, the median times to progression were similar (approximately 8 weeks.). There were 19 partial responses (8%) among the 231 patients randomized to panitumumab; the median response duration was 17 weeks. There was no difference in overall survival between the two study arms.

Approximately 75% of patients in the BSC alone arm crossed over to receive panitumumab after determination of disease progression by the study investigator. The majority of patients' tumors exhibited EGFR expression in tumor cells with no evidence of a correlation between either the proportion of cells expressing EGFR or the intensity of EGFR expression.

The most serious toxicities identified in clinical studies of panitumumab were pulmonary fibrosis, severe dermatologic toxicity complicated by infectious sequelae and septic death, infusion reactions, abdominal pain, hypomagnesemia, nausea, vomiting, and constipation. The most common adverse events were skin rash, hypomagnesemia, paronychia, fatigue, abdominal pain, nausea, and diarrhea. Full prescribing information including clinical trial information, safety, dosing, drug-drug interaction and contraindications is available at www.fda.gov/cder/foi/label/2006/125147lbl.pdf

Warning Changes in the Avastin® Package Insert

Information regarding Reversible Posterior Leukoencephalopathy Syndrome (RPLS) in patients receiving Avastin® has been added to the package insert. It is recommended that Avastin® be discontinuation in patients who develop RPLS. Additionally, Nasal Septum Perforation as a Serious Adverse Event in patients receiving Avastin® was also added. Full prescribing information, including the above changes, is available at http://www.fda.gov/cder/foi/label/2006/125085s082lbl.pdf.

Rituximab Supplemental Applications

On September 29, 2006, the U.S. Food and Drug Administration approved two rituximab (Rituxan®, Genentech, Inc.) supplemental applications for the first-line treatment of patients with low grade or follicular, CD20-positive B-cell non-Hodgkin's lymphoma.

One approval was for the use of Rituxan® combined with CVP chemotherapy (cyclophosphamide, vincristine, and prednisone); the second is for use of Rituxan® following CVP chemotherapy. The first indication was based on a 322 patient study. Patients had an advanced-stage, follicular, CD20+ NHL and were previously untreated

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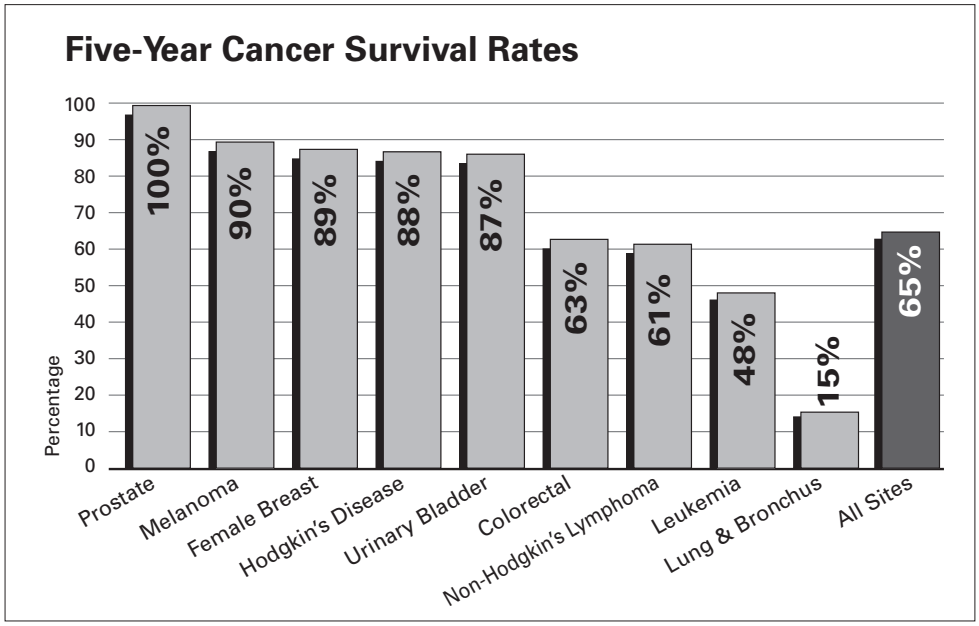
Cancer Survivors: What Comes Next?

Polly Lysen-Halpern, ARNP



Cancer survival rates have risen dramatically in the last several decades in the United States from 3 million in 1970 to over 10 million in 2002. Since the treatments for cancer have proven more and more successful, we now have more survivors than ever before. Along with people living longer after a cancer diagnosis, (see 5 yr survival rates at right) there are often more long term health issues as a result of the treatment.

Survivors often have a difficult time transitioning from cancer patient to survivor. Many survivors are no longer followed by their oncologist and yet do not feel comfortable returning to their primary care provider for cancer related issues. Often times community health care providers are not familiar with the consequences and late effects of cancer and cancer treatment. Furthermore, there is lack of clear evidence for what constitutes best practices when it comes to following survivors concerning the timeline and screening tests for late effects.

From within the cancer survivor community has come the demand for more services, resources, and education devoted to cancer survivors. The Institute of Medicine (IOM) issued a report in 2006 outlining many of the issues that cancer survivors face, with suggestions about how to improve the continuity of medical care as they transition from cancer patient to cancer survivor.

As a result of this IOM report and the increasing demand for more research and medical focus on cancer survivorship, the Lance Armstrong Foundation has funded and developed the LIVESTRONGTM Survivorship Center of Excellence Network that now exist in 7 centers across the country including one at the Fred Hutchison Cancer Research Institute here in Seattle.

Program Overview

The new Fred Hutchinson Cancer Research Center Survivorship Program is a unique program that is available to cancer survivors. This program will augment, and in no way replace, the clinical care cancer survivors are currently receiving from their oncologists or their other health care providers. Patients may be referred by any healthcare provider or maybe self-referred. All cancer survivors are eligible, regardless of their age, diagnosis, place or type of cancer therapy, provided that they have completed their active cancer therapy, with the exception of ongoing hormonal therapy.

The Survivorship Program provides a comprehensive evaluation for cancer survivors with a focus on patient education surrounding the potential long-term non-oncologic medical and psychosocial issues facing cancer survivors. Patients will undergo a risk-adapted history and physical examination and will receive a "Survivorship Care Plan". This plan includes a detailed summary of their cancer treatment, actual and potential therapy-related complications, and evidence-based standards of care for follow-up. Copies of the Survivorship Care Plan will also be provided to the cancer survivor's health care providers. Additional testing or referrals to community resources will be individually tailored, and may include support groups, educational seminars, or health care subspecialty referrals.

Clinical services for the Survivorship Program are provided in the outpatient clinic of the Seattle Cancer Care Alliance (SCCA), located on the Hutchinson Center campus.The SCCA is a collaboration of three world-renowned institutions: the Hutchinson Center, the University of Washington, and Children's Hospital and Regional Medical Center.

We have also established community affiliate survivorship programs to provide survivorship care to previously underserved populations. These include Harborview Medical Center in Seattle WA, Sacred Heart Children's Hospital (SHCH) and Providence Cancer Center (PCC) in Spokane WA and Providence Alaska Medical Center (PAMC) in Anchorage AK, in collaboration with the Alaska Native Tribal Health Consortium. Cancer survivors can receive those services at the community-based centers as they would at the SCCA, allowing them to choose to be seen at the most convenient location for them without compromising their quality of care they will receive.

Clinical evaluations are generally covered by most third party payers and financial counseling is available for those with concerns about ability to pay.

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Cancer Survivors: Referrals Can Result in an Improved Quality of Life

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Survivorship Stories

One of the first cancer survivors that was seen in our program was a 10 year colorectal cancer survivor. He had struggled with many issues as a result of his treatment such as impotence, depression and digestive dysfunction. He didn't feel comfortable going back to his oncologist since he had been out of treatment for many years and wasn't sure if his primary care doctor would be familiar with his cancer diagnosis and treatment and he didn't know where exactly to turn.

One of the most challenging late effects, one that he had struggled with the most was digestive problems. These disturbances had affected his ability to work, his relationship with his wife and his overall quality of life. As part of his visit to the survivorship clinic, he was given education about his cancer treatment and its late effects. He was connected to resources in the community that would be helpful, including several specialists. He was referred to a number of specialists. The referral to a nutritionist proved to make quite a difference in his life. After some dietary changes, his symptoms are nearly gone; he is able to work more effectively and enjoy activities that he had given up on. He and his wife are thrilled with the improvement in their quality of life.

Another cancer survivor that was seen recently was a young male who was treated for AML. He had been married just over a year when he came to the survivorship program. His deepest fear was the unanswered question about whether or not he was fertile, since he had been treated when he was adolescent and was concerned about sterility. After reviewing his treatment records and creating his Survivorship Careplan (SCP) he was given information about his various chemotherapies and the potential late effects. He was counseled about the potential for infertility and given resources and options available to him if he indeed was found infertile. He agreed to have a semen analysis and it was a very happy moment when we were able to give him the good news that his semen analysis was normal.

Most recently, another remarkable cancer survivor was a young woman who battled rectal cancer and won. She was left infertile and menopausal from the radiation, and had had many digestive problems from the multiple intestinal surgeries and radiation treatment. She did not understand the long term consequences of her new menopausal status. She had many questions about supplements and diet, as well as concerns about how to handle recurrence anxiety. Our nutritionists were able to help her clarify many of her questions about supplements and diet. She also received a physical therapy evaluation so that she could begin to plan an exercise program. She had been severely deconditioned after many months of treatment and recovery from her multiple surgeries. Her emotional issues were probably causing her the most difficulty; we were able to spend time talking about the transition from cancer patient to survivor, and she was referred to a therapist with expertise in this area. She like many cancer survivors also struggled with concerns about reoccur-

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PSONS Profile

Michaelle Wetteland RN, MMA, OCN

PSONS Treasurer

Janice Gibson RN, MN, OCN

You may recognize her name since Michaelle has been the treasurer for PSONS for two years. She began her nursing career in Indiana and has had an exciting and varied career that she is still excited about after 30 years. Her nursing roles have included Pediatric oncology for eight years, IV therapy coordinator for seven years, and director of a home infusion center for two years and Nurse Manager of inpatient and outpatient oncology services for twenty years.

She relocated to Seattle from Minnesota in November 1999 and become a staff nurse in the Oncology Infusion Center at Virginia Mason Medical Center (VMMC). She transitioned into the role of manager four years ago and now and coordinates a staff of 20 nurses. She also functions as an instructor for the ONS Chemotherapy and Biotherapy course and is currently participating in management courses and collaboration at VMMC.

Michaelle has been an active member of PSONS and plans to continue in this role after her current term as treasurer ends. The professional attitudes, creative personalities, and phenomenal symposiums have "made me want to stay involved."

Political activity is also a passion for Michaelle. She has been on the board of Doctors Opposing Circumcision for two years and has taken part in legislative action through ONS. This has included writing letters to and receiving responses from Congressman Jim McDermott, and Senators Maria Cantwell and Patty Murray. Issues have included asking Senators to join the bipartisan Senate Cancer Coalition and sending a thank you for supporting cancer reimbursement issues.

Michaelle's role as an oncology nurse took a personal turn when she took time off to care for her parents who were both dying from cancer. She said that the greatest gift that she could have received was being able to take care of parents who were "such wonderful parents to six children". She felt honored to be able to give back for "all that they gave me". When her Mom said that it was the pain that she was most afraid of Michaelle told her that she would take care of her pain. Michaelle felt that because of her oncology nursing background she could discuss dying "fears" openly with her parents.

Michaelle Wetteland

Her husband John is Michaelle's biggest supporter. They have been together since they met in the British Virgin Islands in 1991. She says that he is very supportive of her role and is understanding if she is late for dinner. He tells her often how proud of her he is. In her spare time they enjoy ballroom dancing and sailing on their boat. They are currently planning a move to a houseboat on Lake Union. Michaelle and John enjoy their blended family with daughters Sara and Julian and son Jude (and daughter-in-law Leslee) who will present them with their first grandchild in March 2007.

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Cancer Survivors

Continued from page 10

rence. A gift that she walked away from our visit with was the reassurance that worrying about reoccurrence does not increase her chances of her cancer returning.

Cancer Survivors come from all walks of life. Cancer knows no boundaries. Cancer affects the whole person from physical to emotional to spiritual issues. Cancer affects the cancer survivor's relationships with oneself and others. Cancer affects how each survivor sees the world. Cancer has physical and emotional late effects. Cancer is life altering.

Since we began last March, we have built our program around these basic tenants. We see survivors from every cancer diagnosis, ethnicity and race. We choose to see the whole person and create a Survivorship Care Plan (SCP) that addresses the entire person, not just the cancer.

Our ultimate goal is to empower survivors to be their own advocates and ultimately guide them towards the services and resources that will improve their health and most importantly, their quality of life. Whether it be a simple referral over the phone to a community program or resource or a multidisciplinary clinic visit in the Survivorship program, our main objective is to address the entire survivors' needs. Our program strives to increase the collaboration between medical providers to better serve the overall needs of each cancer survivor.

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with chemotherapy. Patients were randomized (1:1) to receive either a maximum of eight 3-week cycles of CVP chemotherapy alone or CVP chemotherapy in combination with Rituxan® (375 mg/m2 on day 1 of each 21-day cycle). Patients receiving Rituxan® plus CVP showed a statistically significant improvement in progression-free survival compared to those receiving CVP alone (median PFS 2.4 vs. 1.4 years; hazard ratio 0.44, p<0.0001 two-sided stratified log rank test).

The second indication was based on a 322 patient trial enrolling previously untreated low-grade, B-cell NHL (IWF Grades A, B or C) patients with stable disease or partial or complete responses following 6-8 CVP chemotherapy cycles. Patients were randomized (1:1) to receive either no additional therapy or Rituxan® (375 mg/m once weekly for 4 doses) every 6 months for up to 16 doses. A statistically significant reduction in PFS was observed; the hazard ratio for reduction in the risk of progression, relapse, or death ranged from 0.36 to 0.49 for Rituxan® versus those who received no additional treatment.

The safety profile observed in these trials was consistent with the previously described safety profile provided in the product label. Full prescribing information is available at www.fda.gov/cder/foi/label/2006/103705s5230-s5231lbl.pdf.

Vorinostat Approval

On October 6, 2006, the U.S. Food and Drug Administration granted approval to vorinostat (Zolinza™, Merck & Co., Inc.), a histone deacetylase inhibitor, for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma (CTCL) in patients with progressive, persistent, or recurrent disease on or following two systemic therapies. The major trial supporting approval was a single-arm open-label trial conducted at 18 centers in the US and Canada that enrolled 74 patients with stage IB and higher CTCL who had failed two systemic therapies (one of which must have contained bexarotene). All patients received vorinostat at a dose of 400 mg once daily which could be reduced for toxicity to 300 mg orally daily or 300 mg orally five days a week The median age of patients was 61 years. Sixty-one patients (82%) had stage IIB or higher CTCL and 30 patients (41%) had Sézary syndrome. The median duration of protocol treatment was 118 days.

Skin disease response was assessed using a Severity Weighted Assessment Tool (SWAT). This tool calculated an overall score based on the percentages of the total body surface area involved with patch, plaque, or tumor lesions, with weighting of each by factors of 1, 2, and 4, respectively. Response was defined as a 50% or greater decrease in the SWAT score and disease progression as a 50% increase in the score from the nadir.

In this study, 30% experienced responses; the estimated median response duration was 168 days and the median time to tumor progression was 202 days. An additional single center study enrolled 33 patients with similar baseline and demographic features as in the major trial. Thirteen of the 33 were treated at the same dose of 400 mg/day. The responses in these 13 patients were

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FDA Approvals

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similar to those observed in the major efficacy trial.

Adverse events (AEs) were reported irrespective of the relation to the study drug. In the major efficacy trial, the most common clinical AEs of any grade were diarrhea (51%), fatigue (51%), nausea (43%), and anorexia (27%). Grade 3, 4, or 5 clinical AEs included fatigue (7%), and pulmonary embolism (5.4%). Chemistry laboratory abnormalities observed were hypercholesterolemia (66%), hypertriglyceridemia (66%), hyperglycemia (64%), and increased creatinine (45%). Grade 3 or greater chemistry abnormalities included hyperglycemia, hypertriglyceridemia and hyperuricemia, hypoglycemia, hypokalemia, hyponatremia, hyperkalemia, hypercholesterolemia, hypophosphatemia, and increased creatinine. Hematologic laboratory abnormalities were anemia (54%), thrombocytopenia (42%), low white blood cell (WBC) count (24%), and low neutrophil count (14%). Most of these were of grades 1 or 2 in severity.

For safe use of vorinostat, patients must be kept well hydrated and blood counts and chemistry tests should be obtained every 2 weeks during the first two months of therapy and monthly thereafter. Adjustments in diet and drugs may be necessary in patients with diabetes. Full prescribing information, including clinical trial information, safety, dosing, drug- drug interactions and contraindications is available at www.fda.gov/cder/foi/label/2006/ 021991lbl.pdf.

Labeling extension for Bevacizumab

On October 11, 2006, the U.S. Food and Drug Administration granted approval for a labeling extension for bevacizumab (Avastin®, Genentech, Inc.), administered in combination with carboplatin and paclitaxel, for the initial systemic treatment of patients with unresectable, locally advanced, recurrent, or metastatic, non-squamous, non-small cell lung cancer. This recommendation is based on the demonstration of a statistically significant improvement in overall survival (OS) in patients receiving Avastin® with carboplatin and paclitaxel compared to those receiving carboplatin and paclitaxel alone.

The primary trial (E4599) supporting this approval was a randomized, active controlled, open label, multicenter clinical trial evaluating Avastin® plus carboplatin and paclitaxel (n=434) versus carboplatin and paclitaxel alone (n=444). Patients with squamous histology, mixed cell tumors with predominant squamous cell histology, central nervous system metastases, gross hemoptysis (1/2 tsp. red blood), or unstable angina and those receiving therapeutic anticoagulation were excluded from the trial. Patients with squamous cell histology were excluded based on four patients with life-threatening or fatal hemoptysis among 13 patients with squamous cell histology enrolled in a randomized, active-control, Phase 2 study (AVF0757g) who received chemotherapy with Avastin®.

Among the 878 randomized patients, the median age was 63, 46% were female, no patients had received prior chemotherapy, 76% had Stage IV disease, 12% had Stage IIIB disease with malignant pleural effusion, 11% had recurrent disease, and 40% had an

ECOG performance status of 0.OS, the primary endpoint, was significantly longer in patients receiving Avastin® in combination with paclitaxel and carboplatin as compared to those receiving paclitaxel and carboplatin alone (median OS 12.3 vs 10.3 mos; hazard ratio 0.80, p=0.013 stratified log rank test). Although a consistent effect was observed across most subgroups, in an exploratory analysis, evidence of a survival benefit was not observed in women. (HR 0.99; 95% CI 0.79, 1.25).

In E4599, data collection was limited to NCI-CTC grade 3-5 adverse events. Severe and life-threatening adverse events occurring more frequently in patients receiving Avastin® and chemotherapy were neutropenia (27% vs 17%), fatigue (16% vs 13%), hypertension (8% vs 0.7%), infection without neutropenia (7% vs 3%), thrombosis/embolism (5% vs 3%), pneumonitis or pulmonary infiltrate (5% vs 3%), infection with grade 3 or 4 neutropenia (5%

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Letters, articles and announcements are requested from all PSONS members and other readers on topics of interest. Submissions and questions should be sent in electronic format to **janice.gibson@vmmc.org**. Neither the Puget Sound Chapter of the Oncology Nursing Society, the Oncology Nursing Society, the editorial board of the Quarterly, nor the American Cancer Society assume responsibility for the opinions expressed by authors. Acceptance of advertising does not indicate or imply endorsement by any of the above-stated parties. Published four times a year by the Puget Sound Chapter of the Oncology Nursing Society with the support of the American Cancer Society.

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between 9 a.m. and 5 p.m.

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vs 2%), febrile neutropenia (5% vs 2%), hyponatremia (4% vs 1%), proteinuria (3% vs 0), and headache (3% vs 0.5%).

Fatal, treatment-related adverse events in patients receiving Avastin® were pulmonary hemorrhage (2.3% vs. 0.5%), gastrointestinal hemorrhage, CNS infarction, gastrointestinal perforation, myocardial infarction, and neutropenic sepsis.The most serious, and sometimes fatal, Avastin® toxicities are gastrointestinal perforation, wound healing complications, hemorrhage, arterial thromboembolic events, hypertensive crisis, nephrotic syndrome, congestive heart failure, and neutropenic sepsis.

The most common adverse events in patients receiving Avastin® are asthenia, pain, abdominal pain, headache, hypertension, diarrhea, nausea, vomiting, anorexia, stomatitis, constipation, upper respiratory infection, epistaxis, dyspnea, exfoliative dermatitis, and proteinuria. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at www.fda.gov/cder/foi/label/2006/125085s085lbl.pdf.

New Use for Docetaxel in Head and Neck Cancer

On October 17, 2006, the U. S. Food and Drug Administration (FDA) approved docetaxel (Taxotere® Injection Concentrate, sanofi-aventis) for use in combination with cisplatin and fluorouracil for the induction treatment of patients with inoperable, locally advanced squamous cell carcinoma of the head and neck (SCCHN). The safety and efficacy of Taxotere® as induction chemotherapy for patients with SCCHN were evaluated in a multicenter, open-label, randomized trial. In this study 358 patients with previously untreated inoperable, locally advanced SCCHN, and WHO performance status 0 or 1, received either Taxotere® 75 mg/m2 followed by cisplatin 75 mg/m2 on Day 1, followed by 5-fluorouracil 750 mg/m2 /day as a continuous infusion on Days 1-5 (TPF) or cisplatin 100 mg/m2 on Day 1, followed by 5-fluorouracil 1000 mg/m2 /day as a continuous infusion on Days 1-5 (PF). These regimens were administered every three weeks for 4 cycles. Four to 7 weeks after chemotherapy, patients whose disease had not progressed received radiotherapy. Radiation was delivered either with a conventional or an accelerated/hyperfractionated regimen. Surgical resection was allowed following chemotherapy, before or after radiotherapy.

The trial's primary endpoint was progression-free-survival (PFS) and was defined as time from randomization to disease progression or death from any cause, whichever occurred first. Median PFS was significantly longer in the TPF arm (11.4 months) than in the PF arm (8.3 months), (p= 0.0077) [hazard ratio 0.71 (0.56, 0.91)]. Median overall survival was significantly longer in the TPF arm (18.6 months) than in the PF arm (14.2 months), [hazard ratio 0.71 (0.56, 0.90)].

The most frequent adverse events on the TPF arm were neutropenia (93%), anemia (89%), alopecia (81%), stomatitis/esophagitis (55%), and nausea (47%). Grade 3 or 4 adverse events with a greater than 5% frequency in patients on the TPF arm were neutropenia (76%), alopecia (11%), infection (9%), anemia (9%), weight loss (7%), and thrombocytopenia (5%). Approximately 5% of the TPF arm patients had febrile neutropenia and 14% had neutropenic infection. Compared to patients receiving PF, patients receiving TPF had more alopecia, neutropenia, diarrhea, neurosensory abnormality, neutropenic infection, fluid retention, and altered taste or sense of smell.

For this SCCHN indication, the recommended Taxotere® dose is 75 mg/m2 administered as a 1-hour intravenous infusion, followed by cisplatin 75 mg/m2 intravenously over 1 hour on Day 1, followed by fluorouracil 750 mg/m2 day given as a 24-hour intravenous continuous infusion on Days 1-5. Treatment is repeated every 3 weeks for 4 cycles. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at www.fda.gov/cder/foi/label/2006/020449s039lbl.pdf.

Single Agent Gleevec

On October 19, 2006, the U. S. Food and Drug Administration (FDA) granted approval to imatinib mesylate (Gleevec®, Novartis Pharmaceuticals) as a single agent for the treatment of dermatofibrosarcoma protuberans (DFSP), myelodysplastic/myeloproliferative diseases (MDS/MPD), aggressive systemic mastocytosis (ASM), hypereosinophilic syndrome/chronic eosinophilic leukemia (HES/CEL), and relapsed/refractory Philadelphia chromosome positive acute lymphocytic leukemia (Ph+ ALL).

For the treatment of adult patients with unresectable, recurrent and/or metastatic DFSP the recommended dose is 800 mg/day. For the treatment of adult patients with MDS/MPD associated with PDGFR (platelet-derived growth factor receptor) gene rearrangements the recommended dose is 400 mg/day. For the treatment of adult patients with ASM without the D816V c-Kit mutation or with unknown c-Kit mutational status the recommended dose is 400 mg for patients without the D816V c-Kit mutation or with c-Kit mutational status unknown. For patients with ASM associated with eosinophilia the starting dose is 100 mg/day. For the treatment of HES/CE the recommended dose is 400 mg/day. For HES/CEL patients with demonstrated FIP1L1-PDGFR_ fusion kinase, a starting dose of 100 mg/day is recommended. Gleevec® has also been approved as single agent for the treatment of adult patients with relapsed or refractory Ph+ ALL. Recommended dose: 600 mg/day. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at www.fda.gov/cder/foi/label/2006/021588s011-s012-s013-s014-s017lbl.pdf.

Transtuzamab for Adjuvant Treatment

On November 16, 2006, the U.S. Food and Drug Administration granted approval to trastuzumab (Herceptin , Genentech®) as part of a treatment regimen containing doxorubicin, cyclophosphamide, and paclitaxel for the adjuvant treatment of women with node-positive, HER2-overexpressing breast cancer. The approval is based on evidence of a significant prolongation in disease-free survival in women receiving Herceptin and chemotherapy compared to those receiving chemotherapy alone.

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An integrated interim analysis of 3752 women from two NCI-Cooperative Group trials (NSABP B31 and NCCTG N9831) were reviewed. Both studies restricted enrollment to women whose breast cancer demonstrated 3+ overexpression by immunohistochemistry or gene amplification (FISH). All women received standard adjuvant chemotherapy [four 21-day cycles of doxorubicin and cyclophosphamide (AC) followed by paclitaxel administered weekly or every 3 weeks for a total of 12 weeks]. As appropriate, women also received hormonal therapy and local radiotherapy.

Patients were randomized to receive either no additional therapy or to receive Herceptin at 4 mg/kg on the day of paclitaxel initiation and subsequently at 2 mg/kg weekly for a total of 52 weeks. Disease-free survival (DFS), defined as the time from randomization to recurrence, occurrence of contralateral breast cancer, other second primary cancer, or death, was the primary endpoint of the combined efficacy analysis. There were 401 patients without follow-up assessment for DFS at the interim analysis and were censored at study day 1.

At the time of the interim analysis, there were 261 events among 1880 women in the chemotherapy alone arm and 133 events among 1872 women in the Herceptin plus chemotherapy arm. The reduction in the risk of recurrence, second primary or death was 52% (hazard ratio 0.48, 95% CI: 0.39; 0.59). An analysis of overall survival was conducted showing fewer deaths in the Herceptin plus chemotherapy arm; however, the findings were not significantly different and were based on small number of deaths with 96% of the population alive.

The most serious Herceptin toxicities were cardiomyopathy, pulmonary toxicity (respiratory failure, pneumonitis, pulmonary infiltrates), infusion reactions, and febrile neutropenia/exacerbation of chemotherapy-induced neutropenia. The most common adverse reactions with Herceptin were fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia. Adverse reactions requiring Herceptin interruption or discontinuation included severe infusion reactions, congestive heart failure, and significant declines in left ventricular cardiac function. Serial measurement of left ventricular ejection fraction (LVEF) was obtained in the two clinical trials.

Six percent of patients were unable to receive Herceptin following completion of AC chemotherapy due to cardiac dysfunction (LVEF 50% or 15 point decline in LVEF from baseline to end of AC). Following initiation of Herceptin therapy, the incidence of new-onset, dose-limiting myocardial dysfunction was higher among patients receiving Herceptin and paclitaxel as compared to those receiving paclitaxel alone. Of those patients with normal LVEF prior to initiation of Herceptin/paclitaxel, 16% discontinued Herceptin therapy due to clinical evidence of myocardial dysfunction or significant declines in LVEF. Approximately 2% in the Herceptin plus chemotherapy arm and 0.4% in the chemotherapy experienced clinically symptomatic, laboratory-confirmed cardiomyopathy determined by an external review committee. One death was observed among 32 Herceptin-treated patients with clinical evidence of cardiomyopathy. Among the 31 surviving patients, all were receiving cardiac medication at last follow-up and approximately half had evidence of recovery to a normal LVEF (defined as 50%) on continuing medical management. Full prescribing information including clinical trial information, safety, dosing, drug-drug interaction and contraindications is available at www.fda.gov/cder/foi/label/2006/103792s5150lbl.pdf.

As healthcare professionals nurses are a key part of drug safety monitoring. We should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by phone at 1-800-FDA-1088, by facsimile 1-800-FDA-0178, by mail, or by using the Form 3500 at http://www.fda.gov/medwatch/.

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TREASURER'S REPORT

Third Quarter 2006

Balance	$132,813.03
Uncleared checks last quarter	$58,605.59
A. BEGINNING BALANCE	**$74,207.44**
REVENUE	
Dues	105.00
Program Fees	9492.50
Interest Checking	14.68
Interest Savings	0.82
Gains	3182.92
Exhibit Fees	0
Ads	0
Grants/Awards	1275.00
B. TOTAL REVENUE	**$14,070.92**
EXPENSES	
Printing (Typing, xeroxing, etc.)	1730.95
Postage	392.59
Supplies	0.00
Symposium/Meetings	4,556.69
Travel	0.00
Honorariums/Speakers	300.00
Scholarships/Grants	0.00
Website	0.00
Office Support	2,022.34
Chapter Insurance/Dues	0.00
C. TOTAL EXPENSES	**$9,002.57**
D. ENDING BALANCE THIS QUARTER	**$79,275.79**
E. Outstanding Checks	**$730.19**
F. TOTAL (Balance + Checks + Deposits)	**$80,005.98**

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