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PUGET SOUND ONS

ONCOLOGY NURSING SOCIETY

Research Issue

... and other exciting questions

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From the Editor

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In graduate school, thanks to Dr. Betty Gallucci and others, I gained a reluctant respect for the research process, which I thought I had left in the closed binder containing my thesis. However, over the years in practice I became intrigued at how many different ways we treated the same problem, sometimes with seemingly little or no rationale. Finally I came to the realization that I wanted to know *why* we should do things one way or the other. Last April thanks to Dr. Stuart Du Pen and a certain pharmaceutical company I got a chance to try out my wings as a research nurse working with cancer pain management. It was a job I wanted badly. Since that time, with some help, I have learned a lot about research — the importance of a solid study design, the significance of careful subject selection, the sometimes painstaking process of data collection, the excitement of watching a new drug or a new technique work beautifully - just the way you knew it would, the complexities of data analysis, and the painful and somewhat laborious task of preparing the results for publication.

Perhaps the most important research task is that of disseminating information. Easier said than done. Results of medical research involving new drugs or new biologicals may contain sensitive information with implications for corporate marketing, regulatory agency approval, patent applications and other legal details and difficulties. Some of our authors found such pitfalls while putting together this issue of the PSONS Quarterly. Our focus is on current research that is now or will soon impact your practice as oncology nurses. Hopefully the necessary evils of monitoring investigational research reports will not hinder our preparation to care for patients receiving these therapies. The authors represented here offer us a look at the latest and most promising developments in oncology.

Finally, while medical research impacts nursing practice greatly, research *by* nurses focused *on nursing* is perhaps our most pressing need and nicely illustrated in the work described by Dr. Coward. On behalf of the PSONS Board I extend our sincere appreciation and compliments to Patra Grevstad and the PSONS Research Committee for their work also reported here. If you've thought about becoming more involved in research, talk to the people in your institution who do it, pick up the phone and call one of the authors in this issue of the Quarterly, or check in with the Research Committee.

President's Message

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A Happy New Year to you all! I hope you have been able to get away from work pressures and enjoy the holidays with family and friends. I want to update everyone on discussions from our last board meeting.

Frequently, we have inquiries from vendors asking how they can support our organization. As you may know, many companies help support our educational programs, annual symposium, and newsletter. In order to assure best utilization from these sources in the direction that our membership desires, the board will be asking you to rank priorities in the up coming election. In addition, we will be appointing an individual who is designated to solely deal with requests from vendors.

It has also been decided that a Financial Committee be established to oversee the financial management of PSONS. This committee will include the treasurer, the newsletter advertising coordinator, and the vendor contact.

We continue to be pleased with our secretarial service and will be turning over more tasks to them (e.g. membership renewal, hotline and messages, etc.) in the near future.

Looking forward to seeing you at our February Symposium.

PSONS Research Committee Study Results:

A Survey of Hospital Nurses' Awareness and Membership in PSONS and ONS

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The Puget Sound Oncology Nursing Society's Research Committee had its inception in the winter of 1986. It was the idea of the Board at that time to introduce a new committee that would focus on research activities. The primary goal as decided by the committee members was to learn how to conduct a research study, and a second goal was to further the goals of PSONS by conducting a study that would be helpful to the organization in some way.

The project decided upon was "A Survey of Hospital Nurse's Awareness and Membership in PSONS and ONS." The purpose of the study was to examine the membership population in the PSONS organization. We wanted to look at why nurses joined, why they didn't join, why they quit, and any other factors that might affect their participation in this organization. It was decided that the pilot study be conducted at two Seattle area hospitals. A survey was developed and upon completion was distributed to medical-surgical and/or oncology units at both institutions. There were several hundred surveys distributed and 150 surveys returned.

The major findings of the study were as follows. One of the questions asked in the survey was, "Do nurses who care for oncology patients consider themselves oncology nurses?" We found that 54% of those who completed the survey view themselves as oncology nurses. This was an interesting finding and actually a low percentage as all nurses surveyed had some contact with oncology patients. Another question asked was, "Of the nurses who viewed themselves as oncology nurses, what was the percentage that chose to belong the oncology organization?" We found that 14% belonged to PSONS and only 15% belonged to ONS. There were several major reasons which people cited for not belonging to the organizations. Lack of familiarity with PSONS and ONS was the primary reason. Fifty percent stated that they did not have sufficient time to make a commitment to an organization. Thirty percent stated they did not have sufficient financial resources to join the organization. For the nurses who did belong, the most frequently reported reason for joining the organizations was for educational and/or professional growth. In addition, what the nurses liked most about being members was the camaraderie and the publications.

All of the results of the survey have been shared with the PSONS Board Members and Committee Chairs for their information and review. If you would like additional information about the study, please contact Patra Grevstad at the Swedish Hospital Tumor Institute (386-2442).

PSONS Profile

PATTY JORDAN

Pat "Patty" Jordan is President-Elect of PSONS. Patty has been actively involved in PSONS since 1984. Having lived in Seattle since she was five years old, growing up in the northend, Patty considers herself a "native". After receiving her undergraduate degree from Seattle University in 1977, she worked at Swedish Hospital in Seattle. In 1979 she left Seattle to be a Jesuit Lay Volunteer at Hospice of Spokane. Patty worked in her role as a volunteer for a year before moving into a part-time role with the hospice program, filling the rest of her work time as an inpatient oncology nurse in Spokane.

In 1984 Patty moved back to Seattle and began working with the Group Health Cooperative (GHC) Hospice Program. She has been a hospice visiting nurse, an inpatient liaison, and is now the homecare coordinator of the GHC hospice program.

In 1986 she completed her master's degree in nursing from the Oncology Transition Services program through the Department of Community Health Nursing at the University of Washington. Patty is seen by her colleagues as one of the key resource people in the city with respect to hospice care.

Patty's experience on the PSONS Board over the last year has helped to prepare her for the important job of leading PSONS into the 90's! She has also played a major role in the development of PSONS's Legislative Committee. Her professional interest include hospice, home care, palliative care management, governmental affairs, issue affecting nursing in general, and professional challenges of all kinds.

On a more personal note, Patty pushes her imagination and creativity with artistic ventures in weaving, spinning, pottery, and wood working. She likes swimming, exploring Irish folk dancing, and spending time with friends and family. All of us will benefit from getting to know this committed fun-loving lady. Welcome aboard Ms. President.

Patty Jordan

PSONS Profile is contributed by the Public Relations Committee, Irene Karlsen, RN, MSN, OCN, Chair.

Compassionate Use of an Investigational Agent

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Most of you reading this article may already be aware that, prior to the approval of a new pharmacologic or biologic agent, rigorous phase I-III clinical trials must be conducted in order to prove the agent's safety and efficacy. These trials are usually conducted under a commercial IND (Investigational New Drug application). The IND allows only the sponsor and the clinical investigators specifically listed in the application to study the drug.[1] Upon successful completion of these trials, and following submission of an NDA (New Drug Application) for a pharmacologic agent or a PLA (Product License Application) for a biologic agent, the data is reviewed by the FDA, audits may be performed at some of the participating sites where the studies were conducted, and the manufacturing facilities are inspected. If the drug is recommended for approval it will then be released for use in the USA market. Phase IV marketing trials may be conducted at this time, the agent will continue to be monitored for safety and efficacy and new indications for use may be approved. The entire process for initial approval may take anywhere from 6 to 8.5 years.

In 1988 the FDA established procedures to make promising investigational drugs, that are not yet generally marketed, available for patients with immediately life-threatening or serious diseases. As a result breakthrough drugs that are still undergoing clinical phase II-III trials can be used for patients when there is no satisfactory alternative treatment.[2] The criteria for this include the following:

(1) the drug is intended to treat a serious or immediately life-threatening or severely debilitating disease ("life-threatening" being defined to include diseases in which the likelihood of death is high unless the course of the disease is interrupted, as well as diseases or conditions with potentially fatal outcomes; "severely debilitating" referring to diseases or conditions that lead to major irreversible morbidity [3]);

(2) there is no comparable or satisfactory alternative or other therapy to treat that stage of the disease in the intended population;

(3) the drug is under investigation in a controlled clinical trial under an IND in effect for the trial or all clinical trials have been completed;

(4) the sponsor for the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence.[2]

The corporate sponsor applies for use of the investigational agent under a Treatment IND or Treatment Protocol placed under the sponsor's current IND. The sponsor will have on file with the FDA information that includes:

(1) the intended use of the drug;

(2) an explanation of the rationale for use of the drug, including, as appropriate, a list of alternative treatments which ordinarily should be tried before using the investigational agent or an explanation of why the use of the agent is preferable to the use of these approved treatments;

(3) a brief description of the criteria for patient selection;

(4) the method of administration of the drug and dosages;

(5) a description of clinical procedures, laboratory tests, or other measures to monitor the effects of the drug and to minimize risk;

(6) an informational brochure to be supplied to each treating physician;

(7) a commitment by the sponsor to ensure compliance of all participating investigators with the informed consent and Institutional Review Board requirements of the FDA regulations.[2]

The decision by the FDA to support a Treatment Protocol is based on a review of the drug's IND file. There must be supportive evidence from previous and current controlled clinical trials as to the drug's therapeutic benefit.[1] Under the regulations, the manufacturer may charge for its treatment use of a drug to the extent that the charge reflects costs associated with the manufacture, research, development and handling of the investigational agent.[4] Emergency situations sometimes arise in which there is not time to file an IND. In these cases, an investigator or corporate sponsor contacts the FDA and requests authorizations to ship an investigational agent in advance of an IND submission under the Emergency Use provisions as stated in 21 CFR 312.36. I would like to review a current practical example of this FDA program to provide a promising new drug to desperately ill patients.

Recombinant Human Granulocyte-Macrophage Colony Stimulating Factor (LEUKINE™ analog rhu GM-CSF, manufactured by Immunex Corporation in Seattle, Washington) stimulates production of granulocytes, macrophages, and, occasionally, platelets in vivo. It is a bone marrow growth factor or hemopoietin that stimulates the proliferation of marrow progenitors that are committed to myeloid differentiation.[5] **Table 1** details its biologic action. The potential therapeutic applications are numerous. While Immunex research has centered primarily upon its use in bone marrow transplantation, it is also being investigated as an adjunct to chemotherapy to assist in reversing neutropenia, and as a therapeutic agent for persons with diagnoses such as aplastic anemia, myelodysplastic syndrome, i.e., as a potential therapy for granulocytopenic or impaired granulocyte function states, and various infectious disorders.[6]

In response to a large number of emergency use requests for patients with severe granulocytopenia, Immunex, in conjunction with the FDA's Division of Investigational New Drugs, agreed to initiate both a "Compassionate Use" Protocol for GM-CSF and a Treatment IND for marrow transplantation patients not participating in the formal clinical trial. The Compassionate Protocol defines specific eligibility criteria which has allowed a number of patients with granulocytopenia and infection to receive Leukine GM-CSF. Immunex, through these investigational applications, provides the colony stimulating factor free of charge. Patient care costs involved in the administration of the medication, however, remain the responsibility of the participant. This article will discuss the Compassionate Use study and the method of participation.

The compassionate use study allows for participation in the United States of any person with life-threatening neutropenia as defined by an Absolute Neutrophil Count (ANC) of $<500/mm^3$ usually for a period of 2 weeks or more. If the patient meets the other criteria as listed in **Table 2** they are placed on study. At the physician's discretion the participant is given GM-CSF via IV infusion at a dose of $250mg/m^2/day$ (it may be a 2-or 24-hour infusion) or via SQ

injection at a dose of 500mg/m^2/day (divided into 2 doses). The treatment is given over 14 days irregardless of method of administration. Any changes in this schedule must be discussed with and approved by the Immunex Medical Monitor.

As with many drugs there may be side effects; but due to the health and disease status of the majority of participants in this study it may be difficult to determine whether some side effects are the result of the GM-CSF or another causative factor. Therefore it should be emphasized that any toxicity that is unexpected or considered severe should be reported to Immunex whether or not it is believed to be related to Leukine GM-CSF. Previously unreported toxicities must be reported to the FDA by Immunex, as well as serious adverse events as was discussed above. This is one of the sponsor's most important responsibilities during the clinical study period.

Immunex has been conducting the Compassionate Use GM-CSF Protocol (Immunex 8903) under its own IND since Septmeber 1989. This compassionate use treatment is for patients with severe, life-threatening neutropenia, either acquired or genetic. If the patient meets the criteria for the study they are given a 14-day cycle of Leukine GM-CSF after an appropriate (written) IRB approval (either for emergency use in one patient or full approval for all eligible patients) and informed consent are obtained. Copies of these documents must be received by Immunex prior to shipment of GM-CSF. The patient's course of therapy is closely monitored and a Case Report Form (CRF) is completed which documents the patient's response and any adverse events which may have occurred. Additional cycles are approved following review of the therapeutic response by the principal investigating physician at the institution and the medical monitor and clinical research associate at Immunex. The physician must agree to provide this information via the CRF in exchange for the medication (**Table 3**). As is the case with a Treatment Protocol, each physician enrolling a patient in the Compassionate Use Protocol is an "investigator" and must fulfill all investigator responsibilities identified on the Form FDA 1572 and in 21 CFR. The physician must complete an FDA Form 1572 which lists the principal investigator and any co-investigators, the participating institution(s), clinical laboratory facilities to be used, and Institutional Review Board name and address for each participating institution listed. The

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Table 1

BIOLOGIC ACTION OF GM-CSF

On Hematopoietic Progenitors:

Enhances:
- Survival
- Production of:
  - Granulocytes
  - Macrophages
  - Eosinophils
  - Platelets

Stimulates:
- Proliferation of Colony Forming Units (CFU):
  - CFM-GM (granulocyte macrophage)
  - BFU-E]
    CFU-GMM] (in presence of IL-3 and/or EPO)
    CFU-REG]
- Differentiation in the macrophage/neutrophil lineage

On Mature Cells:

Enhances:
- Survival of mature neutrophils
- Neutrophil Phagocytic and chemotactic activity
- Antibody dependent cellular toxicity

Table 2

Inclusion Criteria:
- Neutropenia ANC <500/mm^3 for 2 weeks or more.
- For acquired deficiencies, life-threatening will usually mean recent history of severe infection, with deteriorating symptoms, which antibiotics are not adequately controlling.
- Signed informed consent by the patient or legal guardian which fulfill FDA and institutional guidelines.

Exclusion Criteria:
- Patients with peripheral blast cells >10%.
- Patients with myeloid leukemia, acute or chronic in blast crisis (>10% blasts in marrow)
- Pregnant or lactating women
- Liver disease: Total bilirubin >3x the institutional upper limit of normal
- Renal failure: Serum creatinine >2.0 mg/dl
- Heart disease: Ejection fraction <50%
- Fibrotic marrow (myelosclerosis)
- Patients receiving other experimental drugs
- Patients who are HIV positive
- Patients with unstable blood pressure
- Patients with cardiac arrythmias (atrial fibrillation or ventricular arrythmias) other than unifocal VPCs
- Patients with abnormal coagulation times

Compassionate Use

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Curricula Vitae of the participating physicians listed on this form (principal and co-investigators) must also be provided. These materials are then filed with the FDA and copies are kept in the sponsor's file. Since this study is designed for patients with severe, life-threatening neutropenia, treatment is not delayed until all of this material is received; only the IRB approval and informed consent copy must be in the sponsor's hand prior to shipment of any drug. The additional paperwork should be sent within 2 weeks of starting treatment.

Once treatment is in progress any serious or unexpected adverse event, whether or not it is believed to be related to Leukine GM-CSF, must be reported to Immunex. If GM-CSF is discontinued prior to the completion of the 14-day therapy cycle it must also be reported. If the participant expires during the cycle or within 30 days of its completion it too must be reported to Immunex (the sponsor). Appropriate forms must then be completed by the physician and sent to the sponsor for review. If the incident is to be reported to the FDA the sponsor must do so within a certain period of time, dependent upon the severity of the event and subsequent evaluation. The participating institution's IRB must also be notified of the event either immediately or in an annual report. It is advised that the physician check with the IRB to determine which is most appropriate for the particular situation. The participant's welfare as well as continued surveillance of the safety and efficacy involved in administration of the drug remain primary concerns.

The FDA considers its role and responsibility to be to facilitate the swift transfer of new discoveries from the laboratory to the marketplace. It has "no higher priority" than facilitating the timely availability of important safe, and effective new drug products to treat desperately ill patients.[2] Since the key words here are probably "safe" and "effective" the approval process will not always be "swift." Therefore, the introduction of the Treatment and Compassionate INDs have provided a flexible means of introducing promising new agents into the health care system provided that adherence to the regulatory guidelines for these INDs are followed. Issues concerning third-party reimbursement for investigational agents, patient access to these INDs, their impact on clinical research, and the effects of public pressure on the pharmaceutical industry to release agents for compassionate use balanced by the physician's responsibility to report any adverse events (& the company's responsibility to monitor that compliance) must be addressed for current and future implications. The increase in the activity and expenses involved resulting from the use of investigational agents in this setting impact both the public sector (in the form of the participant, the family, the physician and the cooperating treatment facility) and the pharmaceutical industry today and will continue to play a major role in the future of health care.

Table 3

GM-CSF COMPASSIONATE USE PROTOCOL 8903

1. Physician phones Immunex.
2. Eligibility criteria and patient history is reviewed.
3. If patient meets eligibility criteria or otherwise requested by physician, first packet is sent out.
   - If patient does not meet criteria, case is discussed with Medical Monitor for possible protocol exception.
4. Physician obtains IRB approval and patient consent. Written IRB approval and signed informed consent is returned to Immunex.
5. If eligible, patient is enrolled.
6. Drug is shipped via Federal Express. Case Report Form and Investigator Brochure is forwarded to investigator.

By enrolling patient on study physician contracts to supply Immunex with all required regulatory documentation and return the completed Case Report Form within 2 weeks of completing the treatment period.

References

1. Kessler, DA The Regulation of Investigational Drugs. *New England Journal of Medicine*, 1989, 320 (5); 281-288

2. Young, FE; Norris, JA; Levitt, JA; Nightingale, SL. The FDA's New Procedures for the Use of Investigational Drugs in Treatment. *Journal of the American Medical Association*, 1988, 259 (15); 2267-2270

3. Nightingale, SL. From the Food and Drug Administration: New Procedures to Expedite the Approval of Drugs for Life-Threatening and Severely Debilitating Illnesses. *Journal of the American Medical Association*, 1988, 260 (20); 2980

4. Mattison, N. The FDA's Treatment IND: Current Controversies. *Pharmaceutical Medicine*, 1988, 3; 159-171.

5. Salmon, SE & Liu, R. Effects of Granulocyte-Macrophage Colony-Stimulating Factor on In Vitro Growth of Human Solid Tumors. *Journal of Clinical Oncology*, 1989, 7(9); 1346-1350.

6. Mooney, DF; Gamelli, RL; O'Reilly, M; et al. Recombinant Human Granulocyte Colony-Stimulating Factor and Pseudomonas Burn Wound Sepsis. *Archives of Surgery*, 1988, 123; 1353-1357.

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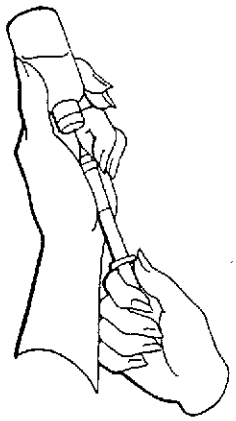
Clinical Research in Antiemetic Therapy



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As the field of oncology grows, we as oncology nurses, find our jobs more challenging with each passing day. Whether we are treating patients with standard or investigational treatments, one concern still rings loud and clear. This is the need for better control of chemotherapy induced nausea and vomiting. Nausea and vomiting continue to be a major side effect of most chemotherapy agents. With the increased use and continued development of chemotherapy agents in which nausea and vomiting are the primary side effects, the need for improved control of nausea and vomiting is an important consideration **not only for the patient being treated, but** for the nurse treating the patient. The severity of a patient's nausea and vomiting secondary to chemotherapy may be the deciding factor in whether a patient continues with treatment. Also, other side effects that result from prolonged nausea and vomiting can be debilitating to the patient and may render them unfit to continue with therapy. It has become "our" responsibility to try our best at preventing this problem for our patients receiving treatment.

We have a "mixed bag" of anti-nausea medications to choose from which include 1) substitute benzamides (Reglan), 2) Butyrophenones (Droperidol), and 3) Phenothiazines (Compazine). We also often use corticosteroids, benzodiazepines, and cannabinoids which play a role in combination antiemetic regimens. One of the most frequently used class of drugs are those that block dopamine receptors such as Reglan. However, at higher doses, which are required to control nausea and vomiting, symptoms may be seen. Combination regimens are frequently used and are quite effective in controlling not only the nausea and vomiting but the side effects of the individual antiemetics themselves. These combinations are quite sedating which may or may not be desirable to the patients.

Granisetron Hydrochloride (BRL 43644A) is a selective 5HT-3 receptor antagonist which is currently under study at the Swedish Hospital Tumor Institute. This drug has been developed by SmithKline-Beecham Pharmaceuticals. 5HT-3 receptors are located at peripheral and possibly central sites and play a large role in evoking emesis[1]. The recent discovery of 5HT-3 receptor antagonists has led to the demonstration in animal models of the importance of these antagonists in chemotherapy induced emesis[2,3]. In animals, these selective antagonists have been shown to potently prevent emesis without side effects.

The Granisetron clinical trial is open to patients receiving cisplatin (50-120 mg/m^2) for the first time (no prior chemotherapy) alone or in combination with other chemotherapy agents. Patients receive one blinded dose of Granisetron (5,10,20,40 mcg) 25 minutes prior to the start of cisplatin. If given in a combination chemo regimen the cisplatin must be given first and over a time period of 3 hours or less. Doses are given intravenously over 15 minutes. Cisplatin must start within 10 minutes of the completion of Granisetron. Patients may receive two additional doses of Granisetron, 3 mgs. each, if necessary, within the first 24 hours of treatment. These are given as "rescue doses" if the patient develops nausea and/or vomiting. This is in hopes that patients will not require any additional antiemetics such that Granisetron will be the only antiemetic used. Patients are monitored for vital signs and a 2 hour assessment of appetite, retching, nausea and vomiting. After the initial 24 hour period, patients may take anything orally for nausea as prescribed by their physician. Patients are followed for 7 days post-dosing to evaluate any latent nausea and vomiting and the need for antiemetics after the initial 24 hours. Side effects of Granisetron noted in the protocol are as follows: increased thirst, headache, increased perspiration, muscle weakness, slight drowsiness, and temporary joint pain.

Thirty-four patients have been treated to date at the Swedish Hospital. In those 34 patients no serious adverse experiences were noted. We have considered 2/34 patients treatment failures (more than 4 emesis events in the first 24 hours). Data on the first 28 patients treated shows that only 1 vomiting episode lasting 3 minutes occurred before 12 hours and 19/28 patients had no vomiting within the first 25 hours. The latent nausea and vomiting was not seen as often and was not as significant as sometimes noted with cisplatin.

Granisetron has shown many benefits for both patients and nurse. The patient can better tolerate chemotherapy lending many benefits such as better nutrition during treatment, decreased length of hospital stay, less risk of dehydration after discharge, and the prevention of nausea and vomiting without sedation. On the other hand, the nurse spends less of her time drawing up and administering antiemetics and has the ability to treat her patient effectively with a single medication. I believe Granisetron will be the drug of the 90's. It has the potential of making a significant difference in the way we treat nausea and vomiting. I believe it will also make a tremendous impact on the way our patients will perceive one of the most significant side effects of most chemotherapy.

References

1. Fozard, J.R. Neuronal 5HT Receptors in the Periphery. Neuropharmacol., 23:1473, 1984.

2. Miner, W.D. and Sanger, G.J. Inhibition of Cisplatin-induced Vomiting by Selective 5HT-3 M-Receptor Antagonism. Br.J.Pharmacol., 88:497-499, 1986.

3. Miner, W.D., Sanger, G.J, and Turner, D.H. Evidence that 5-3 Receptors Mediate Cytotoxic Drug and Radiation Evoked Emesis. Br.J. Cancer., 56:159-162, 1987.

Correlates of Self-Transcendence in Women with Advanced Breast Cancer

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Self-transcendence is defined by Reed as the experience of extending self boundaries inwardly, outwardly, and temporally to take on broader life perspectives, activities, and purpose. In this study, self-transcendence was conceptualized as an indicator of more-being, a term defined by nurse theorists Paterson and Zderad. More-being is the becoming as much more as is humanly possible within the limitations of a particular life situation. Paterson and Zderad believed that the concern of nurses is not just with patients' physical well being, but also with their more-being. They further believed that more-being may be promoted by nurses through relationships with patients that enhance the patient's potential for making choices that lead to increased personal development.

In previous research, self-transcendent views and behaviors in the well elderly and in women with Stage IV breast cancer were associated with emotional well-being. The present study examined relationships among illness distress from cancer and cancer treatment, perceived psychosocial resources available to manage illness distress, self-transcendent views and behaviors, and emotional well-being in women with Stage IIIb and Stage IV breast cancer. It was anticipated that knowledge of how psychosocial resources were useful to women with advanced disease would help nurses facilitate self-transcendence and emotional well-being at a time in their patients' lives when the potential for physical good health was limited.

The study employed a cross-sectional correlational design in a convenience sample (n=107) of women in a large Southwestern city who ranged in age from 29 to 86 years (mean age = 62). The majority of subjects were Caucasian, had completed two years of college, were living with spouses, and had yearly incomes ranging from $20,000 to $29,000. The mean length of time since initial diagnosis of breast cancer was four years. Subjects had lived with advanced disease for a mean length of time of 1.7 years with bone being the most common site of metastases. Almost all the subjects (n=103) had experienced surgery as their initial treatment for breast cancer. At the time of the study, 44 women were receiving chemotherapy, 34 were taking an anti-estrogen, 8 were receiving radiation therapy, and 1 was receiving hyperthermia. Twenty subjects were receiving no treatment for breast cancer at the time of the study.

Subjects completed a paper and pencil questionnaire with 8 instruments indexing symptom distress, functional disability, perceived social support, sense of personal control, spiritual perspective, self-transcendence, affective well-being, and cognitive well-being. Internal consistency coefficient alphas ranged from .76 to .93 and all instruments demonstrated support for validity in the study population. Data were analyzed with descriptive statistics and factor analytic structural equations modeling.

There was no relationship between the amount of distress reported from illness and treatment (measured as symptom distress and functional disability) and the perceived availability of the psychosocial resources of social support, sense of personal control, and spiritual perspective (Beta=.09). However, women who rated themselves high in social support, personal control, and spiritual perspective were also high in self-transcendence (Beta=.70). Women scoring high in self-transcendence were high in emotional well-being (measured by affective well-being and cognitive well-being) (Beta=.40). There was no direct relationship between perceived available psychosocial resources and emotional well-being, or any significant correlations between demographic variables (such as age, income, or education) and self-transcendence or emotional well-being.

The findings indicated that nurses may be able to help women with advanced breast cancer through supporting/facilitating those psychosocial resources that lead to self-transcendent views and behaviors that, in turn, are associated with emotional well-being. Further research is planned to validate the findings of this study and to study nursing interventions related to facilitating increased interconnectedness with others, promoting a sense of personal control, and finding personal meaning in the illness.

Attention!

Curriculum Review tapes are missing!

If you know where these tapes are, please call Anna Williams at 386-2717.

Clinical Practice Review

Case Management of Head and Neck Surgical Patients

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In 1988 the nursing staff of 4 West Oncology at Providence Medical Center in Seattle, identified the need for a consistent program to deal with patients who have surgical procedures involving tracheostomies for head and neck cancers. Staff was unsure of care needs for this population and lacked direction for patient teaching and discharge planning. In developing our plan we knew that our key objectives were to provide consistent, high level care to those patients, and secondarily was the reduction in length of stay which serves to maximize the DRG reimbursement for this category.

During the early months of 1989 a project was undertaken to develop a comprehensive program for head and neck cancers. This program involved a multidisciplinary approach. Team members involved included the clinical nurse specialist, director of the oncology unit, interested staff nurses, respiratory care, speech therapy, nutritionist, cancer care manager, cancer care program assistant, with input from a head and neck surgeon. This committee developed a general patient booklet which serves as a guideline for administering care to this patient population. This booklet was written by the members of the planning committee and includes:

I. Head and Neck Surgery: Surgical descriptions, communication issues, discharge planning, and anatomical descriptions.

II. Resources: Includes those resources available to the patient with a tracheostomy and general cancer care resources.

III. Living with a Tracheostomy: Describes the everyday aspects of coping with a tracheostomy.

IV. Discharge Instructions: Stoma care, changes in daily living that might occur, bathing/showering/swimming, when to call the M.D., and neck and shoulders exercises.

V. Tracheostomy Procedures: Stoma care, tracheostomy tube care and dressing changes, and suctioning.

Procedures were written and inservicing of the nursing staff was accomplished. In June of 1989 the program was completed and implemented. When patients with head and neck cancers are scheduled for surgery they are first seen by a speech therapist where they are initial exposed to the patient booklet. Patients are encouraged to read this book before surgery and bring it with them to the hospital when they come in for surgery. This patient population is then placed on 4 West, a medical/surgical oncology unit, where the staff has been trained to care for these difficult patients with complicated needs.

At the time the project was implemented the average length of stay for head and neck surgery was 16.00 days, but if a simple moving average is applied the length of stay is 12.67 days. The trend of the project has been a reduction in the length of stay, but not as large a difference as averaging would lead us to believe. The forecasted length of stay is now 12.17 days which is roughly .5 days less. This is still off the DRG target length of stay (11.2) by approximately one day. The length of stay appears to show a more constant time frame with less fluctuations which indicates that the program has established some of its objectives through consistency of care.

By looking at the impact of the Head and Neck program as it related to the length of stay we were able to visualize where improvement might take place. All aspects of the patients stay were reviewed and the one area that consistently appeared was a need for a more organized teaching plan. A time line was developed for learning goals so that teaching needs are met over a broader more manageable period of time. Despite a smaller than expected change in the length of stay since the implementation of the program, staff is very satisfied with the completeness and overall organization of the care management of these patients. Our goal is to continue to improve this project as we learn better case management skills.

Business Beat

Judy Kornell, R.N., M.N., O.C.N.
Pain and Toxicity Research
Fred Hutchinson Cancer Research Center
Seattle, WA

Symposium Committee: Pat Buchsel and Joan Bjeletich

The annual symposium is upon us! There are many exciting happenings planned. We have Connie Yarbro, former ONS President, and Editor of Seminars in Oncology Nursing as Keynote Speaker. Also of note is Edith Burkey from Children's Hospital in Philadelphia speaking on high tech home care of pediatric oncology patients. We look forward to Janet Appelbaum presenting this year's Ruth McCorkle Lecture. An abundance of roundtables, 35 in all, will be offered this year. There is a new location for the reception this year - the Lakes Club. Ambiance is assured at this lovely facility which is a sister to the Columbia Towers penthouse club!! ADRIA will again sponsor this event. If you haven't received a symposium registration flyer be sure to call the hotline for information!

Clinical Practice Committee: Joanne Iritani and Annemarie Maguire

The Clinical Practice Committee continues to support the educational programs, helping out with last November's teleconference and this month's program at Northwest Hospital. New in the planning stage are every other month brown bag lunch meetings focused on symptom management. The group plans to cover everything all kinds of topics such as fatigue, pain, nausea, and anything else they can come up with. Clinical Practice Committee meetings are upon to interested members.

Education Committee: Betty Gallucci

Planning is proceeding for upcoming

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PSONS NEWSLETTER
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Editor: Anna Williams

Letters, articles and announcements are requested from all PSONS members and other readers on topics of interest. Neither 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 either of the above-stated parties.

Submit materials for publication to Anna Williams, PSONS Editor, Lake City Professional Center, 2611 N.E. 125th St., Suite 305, Seattle, Washington, 98125-4357. (206) 386-2013

PUGET SOUND CHAPTER HOTLINE!
PSONS has a telephone answering machine. For questions, concerns and comments regarding Chapter activities, please call:
(206) 462-5385
24 Hours
Leave your message, name, telephone number and best times to reach you, on the tape recording.

The Last Word

Renee Yanke, R.N., M.N.
Oncology Clinical Specialist
Whidbey General Hospital
Coupeville, WA

GREETINGS TO ONE AND ALL —

So, What's the latest word from "around the sound"??

There was quite a bit of news from the Tacoma-Olympia area this time around . . .

Congratulations to Carrie Boulet (Good Sam in Puyallup) for being awarded the Founders Award for excellence in Professional Education from the Pierce County Unit of the American Cancer Society. Way to Go, Carrie!

Farewells are sent to Lucy Gorman (Good Sam) who is moving to Texas, accompanying her husband while he attends Nurse Anesthetist school. Good luck!

For those of you interested in pursuing a master's degree, Pacific Lutheran University now has a program for folks interested in becoming a medical-surgical clinical nurse specialist. I understand there is scholarship money available from ACS if your thesis has a focus on prevention and early detection.

Several nurses have changed jobs at St. Joseph's in Tacoma, moving from the Oncology Inpatient unit to Home Health Care or the Outpatient Department. Pam Ketzner, Betsy Reed, and Sharon Anderson have "relocated" to Home Health Care, while Joy Martin and Julie Peerboom have gone to the Outpatient Clinic. Good Luck and have FUN with your new jobs.

PERSONAL: Lee MacDonald, formerly of Skagit Valley Hospital and graduate of Transition Services at the University of Washington - where are you? - please drop us a line or call Hattie Hillier at Skagit Valley Hospital (206) 428-2146.

Finally on a little more serious note . . . we want to remember all the health professionals who have been called up in Reserves or who are active military and involved with Desert Shield. PSONS wants you to know you are in our thoughts and prayers. These also include those family members who are keeping things going at home, like Glenda Sutton (Madigan) commanding troops at home while her husband is in Saudi. I'm sure there are others, too.

Ann McElroy who is working in Saudi - we hope you're safe and doing well - keep in touch!

Well that's it for this edition - keep the information coming, and mark your calendars for the PSONS Symposium in February - see you there!!

Business Beat

Continued from Page 9

spring programs. The March program will be on Colony Stimulating Factors and Bone Marrow Suppression. In April the program will feature a panel of research nurses discussing the clinical trials process.

Membership Committee: Susan Ford

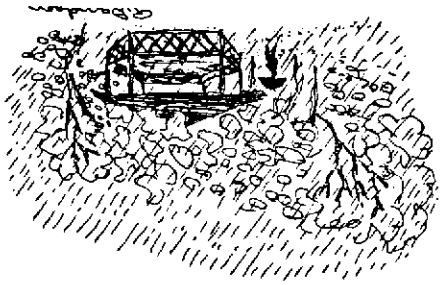
Chapter dues will remain the same low price of $20.00. Please remember the chapter year is January 1 thru December 31. This is probably different than your national dues which cycle from whenever you joined. If you return a completed application (needed for record update and accurate directory information) for chapter renewal by January 15th we will enter you in a drawing for a $25.00 Nordstrom gift certificate to take place at the Symposium (note: need not be present to win, but would be more exciting if you were there to shriek and jump up and down). Unfortunately if we do not receive your dues by the symposium - you're off the mailing list for life (or until you pay dues plus late charge of $5).

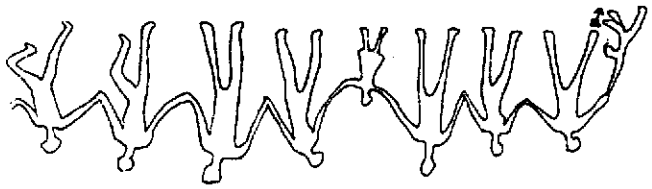
Public Relations Committee: Irene Karlsen

A relatively new committee, the PR Committee seeks to keep PSONS and its members in the forefront of the community. PR is responsible for the PSONS Profile that appears here in the newsletter and will be identifying other ways to spotlight our members. the Public Relations Committee is actively seeking new members. If you are interested in helping out PR please call Irene Karlsen at 386-6959.

WELCOME, NEW MEMBERS!

Jeannine Vedera	Bothell	Shellie McQuarrie	Seattle
Deirde Jones	Seattle	Ellen Rubin	Seattle
Marlene McCulloch	Kent	Doris Coward	Seattle
Janet Imus	Olympia	Annette Yanisch	Chehalis
Peg Bochan	Tacoma	Nancy Paxton	Seattle
Lou Grogan	Cosmopolis	Marianne Sterling	Bellevue
Martha Purrier	Seattle	Cherie Cash	Seattle
Steve Acluff	Federal Way	Teresa Cunningham	Mt. Lake Terrace
Diana Wilke	Seattle	Elizabeth Dunham	Seattle
Lori Krayer	Marysville	Della Durr	Olympia
Nancy Dell	Bellevue	Bruce Markey	Issaquah
Patricia Line	Auburn	Janelle Olney	Seattle





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