This is Where It's At...

Message from the Chairman . Page 1
Cancer Control Research Committee
............................................... Pp 2-3
The Cutting Edge - Surgery
Committee . Page 4
Pharmacy Committee . Page 5
Protocol Update . Pp 6-7
Manuscripts Published . Page 7
The Hope Foundation . Pp 8-9
Plenary Session — Manuscripts & Abstracts Presented . Pp 10-14
Check This Out! CURE — An NCI Funding Program . Page 14
Manuscript Procedures . Page 15
“Crush the Crab” 5K Run . Pp 16-17
Operations Office & Statistical Center News . Page 18
Job Notices . Page 18
Update on New Drugs — ONTAK .
............................................... Page 19
Cancer Survivors Celebration .
............................................... Page 20
CRA Committee News .
............................................... Page 20
Group Meeting Dates . Page 21
Nurse Oncologist Committee .
............................................... Pp 23-24
The Cost of Cancer Trials Study (CCTS) . Page 24
Nurse Oncologist Committee
Membership Form . Page 25
Clinical Research Associates (CRA)
Roster Update Form . Page 26
CRA Committee Videotape Order Form . Page 27
CRA Posters Acknowledgements .
............................................... Page 28

Message From the Chairman

Future of Clinical Trials, 2000 and Beyond

The Cooperative Groups are involved in a major transformation in the way that cancer clinical trials will be conducted. We are planning a Plenary Session at the Southwest Oncology Group meeting in San Diego on the 23rd of October, in which we will discuss all aspects of this new transformation. Many of these issues are a product of the international harmonization efforts conducted jointly by the European community, the United States, and Japan. Many of you have been exposed to the new international common toxicity criteria through tutorials at several of the last Group meetings. The Plenary Session will cover the new international response criteria for solid tumors. This new system employs uni-dimensional rather than our current bi-dimensional system for measurement of solid tumors. This will be established as the new Group response criteria and will apply to all new solid tumor protocols.

We will have a presentation on the new international response criteria for lymphoma, which has been implemented in all new lymphoma protocols. The new web-based Southwest Oncology Group registration system will be demonstrated and will soon be implemented throughout the Group.

Many of you have read about the NCI’s development of a centralized clinical trial monitoring system which will provide for a centralized registration for selected protocols for Cooperative Group and non-Cooperative Group partners to assess Phase III clinical trials. Many of you attended the Clinical Therapy Evaluation Program “Cyber Cafe” and had access to the CTEP internal resources and tools for Internet users. It included such items as adverse drug reporting, common toxicity criteria, common data elements and others. During the Plenary Session at the Group Meeting in San Diego, we will have a number of these web-based presentations to familiarize Group members with these important new tools.

The Southwest Oncology Group is currently exploring two software packages as tools for managing Group clinical trials data at the institutional level. These include KnowMed® and the software package developed by The Computer Department, Inc. We are planning to test these two software packages at a number of major approved sites in the Southwest Oncology Group over the next six months. We will have demonstrations of these two software packages as part of the Plenary Session. These presentations will be open for discussion, and we look forward to your active participation in these new efforts as we begin this new era of web-based conduct of cancer clinical trials.

The purpose of The Group Newsletter is to facilitate Group-wide communication. Articles are welcome; typed hard copy, computer disc and electronic transmission are all acceptable formats for submission. Please send articles to the Operations Office to the attention of Dee Daniel. Next publication date is August 1999. The deadline for receipt of articles in the Operations Office is July 1, 1999. © Copyright 1999.
A Letter from the
Cancer Control Research Committee

Wanted: CCOP Involvement in Cancer Prevention and Control Protocols

Patient or subject recruitment is the lifeblood of any successful program of clinical or translational research. Certain prevention trials, including the large-scale Prostate Cancer Prevention Trial (PCPT) and Breast Cancer Prevention Trial (BCPT), have been very successful in recruiting subjects. Others, however, including smaller translational chemoprevention trials in colorectal, bladder and oral carcinogenesis, have been less successful in subject recruitment.

Cancer therapy trials target patients with a diagnosed cancer needing treatment. These patients likely are strongly motivated to participate in a clinical trial. Cancer chemoprevention protocols target relatively healthy individuals. Compared with that of cancer patients, a greater sense of physical well being can lessen these individuals’ motivation to participate in a clinical trial, especially one with some inconvenience and/or discomfort. Prevention and control recruitment is facing major obstacles in the Cooperative Groups and nationwide. Dr. Lori Minasian (Chief, NCI Community Oncology and Prevention Trials Research Group) recently emphasized the national scope of this issue during the spring meeting of the Cancer Control Research Committee (CCRC) at the Group Meeting in Phoenix. Dr. Minasian also emphasized that recruitment to large prevention trials is very different from recruitment to small phase II translational chemoprevention trials.

One solution, or partial solution, would be to increase prevention and control recruitment and participation within the Southwest Oncology Group Community Clinical Oncology Program (CCOP) members. This has become a major recent focus of the CCRC, in addition to increasing CCOP participation in CCRC planning meetings and activities, especially during the semiannual Group Meetings.

In 1998, the CCRC invited Dr. Harry Hynes to join the Executive Committee as special liaison to the Group CCOPs. With Dr. Hynes’ acceptance, the CCRC embarked on a renewed program of utilizing CCOP expertise and recruitment potential.

CCOPs Featured in Phoenix CCRC Open Meeting

One of Dr. Hynes’ first official acts in his new CCRC role was to conceive and organize a special panel discussion on CCOP issues during the Phoenix Open CCRC Meeting held on May 1. Dr. Hynes and CCRC Chair Dr. Lippman jointly extended personal invitations to PIs and members of all 29 Group CCOPs and of 5 new CALGB/Group CCOPs to attend the meeting and discussion. The 5 new CCOPs are part of a pilot program allowing CCOPs to participate in more than one multispecialty research base.

Entitled “Cancer Control Research: The CCOP Perspective,” the panel discussion was listed second on the meeting agenda, following Dr. Lippman’s scientific presentation “Cancer Chemoprevention: Progress and Promise.” By the time Dr. Lippman introduced panel moderator Dr. Hynes, the audience had swelled to over 100 members. Other panelists were CCRC Biostatistician Laura Lovato and Drs. Ganz, Goodman, Brown, and Lippman.

Dr. Hynes began the discussion with an excellent slide presentation. Explaining that CCOPs are a diverse group, he emphasized that he represents the views of Wichita CCOP, which may differ substantially from other CCOPs’. Dr. Hynes summarized the history and structure of CCOPs in the Group. In 1986, the NCI mandated that CCOPs participate in cancer prevention and control studies. Recruitment to these trials requires more planning than does recruitment to therapy trials, which have enjoyed a better history of CCOP recruitment. CCOP doctors typically are oncologists, and do not routinely see “healthy” patients/subjects in their normal scope of practice. Dr. Hynes gave an example of an initial recruitment plan for the BCPT that called for the family practice physicians to enroll and register their healthy patients. The Wichita CCOP quickly realized that the family practice physicians were uncomfortable with consenting these patients, and so the CCOP investigators changed their recruitment strategies. Dr. Ganz emphasized that oncologists should be the leaders in the field of prevention.

Dr. Hynes also outlined several unresolved logistical issues, including clinic infrastructure and patient referral bases, that limit CCOP participation in prevention and control activities. Cancer control chemoprevention protocols require considerably more staff time than do treatment protocols. Accordingly, Dr. Hynes recommended that new chemoprevention protocol proposals should preview realistic staff time requirements, which also should be clearly detailed in early protocol drafts. Faced with limited staff, CCOP PIs feel uncomfortable in responding to requests to commit to protocols at the concept if they don’t have adequate information about the “staff commitment” involved. Dr. Hynes further recommended that chemoprevention protocols should receive higher “credits” to cover the necessary additional demands on staff.

The CCOPs agree with the importance of cancer control research, but there are problems that must be overcome before CCOPs can substantially increase recruitment to cancer...
Several constructive solutions were proposed during an interactive discussion between CCOP audience members and the panelists. And foremost, the CCRC should solicit input from CCOP administrative and clinical personnel before launching new protocols. CCOPs should formulate specific protocol recruitment plans—addressing, for example, numbers of potential patients/subjects they could put on specific protocols and cancer control credits and other cost/reimbursement issues—before joining clinical/translational trials. This was done in advance of the PCPT and NSABP P-1 (Breast Cancer Prevention Trial), which led to very successful CCOP recruitment to these studies. The NSABP P-2 (Study of Tamoxifen and Raloxifene) in breast cancer prevention is pursuing the same procedure, creating good prospects for similar CCOP recruitment success. Also, CCRC protocols, especially scientifically complex translational cancer chemoprevention protocols, can require lengthy and complex explanations to medical personnel, let alone patients. Specific efforts by CCRC investigators to educate all Group investigators in these areas would help CCOPs in deciding whether to join such protocols. Streamlined protocols and forms will facilitate CCOP participation in Group studies rather than others offered by competing research bases.

Addressing these suggestions, Dr. Lippman commented that Dr. Hynes’ seat on the CCRC Executive Committee was designed to facilitate the bi-directional flow of information and actions between the CCOPs and CCRC. Dr. Hynes is positioned to channel specific proposals to the most appropriate CCOPs, for example directing a proposal to study an agent in preventing colon cancer to CCOPs with strong GI oncology programs and established affiliations with gastroenterologists.

Panelist Dr. Goodman discussed his recent proposal to conduct pilot recruitment studies to assess feasibility of proposed cancer chemoprevention studies. This proposal had been discussed in detail in the Chemoprevention Subcommittee Meeting of the previous day, primarily from the perspective of study coordination in academic institutions. Two cancer chemoprevention protocols, SWOG-9460 (4-HPR in superficial bladder cancer patients) and SWOG-9507 (4-HPR in oral leukoplakia patients), are encountering profound recruitment difficulties and may have benefited greatly from recruitment piloting prior to activation. It would be the responsibility of the primary Study Coordinator to conduct such a pilot study, probably within his or her own institution, before the main study would be considered for Group-wide participation. Logistical obstacles to conducting pilot recruitment studies in CCOPs, such as funding support, were raised, and Dr. Lippman explained that the CCRC has limited discretionary funds for supporting such studies. Dr. Hynes acknowledged feeling a surge of relief upon realizing that Dr. Goodman’s extensive suggestions for conducting recruitment pilot studies were aimed at “protocol PIs,” not “CCOP PIs.”

Panelist Dr. Ganz addressed issues of CCOP participation in behavioral and health outcomes protocols. She straightened out an important misconception and confusion; i.e., that quality of life (QOL) companion studies (to cancer therapy protocols or other non-medical outcome studies) are not assigned independent cancer control (CC) credits. Dr. Ganz assured the meeting that CC credits, or partial credits, which are vitally important to the CCOPs, are assigned independently to these companion protocols, e.g., SWOG-9208 (a QOL companion to the S9133 therapy trial in early stage Hodgkin’s disease) and SWOG-9342 (a health outcomes companion to the S8897 therapy trial in breast cancer patients), both with 0.5 CC credits.

Other issues raised in the discussion included the suggestion to develop more Intergroup protocols to give CCOPs opportunities to participate in a greater number of cancer control studies. It was also suggested that the Group work with drug companies to support trials of nutritional compounds, which, regardless of research status, are increasingly coming into play because of positive publicity in the popular press.

CCOP Discussions to be Regular Feature of Future CCRC Open Meetings

Before closing the discussion, Dr. Hynes queried CCOP members on whether they felt the panel and follow-up discussions were worthwhile and whether they would like similar CCOP discussions to be incorporated in future CCRC Open Meetings. The consensus responses to both queries were positive, and Dr. Lippman announced that 30-to-45-minute CCOP discussions and presentations would become a regular feature of future open meetings. He also commented that the CCRC secured CME credits for open meeting attendance so as to encourage the participation of CCOP and other members.
Spring 1999 Surgery Committee Meeting Report

The Spring 1999 Surgery Committee meeting was held on April 30th in Phoenix, Arizona. It was another exciting meeting for Southwest Oncology Group surgeons. Here are some highlights and previews of coming attractions.

Minimally Invasive Cancer Surgery Subcommittee

The Minimally Invasive Cancer Surgery Subcommittee had a very successful first meeting. Dr. Jay Stauffer, chair of the subcommittee, provided an overview of the topics that the subcommittee will be addressing. They include diagnostic and therapeutic applications of laparoscopy, thoracoscopy and other endoscopic techniques, as well as low-morbidity staging procedures like sentinel lymph node biopsy. This organizational meeting was attended by a number of surgeons representing a variety of disciplines with an interest in these areas. It was agreed to to organize an educational symposium for an upcoming Group meeting on the current status of minimally invasive cancer surgery. This meeting would be targeted to the entire SWOG community, and not just surgeons. We are negotiating with Dr. Coltman for a time slot, perhaps as early as the Fall 1999 meeting in San Diego. Stay tuned to this column for news about this symposium. If you are interested in possibly being a speaker at the symposium, contact Jay Stauffer by electronic mail at jst@uthsc.edu. Beyond that, we are looking for ideas for protocols testing minimally invasive surgery in a variety of settings, and we are working to establish credentialing and guidelines for physicians performing minimally invasive procedures as either qualifying or protocol-mandated surgery on SWOG trials. Right now, the focus remains on breast cancer, where we anticipate that some next-generation adjuvant therapy trials will allow patients properly staged by sentinel lymph node biopsy. Dr. Klimberg is working with the Breast Committee to develop appropriate guidelines and recommendations for inclusion in these trials.

Priority Slot Update

In order to increase the ability of the Group to conduct clinical trials involving local/regional therapy (surgery and radiation), we formed a partnership with the Radiotherapy Committee and requested that Dr. Coltman set aside local/regional protocol development priority slots that would be assigned in a joint Radiotherapy-Surgery effort. The designated protocols will get priority development and be administered by the parent disease committee just like any other protocols of that committee. Dr. Coltman agreed, and the first protocols are beginning to move through the system. The Head and Neck Committee and the GYN Committee are both proceeding with new local/regional therapy trials in the development stage, and the GU Committee is going to use a local/regional protocol development slot to develop a new trial involving brachytherapy (implant radiotherapy) in the management of localized prostate cancer patients who are not considered good candidates for radical prostatectomy. Over the next several months, we hope to formalize the process whereby local/regional protocols get reviewed and assigned a priority slot by forming a joint Surgery-Radiotherapy steering committee. So keep working on ideas for new protocols involving surgery, and we’ll try to find a way to bring them to fruition.

Colorectal Cancer Surgery Consensus Development Conference

In early April, the National Cancer Institute convened a two-day consensus development conference on surgical issues relating to clinical trials in colorectal cancer. Among the aims of this conference were standardizing definitions relevant to colorectal surgery (like where does the colon end and the rectum begin!) and identifying areas for future cooperative group trials. SWOG surgeons were ably represented at this conference by Drs. Jay Stauffer and Norm Estes. Dr. Stauffer reported on the conference to the Surgery Committee. If you have specific questions, comments or suggestions about the conference, contact Jay Stauffer by electronic mail at jst@uthsc.edu.

Group Meeting Registration Surpasses 900 Mark

Registrations at the 1999 Spring Group Meeting in Phoenix, April 28 through May 2, reached 958. This includes those individuals who did not register for the entire meeting, but who attended the Clinical Trials Training Course (CTTC) or the Prostate Cancer Prevention Trial (PCPT) Workshop. We’ll see you by the sea in San Diego, October 20 - 24, 1999!
**Pharmacy Committee**

**News From the Spring 1999 Meeting in Phoenix**

An Update from Siu-Fun Wong, Pharm.D., Pharmacy Committee Chair

"Where Are We?"

Since its formation in 1995, the Pharmacy Committee has recruited over 20 pharmacy members. The committee meetings at the Southwest Oncology Group Meetings are usually attended by about 50% of the members. Our goal in the near future is to bring more pharmacists to the Group Meetings. The Investigational Drug Handling video continues to be used nationally in the training of new personnel at all the member institutions and affiliates. The Research Drug Handling Workshop is being held at each of the Group Meetings and is now providing 1.0 CEU for the clinical research associates. The Pharmacy Committee has recently presented the Body Surface Area Dosing proposal to the Board of Governors and we just completed the creatinine clearance estimation proposal that will be submitted to Dr. Coltman in the next month. The Pharmacy Committee continues to work closely with the Nurse Oncologist Committee and the Clinical Research Associates Committee in providing education programs to the members. All the Pharmacy Committee members continue to compose and update the protocol Drug Information Sections and the Drug Monographs for the upcoming Drug Information Manual. The Drug Information Subcommittee is working hard to compile and coordinate all the drug information materials. The Pharmacy Committee has just received preliminary approval to have pharmacist liaisons at various Disease Committees and we will be looking for more support from all our Pharmacy Committee members.

I would like to express my deepest appreciation for the support of the Pharmacy Committee members:

- **Drug Information Subcommittee:** Janet Linam (chair), Anthony Abang, Aiman Shalabi
- **Research Drug Handling Workshop:** Richard Shine, Suzie Rosendahl, Aiman Shalabi
- **Clinical Research Associate Training Session:** Janet Linam
- **Newsletter:** David Cornelius and Wendy Longmire for her previous contribution.
- **Body Surface Area Dosing Guideline Proposal:** J Aubrey Waddell, John Kuhn
- **Creatinine Clearance Estimation Proposal:** Larry VanHole, Gerald Migaki, Jodee Ireland
- **Nurse Oncologist Liaison:** Dorothy Coleman
- **Clinical Research Associate Liaison:** Sylvia Sluder

In addition, I’d like to acknowledge Dana Sparks and all the individuals at the SWOG Operations Office for their endless support and guidance.

**Membership Application Information**

You are needed! and you are invited to join us! All applications for membership in the Pharmacy Committee should be addressed to Dr. Charles A. Coltman, Jr., at the Southwest Oncology Group Operations Office. The application must include a letter of recommendation from the Principal Investigator of your institution and the curriculum vitae of the applicant. For pharmacists who are already SWOG members, a letter of interest in joining the Pharmacy Committee may be sent directly to Dr. Siu-Fun Wong or Dr. Coltman.

*Next Pharmacy Committee Meeting — Friday, October 22, 1999, 3:00 – 5:00 pm, see you in San Diego!!*

---

**DRUG MONOGRAPH -- Pamidronate (Aredia)**

**Generic & Trade Name:** Pamidronate, Aredia (Novartis)

**Classification:** Bisphosphonates, a bone resorption inhibitor

**Action:** Pamidronate adsorbs to calcium phosphate (hydroxyapatite) crystals in bone and may directly block dissolution of this mineral component of bone. It does not inhibit bone formation and mineralization.

**Indication:** Hypercalcemia of malignancy, Paget’s disease, and osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma.

**Dose Form:** 30mg & 90 mg sterile lyophilized powder with mannitol.

**Storage/Stability:** The dose should be diluted to a concentration not to exceed 0.35 mg/ml. The drug may be further diluted in DSW, NS, and _ NS and is stable for up to 24 hours at room temperature. The rate of administration should not exceed a rate of 1 mg/minute. Pamidronate should not be mixed with Ca++ containing solutions.

**Dose/Administration:**

- **Hypercalcemia** – 60-90 mg (corrected serum Ca <13.5 mg/dL); 90 mg (corrected serum Ca >13.5 mg/dL) IVPB over 2-4 hrs may repeat in 7 days if etiology of hypercalcemia not corrected.
- **Paget Disease** – 30 mg/day x 3 days, may repeat as clinically indicated.

**Adverse Effects:**

- 1. Transient elevation of temperature by at least 1°C 4 to 24 hrs after administration (34% compared to 18% in placebo trial).
- 2. Drug-related local soft tissue reaction (18% for 90 mg dose) manifested by redness, swelling or induration and pain on palpation at the site of infusion.
- 3. Asymptomatic hypophosphatemia and hypomagnesemia.
- 5. Hypocalcemia may lower seizure threshold in patients with malignant disease and brain metastasis (3% reported in three US hypercalcemia trials).

**Nursing Implications:**

- 1. Avoid calcium containing intravenous solution.

S9804. Evaluation of Vinorelbine Tartrate (Navelbine®) in Patients with Disseminated Malignant Melanoma and at Least One Prior Systemic Therapy, Phase II. Study Coordinator: Dr. R. Lavey. Activation, 5/15/99.


C9741. A Randomized Phase III Trial of Sequential Chemotherapy Using Doxorubicin, Paclitaxel, and Cyclo-
phosphamide or Concurrent Doxorubicin and Cyclophosphamide Followed by Paclitaxel at 14 or 21 Day Intervals in Women With Node Positive Stage II/IIIA Breast Cancer. Southwest Oncology Group Study Coordinator: Dr. S. Martino. Permanent Closure (effective 3/31/99).

G0164 A Randomized, Controlled Intergroup Trial of Salvage Therapy With Paclitaxel and Carboplatin Versus Salvage Therapy With Stem Cell Supported High-Dose Carboplatin, Mitoxantrone and Cyclophosphamide in Patients With Persistent Low Volume Ovarian Cancer and Response to Primary Therapy. Southwest Oncology Group Study Coordinator: Dr. P. Stiff. Permanent Closure (effective 6/1/99).


Publications and abstracts listed below have been received in published form by the Operations Office Publication Specialist from February 3 to May 24, 1999.


The Hope Foundation is proud to announce its new website location at [www.thehopefoundation.org](http://www.thehopefoundation.org). Our exciting new site is designed to establish a comprehensive global awareness and understanding for The Hope Foundation and The Southwest Oncology Group. Some highlights of our new site include a current news section, a special “Platinum Association” section, and a survivors section. In addition, we have a page devoted to all of our current corporate supporters. This page features direct links to companies such as Porsche, Zeneca, Bristol-Myers Squibb and more. For individuals who are interested in supporting The Hope Foundation online, we have a special secure “support” page for this purpose as well. So, the next time you find yourself on the Internet, please drop by our new site and “reach for the stars!”

In other exciting news, The Hope Foundation continues to achieve great success with its “Platinum Association” campaign as well as an exclusive new campaign designed for all CRA, Nurse, Operations, and Statistical Center staff. We recently celebrated our incredible success in both campaigns at our Spring Group Meeting in Phoenix. Each campaign featured drawings for some very distinguished participation prizes. Our Platinum Association winners were: Dr. Bart Barlogie, Dr. Harry E. Hynes, and Dr. Paul G. Montgomery. Our CRA, Nurse, Operations and Stat Center winners were: Rose B. Ermete, RN, OCN, Oakwood Hospital, Dearborn, MI, and Jennifer S. Gazvoda, Protocol Coordinator, Operations Office, San Antonio, TX. Congratulations to our winners and sincerest thanks to all of those who have supported our efforts!

In addition, during the 1999 Spring Group Meeting Plenary Session, the Hope Foundation received a special gift and presentation from Jeannie Parzuchowski, RN, MS, OCN, on behalf of the Nurse Oncologist Committee. We are grateful for this precedent-setting effort in support of our mission.

The Hope Foundation is already developing our next fund-raising and awareness campaigns, and they promise to offer all of the excitement and fun experienced during our last two Group Meetings. Already planned for our fall Group Meeting in San Diego is the Platinum Association’s Exclusive Porsche Boxster Giveaway! Stay tuned for details.

For more information on The Hope Foundation and its activities please contact Foundation Chief Operating Officer Brian D. Chavez at 210-677-8808. Or write to The Hope Foundation, 14980 Omicron Drive, San Antonio, TX 78245-3217.

---

**The Hope Foundation Platinum Association Corporate Sponsors**

- Porsche
- Zeneca Pharmaceuticals
- Hyatt Hotels and Resorts
- Corporate Travel Planners, Inc.
- Mr. Doug Wegrzyn and Armour Golf

**Charter Platinum Association Members**

- Kathy S. Albain, MD
- David S. Alberts, MD
- Sanjay Awashti, MD
- Laurence H. Baker, D.O.
- Bart Barlogie, MD
- Harry M. Barnes, III, MD
- James D. Bearden, MD
- Joseph T. Beck, MD
- Mitchell C. Benson, MD
- Nirmala Bhoopalam, MD
- Anton J. Bueschen, MD
- Manuel H. Castillo, MD
- William F. Cathcart-Rake, MD
- Jonathan K. Cho, MD
- Dr. & Mrs. Charles A. Colman, Jr.
- Johnny B. Craig, MD
- E. David Crawford, MD
- John J. Crowley, Ph.D.
- Daniel J. Culkin, MD
- Sheldon J. Davidson, MD
- John F. Ensley, MD
- Richard J. Fischel, MD
- Richard I. Fisher, MD
- William C. Goad, MD
- John E. Godwin, MD
- Stephanie J. Green, Ph.D.
- Thomas C. Hall, MD
- Dr. & Mrs. Khadar K. Hussein
- H.E. Hynes, MD
- Brian F. Issell, MD
- Mark R. Keaton, MD
- Steven J. Ketchel, MD
- Parvez Khan, MD
- Gerald W. King, MD
- Meng L. Lim, MD
- Mr. Mark Livingston
- Robert B. Livingston, MD
- John S. Macdonald, MD
- Dr. & Mrs. James R. Mason
- Kenneth M. Matchett, MD
- Nickey McCasland, RN
- Paul G. Montgomery, MD
- Bharat N. Nathwani, MD
- Nadim F. Nimeh, MD
- Timothy J. O’Rourke, MD
- Diane L. Persons, MD
- Derek Raghavan, MD, Ph.D.
- Peter M. Ravdin, MD, Ph.D.
- Saul E. Rivkin, MD
- C.J. Rosenthal, MD
- Paul F. Schellhammer, MD
- Dr. Thomas E. Seay
- and Mrs. Teresa Bailey-Seay
- Anthony F. Shields, MD, Ph.D.
- Peter K. Sien, MD
- Oscar R. Signori, MD
- Joseph G. Sinkovics, MD
- Surendra K. Sirpal, MD
- Vernon K. Sondak, MD
- Margaret C. Sunderland, MD
- Lode J. Swinnen, MD
- Ms. Angela R. Taylor
- Howard Terebelo, DO
- Philip T. Valente, MD
- Robert W. Veith, MD
- Dr. and Mrs. Paul L. Weiden
- Dr. and Mrs. Charles A. Colman, Jr.
- Stephen K. Williamson, MD
- Howard Terebelo, DO
- Philip T. Valente, MD
- Robert W. Veith, MD
- Dr. and Mrs. Paul L. Weiden
- Stephen K. Williamson, MD

---

**THE GROUP NEWSLETTER**

**JUNE 1999**
The Following Gifts were received February 16 through May 15, 1999.

**Special Gifts**
Nurse Oncologist Committee

**Individual Contributions**

Connie Barnes  
Jacqueline K. Benedetti, Ph.D.  
Manuel H. Castillo, MD  
Eva Celnik, MPH  
Debra W. Christie, MBA  
Maria L. Comillas, RN  
Jeana N. Cromer, CCRA

Mary Elizabeth Davis, CCRA  
Amy D. DeBlaise, BA  
Nancy I. Deegan, RN  
Karen M. Denolf, RN  
Rose B. Ermete, RN  
Sharon S. Forrester, RN  
Sharon Frelleson, RN

Gina M. Gregovich, CCRA  
Holly M. Gundacker  
Hollianne N. Hunt, RRA  
Dorothy W. Lisk, RN  
Nickey McCasland, RN  
Steven K. McGee  
Susan P. Mihalevich, RN

Carol M. Moinpour, Ph.D.  
Suzan J. Myers  
Larry and Melinda Navarro  
Debra D. O’Rourke, RN  
Marguerite M. Ramsey, RN  
Anne M. Ryan, RN  
Gary Shelton, MSN  
Kathleen T. Shota, CCRA

**Special Occasion Gifts & Special Tributes**

Mr. & Mrs. Gary Gazvoda *in memory of* Rev. Jack Nelson Cobb  
Nickey McCasland *in memory of* Mrs. Minnie Ryan  
Rollin & Jane Moerschel *in memory of* Charles Everet Long

Shawn & Patricia O’Kane *in memory of* Linda Campbell  
Southwest Oncology Group Operations Office *in honor of* Dr. James K. Weick

**The Hope Foundation Prize Recipients**:  
1999 Spring Group Meeting

Counter-clockwise from top left: Dr. Harry E. Hynes receives a pair of Worldwide Roundtrip Tickets on American Airlines from Dr. Coltman. Jennifer Gazvoda accepts a pair of Worldwide Roundtrip Tickets on American Airlines with accommodations at The Hyatt Phoenix. A surprised and delighted Dr. Bart Barlogie after hearing the announcement that he won Worldwide Roundtrip Tickets on American Airlines. Dr. Paul G. Montgomery contemplates hitting the links with his set of Armour Golf Clubs with Golf Bag. Not pictured: Rose B. Ermete, RN, OCN, recipient of Worldwide Roundtrip Tickets on American Airlines with accommodations at The Hyatt New Orleans.
Karyotypic analysis predicts outcome of pre- and post-Remission therapy in adult acute myeloid leukemia. SWOG-9034 (EST-3489 and CALGB-9120). Presented by Marilyn L. Slovak, Ph.D., Southwest Oncology Group Cogenetics Office, City of Hope National Medical Center, Duarte, CA.


Potential strategies to improve the prognosis of patients with AML may benefit from analysis of treatment response according to disease karyotype. The results of an intergroup trial in AML of patients (pts) <56 years old that included three intensive post-remission therapies [intensive chemotherapy, autologous (ABMT) and allogeneic (alloBMT) bone marrow transplantation from matched related donors], were examined for correlation with complete remission (CR) rates, overall survival (OS) and outcomes after CR. 609/763 (80%) eligible patients had evaluable cytogenetics (284 F, 325 M; age 16-55, median 39). Cytogenetic risk group assignment was organized as follows: Favorable (FAV) as inv(16) (n=49) and t(15;17) (n=27) with any abnormalities (abn), or t(8;21) lacking del(9q) or complex karyotypes (n=40), Intermediate (INT) as +8 (n=28), -Y (n=2), +6 (n=2), del(12p) (n=1), or normal (n=245) karyotypes, and Unfavorable (UNF) as −5(del5q) (n=36), −7(del7q) (n=52), inv(3q) (n=11), abn of 11q (n=42), 20q (n=6), or 21q (n=6), del(9q) (n=17), t(6;9) (n=11), t(9;22) (n=8), abn 17p (n=12), and complex karyotypes defined as >3 abn (n=70). Other abns were listed as Unknown (UNK). Cytogenetic status at presentation was 19% FAV (n=116), 46% INT (n=278), 32% UNF (n=189), and 4% UNK (n=26). CRs were achieved in 412 (71%) of 584 pts evaluated for response. CR rate and OS decreased significantly (p<0.0001) with worsening risk status. CR rates ranged from 84% [94/112; 95% confidence interval (CI), 77-91%] for FAV to 76% (205/270; CI 71-81%) for INT to 56% (100/178; CI 49-63%) for UNF. In multivariate analyses the effects of cytogenetic risk status on CR rate and OS could not be explained by other patient or disease characteristics. 206/609 pts have survived a median of 58 months. Estimated relative risk (RR) of death from any cause, compared to the FAV group, was 1.59 (CI 1.16-2.19) for INT and 3.54 (CI 2.57-4.89) for UNF. Among post remission pts, there was marginally significant interaction (p=0.010) between the effects of treatment and risk status on survival. In 93 ABMT pts, survival decreased sharply from the FAV to INT (RR=3.09) to UNF (RR=6.34), while the RRs were smaller in the alloBMT arm (INT 1.52; UNF 2.05), suggesting that alloBMT is more effective in overcoming poor risk cytogenetics than ABMT. Essentially the same results were seen for disease-free survival. This study indicates that cytogenetic status is a significant factor in determining response to AML induction therapy and suggests that pts with poor risk cytogenetics do better with matched related alloBMTs. These results support the recommendation that alloBMT should be offered to all pts with poor risk cytogenetics.

Alternate day oral prednisone maintenance therapy improve progression-free and overall survival in multiple myeloma patients (SWOG-9210). Presented by James R. Berenson, M.D., UCLA/VA Medical Center, Los Angeles, CA.

ALTERNATE DAY ORAL PREDNISONE MAINTENANCE THERAPY IMPROVES PROGRESSION-FREE AND OVERALL SURVIVAL IN MULTIPLE MYELOMA PATIENTS. J. Berenson, J. Crowley,* B. Barlogie, and S. Salmon. WLA VAMC and UCLA, Los Angeles, CA, Fred Hutchinson Cancer Research Center, Seattle, WA, University of Arkansas, Little Rock, AR, and University of Arizona, Tucson, AZ, and the Southwest Oncology Group, San Antonio, TX.

Glucocorticoids alone have been shown to be effective in inducing remissions in multiple myeloma (MM) patients. Although interferon (IFN) has been used as maintenance therapy, it is still unclear whether it improves either progression-free (PFS) or overall survival (OS). The recently published Southwest Oncology Group (SWOG) 9028 trial showed an improvement in both PFS and OS in MM patients receiving maintenance treatment with a combination of IFN and prednisone (P) compared to IFN alone. Since IFN alone as maintenance therapy showed no benefit over observation in a previous SWOG trial, it may be possible that P alone would be effective as maintenance therapy. Two hundred sixty-two eligible and previously untreated MM patients were registered on SWOG 9210, which included induction therapy with VAD alone or with quinine (Q). Patients achieving a >25% reduction in tumor burden were randomized to either pharmacological (50 mg) or physiological (10 mg) doses of alternate day oral P until disease progress. Patient characteristics were similar at the time of study entry between VAD and VAD-Q patients, and between the two arms randomized to maintenance therapy. After a median follow-up of 31 months, there was no difference in either PFS or OS in patients receiving VAD compared to VAD-Q. Eligible patients (n=126) were randomized to receive either the high dose (HD) or low dose (LD) P. From the time of this randomization, the median PFS was improved in the HD group compared to the LDP-treated patients (13 vs. 6 months, p=0.002). The median OS was markedly prolonged in the HD group compared to those individuals receiving LDP (43 vs. 28 months, p=0.01). There was no difference in treatment-related overall or specific adverse events between these arms. These data provide clear evidence of the benefit without significant toxicity of 50 mg of alternate day prednisone alone as maintenance treatment for MM patients following a response to conventional chemotherapy. Studies should be initiated in patients undergoing high-dose therapy to establish whether similar treatment is effective in that setting.
Abstracts of the Scientific Presentations...(Continued)

A phase II trial of a combination of fludarabine oral presentation and mitoxantrone (FN) in untreated advanced low grade lymphoma. An effective, well tolerated therapy. (SWOG-9501). Presented by William S. Velasquez, M.D., University of Texas Medical Branch, Galveston, TX.

SWOG-9501: A PHASE II TRIAL OF A COMBINATION OF FLUDARABINE AND MITOXANTRONE (FN) IN UNTREATED ADVANCED LOW GRADE LYMPHOMA. AN EFFECTIVE, WELL TOLERATED THERAPY. W. Velasquez, D. Lew, T. Miller, R. Fisher; U of Texas Medical Branch, Galveston, TX; SWOG Statistical Center, Seattle, WA; Arizona Cancer Center, Tucson, AZ; and Loyola U., Chicago, IL.

The combination of fludarabine (25mg/m²/day IV, Days 1 to 3) and mitoxantrone (10mg/m² IV, Day 1) was tested in previously untreated Working Formulation low grade lymphoma patients (pts). Eligibility included age >15, good performance status (0-2), Stages III and IV, and no prior history of heart disease or HIV infection. Chemotherapy was repeated every 4 weeks for a maximum of 8 cycles. Bactrim was used for pneumocystis carinii prophylaxis. A total of 92 pts were registered; 11 were found to be ineligible: (8 due to pathologic assessments, 2 due to prior heart disease). Among the 81 eligible pts, 67 (83%) have follicular lymphoma and 14 (17%) were diagnosed as small lymphocytic lymphoma. Median age was 53 years ranging from 28 to 80 years of age. A total of 74 eligible pts, (91%) responded to treatment, including 35 (43%) who attained CR. With a median follow up time of 31 months, 27 pts have progressed after a response. The estimated 2 year progression free survival (PFS) for all pts was 63%; while overall survival (OS) is 93%. When the plots are compared with prior SWOG trials with CHOP and PROMAC MOPP, the 2 year PFS are similar. FN in general was well tolerated; only toxicity was hematological with 18 pts (22%) having transient grade 4 (AGC <500 in 18 pts, and one of these pts also developed severe thrombocytopenia with platelets <25,000). Two ineligible pts with prior heart disease underwent cardiac surgery. No serious opportunistic infections or deaths were associated with the administration of FN. A total of 78 eligible pts had a pre-treatment serum B₂ microglobulin (B₂ mic.) determination which was found to have strong correlation with CR and PFS. Among the 45 pts with B₂ mic. of <2.5 mg%, 27 (60%) attained CR while only 7 of 33 (21%) pts with B₂ mic. ≥2.5 mg% attained CR. Likewise, the 2 year PFS for lower B₂ mic. (<2.5 mg%) pts was 82% and 47% for those pts with higher B₂ mic. This preliminary data shows FN is a very active, well tolerated combination chemotherapy for pts with advanced low grade lymphoma. Pts with B₂ mic. <2.5 mg% had better CR rate and PFS.

Cisplatin, 5-fluorouracil plus radiation therapy are superior to radiation therapy as adjunctive therapy in high-risk, early-stage carcinoma of the cervix after radical hysterectomy and pelvic lymphadenectomy; report of a phase III intergroup study. (SWOG-8797, INT-0107). Presented by P.Y. Liu, Ph.D., Statistician, Southwest Oncology Group Statistical Center, Seattle, WA.


OBJECTIVE: To determine if the addition of chemotherapy (CT) to pelvic radiation therapy (RT) will improve the survival of early-stage, high-risk patients with carcinoma of the cervix.

METHODS: Patients with clinical stage IA2, IB and IIA carcinoma of the cervix, initially treated with radical hysterectomy and pelvic lymphadenectomy, and who had positive pelvic lymph nodes and/or positive margins and/or microscopic involvement of the parametrium, were eligible for this study. Patients were randomized to receive radiation therapy or radiation therapy plus chemotherapy. Patients in each group received 4,930 cGy in 29 fractions to a standard pelvic field. Chemotherapy consisted of bolus cisplatin 70 mg/m² and 96-hour infusion of 5-FU 1,000 mg/m²/day x 4D q.3w. for four total cycles, with the first and second cycles given concurrent to radiation therapy.

RESULTS: Between 1991 and 1996, 268 patients were entered into the study. 241 are currently evaluable (126 RT+CT and 115 RT). Progression-free (P=0.01) and overall survival (P=0.01) are significantly improved in the patients receiving CT. The hazard ratio for overall survival in the RT only arm vs the RT+CT arm is 2.02. The projected progression-free survivals at four years are 63% with RT and 81% with RT+CT. Grade 3/4 hemotologic and gastrointestinal toxicity were more frequent in the RT+CT group. There was one possibly treatment related death in a patient randomized to RT+CT who refused CT and received RT only.

CONCLUSIONS: The addition of chemotherapy to radiation therapy significantly improves progression-free and overall survival for high-risk, early stage patients who undergo radical hysterectomy and pelvic lymphadenectomy for carcinoma of the cervix.
Abstracts of the Scientific Presentations…(Continued)


The pivotal trial E1684 demonstrated improvement of continuous relapse-free survival (RFS) and overall survival (OS) of high-risk resected melanoma with high-dose IFNa2b for one year. Intergroup E1690/SWOG-9111/CALGB9190 was designed to confirm and extend E1684, testing (A) high-dose IFNa2b (HDI= 20µg/M2/day IV x 5/7 d/wk x 4, then 10µg/M2/d SC TIW x 48 wks), or (B) low-dose IFNa2b (LDI= 3 µg/day SC TIW for 104 wks), vs (C) observation. Primary endpoints were relapse-free (RFS) and overall survival (OS) comparing A vs C, and B vs C in log rank analysis stratified by stage and number of +nodes (+N#) for eligible and intent-to-treat populations. Of 642 pts entering E1690, 608 (95%) are evaluable at 52 mos median follow-up (91% information time). Entrants included 163 +N#0, 217 +N#1, 134 +N# 2-3, and 128 with +N# >=4. ITT analysis demonstrates RFS improvement for HDI (HR= 1.28 p= .05), more than LDI (HR= 1.09, p= .17). Analysis by number of positive nodes reveals RFS benefit of HDI in both node-negative and node-positive pts which is greatest for +N# 2-3 pts (HR 1.9, p=.02), and least for +N# 1 pts (HR 1, p=.99). RFS benefit for HDI persists in a Cox model adjusting for stage and +N# (p= 0.03). No impact upon OS exists for HDI or LDI in this analysis. Fatal toxicities (2) were observed only with LDI in E1690. Comparison to E1684 demonstrates treatment impact is consistent, but interstudy improvement has occurred for observation in RFS (p= 0.04) and OS (p= 0.001). The explanation of this change awaits ongoing analyses. Pooled data for HDI from E1684 & E1690 show improvement of RFS (p=.002), but not OS (p=0.21). Conclusion: HDI remains the most active adjuvant agent evaluated to date for high-risk melanoma, with prolongation of RFS but not OS at 52 months in E1690. RFS benefit for LDI is less than that of HDI.

A randomized phase III trial of paclitaxel plus carboplatin (PC) versus vinorelbine plus cisplatin (VC) in untreated advanced non-small cell lung cancer (NSCLC): A Southwest Oncology Group (SWOG) Trial. (SWOG-9509). Presented by Karen Kelly, M.D., University of Colorado HSC, Department of Oncology, Denver, CO.

A RANDOMIZED PHASE III TRIAL OF PACLITAXEL PLUS CARBOPLATIN (PC) VERSUS VINORELBINE PLUS CISPLATIN (VC) IN UNTREATED ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC): A SOUTHWEST ONCOLOGY GROUP (SWOG) TRIAL. K. Kelly, J. Crowley, P.A. Bunn, R.B. Livingston, D.R. Gandara, Southwest Oncology Group. San Antonio, TX.

This phase III trial was designed to determine if PC offers any advantage over the SWOG standard of VC for patients (pts) with advanced NSCLC. 444 pts were registered between 4/98 and 10/98. 408 pts were eligible. 307 pts received PC (P at 225 µg/m2 over 3 hours, IILC with C AUC = 6, IILC q 21 days) and 201 pts received VC/C at 100 mg/m2, d1 and V 25 mg/m2 weekly q 28 days). All pts were required to have measurable or evaluable disease, a PS of 0–1, adequate organ function and no prior chemotherapy. Pt characteristics were similar between the two arms. 12% and 11% had Stage IIIIB, respectively. Preliminary efficacy, toxicity data, tolerability and quality of life (QOL) data:

<table>
<thead>
<tr>
<th></th>
<th>PR (%)</th>
<th>MST (mos)</th>
<th>1 YR OS (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC n = 184</td>
<td>27</td>
<td>8</td>
<td>36</td>
</tr>
<tr>
<td>VC n = 181</td>
<td>27</td>
<td>8</td>
<td>33</td>
</tr>
<tr>
<td>VC-S9308 n = 206</td>
<td>26</td>
<td>8</td>
<td>36</td>
</tr>
</tbody>
</table>

S9308 refers to the results from SWOG 9308 a randomized trial of VC versus cisplatin

<table>
<thead>
<tr>
<th>(%)</th>
<th>Gr4 ANC</th>
<th>Gr3 Nausea</th>
<th>Gr 3 Neuropathy</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC n = 188</td>
<td>36&lt;sup&gt;a&lt;/sup&gt;</td>
<td>6&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>VC n = 181</td>
<td>47</td>
<td>17</td>
<td>3</td>
</tr>
</tbody>
</table>

p-values: a = <.05, b = <.01, c = <.05.

<table>
<thead>
<tr>
<th>Completed Therapy</th>
<th>Off Study Due to Toxicity</th>
<th>QOL at 25 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Improved</td>
<td>Stable</td>
</tr>
<tr>
<td>PC n = 190</td>
<td>26%&lt;sup&gt;a&lt;/sup&gt;</td>
<td>13%&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>VC n = 186</td>
<td>14.5%</td>
<td>30%</td>
</tr>
</tbody>
</table>

p-values: a = <.05, b = <.01.

In summary, PC and VC had equal efficacy, and VC produced similar results as in the previous SWOG study (9308). Hematologic toxicity and nausea were higher on the VC arm whereas peripheral neuropathy was improved on the PC arm. More pts on the VC arm were unable to complete therapy as planned due to toxicity. QOL was maintained (improved or stable) in about 60% of pts on both arms. We conclude that both regimens provide effective palliation in advanced NSCLC but favor the paclitaxel and carboplatin regimen for future studies due to a favorable toxicity profile and better tolerability and compliance. Pharmacoeconomic data are pending.
Preliminary toxicity results from Southwest Oncology Group Trial S9705: A phase II trial of cisplatin, etoposide and paclitaxel (PET) with G-CSF in untreated patients (PTS) with extensive small cell lung cancer (SCLC). Presented by Paul A. Bunn, Jr., M.D., University of Colorado Health Science Center, Denver, CO.

Preliminary toxicity results from Southwest Oncology Group trial S9705: A phase II trial of cisplatin, etoposide and paclitaxel (PET) with G-CSF in untreated patients (PTS) with extensive small cell lung cancer (SCLC). P.A. Bunn, K. Kelly, J. Crowley, R.B. Livingston, D.R. Gandara, and SWOG. San Antonio, TX.

This phase II trial was designed to determine the efficacy and toxicity of paclitaxel added to cisplatin/etoposide in extensive stage SCLC based on promising data from a University of Colorado Lung Cancer Center phase I trial. 89 eligible pts registered between 9/97 and 6/98 had histologically proven disease, a PS of 0–2, adequate organ function and no prior chemotherapy. Pts received 6 cycles of paclitaxel at 175 mg/m2 IV over 3 hours on day 1 with cisplatin at 80 mg/m2 IV, day 1 and etoposide at 80 mg/m2 IV, on day 1 and 140 mg/m2 PD on days 2 and 3 of a 21 day cycle. G-CSF (5 mg/kg) was given SQ on days 4–14. Toxicity data is available on 59 patients (27 pts had a PS = 2) and is presented in the table below.

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
<th>Grade 5 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>12</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Dehydration</td>
<td>3</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Emesis</td>
<td>8</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Malaise/Fatigue</td>
<td>15</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>3</td>
<td>34</td>
<td>0</td>
</tr>
<tr>
<td>Electrolyte imbalance (Na+, K+, Mg2+, Ca2+)</td>
<td>5</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Infection</td>
<td>3</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Renal failure</td>
<td>0</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>10</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

Although the rates of grade 4 neutropenia and thrombocytopenia were similar to prior SWOG trials, five pts died from neutropenic sepsis and 1 pt died from complications of renal failure, giving an overall rate of toxic death of 10%. This is slightly higher than in prior SWOG trials with CAV +/- EP and similar to that seen with CDE. The high death rate is most likely due to patient selection factors including PS 2, but no significant predictors of fatal outcome were discovered in this trial. Neurotoxicity was tolerable; 3 grade 3 to 4 labial paresthesia, 1 ymalgias and myalgias were observed. In conclusion, neutropenia is the major toxicity of the PET regimen. Death from toxicity is 10%. This forms the largest database on toxicity for the PET regimen and will provide valuable information for the ongoing randomized intergroup trial of PE versus PET in extensive stage SCLC. A detailed and updated toxicity analysis and efficacy data will be presented.

Long-term survival after concurrent cisplatin/etoposide (PE) plus chest radiotherapy (RT) followed by surgery in bulky, stages IIIA(N2) and IIIB non-small cell lung cancer (NSCLC): 6-year outcomes from Southwest Oncology Group Study (SWOG-8805). Presented by Kathy S. Albain, M.D., Professor of Medicine, Loyola University Medical Center, Maywood, IL.


Very few long-term survival data exist for patients with bulky, pathologically-proven stages IIIA(N2) and IIIB NSCLC treated with induction chemoRT prior to surgery. We previously reported feasibility of induction PE (7 cycles) plus concurrent RT (45 Gy) followed by surgery in the absence of progression for pathologic N2, T4(no effusion), or N3 disease (J Clin Oncol 13:1880, 1995). The 3-year survival was similar for IIIA(N2) and IIIB (27%, 24%), but its durability was uncertain. Here, we report the 6-year survival of the initial 1167 patients (75, IIIA(N2); 51, IIIB), as well as predictors of favorable long-term outcome from time of thoracotomy for the 107 patients eligible for surgery.

SWOG-8805 SUBSET

<table>
<thead>
<tr>
<th>From registration, entire cohort (n=126)</th>
<th>6-YR SURVIVAL (%)</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage IIIA(N2)/stage IIIB</td>
<td>20/22</td>
<td>ns</td>
</tr>
<tr>
<td>Female/male</td>
<td>31/14</td>
<td>.03</td>
</tr>
<tr>
<td>T4N0-1/N2-3</td>
<td>49/18</td>
<td>.02</td>
</tr>
<tr>
<td>From time of thoracotomy (n=107)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Induction response on CT scan CR+PR/stable</td>
<td>27/18</td>
<td>.17</td>
</tr>
<tr>
<td>Complete resection yes/no</td>
<td>30/5</td>
<td>.04</td>
</tr>
<tr>
<td>Downstage from N2/3 to N0 yes/no</td>
<td>33/11</td>
<td>.002</td>
</tr>
</tbody>
</table>

In conclusion, long-term survival plateaus at 20% and is still identical for bulky IIIA(N2) and IIIB subgroups treated with trimodality therapy. Exploratory subset analyses suggest that: 1) response to induction chemorT by CT scan is a poor discriminant of favorable late outcome, 2) with resection of stable disease, nearly 50% with T(N0-3) tumors survived 6 years, and 3) clearance of mediastinal nodal involvement remains the strongest favorable outcome predictor for those patients with initial N2-3 disease.
NEW!!! NCI Grant Funds In Support Of Students From Underserved Populations Performing Research In Your Lab

The National Cancer Institute is offering grantees the opportunity to participate in a new program that provides a continuum of opportunities for underserved minorities extending from high school student, to undergraduate student, to graduate student, to postdoctoral fellow, to independent scientist. This new initiative is called the CURE (Continuing Umbrella of Research Experiences Program). CURE is strategically linked to most NCI programs and award mechanisms and relies on a continuum of administrative supplements from the high school to the investigator stage, with a final peer-reviewed career development award (i.e., K01) that prepares underserved ethnic and racial groups to participate in cancer research as independent scientists.

In an effort to maintain a scientific balance between basic, clinical and population sciences, we are encouraging you to take advantage of this opportunity to add new positions to your grant through “Research Supplements for Underrepresented Minorities” if you can identify qualified minority candidates from high school students through junior investigators, who are not currently supported on your grant. This can benefit your research program and give you the satisfaction that the individual you choose will continue to benefit from the CURE Program in the pursuit of a research career.

Supplemental applications submitted will be reviewed by NCI program directors and the Comprehensive Minority Program Advisory Committee. Those interested in applying should examine the NIH GUIDE, Volume 26, Number 37, November 7, 1997; or the NIH website at www.nih.gov/grants/guide/index.html; or email (ss165i@nih.gov), or call 301-496-7344 for specific instructions.
Manuscript Procedures...

It is the responsibility of the primary Study Coordinator on any Southwest Oncology Group study to submit a manuscript for publication within one year after closure, unless the Data and Safety Monitoring Committee decides publication is premature. This includes negative trials and, if possible, studies closed prematurely (due to poor accrual or lack of benefit). The proposed draft manuscript must be submitted to the Operations Office where a face sheet will be formulated to include selection of co-authors.

Selection of Co-Authors: Group Policy dictates that the Primary Author is the Study Coordinator. The contributing Biostatistician is listed as second author, followed by the other Study Coordinators involved in study management and evaluation (e.g., radiation therapy, surgery, pathology, etc.). The Disease Committee Chair will be listed as the senior author. The Statistical Center will provide a list of patient contributions by institution for each protocol and the Operations Office will select top accruing institutions, with the cutoff occurring at either the natural break, or at a total of ten co-authors. When selecting co-authors based on accrual, the Principal Investigator at the corresponding institution will be named. It is the responsibility of that Principal Investigator to reassign authorship to the appropriate individual at that institution (individual who treated majority of patients on study). The Operations Office and the Primary Author should be notified, in writing, of the change.

The Operations Office will provide a face sheet (cover page) listing the following: Title; Primary Author and Co-Authors; Institutions; Grant Numbers (Institutions, Statistical Center, Operations Office); Address for Editorial Correspondence; and Reprint Request Address. This face sheet MUST be included with your manuscript when it is submitted for publication.

At the time of submission of a manuscript to a journal, a copy of the letter of submission and a clean copy of the final manuscript must be submitted to the Operations Office. When the journal notifies the primary author that the manuscript has been accepted for publication, a copy of the acceptance letter should be sent to the Operations Office.

When the galley proofs and reprint form are received from the journal, please forward the reprint request form to the Operations Office Publication Program for completion. The form will then be forwarded to the publishers. All reprints of Southwest Oncology Group publications are ordered and distributed by the Operations Office. Ten reprints will be sent to the primary author and two to each co-author(s).
Look Out, Crabs!

Thirty-eight runners were ready to stomp out cancer at the early-morning “Crush the Crab” 5K Fun Run on Saturday, May 1, 1999. With nearly half the competitors timed in the teens and low twenties, it is easy to see why the scenic course in Tempe’s Kiwanis Park is a favorite of many of the Group’s runners.

Participating in the competition were: James D. Bearden III, MD; Mark J. Biery, RN; Natalie S. Callander, MD, (1st Place Women 40-49); David Chu, MD; Joseph I. Clark, MD, (1st Place Men 39 & Under); Lewis Clayman, MD, (3rd Place Men 50 & Over); Thomas F. DeLaney, MD, (3rd Place Men 40-49); Laurence Elias, MD, (1st Place Men 50 & Over); Rita Glaze, RN, CRA; Greg D. Gorgas; Dennis Hallissey; Brian F. Issell, MD, (2nd Place Men 50 & Over); Ismail Jatoi, MD, PhD; Julie A. Kish, MD, (1st Place Women 50 & Over); Kenneth G. Linden, PhD, MD; Candice McCoy, MD, (2nd Place Women 39 & Under); Steven McGee; Alan M. Miller, MD, PhD; George Missailidis, (2nd Place Men 39 & Under); Shawn O’Kane; Timothy J. O’Rourke, MD; Finn B. Petersen, MD; Maggie Ramsey, RN, MS; Elliot K. Reno, (3rd Place Men 39 & Under); Elisabeth J. Rushing, MD, (2nd Place Women 40-49); Kathryn Rusk, RN; Janice S. Sanders, RN, (3rd Place Women 39 & Under); Lee Shaw, (1st Place Women 39 & Under); Gloria Smith, RN; Lon S. Smith, MD; Linda Smull, RN; Gregory P. Swanson, MD, (2nd Place Men 40-49); Peter J. Van Veldhuizen, Jr., MD; James A. Waddell, PharmD, (1st Place Men 40-49); Rebecca J. Whitfill, RN, CRA, (3rd Place Women 40-49); Patrick Williams, MD; Stephen K. Williamson, MD; and Clive S. Zent, MD.

The “Crush the Crab” 5K competition is sponsored at each Group Meeting by The Schering Corporation. Runners, as well as walkers, are welcome to participate. Each registrant receives a tee-shirt at the spring event and a sweat shirt at the fall run. We look forward to crushing those crabs in San Diego and hope that you will join us then!

Winners all! Above, from left to right, Men 39 & Under: George Missailidis (2nd Place); Joseph Clark (1st Place); and Elliot Reno (3rd Place). Below, from left to right, Women 40-49: Natalie Callander (1st Place); Elisabeth Rushing (2nd Place); and Rebecca Whitfill (3rd Place).

Congratulations! Above, from left to right, Men 50 & Over: Lewis Clayman (3rd Place); Laurence Elias (1st Place); and Brian Issell (2nd Place). Below, from left to right, Women 39 & Under: Janice Sanders (3rd Place); Candice McCoy (2nd Place); and Lee Shaw (1st Place).
Follow us! From left to right, Men 40-49: James Aubrey Waddell (1st Place), and Thomas DeLaney (3rd Place). Not pictured is 2nd Place winner, Greg Swanson.

Way to go! Julie Kish, 1st Place winner, Women 50 & Over.

Special Thanks from the Southwest Oncology Group to those who supported the Spring 1999 Group Meeting in Phoenix, Arizona

PATRON
Bristol-Myers Squibb, Onc.

Centurion
Glaxo Wellcome
Pharmacia & Upjohn, Inc.

Pacesetter
Amgen
Genentech BioOncology
Immunex
Novartis
Roche Laboratories
Schering Oncology/Biotech

Supporter
Agouron Pharmaceuticals
Alza Pharmaceuticals
Berlex Laboratories
Chiron Therapeutics
Eli Lilly
Genetics Institute, Inc.
IDEC Pharmaceuticals
Maxim Pharmaceuticals
Roxane Laboratories
SmithKline Beecham
SuperGen, Inc.
U.S. Bioscience
Operations Office News

“Hello again!” to Bonnie Granados who left the Operations Office in 1996 when her husband’s job took him to Florida. Previously with the Operations Office, Bonnie served as Quality Assurance Assistant; upon her return in February 1999, she accepted the position of Publications Specialist.

Statistical Center News

Welcome back to Cathy Tangen, who rejoins the Statistical Center as the Faculty Statistician on the GU committee. Many of you will remember Cathy who was a statistician on the GI and Myeloma committees in the early 90’s and who left to pursue her doctorate at the University of North Carolina. We are pleased to have Cathy back with us in her new role.

Spencer Boddy has joined the Statistical Center as a Data Coordinator for the PCPT. He comes to us from InControl, Inc. where he was responsible for patient data management, verification, and monitoring data compliance to protocol and procedures. He has been with the PCPT since March 1.

Linda Messent has also joined the PCPT staff as a Data Coordinator. She has been working in the Clinical Division of Fred Hutchinson Cancer Research Center, most recently as a Laboratory Coordinator in the Clinical Immunogenetics Lab. Linda has been working with the PCPT since April 1.

Jenni McNurlin is a new member of the Administrative Staff. She has an eight-month-old daughter Kennedy, lives in Auburn, and is crazy about horses. She joined us in February.

Debbie Sopher is a new addition to the Statistical Center programming team. She will be working on registration and related programs. She is a recent graduate from the computer programming department at North Seattle Community College, and a previous middle school teacher. She enjoys spending time with her two boys, who currently attend Hutch Kids.

We are pleased to welcome the newest little SWOGGIE, Matthew David Chansky, born April 30, 1999 to Kari and Howard Chansky. Kari is a statistician on the GI and Lung Committees.

~ COMBINED HOLIDAY SCHEDULE ~

Statistical Center & Operations Office

Independence Day, Monday, July 5, 1999
Labor Day, Monday, September 6, 1999
Christmas Eve, Friday, December 24, 1999

Statistical Center - Additional - Veterans Day, Thursday, November 11, 1999

Job Opportunities...Job Opportunities...Job Opportunities...Job Opportunities

Loyola University Medical Center, Cardinal Bernardin Cancer Center, Chicago

Data Management/Clinical Research Supervisor: Responsibilities include directing, coordinating and maintaining computerized and manual collection, reporting, and analysis of data for oncology clinical research projects. Develop in-service programs for clinical staff; develop outreach strategies. BSN required, Masters preferred. Data Management/Clinical Research Program Coordinator: Manage and coordinate the STAR breast cancer prevention trial, including Loyola’s primary care accrual sites, with the critical job responsibility of development and implementation of successful recruitment strategies for a diverse network of participants. Coordinate and maintain accrual, treatment compliance, and computerized data management from recruitment to long-term follow-up. Develop and conduct educational programs for primary care staff and patients. BSN required, Masters preferred. Both positions require previous experience in oncology nursing and clinical research, with excellent computer skills. Send or fax your resume to: Noreen Balch, Administrator, Hem/Onc, Loyola University Chicago, 2160 S. First Avenue, Bldg. 112-256, Maywood, IL 60153. Fax: 708-327-3319.

Swedish Tumor Institute, Seattle

Clinical Research Associate: Coordinates data management and patient enrollment activities. Knowledge of oncology, anatomy and physiology, medical terminology and medical records is required. Research field experience, data management experience, ART or RRA and a BS degree in a related field are also required. Apply by resume and/or application to: Swedish Medical Center, Human Resources, 747 Broadway, Seattle, WA 98122. Fax: 206-386-2145. Email (ASCII format) to: employ@swedish.org. Jobline Phone: 206-386-2888. Internet: www.swedish.org/employment. Toll-free phone: 800-378-8236.

St. Vincents Comprehensive Cancer Center, New York

Clinical Research Coordinator: An excellent opportunity to manage clinical research program including preparation of grant proposals, protocol implementation, patient accrual, data management, regulatory compliance, budget and other administrative functions. Requires BSN, RN license, 3-5 years clinical research experience in leadership role. Fax/send resume to: Ann McNicholas at 212-462-2919; St. Vincents Comprehensive Cancer Center, 111 8th Avenue, Suite 1513, New York, NY 10013.

~ SWOG HOME PAGE ~

SWOG Home Page: http://www.swog.org

Phone: 210-677-8808 FAX: 210-677-0006
San Antonio, TX 78245-3217

Phone: 206-667-6868 FAX: 206-667-6869
Seattle, WA 98109-1024

Phone: 415-476-5800 FAX: 415-476-5809
San Francisco, CA 94118

1100 Fairview Avenue North, MP-557
Fred Hutchinson Cancer Research Center
Southwest Oncology Group Statistical Center
Seattle, WA 98109-1024
Phone: 206-667-4623 FAX: 206-667-4408

P.O. Box 19024
Seattle, WA 98109-1024
Phone: 206-667-6868 FAX: 206-667-6869

P.O. Box 19024
Seattle, WA 98109-1024
Phone: 206-667-4623 FAX: 206-667-4408

P.O. Box 19024
Seattle, WA 98109-1024

P.O. Box 19024
Seattle, WA 98109-1024
Update On New Drugs

ONTAK™ (denileukin diftitox) — For Treatment of Patients with Cutaneous T-Cell Lymphoma

On February 8, 1999, under accelerated approval regulations, the FDA approved denileukin diftitox (Ontak™, Ligand Pharmaceuticals) for the treatment of cutaneous T-cell lymphoma (CTCL). CTCL is a relatively rare, lymphoproliferative disorder of epidermotrophic T-cells with a wide range of dermatologic clinical manifestations. Denileukin diftitox is a recombinant, DNA-derived, cytotoxic protein composed of the amino acid sequences for diphertheria toxin followed by the sequences for interleukin-2. This fusion protein is designed to direct the cytotoxic action of diphertheria toxin to cells which express the IL-2 receptor in one of its three forms: low (CD25), intermediate (CD122/CD132), and high affinity (CD25/CD122/CD132). The high affinity form is usually found only on activated T lymphocytes, activated B lymphocytes, and activated macrophages. Malignant cells expressing one or more of the subunits of the IL-2 receptor are found in certain leukemias and lymphomas including CTCL.

Denileukin diftitox is indicated for the treatment of patients with persistent or recurrent CTCL whose malignant cells express the CD25 component of the IL-2 receptor. Prior to administration of the product, the patient’s malignant cells should be tested for CD25 expression. A testing service for the assay of CD25 on skin biopsy samples is available from Ligand Pharmaceuticals by calling 1-800-964-5836. The expression of the CD25 component indicates a higher probability that the patient will also express the other IL-2 receptor subunits indicating probable response to the drug. The safety and efficacy of denileukin diftitox in patients with CTCL whose malignant cells do not express the CD25 component have not been determined. Denileukin diftitox was approved by the FDA based on results from two clinical studies which included 106 patients with CTCL. Two additional studies evaluating the drug in CTCL are currently ongoing.

A phase I/II, dose escalation study was done in 35 heavily pre-treated patients with Stage IA to IVB CTCL. Patients were treated with denileukin diftitox doses ranging from 3-31 mcg/kg/day daily for 5 days every 3 weeks. The optimal duration of therapy has not been determined; however, there was a trend favoring an increased response in patients with ≥ stage IIB disease who received the 18 mcg/kg dose (p=0.07). The overall median duration of response, measured from first day of response, was 4 months.

Denileukin diftitox is contraindicated for use in patients with a known hypersensitivity to the drug or any of its components. Acute hypersensitivity-type reactions were reported in 98 of 143 patients (69%) during or within 24 hours of drug administration. This toxicity data is based upon 2 clinical studies of patients with lymphoma, including 105 patients with CTCL. Approximately half of the events occurred on the first day of treatment regardless of cycle. Hypersensitivity reactions should be managed by either an interruption or decrease in the rate of infusion, as well as the administration of IV antihistamines, corticosteroids, and epinephrine as necessary. Vascular leak syndrome was reported in 27% (38/143) of patients in clinical studies. All patients experienced one or more adverse events. Twenty-one percent of patients required hospitalization for drug-related adverse events with the most common reasons including evaluation of fever, management of vascular leak syndrome or dehydration secondary to gastrointestinal toxicity. A flu-like syndrome was experienced by 91% of patients within several hours to days after infusion. Other adverse effects included infectious complications, GI side effects, and rash.

The recommended dose of denileukin diftitox is 9 or 18 mcg/kg/day administered intravenously for 5 days every 21 days. The drug should be infused over at least 15 minutes. The drug is usually administered as an IV infusion daily for 5 days every 3 weeks. The drug should be infused over at least 15 minutes. The median duration of infusion, as well as the administration of IV antihistamines, corticosteroids, and epinephrine as necessary. Vascular leak syndrome was reported in 27% (38/143) of patients in clinical studies. All patients experienced one or more adverse events. Twenty-one percent of patients required hospitalization for drug-related adverse events with the most common reasons including evaluation of fever, management of vascular leak syndrome or dehydration secondary to gastrointestinal toxicity. A flu-like syndrome was experienced by 91% of patients within several hours to days after infusion. Other adverse effects included infectious complications, GI side effects, and rash.

The recommended dose of denileukin diftitox is 9 or 18 mcg/kg/day administered intravenously for 5 days every 21 days. The drug should be infused over at least 15 minutes. The optimal duration of therapy has not been determined; however, only 2% (1/50) of patients who did not demonstrate at least a 25% decrease in tumor burden prior to the fourth course of treatment subsequently responded.

References:
- Ontak™ Package Insert.
“Cancer Survivors Are The Most Important Product...”

The 1999 Spring Group Meeting of the Southwest Oncology Group in Phoenix featured three long-term cancer survivors from the Phoenix, Arizona, area. Survivors Louise Conrad and Nicholas Adamakis are from Tucson and Lenore Barney resides in Safford. All three are survivors of lymphoma. Mrs. Conrad’s husband accompanied her to the meeting, while Mr. Adamakis brought his son Nicholas and Mrs. Barney was joined by her daughter Janet.

The survivors were honored at the “Cancer Survivors Celebration” and Principal Investigator Dr. Thomas P. Miller, Arizona Cancer Center, introduced them to the invited guests. To help the survivors find their way around the Group Meeting, Clinical Research Associates (CRA) Committee volunteers serve as escorts; we are grateful to Beth Davis, Leora Tanaka, and Gina Gregovich who made them feel very much at home.

Under the “Cancer Survivors Celebration” program, invitations to attend a Group Meeting are extended to long-term cancer survivors (ten years or more) who completed treatment under Southwest Oncology Group cancer clinical trials and who reside in the local geographic area where the Group Meetings are held. The survivors are honored at a special reception and recognized before the Group’s membership at the Plenary Session. They may attend a Disease Committee meeting where they gain insight into the development process of the research that has so profoundly affected their lives. In keeping with the emerging focus on cancer survivorship, this program was created in 1997 to heighten national, local and Group-wide awareness of cancer survivors and the significant role they play in the research process.

“Cancer survivors are the most important product of the Southwest Oncology Group,” states Dr. Coltman. “We are pleased to be able to join with them in celebrating the successful partnership of science and life.”

LOOK HERE!!! CRA Poster Session News!!!

Exciting news! Starting with the Group Meeting in October 1999, four $100 cash awards will be presented to select CRAs and/or groups who prepare and present posters. Annette Brown, Chairperson of the Poster Committee, is in the process of developing an entry blank with rules and regulations. Winners will then be selected by Annette and two Executive Committee members at large.

The Continuing Education (CE) Workshop at the next meeting will be on head and neck cancer and treatment. Feel free to prepare a poster on this topic or any other aspect of data management.

Not only will your poster be educational for other CRAs, your institution will receive credit for your efforts, and now, you could get a nice reward for your hard work! Start planning your poster now!

For further information, please contact Annette Brown at 818-359-8111.
Clinical Research Associates (CRA) Committee Update

Thanks go to Anita Crosena, Susan Majeski, Amalia Rincon and Lyndon Evans for presenting excellent educational programs during the Spring 1999 Group Meeting in Phoenix. If you were unable to attend the Continuing Education (CE) Workshop on colorectal carcinoma, you may order the videotapes using the videotape order form included in this edition of The Group Newsletter. Head and neck cancers have been selected for the October 1999 workshop and brain tumors will be presented at the April 2000 workshop.

The Head CRA meeting was well attended and had good interaction from participants. Thanks to Jackie Benedetti, Ph.D., from the Southwest Oncology Group Statistical Center for providing an informative presentation on the expectation report. Plans are to send out a summary from the meeting to Head CRAs. Betsy Higgins at Brooke Army Medical Center will be coordinating this educational session for the October meeting. The session will be moved to 12:30—1:30 p.m. for the meeting in San Diego. This will help eliminate conflicts with Nursing Committee activities. If you were unable to attend and have suggestions on topics to be discussed in this forum, please contact Betsy Higgins with your ideas at:
phone: 210-916-4777 or
email: betsy_higgins@smtplink.bamc.amedd.army.mil

Do You Have New CRAs?

The membership of the Clinical Research Associates Committee is composed of all Clinical Research Associates (CRAs) within the Southwest Oncology Group. All active CRAs in the Group should be listed in the Group Roster maintained by the Group’s Operations Office. Your help is needed to assure the information in the roster is current as it is the source utilized for creating mailing labels for The Group Newsletter and any other information that may go directly to clinical research associates.

Please be sure you notify the Operations Office of any new CRAs joining the staff at your institution as well as CRAs that have left your institution. Member institutions should keep information current for their CGOPs, and CCOPs should provide updates for facilities affiliated with the CCOP. Included on page 26 in this issue of The Group Newsletter is the Clinical Research Associates Roster Update Form. Please be sure your institution’s roster is current. If you have questions about the roster, contact Janet Graff at the Operations Office.

CCRA Exam To Be Offered At October Group Meeting

Twenty-four clinical research associates took the Society of Clinical Research Associates (SoCRA) clinical research associate certification examination in Phoenix. Due to the response of our CRAs, we will offer the examination again at the October 1999 Southwest Oncology Group Meeting in San Diego. The examination, conducted by SoCRA, is scheduled for Wednesday, October 20. Please check SoCRA’s web page (www.socra.org) or contact SoCRA at 800-SOCRA92 or 215-345-7749 for application deadline information.

The purpose of the certification program is to create an internationally accepted standard of knowledge, education and experience by which clinical research associates will be recognized as professionals in medical research. Those who achieve a passing score on the examination may use the title “Certified Clinical Research Associate” or the initials “CCRA” after their name.

Applicants must be current members of SoCRA in good standing and have been employed two of the last five years as a clinical research associate. You may apply for membership in SoCRA at the same time you apply for the certification examination.

The certification examination consists of five major areas of content: 1) conduct of clinical trials; 2) institutional review boards and regulations; 3) ethical issues; 4) ability to follow directions; and 5) abstracting information from medical records. Applications for the certification examination and membership in SoCRA may be obtained by calling 800-SOCRA92 or 215-345-7749. Information may also be obtained from the web site at the address as noted above.

The Southwest Oncology Group contact persons are Debbie Christie (601-984-1099) and Jeana Cromer (501-686-8274).
Amalia Rincon, CTR, CCRA, and Lyndon Evans, RN, CCRA, thank all those who attended the CRA Open Forum in Phoenix, Arizona. Your participation in the Phase I survey to determine the effectiveness of the round tables was a great success. Approximately one hundred participants attended the Open Forum. We are happy to report that all the tables were well attended with 212 contacts (those who remembered to sign in at each table). Average attendance ranged from 11 to 25 participants per table; participants attended from 1-4 tables with the majority (80%) attending 3 tables. Of those responding, 75% found the tables “very useful” and 25% found them to be “useful.” Happily no one found them “not useful.” The table most widely attended dealt with organizational tips.

As a result of the high attendance, we will be maintaining all the topics presented at this meeting. However, per your suggestions, not all topics will be presented at every meeting. We will be rotating the topics so that new topics can be presented at future meetings.

It was suggested that we offer a table on Lab values. Therefore, at our October meeting, we will be offering a table on “Understanding Lab values and how they relate to protocol treatment and toxicity.” A few suggested that more than one disease site be presented at the staging table. It is very difficult to try to review all cancer sites and allow time for questions in 30 minutes. In the past, we have tried to have a staging table limited to one disease site and have it correlate with the Continuing Education program. As a result of your suggestions, we are working toward establishing another table on Breast staging in addition to a table on Head and Neck (planned continuing education topic).

Concerning the time allotted for each table (30 minutes), 92% felt it was just right, so we will keep table rotation at this time interval. Attendance by first timers and experienced participants was about 50/50. Experience ranged from none to 25 years. Job titles included CRAs, RNs, RTs, a couple of managers, and one MD.

As you can see, there is something for everyone! Only one person indicated he/she did not plan to attend any future CRA Open Forum meetings. The reason given was that there were not enough new topics to choose from.

Remember, this is your Open Forum, we can only present what you want if you let us know. If you have any suggestions for additional topics you would like to see or if you would like to present a topic, please feel free to contact:
Amalia Rincon at (310) 825-3706
e-mail mrincon@med1.medsch.ucla.edu
or
Lyndon Evans at (864) 240-2966
e-mail levans@ghsms.ghs.org

**Wanted: CRA “Tools of the Trade”**

As we have done in the past, we are asking all CRAs for any “tools of the trade” they have developed and are using to make their research duties easier and/or more efficient. “Tools” might include reminder systems to keep up with follow-up appointments, new and improved filing systems, pocket-sized protocol books for physicians, unusual sources of information for those hard-to-find follow-up cases, etc. Any ideas or tips that make your job run more smoothly are welcomed.

Beth Davis is planning to make a packet of “tools” that will be distributed to participants at the CRA Training Course at the October 1999 Group Meeting in San Diego.

Please forward your “tools” to Beth at the following address:
Beth Davis, CCRA
Research Coordinator
Alta Bates Comprehensive Cancer Center
2001 Dwight Way
Berkeley, CA 94704
Phone: 510-204-3428 Fax: 510-649-9857
e-mail: bdavis@abccc.salick.com

**SWOG-9304 — CRAs Take Note!**

CRAs should be aware that several patients have been declared ineligible for this trial. Problems have been encountered due to patients having microscopically positive margins.

Also, CRAs should be very careful in screening patients whose operative report states, “...tumor extends to the serosa...” The majority of the rectum has no serosa and if tumor extends to “serosa” it may be that the patient is not eligible for the study.

The exact area of resection and tumor should be verified very carefully before the patient is enrolled.

CRAs...Turn to page 28 for more news!
Nurse Oncologist Committee News

The Nurse Oncologist Committee wishes to express deepest appreciation to Jeanne Parzuchowski, RN, MS, OCN, for the years of dedicated service she provided as Committee Chair. Marcia Grove-Conrad, RN, MSN, MPH, OCN, has been appointed as new Chair of the Nurse Oncologist Committee. Our warmest welcome is extended to Marcia in her new role. Members of the Nurse Oncologist Executive Committee are happy to address any questions regarding committee and subcommittee activities. Oncology nurses within the group are welcome to become active participants in the Nurse Oncologist Committee. Please feel free to contact us!

Marcia Grove-Conrad, Chair — 334-460-7194
Lisa Hansen, Vice Chair & Exec Liaison, Cancer Control — 503-413-6285
Linda Davis, Secretary — 313-745-2188
Patra Grevstad, Chair - Membership — 206-386-2442
Carolyn Schmidt, Co-Chair, Disease & Discipline — 313-876-7277
Dorothy Coleman, Co-Chair, Education — 808-586-2979
Pam Williams, Co-Chair, Education — 864-560-6812
Sandy Remer, Chair, Program — 248-424-5337
Marge Good, Executive Liaison CCOP Program — 316-268-5696

Subcommittee Reports
from the Spring 1999 Group Meeting

CCOP/CGOP: An NCI update was presented by Rosemary Padberg, RN, and Lori Minasian, MD. They discussed changes in DCP organizational structure. Treatment trials accrual increased during the past year. Budgets for CCOPs should be out in June, 1999. The new informed consent format being used by two NSABP trials was reviewed. CCOPs participating in the pilot project adding a 6th research base shared their experiences. New research base studies passed IRB review and accrual has begun over the past 1–2 months. An update on the 6th research base project will be held at the Fall Group Meeting. Contact Marge Good at 316-268-5696 to add agenda items to the Fall 1999 CCOP/CGOP meeting.

Disease & Discipline: Eighteen very enthusiastic nurse oncologists attended the Disease & Discipline Subcommittee meeting. Reports were given by designated nurse liaisons regarding activities with the various disease committees. Some communication channels remain that need strengthening; this will continue to be a goal of this Subcommittee. Presently, there is still a nurse liaison vacancy in the Lymphoma and the Head & Neck Committees. There is also interest in identifying individuals interested in representing radiation oncology and surgical oncology. Anyone interested in these areas may contact Carolyn Schmidt at 313-916-7277.

The working relationship between this Subcommittee and the Pharmacy Committee continues through linkage of disease-specific nurse liaisons and pharmacists.

A subgroup of individuals agreed to collaborate prior to the next Group meeting on a special project that is hoped to utilize the talents of many individuals and provide recruitment support to clinical sites. Stay tuned, more information to come.

Education Subcommittee: Ongoing projects include: coordination of posters from nurse oncologists; newsletter submission for Nurse Oncologist Committee; BSE workshop; orientation program at Nurse Oncologist Plenary Session & CRA Roundtables; development of new patient and nursing education tools pertaining to SWOG trials; revising the Nursing Manual; and developing the Drug Manual in collaboration with the Pharmacy Committee. The Pharmacy/Nursing Subcommittee continues to draft and review drug monographs; the initial Drug Manual will be distributed to members this summer. Pam Williams presented a poster entitled, “The Five Days of a SWOG Meeting.” A new project initiated at this meeting was development of a brochure on “What is a Cooperative Group?” spearheaded by Beverly Orazen, RN.

Membership: Welcome new members:

Stacey L. Brian, RN, OCN, CRNI, New Milford Hospital
Karen M. Denolf, RN, BSN, OCN, Munson Medical Center
Kimberlee A. Hanna, RN, BSN, OCN, Wichita CCOP
Cynthia M. Licavoli, RN, BSN, St. John’s Mercy Medical Center
Victoria Ratts, RN, MS, LSU Moll Cancer Center

Total membership is 105 Nurse Oncologists. The Breast Self Exam Courses went very well and will continue at future meetings. Anyone interested in helping teach the courses can contact Patra Grevstad at 206-386-2442. We are also looking for Membership Committee members.

Research Subcommittee: The structure and relationships between the Cancer Control Research Committee, Behavioral and Health Outcomes Subcommittee, and the Nursing Research Subcommittee were reviewed. Historical perspectives were shared on nursing research generation, barriers, and triumphs for nurse researchers. Nursing involvement in the upcoming oral mucositis and smoking cessation trials was stressed. New leadership for the Nursing Research Subcommittee was established. Anna L. Schwartz, PhD, ARNP, will be the new chair and Maggie Ramsey, RN, MS, AOCN, will serve as co-chair. Nurses interested in membership on the Nursing Research Subcommittee should contact Lisa Hansen at 503-413-6285.

(Continued on page 24)
The Cost of Cancer Trials Study — Study Description

Following is important information about a study that is being conducted by RAND, a private, non-profit research institution based in Santa Monica, California:

The Cost of Cancer Trials Study (CCTS) is a study of cancer patients throughout the United States, with principal funding and scientific guidance from the National Cancer Institute. Additional funding is being provided by the Office of the Director, National Institutes of Health and by the National Science Foundation as part of its support from the White House Office of Science and Technology Policy.

Clinical trials are a critical component of the high quality medicine practiced in the United States. The cost of clinical research on cancer in the United States is borne by a combination of third-party reimbursement and institution and research study support. However, anecdotal evidence suggests payers are becoming increasingly reluctant to pay for care associated with clinical trials. This limits patient access to trials; in addition, cancer researchers face the daunting prospect of curtailing or biasing future clinical research. Unfortunately, these decisions are being made without data on the true cost of trial participation.

The CCTS study will estimate the “marginal cost” of medical treatment provided as part of NCI-sponsored protocols; that is, the cost of additional medical resources, if any, provided to patients on protocols above and beyond those that would have been received in the absence of trial participation. The results from this study should be of interest to policymakers, insurers, and health-care decision makers trying to determine appropriate reimbursement for clinical trials. As secondary endpoints, RAND will also compare patient satisfaction and health outcomes of patients in trials with those not in trials.

RAND will use a multistage study design to select up to 2,000 patients at 50-60 study sites among all of the institutions, clinics or practices in the United States that are participating in NCI-sponsored Phase II or III clinical trials. Your institution could be among those selected to be a part of this study! RAND will select the patient sample by randomly selecting patients who have enrolled in a clinical trial during a specified period of time at these sites. Using cancer registries and chart reviews, RAND will also sample and follow a matched control group of cancer patients who did not enroll in a clinical trial. The study will collect data from several sources, including a patient interview and medical, financial and pharmacy records. Using economic models of costs, RAND will then compare the two groups to estimate the cost of trial participation.

For additional information about the Cost of Cancer Study, please contact:

Kathryn Davis, Survey Coordinator
RAND
1700 Main Street
Santa Monica, CA 90401
Phone: 310-393-0411, ext. 7267
Fax: 310-451-6921
Email: Kathryn_Davis@rand.org

Program Subcommittee: The Fall Programs include:

CANCER CLINICAL TRIALS EDUCATION PROGRAM (CCTEP) — This workshop will be repeated in San Diego at the October meeting and then yearly thereafter during fall Group Meetings. Goals of this workshop are: 1) Inform participants about importance of clinical trials and the need to increase patient accrual; and 2) Provide participants with understanding of the National Cancer Institute Cancer Clinical Trials Education Program (CCTEP) resource kit. This program and kit will provide participants with skills and knowledge to conduct clinical trial education programs in their own communities. The program and materials will be offered free of charge, but it will be necessary to pre-register, as space is limited. Watch for information on the meeting time and the registration form in the fall Group Newsletter.

NURSE ONCOLOGIST PLENARY SESSION PLANS — WE NEED YOUR HELP! The topic of the October 1999 Nurse Oncologist Plenary Session will focus on patient education from the perspective of the NCI, ONS and the patient. The program committee is looking for teaching tools to present at this meeting. If you have any educational materials you are currently using and are willing to share them with the group please forward a copy along with your name, institution, address and phone number to:

Beverly Orazen, RN, ADN, OCN
Grant/Riverside Hospital
3545 Olentangy River Road
Columbus, Ohio 43214

or

Karen Rohan, RN, MN, OCN, CCRA
Greater Phoenix CCOP
925 E. McDowell Rd
2nd Floor
Phoenix, AZ 85006
SOUTHWEST ONCOLOGY GROUP
NURSE ONCOLOGIST COMMITTEE MEMBERSHIP FORM

Date Submitted ___________________________
Date Received ___________________________

Please note that you are required to attend at least one out of every four meetings to become a member and maintain membership status.

Name and Credentials: _____________________________________________
Address (Workplace): _____________________________________________
Phone: ___________________________ FAX Number: _______________________
E-Mail Address: _____________________________________________

Address (Home): _____________________________________________

Telephone (Optional): _____________________________________________

Current Work Position: _____________________________________________
Speciality: _______________________________________________________
Principal Investigator: _____________________________________________

Group Status: Member ________ CCOP ________ CGOP ________
Other _________

Are you interested in becoming a member of a specific Disease Committee?
Yes ________ No ________ Please send me more information _____________

Membership Request (check all that apply): Nursing Subcommittees
Disease and Discipline ____________
Research ____________
Program ____________
Education ____________

Required information (Must accompany application):
- Curriculum vitae
- Principal Investigator's letter of recommendation addressed to: Charles A. Coltman, Jr., M.D., Southwest Oncology Group Chairman, Operations Office, 14980 Omicron Drive, San Antonio, TX 78245-3217

Mail to: Patra K. Grevstad, RN, Swedish Hospital Tumor Institute, 1221 Madison Street, Seattle, WA 98104. You may call with questions 206-386-2442.
CLINICAL RESEARCH ASSOCIATES (CRA) UPDATE FORM

Complete the form below and submit to the Southwest Oncology Group Operations Office to update, add or delete, Clinical Research Associate information from your CCOP, member institution or affiliate in the Southwest Oncology Group Clinical Research Associates Committee Roster.

When deleting a Clinical Research Associate and adding a new one, complete the "FROM" section of the form, indicating the information requiring deletion from the Roster, and enter the new Clinical Research Associate information in the "TO" section.

If only adding a new Clinical Research Associate, cross out the "FROM" section of the form and complete the "TO" section.

Change the following:

FROM:

NAME/TITLE ________________________________

INSTITUTION/AFFILIATE ________________________________________________________

PHONE NUMBER ___________________ FAX # ________________

E-MAIL ADDRESS ______________________________________________________________

MAILING ADDRESS _____________________________________________________________

____________________________________________________________________________

TO:

____________________________________________________________________________

NAME/TITLE ________________________________

INSTITUTION/AFFILIATE ________________________________________________________

PHONE NUMBER ___________________ FAX # ________________

E-MAIL ADDRESS ______________________________________________________________

MAILING ADDRESS _____________________________________________________________

____________________________________________________________________________

Mail or FAX completed update form to: Southwest Oncology Group Operations Office
14980 Omicron Drive, San Antonio, TX  78245-3217
FAX:  210-677-0006

JUNE 1999
VIDEOTAPE ORDER FORM

CLINICAL RESEARCH ASSOCIATES COMMITTEE

__Cancer Control: Implementing Cancer Control in a Community Setting; Practical Advice On Implementation (10/92)
__Myeloma: The Disease, Molecular Biology, Role of Bone Marrow Transplants (4/93)
__Myeloma: Assessment of Toxicities, Response to Treatment, Therapeutic Results, Panel Discussion (4/93)
__Lung Cancer: Diagnosis and Treatment (10/96)
__Lung Cancer: Surgical Options for Lung Cancer Patients (10/96)
__Lung Cancer: Role of Radiotherapy in Lung Cancer (10/96)
__Lymphoproliferative Disorders/Lymphoma: Overview; Role of Pathology in Diagnosis & Management (4/97)
__Lymphoproliferative Disorders/Lymphoma: Role of Transplant in Lymphomas; New Directions and Current Studies (4/97)
__Myeloproliferative Disorders - Pathology & Tumor Biology: Role in Diagnosis (10/97)
__Myeloproliferative Disorders - Overview (10/97)
__Myeloproliferative Disorders - Role of Transplants (10/97)
__GU Diseases: Renal Cancer Overview (4/98)
__GU Diseases: Locally Advanced Bladder Cancer Overview (4/98)
__GU Diseases: Advanced Bladder Cancer Overview (4/98)
__Everything You Need to Know About Radiotherapy...But, Were Afraid to Ask (4/98)
__Side Effects and Toxicities of Radiation Therapy (4/98)
__Adrenal, Prostate & Testicular Cancer: Surgical Overview; Pathological Overview (10/98)
__Adrenal, Prostate & Testicular Cancer: Radiation Therapy; Medical Oncology; Introducing CAPRI (Cancer of the Prostate Risk Index); Panel Discussion (10/98)
__Colorectal Carcinoma: Surgical Management; Role of Chemotherapy (4/99)
__Colorectal Carcinoma: Role of Vaccine Therapy; Radiation Therapy; Panel Discussion (4/99)

MAIL TAPES TO:

NAME: __________________________  ADDRESS: __________________________
DEPT: __________________________
CITY: __________________________  STATE: ____________  ZIP CODE: ____________
TELEPHONE: (__) _____________  AFFILIATION/INSTITUTION: __________

_____ I assume responsibility for the prompt and safe return of all tapes requested. There will be a $10 replacement fee for damaged or lost tapes. There is a maximum three (3) week loan period.

SIGNATURE: ______________________

NOTE: If several tapes are ordered, it may take up to several months to complete the order.

MAIL ORDER FORM TO: Debra W. Christie, Cancer Research and Registry, University of Mississippi Medical Center, 2500 North State Street, Jackson, MS 39216. Or, you may fax the form to 601-984-1964.
ATTENTION ALL CLINICAL RESEARCH ASSOCIATES

Beginning at the Fall 1999 group meeting, funding will be available to assist any CRA with the preparation of a poster for upcoming meetings. There will be four $100.00 awards per meeting. The first author must be a CRA and there is only one award allowed per institution per year.

CRA’s are encouraged to present posters at group meetings. Not only will your poster add interest to the meeting, but also your institution will receive credit for your efforts. We try to coordinate poster topics to the topics presented at the Continuing Education Workshop and/or the Plenary Session, but others topics or aspects of data management that interest you are appreciated.

We would like to thank the following who submitted posters at the last two meetings:

FALL 1998 GROUP MEETING - SAN ANTONIO, TEXAS

“Protocol Pathways” — Cindy Licavoli, RN, BSN; St. John’s Mercy Medical Center, St. Louis CCOP; St. Louis, MO.

“The Presentation of Clinical Research to Patients” — J. Hilger, CCRA; M. Grant, DNSc, RN; A. Mercurio, MPH, CHES; L. Roach, CCRA; J. Niland, PhD; City of Hope National Medical Center, Duarte, CA.

“SWOG S9832: Enhancing Well-Being During Breast Cancer Recurrence - A Randomized Phase III Study to Evaluate the Efficacy of Peer Counseling” — C. Gotay, PhD; C. Moinpour, PhD; K. S. Albain, MD; S. Martino, DO; B. Taylor, PhD; Hawaii MBCCOP; Honolulu, HI.

“Training Program for Introduction to Data Management in Oncology Clinical Trials” — Linda Roach, CCRA; Joyce Niland, PhD; Jacqueline Hilger, CCRA; Martha Bellin, RN, CCRA; Annette Brown, CCRA; Gina Farino, BS, CCRA; City of Hope National Medical Center, Duarte, CA.

SPRING 1999 GROUP MEETING - PHOENIX, ARIZONA

“Colorectal Carcinoma” — Anita Crosena, CCRA; Community Cancer Care Specialists, Clinton Township, MI.

“CRA Mentor Poster” — Phyllis Stein, Grand Rapids CCOP, Grand Rapids, MI, for her great preparation of this new poster.

For further information and guidelines contact Annette Brown at (626) 359-8111, ext. 3037 or e-mail abrown@coh.org.