Message from the Chairman

Group to take new direction

By Laurence H. Baker, D.O.

This is a new opportunity for me to share thoughts, concerns, and opportunities.

Firstly, let me again express my appreciation to Chuck Coltman, John Crowley and Mary Godfrey during the transition and to all of you for your support and encouragement.

It has been a whirlwind two months. Our Group meeting in Denver will be remembered not only for David Crawford telling us “the Denver airport never closes,” but more importantly, for a grand party demonstrating the talent, dedication and passion of SWOG.

Thanks also to all of you who enjoyed the party and expressed your views.

A few days later, our Data and Safety Monitoring Committee recommended we close a lung cancer trial (S0023). The data were presented by Karen Kelly at ASCO showing not only that gefitinib wouldn’t be of benefit to patients but might actually be harmful. This thoughtful data analysis led by John Crowley showed once again that “opinions – even expert opinions – are trumped by data.”

Now we face the challenge of responding to the proposals of the Doroshow report (please see page 2) given to the National Cancer Advisory Board:

(1) The days when clinical trial priorities are based upon “political practice” (in which I support your study and then you support my study) need to be replaced by doing the best study every time. Our trials need to aim at improving outcome in cancer patients and lead to fundamental change in the practice of medicine.

(2) We must learn to integrate correlative science questions into clinical trials and ultimately into clinical practice.

(3) We need to develop better incentives to participate in clinical trials by rewarding effectively those sites that participate in our trials and by avoiding Humpty Dumpty leadership…do as I say; not as I do. We have to be cognizant that our organization is based upon volunteerism.

(4) We need to do a better job of including community-based programs (CCOPs and affiliates).

(5) We need to review the cooperative practices and improve their efficiency.

SWOG has begun the process of planning our response. In June, our first two-day summit meeting will be held in Ann Arbor. The SWOG leadership will gather to discuss the Doroshow report. At the next SWOG Group meeting, our expert national advisors will meet with our Scientific Advisory Board to review our proposals. The issues of correlative science and clinical trial design will be straightforwardly discussed by: Dan Hoth (San Francisco), Gary Gilliland (Harvard), Carlos Arteaga (Vanderbilt) and this year’s ASCO Karnofsky lecturer, Charles Sawyer (UCLA). Our executive officers have begun to study group practices and policies and seek

(Continued page 2)
With the installation of a new chairman for the Southwest Oncology Group comes a new Headquarters Office in Ann Arbor, Michigan. This is where our new Chairman Laurence “Larry” H. Baker, D.O., will direct the Group’s business.

The Statistical Center in Seattle, Wash., and the Operations Office in San Antonio, Texas, are already closely integrated with the Headquarters Office. The Headquarters Office staff includes Drs. Baker, Schott, Erba and Redman, Anna Schork, Joy Reilly, Mary Vestich and Denise Reinke.

The three executive officers – Harry P. Erba, M.D., Ph.D., Anne F. Schott, M.D. and Bruce G. Redman, D.O. – will facilitate the development of the Group’s clinical trials. They will also offer medical advice in all areas. More specifically:

- Dr. Erba will work with the lymphoma, leukemia and myeloma committees.
- Dr. Schott will monitor activities of the breast, early therapeutics, lung, and head and neck committees.
- Dr. Redman will provide oversight for gastrointestinal, genitourinary, immunomolecular therapeutics and melanoma studies.

Denise Reinke, M.S., N.P., is administrative director. She will function as the point person for information exchange, mainly between the Headquarters and Operations Offices, and will be involved in all administrative issues. She has the additional responsibility of monitoring delinquent manuscripts and investigating delays in clinical trial development.

Anna Shork, J.D., legal and fiscal administrator, will be responsible for all legal issues for the Group. She also will oversee the contracts between the Headquarters Office and the institutions. She will facilitate contract negotiations and development with our pharmaceutical partners.

Joy L. Reilly is fiscal administrator at the Headquarters Office and will handle all third-party consortium payments and per-case reimbursements for treatment studies.

Mary Vestich is the administrative assistant for the Headquarters staff. She will likely be the person to greet you when you call. She will help answer any questions or concerns you may have. Mary has worked with Larry Baker for over 18 years and handles his schedule.

The Southwest Oncology Group Headquarters Office will be housed within the University of Michigan’s Department of Medicine. The University of Michigan is recognized as a top research institution. In fact, research expenditures for fiscal year 2004 for the Medical School topped $295 million and more than $86 million for the Department of Internal Medicine. The University of Michigan has been a member of the Southwest Oncology Group for more than 20 years and has a record of commitment to oncology research. Marc Lippman, chairman of the Internal Medicine Department, is a medical oncologist and is known for his research in breast cancer. Additionally, University of Michigan Medical School Dean Allen Lichter is a radiation oncologist and former head of SWOG’s Radiation Oncology Committee. With the headquarters of the Southwest Oncology Group being established at the University of Michigan, the tradition of research commitment continues.
‘And Crawford wanted all the Group meetings to be in Denver!’

Survey gives Group members the opportunity to share thoughts about Group meeting locations

Many Southwest Oncology Group members awoke to a major blizzard on Sunday, April 10, the last day of the Spring 2005 Group Meeting in Denver.

While the snow made for great skiing – if you could get to the mountains – it played havoc with leaving Denver because the airport and roads leading to it were closed.

“With the gorgeous weather before the snowstorm (and with Denver being his home town), David Crawford had suggested that there was no better place than Denver to have all of the Group meetings,” quipped Group Chairman Laurence Baker, D.O. “Denver is a wonderful place, but I think we need to look at all the options for where we want to hold Group meetings in the future.”

Although Group meetings have already been booked through 2008, you can use the survey below to state your preference for meetings after that time. You can vote one of four ways:

1. Take the survey to be posted during the week of June 20 at http://swog.org.
2. Respond to the Group-wide e-mail to be sent the week of June 20.
3. Complete the survey below and fax it to 210-677-0006.
4. Fill out the survey below and mail it to the Southwest Oncology Group Operations Office, 14980 Omicron Drive, San Antonio, Texas 78245-3217.

Group Chairman Laurence Baker, D.O., stands in front of the Hope Foundation Porsche outside the hotel during the blizzard in Denver.

Southwest Oncology Group Meeting Survey

1. What is your position:
   ___ Clinical Research Associate
   ___ Nurse Oncologist
   ___ Physician
   ___ Scientist
   ___ Other: _____________________

2. Select where you would most prefer the Group meeting to be held:
   ___ West Coast
   ___ East Coast
   ___ Central location
   ___ Southern location
   ___ Combination of locations

3. Please rank these three factors (1 = most important) in your decision to attend the Group meeting
   ___ Cost
   ___ Location
   ___ Ease of travel

4. Please rank in importance (1 = most important) what you prefer in a meeting location:
   ___ Large metropolitan city
   ___ Smaller more economical city
   ___ Resort location

5. Check which option you prefer:
   ___ Varying locations for each Group meeting
   ___ Spring and fall Group meetings held in the same two locations each year

6. Please select the five consecutive days you would prefer to attend the Group meeting:
   Monday Tuesday Wednesday Thursday Friday Saturday Sunday
Spring 2005 Group Meeting transfers leadership to Dr. Baker

Dr. Baker announces Group initiatives, new Scientific Advisory Board during plenary session speech

In his first speech as Group chairman, during the plenary session of the Spring 2005 Group meeting, Laurence H. Baker, D.O., focused on milestones in cancer research, where the Group stands today and what initiatives will take the Group into the future.

Cancer milestones

Dr. Baker opened his talk by acknowledging the greatest accomplishments in the field of cancer through a “Top 10” list, which he developed and asked his colleagues at the University of Michigan to rank. Among the most significant achievements noted were Marie Curie’s discovery of radiation, Watson and Crick’s work on the structure of DNA and Wynder’s establishing the relationship between cigarette smoking and lung cancer.

Top accruing sites

Dr. Baker then introduced the staff at the new Headquarters Office in Ann Arbor, Mich., (see article on page 2) and noted the top accruing sites in the Southwest Oncology Group. They include:

• Top five Member institutions are Loyola University, University of Rochester, Puget Sound, University of California-Davis and City of Hope.
• Top five CCOP accrual sites include Wichita CCOP, Columbus CCOP, Southeast CCC CCOP, Grand Rapids CCOP and Montana CCOP.
• Top five UCOP accrual sites are the University of Southern California UCOP, Columbia Presbyterian UCOP, University of Colorado UCOP, Wayne State UCOP and University of California-Davis UCOP.

Scientific Advisory Board

One of Dr. Baker’s first tasks was to reorganize the Scientific Advisory Board (SAB) and appoint Richard I. Fisher, M.D., as its chairman. SAB members who are members of the Southwest Oncology Group include Fred Appelbaum, M.D.; Charles Blanke, M.D.; E. David Crawford, M.D.; Cecilia Fenoglio-Preiser, M.D.; David Gandara, M.D.; Robert Livingston, M.D.; Paul Okunieff, M.D.; and Vernon Sondak, M.D.

External advisors to the SAB are Carlos Arteaga, M.D.; Gary Gilliland, M.D., Ph.D.; Daniel Hoth, M.D.; and Charles Sawyer, M.D.

Ex-officio member include Dr. Baker; Charles A. Coltman Jr., M.D.; John Crowley, Ph.D.; Harry Erba, M.D., Ph.D.; Leslie Ford, M.D.; Marjorie Godfrey; Alison Martin, M.D.; Bruce Redman, D.O.; Denise Reinke, M.S., N.P.; Anna Schork, J.D.; and Anne Schott, M.D.

Looking ahead

Dr. Baker focused on four initiatives to lead Southwest Oncology Group into the future. They include:

• Adding monoclonal antibodies to traditional chemotherapy to change the natural history of follicular non-Hodgkin’s lymphoma.
• Incorporating correlative science into lung cancer studies.
• Using functional imaging in collaboration with the American College of Radiology Imaging Network to better understand drug responses in metastatic melanoma.
• Continuing to work with Japanese oncologists to develop a trial in gastric cancer.

Coltman steps down after 24 years

Charles A. Coltman Jr., M.D., stepped down as chairman of Southwest Oncology Group during the Board of Governors meeting on Friday, April 8, passing the gavel to former Chair-Elect Laurence H. Baker, D.O.

Dr. Coltman will continue with the Group as associate chair for cancer control and prevention.

Dr. Baker is deputy director and director for clinical research at the University of Michigan Comprehensive Cancer Center in Ann Arbor, Mich. He also is professor of medicine and associate chief of the Division of Hematology/Oncology in the Department of Internal Medicine.
Plenary session focuses on four scientific presentations

The plenary session of the Spring 2005 Southwest Oncology Group Meeting on April 9 focused on four scientific presentations which were later featured at the American Society of Clinical Oncology (ASCO) annual meeting in May. After each presentation, a discussant commented on the study before questions were accepted from the audience.

Kathy S. Albain, M.D., was the first presenter. Dr. Albain is chair of the Southwest Oncology Group Committee on Special Populations and professor of medicine at Loyola University Medical Center, Maywood, Ill. She presented results of S9336, a Phase III Study of Concurrent Chemotherapy and Radiotherapy (CT/RT) vs. CT/RT Followed by Surgical Resection for Stage IIIA (pN2) Non-Small Cell Lung Cancer (NSCLC): Outcomes Update of North American Intergroup 0139 (RTOG 9309).

Paul A. Bunn Jr., M.D., director of the University of Colorado Cancer Center in Denver, was Dr. Hirsch’s discussant.

Fred R. Hirsch, M.D., Ph.D.

Fred R. Hirsch, M.D., chair of the Radiation Therapy Oncology Group in Philadelphia, Pa., commented on her study and results.

The second presenter was Fred R. Hirsch, M.D., Ph.D., visiting professor at University of Colorado Cancer Center in Denver. Dr. Hirsch also is chief physician, Department of Oncology, National University Hospital, Copenhagen, Denmark. He presented information about S0126. Increased EGFR Gene Copy Number Detected by FISH is Associated with Increased Sensitivity to Gefitinib in Patients with Bronchioloalveolar Carcinoma (BAC).

Paul A. Bunn Jr., M.D.

The third presenter was Frederick R. Appelbaum, M.D., chair of the Southwest Oncology Group Leukemia Committee. Dr. Appelbaum also is clinical research director of the Fred Hutchinson Cancer Research Center, executive director of the Seattle Cancer Care Alliance and professor and head of Medical Oncology at the University of Washington School of Medicine in Seattle, Wash. Dr. Appelbaum presented results of the Clinical Spectrum of Adult Acute Myeloid Leukemia (AML) Associated with Core Binding Factor (CBF) Translocations.

His discussant was Harry P. Erba, M.D., Ph.D., executive officer of the Southwest Oncology Group and clinical assistant professor in the Department of Internal Medicine at the University of Michigan in Ann Arbor, Mich.

Michael C. Heinrich, M.D.

The fourth plenary presenter was Michael C. Heinrich, M.D., professor of medicine in the Division of Hematology/Medical Oncology at the Oregon Health and Science University Cancer Center in Portland, Ore. Dr. Heinrich presented information about the Correlation of Clinical Response to Imatinib Mesylate (IM) and Target Kinase Genotype in Patients with Metastatic KIT + GI Stromal Tumors (GISTs).

Southwest Oncology Group Chairman Laurence H. Baker, D.O., was the discussant for Dr. Heinrich’s presentation.

For more information on these presentations as they were given at ASCO, access http://www.asco.org.
About 450 people braved forecasts of an impending blizzard on April 9 to honor Charles A. Coltman Jr., M.D. during the Spring 2005 Group meeting in Denver.

Dr. Coltman served as the Group’s chairman for 24 years before stepping down April 8 and handing the gavel to longtime friend and new Group Chairman Laurence H. Baker, D.O. Dr. Baker had previously served as the Group’s chair-elect.

After a champagne reception, and an invocation led by Robert B. Livingston, M.D., the guests enjoyed a seated dinner accompanied by a continuous slide presentation taken from the photo archives of Group meetings and events.

Then the “Roast & Toast” began led by Dr. Baker, the master of ceremonies. Presenters, who resembled a “Who’s Who Among the Southwest Oncology Group,” included:

- Marjorie Godfrey, director of the Operations Office
- John J. Crowley, Ph.D., director of the Statistical Center
- Brian Chavez, executive vice present and chief operating officer of the Hope Foundation.
- Richard I. Fisher, M.D.
- John S. “Jack” Macdonald, M.D.
- Paul A. Bunn Jr., M.D.
- Frederick R. Appelbaum, M.D.
- Cheryl L. Willman, M.D.
- E. David Crawford, M.D.

The grand finale of the evening was a tribute to Dr. Coltman based on the song “Don’t Cry For Me Argentina,” with revised lyrics written for the occasion by Beth Sanders, B.S.N., R.N., and sung by Tiffanie Clausewitz, M.P.A.

Following the event, the beautiful fresh flower arrangements on each table gave additional pleasure to an entirely different group of people – patients in four Denver hospitals. Susan Majeski, CCRP, loaded about 70 flower arrangements into her car after the dinner. They stayed fresh in her car during Sunday’s snowstorm. When streets were passable again on Monday, April 11, Majeski and her husband delivered them to the hospitals. “Both car and garage smelled like a florist shop, so I couldn’t complain!” Majeski said in an e-mail the Tuesday following Group meeting.

Order a DVD of the celebration

Whether you experienced the evening’s fun first-hand or through the stories of friends who attended, you can order a complimentary commemorative DVD of Dr. Coltman’s celebration by sending your name and address to the Southwest Oncology Group Operations Office. Send an e-mail to dvd@swog.org or fax your name and address to 210-677-0006. Requests by mail may be addressed to:

“Roast and Toast” DVD
Southwest Oncology Group Operations Office
14980 Omicron Drive
San Antonio, TX 78245-3217
Cool morning greets ‘Crush the Crab’ runners April 9 in the Mile-High City

Winning the Men’s 40 and younger division was George H. Yoo, M.D., followed by Richard O. Wein, M.D., in second place.

Winners of the Men’s 41-54 division were Joseph I. Clark, M.D., first; James A. Warneke, M.D., second; and Daniel F. Hayes, M.D., in third.

In the Men’s 55 and older division Brian F. Issell, M.D., was third; Michael G. Wortman, R.N., was first; and E. David Crawford, M.D. was second.

Winners of the Women’s 40 and younger division were Landi H. Kime, first place; Helen K. Chew, M.D., second; and Julie Ann Bray, CNP, third.

Julie Kish, M.D., was second and Vicki Crawford was first in the Women 55 and older division.

Recognitions

Coltman receives Outstanding Service Award from AACR

Charles A. Coltman Jr., M.D., former chairman of the Southwest Oncology Group, was presented the Outstanding Service Award by the American Association of Cancer Research during its annual meeting April 18.

The award was established this year to recognize significant and sustained contributions in the fight against cancer by an individual. The award recognized Dr. Coltman’s leadership and vision as chairman of the Southwest Oncology Group for 24 years.

Presbyterian Hospital receives Clinical Trials Participation Award

Presbyterian Hospital in Dallas, an affiliate member of the Southwest Oncology Group, was one of three practices to receive the Clinical Trials Participation Award during the 2005 American Society of Clinical Oncology (ASCO) annual meeting in May.

The awards are based on nominations by each of the National Cancer Institute cooperative groups and the ASCO Clinical Practice Committee. James F. Strauss, M.D., accepted the award on behalf of Presbyterian Hospital, which was nominated by the Southwest Oncology Group.

The awards were given to practices that enrolled the most patients in Phase III trials over a three-year period, with special emphasis given to those that achieved high accrual rates in underrepresented populations.
Group receives funding for PCPT program project grant

Five Southwest Oncology Group Prostate Cancer Prevention Trial (PCPT) ancillary studies were funded this spring through a program project (P01) grant. The project involves investigators throughout North America.

The overall goal of the program is to understand the biologic mechanisms underlying the results of the PCPT. Each ancillary will analyze the prostate tissue, blood and white cell samples collected during PCPT. The unifying theme is the genetic, metabolic and environmental factors associated with the risks of prostate cancer and high-grade prostate cancer, as well as the effects of these factors on how effective finasteride is in preventing prostate cancer.

One unusual aspect of this program project grant is that the highly integrated cores and projects will be led by investigators from different research institutions. The three core management areas of the study, however, will reside in established PCPT/Southwest Oncology Group facilities. The Administrative Core, led by the program project’s Principal Investigator Scott M. Lippman, M.D., will be managed jointly by M.D. Anderson and the Southwest Oncology Group Operations Office. The Biostatistics/Data Management Core will be led by Cathy Tangen, Dr.P.H., at the Group’s Statistical Center in Seattle. The Pathology/Genotyping Core will be led by M. Scott Lucia, M.D., at the University of Colorado.

The five ancillary studies, their principal investigators and their institutions are:

• Androgen metabolism, Juergen Reichart, Ph.D., University of Southern California Keck School of Medicine.
• Insulin-like growth factor axis and insulin resistance, Michael Pollock, M.D., McGill University, Montreal, Quebec, Canada.
• Diet and diet-related factors, Alan R. Kristal, Dr.P.H., Fred Hutchinson Cancer Research Center, Seattle, Wash.
• Oxidative damage and DNA repair, Regina M. Santella, Ph.D., Columbia University, New York, N.Y.
• Genotypic and phenotypic studies of inflammation, Elizabeth A. Platz, Sc.D., M.P.H., Johns Hopkins Bloomberg School of Public Health, Baltimore, Md.

The grant application was initially submitted in October 2003 and was approved for funding in February 2005.
Southwest Oncology Group among first to test CTEP’s new streamlined protocol development system

The Southwest Oncology Group is one of the first two cooperative groups to test the new protocol software program from the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI).

The new system, Docu-MART, is a software solution using both desktop and Web technologies to assist in the authoring, reviewing and tracking of clinical trial documents. CTEP’s plan is to reduce the administrative burden of protocol development so that investigators can focus on scientific integrity. This plan is reflected in the goal of reducing the time from concept approval to protocol approval to 60 days.

Seven of the Southwest Oncology Group protocol coordinators were introduced to Docu-MART during a three-day training session March 9-11 at the Operations Office in San Antonio. They include Dana Sparks, M.A.T., protocol product line manager; and protocol coordinators Gilbert Carrizales, M.S.; Cal Bonugli; Gretchen Jackson; Jennifer Scott; Courtney Watson and Connie Ballon-Almanza.

Group Executive Officer Anne F. Schott, M.D., and Denise Reinke, M.S., N.P., administrative director of the Group’s Headquarters Office at the University of Michigan, attended the training.

Yvette Grainger from Capital Technology Information Services Inc. (CTIS) led the training. Sudhir Raju, CTIS Docu-MART project manager, and Yogi Byreddy, CTIS senior systems analyst, attended the sessions for “hands-on” assistance. CTIS is the company that developed Docu-MART for CTEP.

Michael J. Montello, Pharm.D., project officer, Anne Tompkins, deputy project officer, and Troy Budd, computer assistant, represented CTEP’s Protocol Information Office to assist with the training, answer policy questions and see first-hand how Docu-MART assists with workflow.

After the Southwest Oncology Group training session, protocol coordinators at the Eastern Cooperative Oncology Group (ECOG) were introduced to the system for training and input.

The Docu-MART system will allow protocol coordinators to write a proposal, share it for review, accept comments and track the protocol’s progress through the CTEP review process.

The system is currently undergoing beta testing and debriefing with the Southwest Oncology Group and ECOG for Phase III clinical trials. Cancer and Leukemia Group B (CALGB) is expected to begin beta training in early fall. Once the results of the beta testing have been reviewed and the system has been adjusted, the schedule for production will be announced. Docu-MART will be released in phases for availability to all cooperative groups and for early phase trials.

August 26 next deadline to submit membership nominations

The next deadline for submitting membership nominations to the Operations Office is Aug. 26, 2005. Prior to each Group meeting, nominations are considered for Member, CCOP, Affiliate, UCOP and Special Member investigators. Nominations are reviewed by the Membership Committee and recommendations are made to the Board of Governors.

To process a new investigator nomination, all of the following information must be received by the Operations Office by Aug. 26, 2005:

- Application for New Investigator Form
- Nomination letter from the Principal Investigator
- Copy of the nominee’s most recent curriculum vitae stating whether or not the nominee is board certified
- Certification of Education in the Protection of Human Subjects
- New investigator pharmacy information
- Affirmation of Integrity Statement
- Purchase Service Agreement (Affiliate investigators only)

Incomplete nominations will not be processed. For a complete outline of the nomination process, refer to Southwest Oncology Group Policy Memorandum No. 7 at the Group’s Web site, http://swog.org. All application forms can be downloaded and printed.
**QA Corner**

**Preparing for an audit by the Southwest Oncology Group**

On-site auditing is an important aspect of the quality assurance program. It provides an opportunity to assess institutional practices that affect continued participation in Group membership. Following are some helpful hints on how to prepare for an audit.

Approximately four weeks prior to the site visit, the institution will receive a list of the patient records, Institutional Review Board (IRB) records, consent forms and drug accountability records that are to be audited.

The main member or CCOP must notify its affiliates/components of the patient case list for their site with audit instructions, including the date, time, place and requirements of the audit. Each affiliate/component should prepare for the audit in the same manner as the parent institution. Arrangements should be made for at least one representative from each affiliate site to be present at the audit and/or available for questions.

The institution should notify the appropriate Medical Records Department in a timely fashion, in order to obtain the medical records. All supplemental data necessary for the audit should be obtained from the various departments (Radiology, Pathology, etc.). Pertinent electronic medical records must be printed and added to the research chart. If able to obtain the records prior to the day of the audit, data should be kept secure under lock and key. Key study parameters should be tabbed in the source documentation with color tags. If scans or slides are available as electronic data (i.e. online, CD-Rom), arrangements should be made so that the auditor has easy access to the information.

The IRB should be notified of the date of the audit and the list of protocols that will be reviewed. The IRB/regulatory file should be organized in a systematic fashion for easy access to the files pertaining to the audit. Colored tabs should be used to mark the documentation pertaining to initial review, continuing reviews, protocol modifications and Adverse Events/Safety Reports. **Documentation may be in the form of minutes of the IRB meeting or an IRB approval letter that is signed by the IRB chairman or designate. IRB Certification Forms are not considered acceptable documentation of IRB review.** Copies of all versions of IRB-approved consent forms, including specimen collection and banking consents and HIPAA authorizations for protocols to be reviewed, should also be available.

The site must make arrangements with the pharmacy prior to the audit. The auditors will conduct an on-site pharmacy inspection where the investigational drugs are stored and maintained to verify the physical inventory as well as security and storage conditions. Patient records will be compared with the Drug Accountability Records for dosage and date the study drug is dispensed and/or administered.

Specific documentation that must be submitted to the Southwest Oncology Group Operations Office for review **prior** to the audit include: 1) Copies of the signed consent forms for all patients marked with a pound sign (#) on the case list with patient identifiers redacted, and 2) Copies of drug accountability records (including shipping receipts, drug return forms, and transfer forms) for all activity since the last audit date for the protocols marked with an asterisk (*) on the case list. This applies to all satellite pharmacies, as well. Failure to submit this documentation to the Operations Office prior to the audit hinders the audit process and will be noted as a deficiency during the audit.

An exit interview will be conducted with the principal investigator and research staff to discuss the preliminary findings and any recommendations from the audit team. The exit interview is an important part of the audit process as it provides an opportunity for clarification of issues, feedback and education. Representatives of the IRB and pharmacy are also welcome to attend.

Do you have suggestions for future QA topics? If so, please contact Elaine Armstrong, Quality Assurance Manager, at qa@swog.org or 210-677-8808.
The Cancer Control Research Committee (CCRC) and its subcommittees met during the Spring 2005 Southwest Oncology Group Meeting on April 6 and 7. Following is a summary of the most significant discussions and events.

**Behavioral and Health Outcomes Subcommittee (BAHO)**
Chair Carolyn C. Gotay, Ph.D.

- Thanh V. Huynh, M.D., gave a didactic presentation entitled “Mindfulness Meditation: An Overview, Demonstration and Application to a SWOG Protocol.”
- Subcommittee members discussed accrual and data-gathering obstacles to open protocols, such as **S0229**, “Randomized Trial Assessing the Effects of Exercise on Patients with Locally Advanced Non-Small Cell Lung Cancer (NSCLC) Undergoing Curative Intent Combined Modality Therapy (Ancillary to **S0023**),” and **S0316**, “Barriers to Accrual to Clinical Trials in Older (equal to or more than 65 Years) Cancer Patients.”
- Discussion was held on new protocols such as **S0308**, “A Phase III Randomized, Multicenter Non-Inferiority Trial Evaluating the Efficacy of Oral Ibandronate Versus Intravenous Zoledronate in the Reduction of Skeletal-related Events in Patients with Metastatic Breast Cancer,” and a new proposal involving Venlafaxine and Venlafaxine plus Gabapentin to follow J. Wendall Goodwin, M.D. ’s completed **S9626**, “A Phase III Trial of Placebo Versus Megestrol Acetate 20 mg/Dav Versus Megestrol Acetate 40 mg/Day as Treatment of Symptoms of Ovarian Failure in Women Treated for Breast Cancer.”
- Also on the agenda were recent BAHO-related publications (e.g., Petrylak et al, *N Engl J Med* 2004, and Gotay, *J Clin Oncol* 2005).
- After discussing various alternative meeting times, BAHO decided to keep the regularly scheduled time for future meetings.

**Molecular Epidemiology Subcommittee (MES)**
Chair Regina M. Santella, Ph.D.

- The subgroup discussed updates to the PCPT P01 ("Biology of the PCPT"), including National Cancer Institute funding status, the method for genotyping PCPT samples and a data analysis group that would begin planning the data analysis strategies.
- MES also discussed SELECT (**S0000**) issues such as additional blood collection, for which the budget has been approved, and the SELECT consent form modifications; final decision on a case-cohort design; and the possibility of beginning to isolate DNA samples.
- Discussion was held on the Lung Cancer in Women R01, to be submitted soon to the NCI, cohorts of cancer cases for future studies of factors influencing prognosis/survival and a working group to encourage junior investigators to join in the subgroup’s work.

**Chemoprevention Subcommittee**
Chair Gary E. Goodman, M.D.

- The group discussed open protocols **S0300**, “Randomized Placebo-Controlled Biomarker Modulation Trial Using Celecoxib in Premenopausal Women at High Risk for Breast Cancer,” and **S9917**, “L-Selenium-Based Chemoprevention of Prostate Cancer Among Men with High-Grade Prostatic Intraepithelial Neoplasia.”
- Closed protocols discussed included **SWOG-9446**, “Chemoprevention Trial to Prevent Second Primary Tumors with Low-Dose 13-Cis Retinoic Acid in Head and Neck Cancer,” **S9812**, “Pilot Study of L-Selenomethionine in Prostate Cancer Patients Scheduled to Undergo Radical Prostatectomy;” and **S9630**, “A Randomized Comparison of Medroxyprogesterone Acetate and Observation For Prevention of Endometrial Pathology in Postmenopausal Breast Cancer Patients Treated with Tamoxifen.”
- Developing protocols under discussion included **S0513**, “Tamoxifen, Raloxifene, and Letrozole in Postmenopausal Women;” **S0212**, “Oral Celecoxib for High-Grade Squamous Intraepithelial Lesions of the Cervix;” and **S0409**, “Atorvastatin in Melanoma Prevention.”
- New proposals the Chemoprevention Subcommittee discussed included “Calcium, Aspirin and Selenium (CASE) Colorectal Cancer and Polyp Recurrence Prevention,” “A Study of Vitamin E and/or Selenium Effects on Adenomatous Colorectal Polyps in SELECT Patients” and “Chemoprevention Study of Selenium in Barrett’s Esophagus.”

**CCRC Open Meeting**
Chair Scott M. Lippman, M.D.

- Dr. Lippman opened the meeting by introducing the agenda for a joint keynote address and Harry E. Hynes CCOP Symposium on the $14 million “Biology of the PCPT: A Program Project (P01).”

(Continued on page 12)
Quality of Life Survivorship Findings for **SWOG-9208, SWOG-9133**

By Carol M. Moinpour, Ph.D.

This study of survivorship and late effects follows patients annually for seven years and is one of the few prospective, randomized trials to examine quality of life and late effects in patients with Hodgkin’s disease. As a result of the early closure of **SWOG-9133**, “Randomized Trial of Subtotal Nodal Irradiation Versus Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin’s Disease, Phase III,” we will have a smaller quality-of-life sample than originally planned. Therefore, the follow-up assessments for patients we did enroll take on even more significance.

Submission rates for quality-of-life forms for years 5, 6, and 7 are below acceptable levels. Quality of life at year 5 was designated as the primary endpoint for **SWOG-9208**, “Health Status and Quality of Life (QL) in Patients with Early Stage Hodgkin’s Disease: A companion study to **SWOG-9133**, Ancillary,” so it is particularly important to obtain follow-up data at five years. We know that all but one patient has reached that assessment point.

Please check **SWOG-9208** patient charts to make sure that all questionnaires have been submitted for year 5. There are still 19 assessments outstanding for year 6 and 39 assessments outstanding for year 7. Please do your best to contact those patients so that their data can be included in our final analyses.

Patricia A. Ganz, M.D.’s, office is still sending reminders to institutions regarding upcoming assessments and additional reminders will be forthcoming about the remaining year 6 and 7 questionnaires. We thank everyone for the terrific effort made to date but request extra attention to obtaining this important survivorship information. Remember there is funding for collecting the follow-up data.

### CCRC Report

(Continued from page 11)

The CCRC Open Meeting agenda included:

- Introductory comments by P01 Co-Principal Investigator Dr. Santella
  - Brief background comments by Charles A. Colman Jr., M.D., Leslie G. Ford, M.D., Howard L. Parnes, M.D. and Dr. Lippman
  - Scientific highlights were presented by Juergen K. Reichardt, Ph.D., (Project 1); Alan R. Kristal, Dr.Ph. (Project 2); Michael N. Pollak, M.D., (Project 3); Elizabeth A. Platz, S.C.D., (Project 4); and Santella (Project 5)
  - Panel discussion moderated by CCOP Symposium Chair J. Philip Kuebler, M.D., Ph.D., (who announced that he would step down as Symposium Chair and CCOP Liaison to the CCRC and would be succeeded by Dayton CCOP Principal Investigator James L. Wade III, M.D.).
NIH policy encourages investigators to submit manuscripts to PubMed

Effective May 2, 2005: Implementation of Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research

On February 3, 2005, the National Institutes of Health (NIH) issued a new policy to enhance public access to publications resulting from NIH-funded research. Beginning May 2, 2005, NIH requests and strongly encourages all NIH-funded investigators to make their peer-reviewed author’s final manuscripts available to other researchers and the public at the NIH National Library of Medicine’s (NLM’s) PubMed Central (PMC) [http://www.pubmedcentral.nih.gov] immediately after the final date of journal publication.

To facilitate the submission process, the NIH has developed the NIH Manuscript Submission (http://www.nihms.nih.gov) System. NIHMS allows users to submit and manage manuscripts in a wide range of electronic word-processing formats. Any additional files that contain figures, tables, or supplementary information should also be included with the manuscript. No further formatting of the manuscript is necessary beyond that required by the journal that has accepted the article.

At the time of submission, authors are given the option to release their manuscripts at a later time, up to 12 months after the official date of final publication. NIH expects that only in limited cases will authors deem it necessary to select the longest delay period.

This Policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The Policy applies to peer-reviewed, original research publications that have been supported in whole or in part with direct costs from NIH, but it does not apply to book chapters, editorials, reviews or conference proceedings. NIH is requesting that authors submit publications resulting from currently-funded NIH research projects or previously-supported NIH research projects where manuscripts were accepted for publication on or after May 2, 2005. Publications resulting from non-NIH-supported research projects should not be submitted. Comments and suggestions about the submission process can be submitted to PublicAccess@nih.gov.

The NIH Manuscript Submission System

The NIHMS system is a password-protected, Web-based system. This system allows easy identification of NIH grant numbers (past and present) and NIH intramural project numbers by associating them with the corresponding extramural or intramural principal investigator (PI) of the research study.

(Continued on page 14)

How to submit a manuscript to PubMed


2. Select the appropriate login option or create an account (Note: the same login should be used for all subsequent visits to the NIHMS system):
   * NIH extramural investigators select “eRA Commons” (see http://era.nih.gov/).
   * NIH intramural employees select “NIH.”

3. Provide basic information, including the journal title, principal investigator (PI), contact information, and associated NIH award number(s).

4. Upload the complete text of your manuscript(s). The NIHMS supports a wide variety of file types (Microsoft Word, WordPerfect, PDF, PowerPoint, Excel, etc.).

5. Upload any corresponding, supplemental image files that contain figures, tables, or supplementary information along with the manuscript. Just as required by publishing journals, submit high-resolution images to ensure that they can be viewed properly in PMC. The supplemental material that has been submitted to the accepting journal in support of the manuscript will be accepted. The NIHMS will generate a receipt of the uploaded files in PDF format. The PDF receipt summarizes the information entered into the system and merges the manuscript’s files into one viewable document.

6. Confirm that the manuscript and any additional supporting documents have been successfully received by NIHMS, and verify the document.

7. Review and approve the terms and conditions of a submission agreement and specify the timing of posting of the final manuscript for public accessibility through PMC (this must be completed by the PI). Authors and/or their institutions should ensure that their final manuscript submissions to PMC are consistent with any other agreements, including copyright assignments that they may have, or enter into, with publishers or other third parties. Upon approval of the submission by the PI, the manuscript will be converted into XML - the standardized digital format used by PMC.

8. Review the XML manuscript as it will appear in PMC once the conversion has taken place (PIs will be notified by e-mail when the document is ready for review) and correct any errors, if necessary. After PI approval, the article will be publicly accessible through PMC after the time-delay specified by the PI.

Note: Users are able to track the status of their manuscripts throughout the process. For questions about the submission process, refer to the NIHMS FAQ page (http://www.nihms.nih.gov/faq.html). The NIHMS system also maintains a help desk to assist users with manuscript submissions and answers to any questions related to the submission process. Contact the help desk with your queries by accessing (http://web.nihms.nih.gov/db/sub.cgi?page=email&from=home).
Another important notice regarding Group publications

Please remember to share the current status for all Southwest Oncology Group publications with the Publications Specialist at the Operations Office, whether they are abstracts or manuscripts, submitted or published. One of the primary responsibilities of the Southwest Oncology Group is to report the results of completed trials. All studies, whether the results were positive or negative, must be published to assure continued funding of Group activities by the National Cancer Institute. Therefore, keeping this information up to date is of paramount importance.

All phases of the publication process with a journal or society meeting should be reported to the Operations Office. This includes submissions, resubmissions, acceptances, acceptances pending revisions, as well as publications not accepted. This will ensure that complete and accurate publication information is reported on all Group studies for grant and progress report submissions, in all newsletters published by the Group, and on the Group Web page. It will also ensure that investigators and their respective institutions are correctly credited for the various stages of publication on their Investigator Contribution Sheets.

Copies of submissions or correspondence received from the journal can be faxed to the Operations Office at 210-677-0006 or e-mailed to pubs@swog.org.

NIH publications policy

Currently, manuscript files from NIH Intramural PIs can be submitted to the NIHMS system by the PI or designated NIH staff. Manuscript files from extramural PIs may be submitted by the PI only. Beginning July 6, 2005, manuscript files may be submitted to the NIHMS system by either the extramural PI or a third party on the PI’s behalf (e.g., administrative personnel, graduate students, librarians, publishers, etc.)

In all cases, approval of the submitted materials and the determination of the public release date require the PI’s review and authorization. Currently, the system is designed for individual submissions, but procedures for batch processing of multiple submissions are being explored and may be developed in the future. No further formatting of the manuscript is necessary beyond that required by the accepting journals. Special arrangements will be available for unusual cases. Please see the NIH Public Access Web site (http://www.nih.gov/about/publicaccess/) for more information about the policy.

Statistical Center news

Welcome

Data Coordinator Sarah Canning joined the SELECT staff in May. She was previously a patient care coordinator at Children’s Hospital & Regional Medical Center in Seattle.

Bryan Goldman, M.S., is joining the Statistical Center staff as a member of the Genitourinary and Lymphoma committees. He recently completed his master’s degree in biostatistics from the University of Washington.

Farewell

Jeffrey Zacko-Smith is leaving the Statistical Center administrative staff to take a position in the Fred Hutchinson Cancer Center. Zacko-Smith started his career in the Southwest Oncology Group working with the Prostate Cancer Prevention Trial before switching to the Statistical Center administrative staff.
Manuscripts and Abstracts Published

The publications listed below are those that have been received in published form by the Operations Office Publications Specialist from January 7, 2005, through April 22, 2005.

MANUSCRIPTS PUBLISHED


(Continued page 16)
**MANUSCRIPTS PUBLISHED**

*(Continued from page 15)*

S9628  

S9770  

S0000  

Multiple Studies  

Multiple Studies  

Multiple Studies  

None  

**ABSTRACTS PUBLISHED**

*8814  

8894  

* Presented

*(Continued page 17)*
(Continued from page 16)


* Presented
Southwest Oncology Group Protocol Update from January 16 – April 22, 2005

This PROTOCOL UPDATE serves as reference for protocol activity during the stated period. When noting Temporary Closures and Reactivated Protocols, bear in mind that temporarily closed studies are often reopened after observation of some degree of antitumor activity in the initial cohort of patients. Other reasons for reopening studies could include revision of the protocol to enhance the margin of safety for patients or resolution of administrative problems, such as with drug supply or drug distribution. If you have any questions about a temporary closure or reactivation, you may contact the study coordinator for more information.

ACTIVATIONS

S0432, Phase II Studies of Two Different Schedules and Two Different Doses of the Farnesyl Transferase Inhibitor R115777 (Tipifarnib, Zarnestra®, NSC-702818) for Previously Untreated Acute Myeloid Leukemia (AML) in Patients of Age 70 or Older. Study Coordinators: Drs. H. Erba, C. Willman and M. Slovak. Re-Activation 3/22/05.

S0317, A Phase II Study of OSI-774 (NSC-718781) in Patients With Locally Advanced or Metastatic Papillary Histology Renal Cell Cancer. Study Coordinators: Drs. M.S. Gordon and P.N. Lara Jr. Re-Activation Revision 4/1/05.


S0340, A Prospective Observational Study of Patients with Solitary Plasmacytoma Using a Modified Staging System Supplemented by an MRI and Whole Body FDG-PET Scan. Study Coordinators: Drs. A.J. Jakubowiak, J.S. Biermann, P. Okunieff, and R.C. Walker. Activation 4/15/05.

CLOSURES


S0322, Single Agent ZD-1839 in Patients with Advanced Head and Neck Carcinoma or Non-Small Cell Lung Cancer Aged 75 Years and Older (and in a Cohort of Patients 50 Years Old and Younger), Pharmacology. Study Coordinators: Drs. S. Gadgeel and T. Synold. Permanent Closure 2/15/05.

S0207, Phase II Study of Arsenic Trioxide in Male Patients with Refractory Germ Cell Malignancies. Study Coordinators: Drs. T.M. Beer and C.R. Nichols. Permanent Closure 03/01/05.

S0432, Phase II Studies of Two Different Schedules and Two Different Doses of the Farnesyl Transferase Inhibitor R115777 (Tipifarnib, Zarnestra®, NSC-702818) for Previously Untreated Acute Myeloid Leukemia (AML) in Patients of Age 70 or Older. Study Coordinators: Drs. H. Erba, C. Willman and M. Slovak. Temporary Closure 3/15/05.

S0202, A Phase II Trial of Gemcitabine (NSC-613327) and Capecitabine (NSC-712807) in Patients with Unresectable or Metastatic Gallbladder or Cholangiocarcinoma. Study Coordinators: Drs. S. Iqbal and H.J. Lenz. Permanent Closure 4/1/05.

S0336, Phase II Trial of Depsipeptide (NSC-630176) in Colorectal Cancer Patients who have Received Either One or Two Prior Chemotherapy Regimens for Metastatic or Locally Advanced, Unresectable Disease. Study Coordinator: Dr. R.P. Whitehead. Temporary Closure 4/1/05.


S9908, A Double-Blind, Placebo-Controlled Trial to Study the Efficacy and Safety of L-Glutamine (in AES0014 Delivery Vehicle) Upon Radiation Therapy-Induced Oral Mucositis in Head and Neck Cancer Patients, Phase III. Study Coordinator: Dr. V.S. Klimberg. Permanent Closure 4/15/05.


(Continued page 19)
Learning how to communicate more effectively with older patients

By Rose Ermete RN, BSN, OCN, CCRP

The Nurse Oncologist Committee held a dinner meeting at the Spring 2005 Southwest Oncology Group Meeting, sponsored by an educational grant from Pfizer Inc. The program, “Older Adult Sensitivity Training,” was presented by Vicki L. Schmall, Ph.D.

Through her presentation, Dr. Schmall helped the 33 participants see the healthcare experience from an older patient’s perspective. The purpose was to help them understand and anticipate barriers to effective communication with older adults by enhancing verbal and non-verbal communication skills.

Learning effective communication techniques can assist the healthcare provider in improving patient satisfaction as well as clinical outcomes. Despite their advanced age, many older adults have demonstrated extraordinary strength, perseverance, determination, as well as the ability to overcome significant obstacles. This dispels many stereotypes about older adults and emphasizes that each person is an individual with individual needs.

More older patients in the future

Older adults are the fastest-growing population segment in the United States. By the year 2030 the older-adult population is expected to nearly double to 71 million – 20 percent of the total population. Not only are clinicians expected to see more patients and to see those patients more frequently during the year, but are expected to see patients for more years than before.

Communication with patients 65 years of age and older requires a certain set of skills. These include verbal and nonverbal communication skills that are sensitive to the clinical, pharmacological, informational, psychosocial, environmental and other needs of older adults.

Hearing and vision changes are two specific barriers to communication. Dr. Schmall reviewed with the group various techniques to overcome these barriers.

Accommodating for hearing loss

Older adults usually have hearing loss in higher frequencies. This means that you may have to lower the pitch of your voice, instead of increasing the volume. Consonants are harder to hear than vowels. As a demonstration of this, the participants at the dinner were administered a hearing test in which they listened to a tape recording that played words as the older adult would hear.

(Continued on page 20)
News from the Nurse Oncologist Committee

By Marge Goode, R.N., M.P.H., Committee Chair

The Nurse Oncologist Committee is actively involved in many projects and initiatives designed to improve the cancer clinical trials process at your institutions. As you read about our activities below, consider how you might contribute to Southwest Oncology Group activities that assist nurses, clinical research associates (CRA), trial participants and investigators in their endeavors to make progress in cancer treatment, prevention and symptom management.

If you are a nurse and not yet a member of the Nurse Oncologist Committee, please contact our membership chair, Patra Grevstad, R.N., M.N., for guidance on the application process. If you are interested in making a difference in cancer clinical trials at a national level, contact any Nurse Oncologist Executive Committee member and we will be happy to link you with members working in an area of interest to you. The Nurse Oncologist Committee provides a myriad of opportunities for you to make a difference in the care of persons with cancer or those at risk.

Garrison honored

The Nurse Oncologist Executive Committee honored Juanita Garrison, R.N., B.S.N. for her 20 years of service to the Southwest Oncology Group Nurse Oncologist Committee and 19 years as nurse liaison to the Gastrointestinal Committee.

Garrison also served for five years as vice chair of the Nurse Oncologist Committee under the tenure of Jeanne Parzuchowski, R.N., B.S.N., M.S.N.

Garrison contributed extensively toward developing a strategic plan and formal procedures for the operation of the committee.

She served as co-chair of the Education and Quality Assurance Subcommittee (later known as the Education Subcommittee), where many projects were developed including nurse/CRA collaborations, patient education materials, and procedures and tips for undergoing institutional audits.

Membership:

Five new members were approved at the Nurse Oncologist Executive Committee meeting. They are Amanda Dressel, Ann Arbor, Mich.; Tamara Huebner, Ann Arbor, Mich.; Amanda Knight, Lubbock, Texas; Judith Link, Anchorage, Alaska; and Peggy Verrill, Decatur, Ill.

Disease and Discipline:

The Disease and Discipline Subcommittee has three functions. The first is to make sure there are nurse liaisons on each disease committee to review protocols in development and to develop the Fast Fact Sheets that have become so useful. All positions are filled with the exception of leukemia, and I will be contacting those nurses who have expressed an interest. Generally, all business is conducted by e-mail, but liaisons are asked to attend at least one Group meeting each year.

The subcommittee’s second function is the Clinical Trials Nurse Mentorship Program, which was (Continued on page 21)

Communicating with older patients

them. Very few people were able to identify the words on the tape. Other helpful suggestions were to speak to the patient at their posture level, such as sitting if they are sitting, not covering your mouth and providing a quiet location free of background noise.

Strategies for vision changes

Older adults also experience visual changes. These include a decrease in color differentiation; adaptation to darkness, light and visuospatial perception; and an increased sensitivity to glare. Each workshop participant had the opportunity to put on various glasses that allowed them to experience glaucoma, cataracts, diabetic retinopathy, macular degeneration and stroke. With these glasses on, they were directed to read forms, sort pills and complete a health questionnaire. This activity helped the participants understand what their patients may be experiencing.

Suggestions to improve visual communication included providing information in large type, avoiding glossy paper and making sure that there is contrast between the words and the background, such as black lettering on white paper. Another important point was to give patients plenty of time to complete forms rather than rushing them.

The hands-on program gave participants the opportunity to appreciate what older adults experience as they navigate through the healthcare system. They learned new communication skills to help them deal more effectively with older adult patients. And the knowledge they gained will help them improve patient satisfaction, compliance issues for older patients on clinical trials and ultimately clinical outcomes.
Nurse Oncologist Committee

(Continued from page 20)

developed by Rose Ermete, R.N., B.S.N., O.C.N., C.C.R.P. Ermete reported on the program at the ONS congress in the spring and is looking for a member interested in participating in it.

The third function of the committee is providing education for nurses who act as quality-of-life coordinators on the various protocols. We are going to maintain a list of these nurses to use as resources, and have nurses ready to assume the coordinator role. Deb Ward may be contacted at dward@providence-hospital.org in case you have questions.

Research Subcommittee

Research 101 was presented again at the Spring 2005 meeting with 23 participants. Evaluations were very positive with strong indication that the program meets a need for nurses new to the cooperative groups. As a reminder, the program is NOT a duplication of the Clinical Trials Training Course, so all nurses new to the Southwest Oncology Group should attend both meetings. The Nurse Oncologist Committee plans to present Research 101 at each Group meeting. Research 102, Development of Nursing Research Concepts, will be presented only at the spring Group meetings.

Look for a repeat of the Nursing Research Survey conducted in 2000. Plans are to mail the revised survey to all Nurse Oncologist Committee members as well as head CRAs for Southwest Oncology Group institutions in the late summer or early fall. Please complete and return them. Your input is valuable!

The Research Subcommittee has established a list serve to enhance communication among members, particularly between group meetings. If you would like to be added to the listing, please e-mail either Shirley Raltz (Shirley.Raltz@swedish.org) or Maggie Clarkson (mclarkson@cableone.net).

In an effort to promote nursing research, we would like to spotlight nursing research studies conducted by Southwest Oncology Group members via poster presentations at the Group meetings. If you and your colleagues have been involved in a nursing research study at your home institution and would like to share your experience and study results with Group members, complete and return the Poster Abstract form (available from Maggie or Shirley) by June 30 for the fall meetings and January 31 for the spring meetings.

Education Subcommittee

The meeting was called to order by Juanita Garrison, R.N., O.C.N., with an introduction of the guest speaker, Elaine Armstrong, M.S., Southwest Oncology Group quality assurance manager. Armstrong’s presentation, “Internal QA and Audit Site Preparation” included:

- Compliance with Institutional Review Boards (IRB)
- Consent reviews
- Internal QA procedures and policies for the site
- Southwest Oncology Group internal QA procedures
- Drug accountability, oversight and organization of inventory logs, archiving of pharmacy policies and procedures
- Satellite pharmacy and full members oversight of investigational drugs
- Tracking system for submission and follow-up of protocols, amendments, and revisions to IRB

In addition to the internal revisions of the IRB and pharmacy, Armstrong reminded the group that each institution is responsible for accessing the Group Web site on the 1st and 15th of each month to obtain amendments and revisions that need to be addressed and sent to the IRB.

Ongoing education of staff regarding clinical trials and audits is needed to keep staff updated on study changes and requirements. Staff should be taught to track delinquencies for trends and discuss the information with all staff members. Internal QA

(Continued page 22)
procedures should be developed based on the findings.

Preparing for an audit should include the following provisions:

- Radiograph view box
- Computer access close to audit room
- Telephone
- Copier and fax nearby

The new Site Authority Log came about due to past fraud events and the inability to tell whose signatures or initials belonged to whom among past and current staff. All staff, including CRAs, nurses and pharmacists, need to sign the form if they are involved in research. The log should be on file at the site for all future Southwest Oncology Group audits. Electronic data is okay but the Group requires the protocol-related data to be printed out. Registration of patients at one site and patient treatment at another site should not be undertaken unless that site is registered at the time of initial registration and has appropriate IRB approval. The cooperative groups sent a formal response to the Federal Drug Administration this April in regards to the multiple safety reports. Feedback is pending.

Program Committee

The Nurse Oncologist Workshop entitled “New Frontiers in the Treatment of Cancer” was presented to 134 nurses and CRAs on April 8. Judith Degroot, RN, MSN, AOCN®, sponsored by Genentech, opened the program with “Molecular Targets in Solid Tumor Therapy.”

“Drug Development, Diving for Answers” was presented by David H. Sherman, Ph.D, professor of Medicinal Chemistry at the University of Michigan, who provided an exciting look into the ocean for the source of new cancer treatments. A review of National Cancer Institute (NCI) educational materials and ordering information was shared by Rose Mary Padberg, RN, M.S., from the NCI during “Cancer Education: What’s New for You!”

Matt Boron, R.Ph. completed the program with “New Drug Update” focusing on the Tyrosine Kinase Inhibitors GW572016 and Bay 43-9006 as well as the Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA). Continuing Education Units of 4.4 were provided for nurses through the Oncology Nursing Society and education credits for Clinical Research Associates were available through the Society of Clinical Research Associates.

CCOP

Members present were encouraged to look again at S9917, the High Grade PIN trial, to increase accrual since accrual to that study has dropped off since the last meeting. Updates were provided to the group by Marge Good, R.N., M.P.H., pertaining to the results of the Nurse Oncologist Executive Committee meeting and the Selenium and Vitamin E Cancer Prevention Trial Retention and Adherence Committee (RAC) meeting. Members were encouraged to self-monitor their site’s adherence rates, as this will become a focus of the RAC committee.

Members were also encouraged to become Southwest Oncology Group nurse auditors. Those interested may contact Elaine Armstrong at the Operations Office.

Other topics of discussion included issues pertaining to the CTSU and the CIRB. There continue to be issues related to IRB approvals and correct logging at CTSU. Members also discussed various local issues related to joining or not joining the CIRB. Good also asked the group to provide ideas for discussion at future meetings. This is the only opportunity at Groups meetings for CCOP nurses to meet and discuss grass root issues. Those with ideas are encouraged to contact Good at (316)268-5696 or by email at marge_good@via-christi.org.

Seeking committee members for Bone Marrow/Stem Cell and Sarcoma committees

The Clinical Research Associates Committee has openings for disease committee representatives for the Bone Marrow/Stem Cell Committee and the Sarcoma Committee. If you are interested and work with studies in these disciplines, please contact Beth Davis, CRA Communications Committee Chair at bdavis@salick.com.

Need a mentor? Want to share your knowledge with others?

Whether you are new to clinical trials or are experienced but still have some questions, the Clinical Trial Nurse Mentorship Program is here to help.

The program is designed to match a mentor with a novice nurse who shares a similar work environment or to help more experienced nurses who have additional questions, are dealing with something new or who have recently changed jobs and have new responsibilities.

Studies have shown that those who are mentored have greater success in their career and are more likely to mentor others.

Turn to page 23 and fill out the Clinical Trials Nurse Mentorship Program application to request a mentor or to share your knowledge with your colleagues.
### Clinical Trials Nurse Mentorship Program Application

(Circle) I am requesting a mentor I wish to become a mentor

<table>
<thead>
<tr>
<th>Name/credentials:</th>
<th>___________________________________________________________________________________</th>
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<tr>
<td>Institution/affiliation:</td>
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<tr>
<td>Address:</td>
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<td>__________________________________________ State: __________________ Zip Code: __________</td>
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<tr>
<td>Telephone:</td>
<td>____________________________ Fax: ____________________ E-mail: _____________________________</td>
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</table>

**Mentee:** If you would like us to contact your supervisor, provide the name and contact information:

(Circle) I do not wish to give this information.

| Name: | ______________________________________________ |
| Address: | ______________________________________________ |
| City: | _____________________________________________ |
| State/Zip: | ______________________________________________ |
| E-mail: | ______________________________________________ |
| Best time to contact you: | ________________________________ |

Circle the type of institution in which you are employed:

<table>
<thead>
<tr>
<th>University</th>
<th>CCOP</th>
<th>Private office</th>
<th>Clinic</th>
<th>Satellite institution</th>
<th>Other</th>
</tr>
</thead>
</table>

**What is your current position?**

- Clinical trial nurse
- Nurse practitioner
- CRA
- Administration
- Patient care

- Other: ___________________________________________________________________________________

**Time in current position:** ____yrs.______months  **Time involved in clinical trials:** ____yrs._____months

Circle the areas in which you would like support (mentee) or have experience (mentor):

- Audit preparation
- Coordinating a research team
- Budgeting
- Drug accountability
- Educating staff/staffing issues
- Institutional Review Board issues
- Maintaining long-term follow up
- Other support areas: ___________________________________________________________________________________

Circle the type of trials in which you are involved:

<table>
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<tr>
<th>Nursing research</th>
<th>Cooperative Group</th>
<th>Pharmaceutical</th>
<th>Prevention</th>
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<tr>
<td>Treatment</td>
<td>Investigator initiated</td>
<td>Phase I</td>
<td>Phase II &amp; III</td>
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<tr>
<td>Phase IV</td>
<td>Other: ______________________________</td>
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If you work with cooperative group trials, circle the groups with which you are affiliated:

- SWOG
- ACOS
- CALGB
- COG
- CTSU
- ECOG
- GOG
- NSABP
- NCCTG
- NCIC
- NWTSG
- RTOG

- Other: ______________________________

Please list some interests you have outside of work: ___________________________________________________________________________________

---

**Send application to:**

CTN Mentorship Program
c/o Rose Ermete
9820 Levan
Livonia, MI  48150
ermeter@karmanos.org

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**June 2005**
The Southwest Oncology Group Quality Assurance Department is recruiting additional Nurse Auditors to assist in Quality Assurance treatment audits. All travel expenses are covered by the Southwest Oncology Group and auditors are eligible to receive ICS points on their grant continuation for every audit in which they participate.

Turn to page 18 and complete the Nurse Auditor Application.

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 loan period of one month.

NAME: ________________________________________ DEPT: __________________________

ADDRESS: __________________________________________

CITY: __________________ STATE: ______ ZIP CODE: ________________

TELEPHONE: (___) __________ AFFILIATION/INSTITUTION: ________________________

E-Mail: ____________________________ (Circle) Fed Ex or UPS Account # _____________

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 loan period of one month.

SIGNATURE: ____________________________________________________________

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

MAIL ORDER FORM TO: Jacqueline Hilger, B.S., M.S., CCRP, Research Director, Breastlink Medical Group, 701 East 28th Street, Suite 412, Long Beach CA 90806.