STRATEGIES FOR EXP

by Louise Hahn, R.N., M.S.A., Philip J. Stella, M.D., and Linda Beekman, R.N., M.B.A.

Community Clinical Oncology Programs (CCOPs), sponsored by the National Cancer Institute since 1983, offer community institutions the opportunity to participate in formal clinical research protocols through the nation's system of large, cooperative research groups. CCOPs support community hospital participation in cancer prevention and control research, including chemoprevention studies, biomarker and early detection investigations, and symptom management, rehabilitation, and continuing care research. Since clinical trial results are crucial to the development of state-of-the-art cancer therapies, participation in clinical trials is necessary for any organization that wants to provide comprehensive, cutting-edge cancer services. The ability to provide NCI-approved, state-of-the-art treatment within the institution rather than referring patients to other centers is key in positioning an institution for managed care. CCOPs enhance an institution's image and prestige by giving it the opportunity to affiliate with major cancer treatment centers in the United States[1] and please patients by allowing them to receive the latest advances in care in their own communities.

CCOPs also offer experienced investigators access to a wide variety of trials through affiliation with up to five of the major research bases: the North Central Cancer Treatment Group (NCCTG), the Eastern Cooperative Oncology Group (ECOG), the Southwest Oncology Group (SWOG), the Radiation Therapy Oncology Group (RTOG), the National Surgical Adjuvant Breast and Bowel Project (NSAPB), and the Gynecologic Oncology Group (GOG).

To qualify and be funded through the NCI as a CCOP, community cancer centers must file a competing grant application, which undergoes extensive peer and administrative review. NCI may recommend supporting a study for up to five years, but awards are made annually and depend on the project's progress and anticipated accrual for the next year. It is important to note that awards cover only one-half or less of the total research expenses, the remainder of which must be covered by the participating facility.[2]

Choosing Research Partners

Expanding a research program means affiliating with other institutions. To determine whether a facility would make a good research partner, look at its geographic location, community diversity, physician interest, experience in clinical research, and institutional support.

Geographic location. The distance between your institution and the institution you are considering as a partner must be close enough to allow convenient and cost-effective site visits.

Community diversity. New research studies, particularly cancer prevention studies, should be activated only after the potential for accrual within all the partner communities has been evaluated. Minority accrual can be increased by affiliating with institutions that have significant minority populations and by conducting education and screening programs at community churches, fairs, senior citizens groups, and factories. Such programs should be designed to include activities that will attract a wide variety of minority populations, and can also be offered to the minority employees at your hospitals.

Hospital and physician interest. Institutions and investigators choose to take part in clinical trials for a variety of reasons, including access to studies with novel therapeutic drugs and increased income since research programs mean additional income for both the institutions and the investigators who participate.[3] Your investigators will probably participate because it is the "right thing to do" for cancer patients and because the clinical trials give them opportunities to try out innovative treatments.

Experience in clinical research. All the key investigators at your partner sites should have clinical research experience with major national research bases. Only hospitals with experienced lead physicians can successfully introduce trials into their communities and be strong partners in the CCOP. Recruit affiliate partner institutions that have experience in clinical research and have demonstrated success in both accruing patients and producing quality data.

Institutional support. Institutional support is absolutely essential. Research costs money, and the CCOP funding provided by the National Cancer Institute must be cost-shared or matched by a non-federal institution.[4] Your program can meet this requirement through in-kind contributions. The definition of in-kind contributions in the Office of Management and Budget's (OMB) Circular A-1 02.24 is the value of non-federal, third-party, non-cash contributions that apply directly to the grant project,

ANDING A CCOP

How to Make Your CCOP Soar

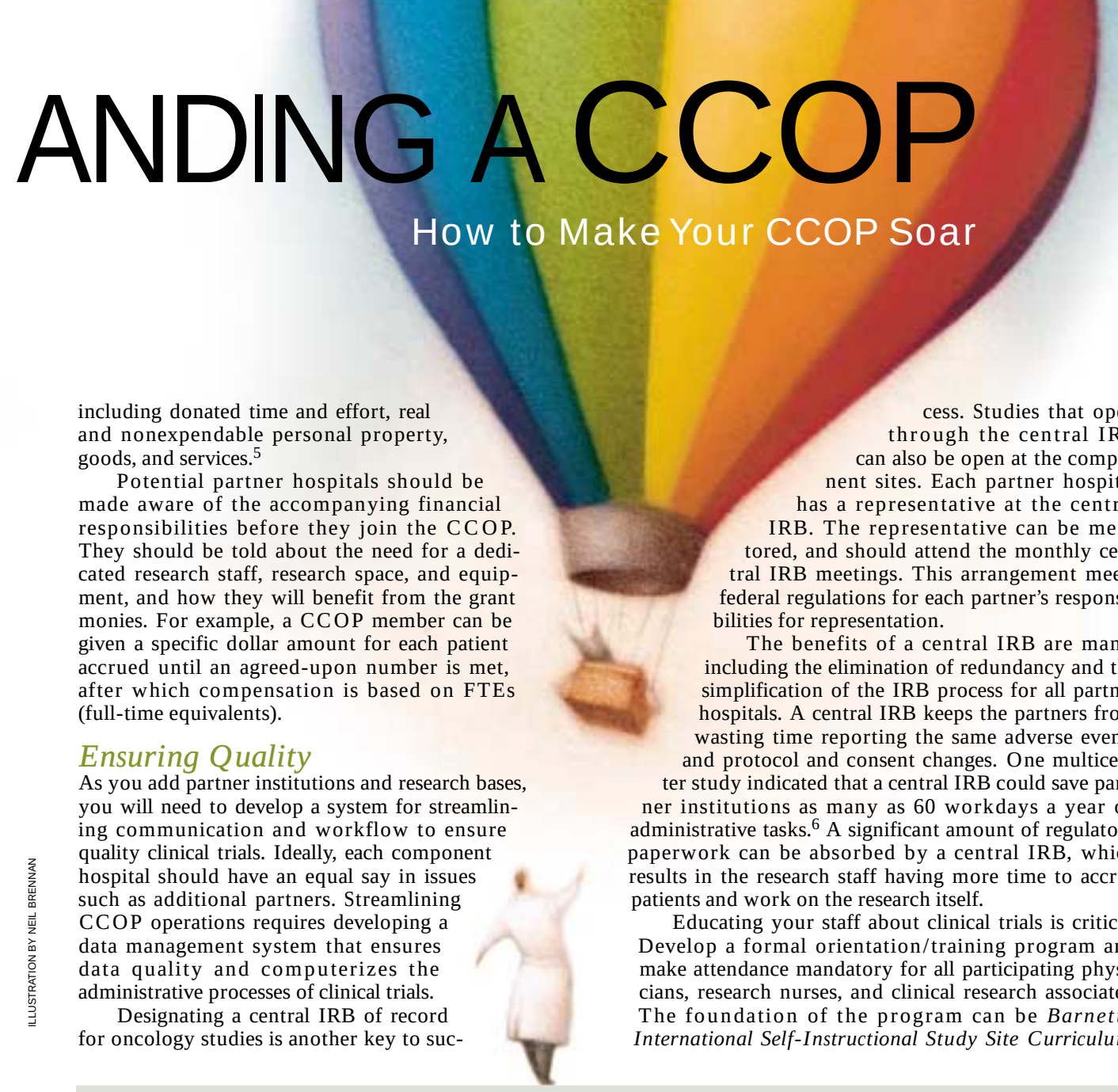

ILLUSTRATION BY NEIL BRENNAN

including donated time and effort, real and nonexpendable personal property, goods, and services.[5]

Potential partner hospitals should be made aware of the accompanying financial responsibilities before they join the CCOP. They should be told about the need for a dedicated research staff, research space, and equipment, and how they will benefit from the grant monies. For example, a CCOP member can be given a specific dollar amount for each patient accrued until an agreed-upon number is met, after which compensation is based on FTEs (full-time equivalents).

Ensuring Quality

As you add partner institutions and research bases, you will need to develop a system for streamlining communication and workflow to ensure quality clinical trials. Ideally, each component hospital should have an equal say in issues such as additional partners. Streamlining CCOP operations requires developing a data management system that ensures data quality and computerizes the administrative processes of clinical trials.

Designating a central IRB of record for oncology studies is another key to success. Studies that open through the central IRB can also be open at the component sites. Each partner hospital has a representative at the central IRB. The representative can be mentored, and should attend the monthly central IRB meetings. This arrangement meets federal regulations for each partner's responsibilities for representation.

The benefits of a central IRB are many, including the elimination of redundancy and the simplification of the IRB process for all partner hospitals. A central IRB keeps the partners from wasting time reporting the same adverse events and protocol and consent changes. One multicenter study indicated that a central IRB could save partner institutions as many as 60 workdays a year on administrative tasks.[6] A significant amount of regulatory paperwork can be absorbed by a central IRB, which results in the research staff having more time to accrue patients and work on the research itself.

Educating your staff about clinical trials is critical. Develop a formal orientation/training program and make attendance mandatory for all participating physicians, research nurses, and clinical research associates. The foundation of the program can be *Barnett's International Self-Instructional Study Site Curriculum*,

CCOP Opportunities

- There are 51 CCOPs in 32 states.
- In those 51 CCOPs, there are 358 participating hospitals with 2,334 physicians that actively accrue patients and 1,123 physicians that refer patients to clinical trials.
- As of June 2001, 78,600 patients had been accrued onto NCI-sponsored cancer treatment clinical trials through CCOPs since the inception of the program in 1983. Several thousand of those patients are still in active follow-up.
- Between 1990 and June 2001, 45,800 participants were accrued to NCI-sponsored cancer prevention and control trials through the CCOPs.
- There are 10 minority-based CCOPs (MBCCOPs) in eight states, the District of Columbia, and Puerto Rico.
- In those 10 MBCCOPs, there are 38 participating hospitals with 264 physicians that actively accrue patients and 210 physicians that refer patients to clinical trials.
- Over the past five years, the CCOPs and MBCCOPs together have put between 5,000 and 6,000 minority patients onto NCI-sponsored treatment clinical trials. For the year 2001, the total accrual to NCI-sponsored treatment trials will exceed 6,000 minority patients.
- Over the past five years, the CCOPs and MBCCOPs together have put between 4,000 and 5,000 patients onto NCI-sponsored cancer prevention and control trials. In 2001, with both STAR and SELECT open to accrual, the CCOPs put between 5,000 and 6,000 minority patients onto cancer prevention and control trials.

7 Steps to a Successful Clinical Trials Program

by James C. Chingos, M.D.

The advantages of having a clinical trials program at your community cancer center or practice are numerous and include improved internal and external marketing of the cancer program, value-added stimulation and education of staff, and improved patient care close to home. Here are seven steps to follow to help ensure that your clinical research program flourishes.

1 *Find a physician champion.* Physician leadership appears to be a common denominator in the success of programs nationwide. The physician champion is responsible for promoting buy-in and commitment among staff. Although many physicians pay lip service to the importance of clinical trials, they may not be committed to the hard work it involves. While other physicians—depending on their particular areas of clinical expertise or interest—may share the responsibilities for clinical trials within a program, the importance of having a single person responsible for the oversight of the clinical trials program appears to be vital to success. Not having a physician champion is often the first issue raised as a criticism of those programs where clinical trial participation has been lackluster or failed.

2 *Pick good partners.* Accessing trials requires developing relationships, often with a tertiary medical facility or cancer center that provides the sponsorship of satellite participation in national, NCI-approved clinical trials.

Building a program of clinical trials may require more than one sponsoring partner. For example, breast and colon as well as general oncology situations may be served by the NSABP or a larger cooperative group. Each of these groups or some combination may necessitate a variety of affiliations.

The process of having clinical trials reviewed and approved by an investigational review board (IRB) often becomes overwhelming. One advantage of national cooperative group trial participation is the potential for your local institution to have IRB approval granted through the IRB overseeing the cooperative trials of your sponsoring institution. This action may avoid excess work at the local level and allow for greater attention to those trials that may be sponsored by the pharmaceutical industry.

3 *Consider pharmaceutical industry trials.* You may want to pursue relationships with the pharmaceutical industry, which is clamoring for clinical trial testing. The financial reward for participating in a pharmaceutical industry-sponsored trial may be substantial. For this reason, careful thought must be given to the balance between national NCI-sponsored cooperative trials in relationship to the pharmaceutical industry-sponsored trials.

4 *Pick a trial that is likely to accrue patients.* Because of the frequently lengthy and tedious IRB approval process, pick trials that are tailored to a population likely to provide the greatest accrual and be appropriate to your patient population. Make sure you define your capabilities to conduct a clinical trial, and avoid overextending the slate of open trials. In so doing, you will minimize the burden on the IRB and on your data management. In addition, avoid adopting clinical trials that compete for the same patient population, which is often counterproductive and possibly confusing. Mastering a single trial is more efficient and helps prevent internal bias in patient selection.

5 *Select a clinical data manager.* Clinical research programs that succeed are likely to have a nurse data manager who evaluates patient eligibility and serves as the liaison between the patient/family and the trial. If you are able to accrue 20 patients, you will be able to pay for a full-time clinical data manager. The clinical data manager can fully explain the logistics of treatment and follow-up as well as answer the many questions from the patient and family regarding the potential side effects and toxicities that were reviewed by the physician.

6 *Hire a full-time, nonclinical data manager.* If your clinical trial program is mature and if accrual is large enough, the nonclinical manager can be of great assistance to the clinical data manager by handling the secretarial functions of data management. This action will allow the clinical data manager to focus on the clinical aspects.

7 *Track your finances.* Know if your program is breaking even. Usually, programs do not break even because the typical $2,000/patient is not sufficient to support following a patient for life. Still, the financial rewards for providing care for a patient on a clinical trial go beyond the per patient reimbursement. Increased patient referrals, patient retention, and the ancillary diagnostics involving clinical trials offer opportunities for increased revenue that might not have been realized if trials were not available in your cancer program.

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which includes chapters on regulations, audits, institutional review boards (IRBs), adverse events/adverse drug reactions, understanding and evaluating clinical protocols, Food and Drug Administration requirements, and good clinical practices.

Require researchers to spend a minimum of one week at the CCOP Operations Office for a comprehensive review of both treatment and cancer control study processes. A second week of orientation can be optional and should focus on casefinding, the completion of data worksheets, and audits.

Finally, to firmly establish your institution's reputation as a leader in clinical research, establish a set of checks and balances that ensure that all submissions to your national research bases are complete and accurate.

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The Ann Arbor Regional CCOP Experience A practical guide for community cancer centers

by Louise Hahn, R.N., M.S.A., Philip J. Stella, M.D., and Linda Beekman, R.N., M.B.A.

In the early 1990s, St. Joseph Mercy Hospital (SJMH) in Ann Arbor, Mich., expanded its oncology clinical trials program as part of its strategic plan to improve cancer services. The National Cancer Institute first funded the Ann Arbor Regional Community Clinical Oncology Program (AARCCOP) in 1994 as a single component CCOP. The total annual accrual to both treatment and cancer control trials was 100 patients at that time. Seven years later, AARCCOP has seven component partner institutions and an annual accrual of more than 250 patients.

When AARCCOP started in 1994, we thought that including the word "regional" in our name would provide more than adequate room to grow; but when the AARCCOP catchment area expanded to include more than 20 counties in Michigan, most of our partner institutions told us they did not consider themselves part of the Ann Arbor "region." Accordingly, the AARCCOP will become the Michigan Cancer Research Consortium within the next few months.

During our initial three-year grant period, we designed and executed a plan to allow the CCOP to grow without compromising its quality of care. The grant and the hospital's financial support allowed the CCOP to hire a second full-time research nurse to manage cancer control and prevention studies and monitor Institutional Review Board (IRB) issues, while the original nurse managed treatment protocols and facilitated workgroups.

Workgroups had already been established for lung, breast, GI, and colon cancer. The primary focus of these groups was to establish standards for treatment and promote a multidisciplinary interest in clinical research, but over time the workgroups have evolved into monthly tumor boards where cases are discussed and treatment options consistently include clinical trials.

In 1995, the SJMH CCOP added its first affiliate. The relationship was unsuccessful but turned out to be a

The treatment and cancer control and prevention teams work closely to coordinate research activities at AARCCOP.

…we developed a coherent and systematic governance structure *to streamline* communication and work flow…

valuable learning experience. Today, the seven AARCCOP partner hospitals are St. Joseph Mercy Hospital/McAuley Cancer Care Center in Ann Arbor, St. John Hospital & Medical Center in Detroit, St. John Macomb Hospital in Warren, Hurley Medical Center in Flint, Genesys Regional Medical Center in Grand Blanc, Sparrow Medical Center in Lansing, and St. Mary's Hospital in Saginaw.

Currently, our CCOP's geographic area provides clinical trial access to approximately 4.2 million people of diverse racial and ethnic backgrounds. The component institutions together accession more than 8,000 new cancer cases a year. New research studies, particularly cancer prevention studies, are activated only after the potential for accrual within all of our communities has been evaluated.

The AARCCOP initially affiliated with five research bases: the North Central Cancer Treatment Group (NCCTG), which is our primary research base; the Eastern Cooperative Oncology Group (ECOG); the National Surgical Adjuvant Breast and Bowel Program (NSABP); the Radiation Therapy Oncology Group (RTOG); and the Gynecology Oncology Group (GOG). GOG ceased to be a research base for CCOPs as of June 2001. In the future, we will access GOG studies through the M.D. Anderson CCOP Research Base.

Helping Our Partners

To help new partners get started, our CCOP manager and operations staff compiled a manual entitled *New Member Binder*, which serves as a comprehensive resource for all clinical trials staff. Included in the front pocket of the manual are the National Institutes of Health Common Toxicity Criteria, TNM staging references, and the date finder/schedulator "wheel," a tool that helps staff members create treatment schedules. The binder is divided into sections including an AARCCOP staff directory, forms, the record retention requirements, web site information, and manuals such as the *NCCTG Pharmacy Manual* and *NCCTG Audit Manual*. There is also a sample patient record that illustrates how a patient chart should be set up and maintained.

To comply with the requirements established by the NIH Office of Extramural Research, our CCOP developed and implemented a mandatory education program in human subject protection for all investigators and key personnel. This program may be completed by 1) reading *Protecting Study Volunteers in Research: a Manual for Investigative Studies* (Centerwatch Publications), 2) watching a video presentation entitled *The Protection of Human Subjects* produced by the Clinical Research Department at St. Joseph Mercy Hospital, or 3) completing an Internet tutorial (*http://ohsr.od.nih.gov/cbt; www.indiana.edu.~rcr*; or *http://www.nci.gov*). Individuals sign a compliance form indicating the program they chose and the date they completed it and send the form to the AARCCOP manager.

Governance

As we added partner institutions and research bases, we developed a coherent and systematic governance structure to streamline communication and work flow and ensure quality in all aspects of the clinical trials. The three main components of the AARCCOP organizational structure are the Governing Board, the Oncology Research Committee, and the Operations Office.

The AARCCOP Governing Board is made up of the principal investigators of each partner institution and is chaired by Philip Stella, M.D. It supports and facilitates strong working relationships and collaborations between the partners through its formal and informal communications, and sets policies for the group. The board meets at least quarterly and is responsible for setting the strategic direction for the CCOP, developing strategies for patient accrual to studies, assuring that the NCI's CCOP performance expectations are met, ensuring compliance with the requirements set by the research bases, and reviewing the performance and audit results of the partner sites.

The AARCCOP Oncology Research Committee (ORC) is an intra/multidisciplinary group of representatives from surgery, medical oncology, radiation oncology, gynecologic oncology, pathology, pharmacy, and nursing and is charged with the review of all new studies available to the CCOP.

When a new protocol is received from a research base, the AARCCOP Oncology Research Committee and the principal investigator review it and determine the appropriateness and priority of the study based on 1) the overall scientific merit of the question under study and the proposed methodology, 2) conflicting studies already available from CCOP research bases and high-priority protocols of the NCI, 3) the potential for accrual, and 4) fiscal feasibility. After a study has been accepted by the Oncology Research Committee, it is submitted to the central institutional review board (IRB) for approval.

The CCOP Operations Office is led by the daily operations manager of the Ann Arbor CCOP partner and serves as the liaison for the other component institutions. The Operations Office:

- maintains a central protocol file and assures the timely dissemination of protocol updates and amendments
- oversees the randomization process for all partners

The research team works closely with investigators as they identify patients for studies. Research coordinators educate and consent patients about studies.

- assures IRB compliance
- performs internal and partner audits
- generates individual patient schedules and tracks the patient's adherence to the protocol
- helps partner sites develop systems and processes to ensure efficient functioning and data quality.

To simplify their work, the administrative and research teams have developed specific tools, including a one-page protocol summary sheet for each disease site, a pocket-size booklet of all open protocols, protocol-specific common toxicity sheets, a multidimensional tumor measurement form incorporating the Response Evaluation Criteria in Solid Tumors (RECIST) guidelines, and patient information brochures.

A major initiative was designating the Saint Joseph Mercy Health System (SJMHS) IRB as the central IRB of record for oncology studies. Studies that open through the central IRB are also open at the component sites. All paperwork is processed at the CCOP administrative office, and the entire cycle of IRB continuing reviews, protocol updates, addenda, revisions, closures, and approvals is handled through the SJMHS IRB by the AARCCOP administrative staff.

Each of our partner hospitals has a representative on the central IRB. The representative is mentored and attends the monthly central IRB meetings, via teleconference or audioconference if necessary. This arrangement meets federal regulations for each partner's responsibilities for representation.

Quality Control

The Ann Arbor Regional CCOP recognized from the outset that a high standard of quality control would be necessary to establish a reputation as a premiere contributor to national research groups. A set of checks and balances was developed to ensure that AARCCOP submissions would be timely, accurate, and complete. The system prevents falsification of data and all investigators in the AARCCOP must sign an Affirmation of Integrity form.

The research nurses and clinical research assistants (CRAs) review patient charts monthly to identify missing data or potential problems. The AARCCOP manager examines delinquency reports and makes rapid follow-up phone calls to responsible parties at delinquent partner sites. Queries are considered monitoring tools to improve data collection and submission procedures.

Any significant protocol data discrepancies are reviewed immediately with all principal investigators. At St. Joseph Mercy Hospital-Ann Arbor, the research nurses and CRAs meet weekly with the principal and associate investigators to discuss ongoing quality and patient management issues for all the partner sites.

To prepare for national audits, internal audits are performed semi-annually by representative physicians from medical oncology. Records from approximately 10 percent of the annual accrual are randomly selected and reviewed for errors, completeness, and compliance with protocols. The results of these internal audits are discussed at the weekly research meetings and the department meetings for medical and radiation oncology. National audit results are reviewed and discussed at the AARCCOP Governing Board meetings. All non-compliance issues are identified and addressed immediately with the partner-site principal investigator and research coordinator.

Auditing is a way to mentor personnel at all our partner institutions. These audits are comprehensive and include records from the pharmacy, the IRB, and patient records from the clinical trials themselves. The AARCCOP administrative and research staff conducts an internal audit at a partner site after five patients have been accrued to a study and reviews all five records. Internal audits are also performed annually at all partner sites and at least 12 charts are examined. If a partner has accrued less than 12 patients, all the patient records are audited.

Development of Data Management Software

The key to streamlining our operations was the development of a data management system that ensured data quality and computerized the administrative functions of clinical trials.

During our initial grant period, we hired a computer software consultant who worked with our research and administrative staff to develop such a software program, and the result was the Clinical Research Environmental Data Information Tracking (CREDIT) system, which was initially installed in 1995 at the AARCCOP.

The CREDIT program can develop schedules for

…we cannot ignore the issue of *cost* since it ultimately *impacts patient access* to these studies.

each patient, automatically adjusting for treatment delays. Patient activity lists for a given time period can be printed that tell the staff which patients are due for treatment or other diagnostic activities. The CREDIT program is capable of tracking all our protocols and their subsequent addenda, revisions, IRB review dates, and IRB actions, and automatically identifies patients who require reconsent. CREDIT also generates all the reports and tables required for NCI annual reviews and grant reapplications, and merges the database with a document module to automatically generate annual reports for the IRB and letters to patients and physicians.

Originally written as a DOS program, CREDIT is now web-based and is available commercially from the software company.

We plan to continuously improve our software so it increases the efficiency and effectiveness of our operations. For instance, our oncology research pharmacist and our computer consultant are collaborating on a comprehensive investigational drug inventory and management system. When complete, this web-based software will enable us to manage the entire process of drug ordering and dispensing, drug tracking, and NCI reporting. This new program will link with the CREDIT patient scheduling software so the pharmacist will be automatically notified of the need to order a drug when the patient is scheduled for treatment.

Cost of Clinical Trials

The highest priority of the AARCCOP has been and continues to be the quality care of patients on clinical trials, but we cannot ignore the issue of cost since it ultimately impacts patient access to these studies.

Institutional support of clinical research programs is critical since the CCOP funding provided by the National Cancer Institute must be cost-shared or matched by a nonfederal institution. Our program meets this requirement through in-kind contributions. SJMH contributes a portion of the salaries and benefits for the CCOP manager, the director of oncology services, the oncology pharmacist, the gyn oncology research nurse, the laboratory liaison, three nurse practitioners, and a portion of the salary of the principal investigator of the CCOP to a total of approximately $200,000.

We participated in the 1999 Clinical Trial Practice Cost Study sponsored by the American Society of Clinical Oncology (ASCO), and the preliminary but gratifying results of this investigation were presented in May 1999 at the ASCO meeting. The findings showed that the average total cost per trial patient was $10,491 at an academic center and $6,924 in a private physician practice. The average total cost for a patient in our research program was only $4,138. We believe this result was due to the streamlining of our operational systems, which has produced efficient and non-redundant care.

Our Accomplishments

The AARCCOP was one of 10 sites selected to participate in the NCI pilot program to evaluate the impact on accrual when access to more than one primary research base is allowed. We chose to affiliate with SWOG, which became fully activated in 1999. Many staff members in the CCOP and at potential partner institutions had experience with SWOG protocols and were eager to continue their affiliation. In fact, several of our partner hospitals were reluctant to join the AARCCOP until SWOG was added because of their longstanding relationships with this group. Adding SWOG to the AARCCOP study base has provided many opportunities for expansion.

The University of Michigan CCOP Research Base (UMCCOP) was also added in 1999 and expands AARCCOP's offerings with cancer prevention and control trials that focus on translational research.

Since its inception in 1994, the AARCCOP has exceeded all the NCI requirements. In the seven years our CCOP has existed, we have increased our accrual, broadened the participation of our investigators, and added six partner sites, which have expanded our patient catchment area to include more diverse patient populations. Adding SWOG to our research base will allow us to add even more component institutions, and the addition of the University of Michigan Cancer Control CCOP Research Base has expanded our cancer prevention and control activities. Finally, the development of a comprehensive data management system has helped to streamline all aspects of our trial administration and patient scheduling.

We are developing our CCOP web site to expedite the distribution of information to our partner hospitals. Soon our partners will have online access to study base information, protocol revisions and addenda, and the most recent consent forms, which will further streamline our operations.

As we transition from the Ann Arbor Regional CCOP to the expanded Michigan Cancer Research Consortium, we are more enthusiastic than ever about the future of clinical trials and the importance of their place in community oncology care.

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