Oncology Issues

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ISSN: 1046-3356 (Print) 2573-1777 (Online) Journal homepage: https://www.tandfonline.com/loi/uacc20

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To cite this article: Louise Snow (1997) Managing a CCOP: The Ann Arbor Regional Experience, Oncology Issues, 12:3, 18-22, DOI: 10.1080/10463356.1997.11904683

To link to this article: https://doi.org/10.1080/10463356.1997.11904683

Published online: 18 Oct 2017.

Managing a CCOP: The Ann Arbor Regional Experience

by Louise Snow, R.N., B.S.N.

Since 1983 the National Cancer Institute has sponsored Community Clinical Oncology Programs (CCOPs), providing community institutions with the opportunity to participate in formal clinical research protocols through the nation's system of cooperative groups.

Programs seek CCOP designation because they offer a variety of benefits for patients, institutions, and physicians.

Advantages to patients. CCOPs offer patients the availability of state-of-the-art care in a health care setting in their community and increased access to treatment options.

Advantages to institutions. Since clinical trials cancer research is a critical component in state-of-the-art 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. The opportunity for patients to participate in clinical trials in their own community is a great patient satisfier. Moreover, CCOPs offer institutions increased image and prestige through affiliation with major cancer treatment centers in the United States.

Advantages to physicians. Participation in CCOPs offers physicians the ability to deliver state-of-the-art care and increased treatment options to patients and their families in their home community. Participation is an avenue by which physicians can respond to the needs of an increasingly well-informed public. Physicians gain an opportunity to participate in national cancer prevention and cancer control studies.

With the benefits come challenges to making the program succeed. Because NCI funding is not adequate to cover a CCOP's entire budget, staff must obtain financial support for the CCOP from the hospital or consortium of hospitals.

Cost control is vital to CCOP-awarded institutions. Hospitals with the technical capability to carry out the trials at a lower cost and at greater convenience to patients and their families are most likely to succeed. In addition, finding sufficient numbers of patients eligible for accrual to trial may be difficult. Finally, NCI reporting requirements and additional studies add to the challenges and staff burden.

THE GROWTH PROCESS

The Ann Arbor Regional CCOP has been operational since 1994 at St. Joseph Mercy Hospital, a 558-bed acute facility serving southeastern Michigan. The CCOP is the culmination of incremental efforts to improve a clinical research program in place at St. Joseph Mercy Hospital since the 1980s. However, before a CCOP grant application was made, the research program needed to be confident the following criteria were in place:

- a minimum number of patients accrued to clinical trials per year (50 in cancer treatment, 50 in cancer control)
- a strong quality control program
- data collection capability
- a team of medical, radiation, and surgical oncologists and other specialists committed to participation in clinical trials.

Participation in cancer clinical trials had been ongoing at St. Joseph Mercy for many years on a small scale. During the 1980s, an affiliation with the Toledo Community Hospital Oncology Program (CHOP) provided access to clinical trials and mentorship. The oncologists and the nurse manager of the outpatient chemotherapy clinic managed research responsibilities. While the oncologists had expressed interest in enrolling patients onto clinical trials, they could not devote the necessary time and support. The clinic was so busy there was insufficient time for the nurse manager to oversee the clinical trials program from a data management and nursing perspective.

In 1990 the oncology program director gained hospital support to fund an oncology research nurse to facilitate development of the clinical research program. The oncologists and the research nurse followed standard procedure: The oncologists would introduce the protocol to the patient with an explanation of standard versus protocol treatment. If the patient had any interest in the protocol, the research nurse would spend the

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the time necessary for the patient to understand the concept of oncology research and the potential risks and benefits.

Once the patient was enrolled onto the study, the research nurse would inform the chemotherapy clinic of the patient's participation in the study and educate clinic staff as to any deviation from normal administration practice. Clinic staff were also provided information on investigational drugs. The oncology research nurse acted as case manager for the patient, ensuring that protocol requirements were scheduled and reported appropriately.

Enlisting a research nurse to support the oncologists proved successful: during the first year of the addition of the research nurse, patient accrual to clinical trials totaled twenty-eight—far better than the four to five patients accrued to studies in previous years.

ENLISTING PHYSICIAN SUPPORT

By the early 1990s multidisciplinary research teams were established to further involve physicians in the clinical research program. Workgroups were established for each primary cancer disease site—lung, breast, and colon. The groups' primary focus was to establish standards for treatment of these cancers at our hospital.

The first team to be formed was the lung workgroup, which consisted of cardiothoracic surgeons, pulmonologists, a pathologist, radiation oncologists, a radiologist, and medical oncologists. The team initially established guidelines for non-small cell lung cancer. For each stage, treatment was discussed and established. Treatment included options based on patient status and choice. For example, a disease stage could have options of surgery, chemotherapy/radiation, or no treatment. Clinical trials were included in those options.

The research nurse facilitated the group meetings, provided notices, prepared agendas, and documented decisions or outcomes. She also ensured that the group was informed of all the active lung cancer protocols. For example, accruing patients to an adjuvant study for stage II and IIIa non-small cell lung cancer had been difficult. The required lymph node sampling was quite specific and not easily remembered during the surgical procedure. To improve communication, during the workgroup meeting the oncology research nurse instructed the surgeons on the required node sampling and addressed the protocol's use of the new lung staging system. The oncology research nurse also inserviced the operating room staff on the adjuvant protocol and its required lymph node sampling and correct nomenclature. Charts of the new staging system were provided for display in offices and operating rooms, and a pocket-sized replica was also provided to physicians.

Workgroup participants also collaborated on an in-house study for the treatment of stage IIIa inoperable and IIIb non-small cell lung cancer. At the time, there was no available national protocol. This endeavor was an opportunity for research development and enhanced collegiality among the different disciplines. These interactions increased the numbers of people involved with clinical trials and aided in case finding.

The breast cancer and gastrointestinal workgroups were established next. Representatives from all involved disciplines, including radiology, pathology, general surgery, radiation, and medical oncology, worked to establish guidelines for care with strong support for national clinical trials. The gastrointestinal workgroup focused primarily on guidelines for colorectal cancer screening and algorithms for the workup and treatment of pancreatic cancer. The breast cancer workgroup established guidelines for all stages of breast cancer. The oncology program introduced these guidelines at respective symposia on breast and colorectal cancers.

Preliminary workgroup meetings were well attended, although initially somewhat tense. The different disciplines all had a slightly different focus for the agenda. After several twice-a-month meetings, participation in clinical research became a multidisciplinary interest and focus. Over time these workgroups have evolved into monthly tumor boards, where cases are discussed and treatment options consistently include clinical trials. These meetings are also used as a forum for discussing and establishing methods for incorporating more difficult clinical trials into the program.

THE CCOP EXPERIENCE

The success of the multidisciplinary workgroups and the continued growth of the clinical research program resulted in our ability to successfully apply for a CCOP grant.

The grant and the hospital's financial support allowed the CCOP to acquire another full-time research nurse, enabling one nurse to manage treatment protocols and facilitate the workgroups, with another nurse managing cancer control and prevention studies and monitoring Institutional Review Board (IRB) issues. Data gathering and reporting responsibilities were shared between the data manager and the nurses. Administrative responsibilities were managed by the oncology program director.

To function more efficiently, the research program now has an administrator who manages the budget and operational issues for the different sites. The change was made to allow one individual to oversee activities, permitting the nurses to devote their time to patient issues of case finding, treatment monitoring, and staff education.

QUALITY CONTROL

The Ann Arbor Regional CCOP recognized from the outset that a high standard of quality control is necessary to establish a reputation as a solid contributor to national research groups. Thus, a set of checks and balances was developed to assure that Ann Arbor Regional CCOP submissions are timely, accurate, and complete. The systems are in place to prevent falsification of data, and the research team is strongly committed to conducting "clean" research. All investigators in the Ann Arbor Regional CCOP have signed an affirmation of integrity form.

Patient charts are reviewed on a weekly basis by the research nurses and clinical research associates (CRAs). These weekly reviews focus on any missing data or potential problems. All queries from the research bases are reviewed and discussed at these weekly meetings. Queries are used as an educational tool to improve our data collection

and submission procedures. Any significant protocol data discrepancies are reviewed immediately with the principal investigator. The research nurses and CRAs meet weekly with the principal and associate investigators to discuss ongoing quality and patient management issues.

On a quarterly basis, an internal audit is performed by representative physicians from medical and radiation oncology. Records from approximately 10 percent of the annual accrual are randomly selected and are reviewed for errors, completeness, and compliance with protocol reporting. The results of these internal audits are reported to the Oncology Research Committee of the Ann Arbor Regional CCOP Governing Board and are discussed at the department meetings for medical and radiation oncology.

As components are added, quality continues as a major focus. The Ann Arbor Regional CCOP operations staff, including the CCOP administrator, pharmacist, and either a registered nurse or CRA, visit each component institution to provide in-service training and internal audits. A minimum of 10 percent of charts of patients accrued each year will be audited at each component site at least semiannually. The frequency of audits will increase with increased accrual. Auditing procedures serve as a means to mentor personnel at our component institutions.

The CCOP clinical pharmacist is responsible for the maintenance of investigational drug supplies and records. Receipt, use, and distribution of investigational agents are documented according to hospital policy and federal regulations. The pharmacist works with the research nurses to complete investigational drug data sheets for all investigational agents and provides inservice education to all applicable personnel. A complete inventory of all investigational agents is performed quarterly. Dose calculations for all investigational agents are performed by two qualified personnel to assure accuracy. Investigational agents are administered only by qualified, trained registered nurses. We strictly adhere to the National Cancer Institute/Federal Drug Administration drug control requirements. Drugs are ordered according to protocol requirements under the name of the principal investigator. OSHA guidelines for the storage and safe handling of antineoplastic agents are followed.

PATIENT IDENTIFICATION, RECRUITMENT, AND RETENTION

Case finding has been a priority issue in maintaining high accrual and increasing accrual to NCI high-priority protocols. A system of case finding has been developed that involves surgeons, radiation oncologists, medical oncologists, and oncology nurses in addition to the tumor registry. Oncology nurses review pathology reports on a daily basis and play a key role in assisting physicians to identify potential study participants as they present for care.

Some patients eligible for protocols are first seen by general surgeons or other specialists. These physicians and their office nurses are kept up to date on protocols of interest through a variety of mechanisms. First, there is broad-scale participation on the Oncology Research Committee and in multidisciplinary workgroups. Non-oncology specialists on these committees are assigned to periodically report to their various medical staff sections on the groups' activities, including the presentation of open protocols. Second, a cancer center newsletter provides the medical staff with information on new protocols and cancer control initiatives. Third, multidisciplinary workgroups and clinics are an opportunity for cases with specific diagnoses to be evaluated for protocol eligibility by the entire team. Fourth, patient management guidelines, developed by the workgroups, include information on available protocols and are widely disseminated to specialists throughout the St. Joseph Mercy Hospital facility as guides to state-of-the-art care. As noted previously, participation by many non-oncologic specialists in the workgroup concept has led to significant increases in target site accruals.

Other case-finding activities include:

- holding frequent in-service programs by the research nurses to keep nurses in the outpatient and inpatient areas and members of the medical staff informed of current and soon-to-be-activated protocols
- maintaining lists of potential study participants while awaiting activation of a new study
- identifying potential participants through the tumor registry.

Advertising through direct mailings, flyers, advertisements, and notices in local papers have been used to increase public awareness and recruit subjects to cancer prevention studies, particularly the Prostate Cancer Prevention Trial and the Breast Cancer Prevention Trial.

A major effort is under way to improve minority recruitment to clinical trials. Staff are provided continuing education on the barriers to study participation faced by minorities and means by which these barriers can be overcome. Research nurses have attended a national conference on "The Recruitment and Retention of

CCOP Opportunities: 1997

- There are 51 CCOPs in 30 states and the District of Columbia.
- In those 51 CCOPs there are 316 participating hospitals, with 2,117 physicians entering patients on protocols and 1,215 additional participating physicians.
- Estimated patient accrual for treatment protocols: 4,206
- Estimated patient accrual for cancer prevention and control trials: 2,680
- There are 8 MBCCOPs in 7 states and Puerto Rico.
- The minority-based CCOPs include 42 hospitals, with 276 physicians entering patients on protocols and 105 additional participating physicians.
- Estimated patient accrual for treatment protocols in minority-based CCOPs: 346
- Estimated patient accrual for cancer prevention and control trials in minority-based CCOPS: 240

Minority Participants in Clinical Cancer Research," as well as a conference on diversity sponsored by St. Joseph Mercy's Ethics Committee. A Minority Recruitment Advisory Council has been formed, composed of prominent minority representatives from the community, including pastors, business leaders, cancer survivors, and physicians. This group will guide the implementation of a program that adequately addresses the needs of the minority community. The group will also have oversight and monitoring responsibilities. Networking with other agencies and organizations can help establish programs for the education of health care providers and the minority population. These programs will also improve access to clinical trials.

Although much energy is devoted to recruitment activities, equally important are efforts to retain patients. Patients are taught how the protocol differs from standard therapy, the importance of research, and the potential gain that the protocol offers. Discussions help patients in making their choice of accepting or declining participation in the study.

The close working relationship that the research nurses develop with patients and families is important for retention. These bonds help ensure that, in a busy and often confusing health care environment, the research patients always have a familiar, personal contact to resolve problems or concerns.

At St. Joseph Mercy Hospital a final tool helps promote retention: a fail-safe data management system for tracking patients in long-term follow-up. This is particularly important as patient numbers increase.

DATA MANAGEMENT/INFORMATION SYSTEM DEVELOPMENT

The research staff has developed the systems to fashion an efficient and effective operation. The Cancer Care Center invested significant human and hard-dollar resources to develop and implement the Cancer Research Environmental Data Information Tracking (CREDIT) data management system. Of more than 500 patients, only one patient has been lost to follow-up, which was clearly a choice of the patient

Streamlining Participation in Clinical Trials

by Joy G. Stair, M.S., B.S.N.

It is somewhat ironic that at a time when the National Cancer Institute is interested in expanding its CCOP program and appears to have the budgetary support to do so, there is a declining interest on the part of hospitals and physicians to participate in the CCOP program because of multiple market forces. The threat to reimbursement for clinical trials plus the increased financial and human resource burden required for participation are only several reasons hospitals and physicians are seriously questioning whether the benefits of participation are truly affordable in today's environment.

Adding to the burden of participation in CCOPs is the antiquated paper-shuffling approach to data management and reporting requirements. In these days of sophisticated information technology systems, the lack of automation of the CCOP processes is dismaying. The approved research bases vary in their automation from minimal to none. The lack of automation as well as the lack of movement in that direction by NCI will only further deter institutions and physicians from taking part in the clinical trials program. As is common knowledge, automated systems clearly improve efficiency and productivity, thereby supporting cost containment initiatives required by all.

We at the Ann Arbor Regional CCOP are spending telephone and staff time to randomize patients when we should be able to do this task on-line with all research bases. Our data managers spend hours faxing pages and pages of patient enrollment data for the Prostate Cancer Prevention Trial when we should be able to painlessly transmit the information electronically from computer to computer. Furthermore, a data management software program should be available to streamline patient and protocol tracking, reporting, and quality control. Although the Ann Arbor Regional CCOP developed its own comprehensive software program, which works wonderfully within the CCOP, it doesn't "talk" to any other systems—because there are none! The CCOP annual reporting and grant renewal processes need to be streamlined and automated where possible to eliminate the procedures that are now duplicative.

Consent forms should be standardized and available on-line. Hours are spent modifying consent forms to build in consistency across protocols. For example, in the consents coming from research bases, side effects of Adriamycin may vary for different protocols. In addition, we are instructed to write consents at a sixth-grade reading level. Yet consents often total twenty pages, more reading than those at a sixth-grade level can tolerate.

The ideal system should be developed as a joint effort of the NCI, research bases, and CCOPs so that processes are standardized across the entire program. A new CCOP coming on board would be given the software so that it starts off with a streamlined system that supports efficiency and quality. The automation of the clinical trials program is not an option if it is both to survive and flourish. Those of us in the trenches implore the NCI to take the lead in this effort.

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rather than any lack on the staff's part.

CREDIT can record and track information about protocols and patients and provides a variety of reports based on that information. Features of the CREDIT system include the capability to 1) enter visit, treatment, and laboratory schedules for each protocol with automatic calculation of an individualized patient schedule; 2) track all protocols and subsequent addenda and revisions with respect to IRB review dates; and 3) generate a myriad of reports, including those necessary for NCI progress reports and reapplication. In this era of cost containment, the CREDIT system was developed with the intention that it would streamline the workflow of the CCOP, freeing staff for case finding, keeping full-time employee needs to a minimum, and strengthening quality assurance efforts. To date, it has far surpassed expectations in all aspects.

We are pleased with our accomplishments. However, the program is still in its infancy and must rigorously strive for improvement in all quality control activities, in community education, in minority recruitment, and in overall patient accrual to clinical trials.

An Open Letter to ACCC Members

by Leslie G. Ford, M.D.

The Community Clinical Oncology Program is fourteen years old this year. As with any parent, I look back with great pride on how the program has developed and matured. Our original aspirations for the CCOP have been realized, and we are approaching adulthood with a renewed sense of accomplishment and anticipation.

In 1982 NCI-sponsored cancer treatment clinical trials were performed exclusively in universities and cancer centers. Cancer patients wanting access to state-of-the art care were referred by their community oncologist to one of these, often distant, locations. The introduction of the CCOP began to change the situation and provide more convenient access.

Today the early struggles of the pioneering community oncologists for acceptance as equal partners into the ranks of the cooperative groups are a distant memory. There has been a paradigm shift of the groups to integrate the community physician into the research process. This shift has subsequently reoriented how the groups define cancer research. The focus has been broadened to include interventions not only for the cancer patient, but also for family members and other individuals at risk. The spectrum has widened to include cancer prevention and early detection research as well as treatment, symptom management, and continuing care.

CCOP physicians hold key research positions on many cooperative group committees, and their contributions to treatment accrual remain strong. One-third of all patients in NCI-sponsored Phase III cancer treatment trials come from the CCOPs. From its earliest conception, the CCOP was envisioned as providing the network necessary to implement large-scale prevention clinical trials. When faced with the challenge, CCOPs responded in an extraordinary fashion. When the new concept of breast and prostate cancer chemoprevention trials in populations without cancer was introduced in 1991, the CCOPs randomized a large proportion of the current total of nearly 35,000 participants. When the results of these landmark prevention trials are in, the CCOPs will be duly recognized for their role in "making it happen." The CCOPs have already made major contributions to the literature in supportive care, quality of life, and pain management. The CCOP budget has grown from its first annual budget of approximately $8 million to the current one of almost $38 million. One feature inherent in the growth of the CCOPs is the increasing inclusion of multispecialty clinicians. CCOPs are no longer organizations of medical oncologists; they also include those specialists in dental, gastroenterology, infectious disease, gynecology, and urology necessary to accrue to the diversity of available clinical trials.

Today's clinical trials face struggles different from those early years. Concerns of reimbursement, managed care, complex informed consent, cancer prevention, and genetic testing have replaced early worries of whether community oncologists could measure up to the standards of the cooperative groups. Again, the CCOPs are uniquely positioned to respond to these challenges and turn them into opportunities. They have the understanding of the current health care delivery environment, the expertise to implement clinical trials, and the access to cancer patients, family members, and individuals at risk to make new research concepts a reality.

The CCOP is entering its adult years at the same time the scientific community embarks on an unparalleled period of research discovery in such areas as genetics, molecular targets for detection and intervention, and vaccines for prevention. The CCOPs provide the vehicle to bring this new technology to the community, as well as to help define it and make sure that issues raised within the community are addressed. The effective partnership between community and academic cancer centers is essential to translate the benefits of clinical research beyond the bench and bedside to the entire population affected by cancer.

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