

Decades of Progress
1983 to 2003



Community Clinical Oncology Program

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Cancer Institute

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DEDICATION

This book is dedicated to the physicians, nurses, and staff of the Community Clinical Oncology Programs and Minority-Based Community Clinical Oncology Programs.

Through their commitment to provide the best cancer care to the people in their communities, the Community Clinical Oncology Program as a whole has flourished.

Without their time, energy, and support, this program could not exist.

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*by Peter Greenwald, M.D., Dr.P.H., Division of Cancer Prevention
Director, and Assistant Surgeon General,
U.S. Public Health Service*

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Dr. Emad Salman and Ben Klassen demonstrate why CCOPs do what they do.

FOUNDATION STONE OF A CLINICAL TRIALS NETWORK

Peter Greenwald, M.D., Dr.P.H.

Director, NCI Division of Cancer Prevention and Assistant Surgeon General, U.S. Public Health Service

For decades, oncologists have been trained in their craft by mentored caring for patients in clinical trials. In the early 1980s, oncologists who had been trained in cancer institutes or teaching universities began practicing in community settings but wanted to continue to participate in cutting edge cancer research. At that time, as always, NCI was looking at ways to provide the best quality of care to cancer patients regardless of their location. It was felt that participation in clinical trials, the cutting edge of medical oncology, would be mutually beneficial for community physicians and their patients.

My colleagues and I in the Division of Resources, Centers, and Community Activities, now the Division of Cancer Prevention, saw other potential benefits from including community hospitals and physicians in clinical trials. Doctors, nurses, and other health professionals who take part in clinical trials have a sense of ownership of the process and the outcome in a way that people reading results in a journal simply do not have. This integration of the community into changing medical practices meant that the diffusion and adoption of newly proven and state-of-the-art cancer practices

would be quickly available to more people than ever before. Community level participation in cancer research would help NCI directly connect to and with the public, helping people relate to progress in clinical cancer research.

In 1983, this simple concept became a reality. The Community Clinical Oncology Program began to link community cancer specialists, primary care physicians, and other health care professionals to the Cooperative Groups and Cancer Centers. In time, the spectrum of research broadened to include chemoprevention and cancer control, including symptom management, continuing care, and quality of life.

There were some skeptics who doubted that community physicians and hospitals could do as well as academic centers in the rigor of clinical trials. On this 20th anniversary of the Community Clinical Oncology Program, I am happy to say that fully one-third of all patients in NCI-sponsored treatment trials and NCI-sponsored prevention clinical trials come from the CCOPs, and that some of the highest quality data for these trials come from CCOPs.

In these 20 years, we have gathered solid evidence that community physicians can make major contributions to cancer clinical trials. Through the CCOP Program, the Cooperative Groups and Cancer Centers have developed their cancer control research agenda. These investigators have become the primary force behind prevention, cancer control, symptom management, and quality of life research. The most important cancer prevention clinical trials ever conducted may never have been launched without the CCOPs. The CCOPs have built a strong program of medical approaches to cancer prevention. They are in the forefront of wide-scale testing of preventive interventions, and conduct them with exemplary quality and efficiency.

The Community Clinical Oncology Program has become one of the foundation stones of the clinical trials network of the National Cancer Program. This straightforward concept, which was sown in 1983, has reaped a multitude of successes.

It has been a pleasure and a privilege to be a part of the CCOP ideal over the past two decades.

Why I Am A CCOP Physician

The treatment of cancer is an evolving process. The knowledge we gain from the results of clinical trials ultimately determines what the standard treatment for a particular type and stage of cancer will be.

During our residencies at academic centers we learn the value of evidence-based medicine. We study the landmark clinical trials that have influenced our current treatment recommendations and we participate in new clinical trials that are destined to influence future standards. We learn to recognize the value of clinical trials in helping to improve the care of cancer patients.

When we complete our residencies, we must choose whether to stay in the academic world or join the ranks of community physicians. Many of us struggle with this decision because we enjoy the stimulation of the university setting, and we feel the good that comes from the knowledge that we are working to advance the treatment.

For those of us who choose to go into private practice, we don't give up our intellectual curiosity and our desire to help advance the knowledge of cancer treatment. The ability to participate in clinical trials allows us to continue to contribute to our profession and to help improve the quality of care we provide to our patients. The CCOP mechanism provides us with that opportunity.

For me, participation in the North Central Cancer Treatment Group (NCCTG) has provided a framework for ongoing collaboration with my academic colleagues. Collaborations like this, along with attendance at semiannual group meetings, allow community physicians the opportunity to stay informed about new developments in oncology.

To summarize, why do I participate?

1. I want to help improve cancer care.
2. I want to be able to offer my patients the most up-to-date treatment possible.
3. I want to be part of a collaborative process with academic physicians in order to continue my own professional development and acquire knowledge related to new developments in oncology.

*Richard L. Deming, M.D., Medical Director
Mercy Therapeutic Radiology Associates
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July 2003*

In the early 1980s, two forces for the advancement of cancer care were in place: physicians trained at academic cancer centers were increasingly entering community practice to care for the majority of cancer patients in the country; but patients still had to travel to cancer centers to participate in cutting edge cancer clinical trials.

The identification of this problem was the impetus for the creation of the Community Clinical Oncology Program. The challenge was to design and implement a program to assure that cancer patients treated in their communities had access to clinical-trial quality medical care. By introducing up-to-date cancer management into the community in the form of research clinical trials, community physicians would also be more ready and able to apply the proven treatment regimens to all their patients. Diffusion of state-of-the art cancer treatment to the practices where people were being treated would be enhanced.

The Call to Physicians and Hospitals

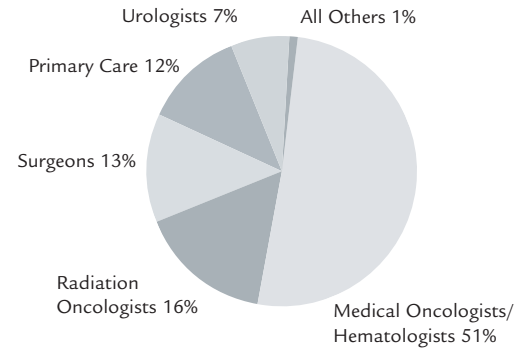
On July 16, 1982, the first call to physicians and hospitals to become part of NCI's new Community Clinical Oncology Program was released. In government parlance, this Request for Application or RFA had the goal of selecting organizations of hospitals and medical practices that would take part in treatment trials and build a network for cancer prevention and control clinical trials. Nearly 200 applications from groups seeking to become CCOPs were peer-reviewed. In September 1983, 62 CCOPs across the United States received

funding, creating a nationwide network for community physicians to enter patients on NCI clinical trials. The sources of these approved clinical trials were 31 existing NCI Cooperative Groups and Cancer Centers, collectively called Research Bases.

All of the funded CCOP sites had some experience participating in clinical research via an earlier NCI program known as the Cooperative Group Outreach Program (CGOP). CGOP was created in 1978 as an avenue for community hospitals to participate in cooperative group cancer treatment trials. This program gave community physicians their first opportunity to show that they were capable of the rigor of clinical trials research. Once the CGOPS became CCOPs, the accrual to clinical trials from these centers markedly increased. (The CGOP program has since been discontinued).

In 1986, the success of the CCOPs in accruing patients to treatment trials was clear, and a second RFA was released to continue the program. In this RFA, the scope of the program was expanded to

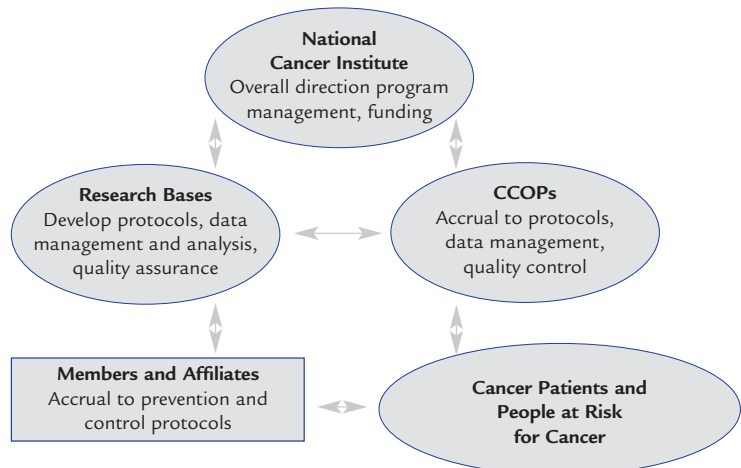
MEDICAL SPECIALITIES IN CCOPS



explicitly incorporate cancer prevention and control. The Research Bases would get funding for the design and conduct of cancer prevention and control clinical trials and would also go through a peer-reviewed application process. The CCOPs were now required to accrue to cancer treatment, prevention, and cancer control trials.

This new requirement represented a significant departure from the status quo of most research institutions and created new

CCOP ORGANIZATIONAL RELATIONSHIPS





Dr. Harry Hynes and Wichita CCOP staff circa 1988 (Pat Kastens by window; Marge Good, standing next to Dr. Hynes and Jodi Carlson at desk)

20-YEAR RESEARCH BASES

Research Bases develop and implement the cancer prevention and control clinical trials of the CCOP program. The following Research Bases have been a continuous part of the CCOP program since 1983 (*listed alphabetically by name with operations center location*):

- Cancer and Leukemia Group B (CALGB), Chicago, Illinois
- Children's Oncology Group (COG), Arcadia, California (via legacy groups Children's Cancer Group and Pediatric Oncology Group)
- Eastern Cooperative Oncology Group (ECOG), Boston, Massachusetts
- National Surgical Adjuvant Breast and Bowel Project (NSABP), Pittsburgh, Pennsylvania
- North Central Cancer Treatment Group (NCCTG), Rochester, Minnesota
- Southwest Oncology Group (SWOG), San Antonio, Texas
- University of Rochester Cancer Center (URCC), Rochester, New York

challenges for both the CCOPs and the CCOP Research Bases. Few of the practicing oncologists had any experience with cancer prevention and control research. Few of the Research Bases were organized to design and implement

large-scale prevention trials or cancer control trials. Many questioned the appropriateness of oncologists, who work with sick patients, participating in clinical prevention research that required healthy populations. However, the belief was that the successful multi-institutional network that was the CCOPs could be equally effective in conducting cancer prevention and control trials. The CCOPs thus became the focus of the full range of cancer care in a community.

Ongoing technical assistance and direction from NCI itself was needed to fully embrace this refined focus and NCI's Community Oncology and Rehabilitation Branch assumed the central coordinating role for cancer prevention and control. The Branch promoted protocol development, established protocol submission procedures, and reviewed and approved study concepts and protocols for study implementation.

In 1988, after the second CCOP RFA had already been awarded, a prospective evaluation that had been put into place with the first RFA was publicly presented. The evaluation reviewed a critical part

of the CCOP program: the enhancement and diffusion of state-of-the-art treatment regimens. In a report to the NCI's Board of Scientific Advisors in October 1988, the results of the evaluation demonstrated that community physicians could accrue patients to cancer treatment trials at a rate equivalent to the university members of the Cooperative Groups. About one-third of all cancer patients participating in NCI treatment trials were being enrolled via the CCOPs. The data generated by the CCOPs met or exceeded all the quality control standards of the Cooperative Groups. Most importantly, the participation in clinical trials through the CCOP mechanism accelerated the adoption of new treatment regimens in the community. One year later, the Board determined that the CCOP program needed not just to be continued, but made a permanent and ongoing part of the NCI program. The Board voted to permit the annual release of the CCOP RFA.

In 1989, the Board also approved the development of a complementary program, the Minority-Based CCOPs (MB-CCOPs). The 1988 evaluation had shown that while community physicians were able to accrue patients within their communities, the participating hospitals did not have access to large minority populations. The Minority-Based CCOPs would also include universities in large, urban settings, which deliver community health care to significant minority populations. The first MB-CCOPs, 12 in all, were funded in June 1990.

In 1990, the second evaluation of the CCOP program, begun in 1986, was also complete. This was an evaluation of the level of implementation of cancer prevention and control research within the CCOP network, i.e., it sought to determine whether the CCOP mechanism was an effective and efficient way to conduct cancer control research in the community setting. There had been concern that the scientific treatment focus of the Research Bases would not be compatible with cancer control research efforts. The evaluation revealed, however, that Research Bases were successful with the integration of prevention and control trials with ongoing research, especially when they created special emphasis within their own systems to address these issues.

Also in 1990, sufficient evidence existed to undertake a large trial to determine if the cancer treatment drug tamoxifen could reduce a woman's chance of developing breast cancer, and it was decided that the CCOP mechanism was the most appropriate for conducting this large-scale trial. The National Surgical Adjuvant Breast and Bowel Project (NSABP), a longtime CCOP Research Base, successfully competed for the peer-reviewed supplement to design and conduct the randomized, placebo-controlled trial for women at increased risk of developing breast cancer, but who did not have the disease.

The Breast Cancer Prevention Trial, as it was named, was considered a natural and crucial progression of the previous research conducted by NSABP and others. The trial, which showed in 1998 that tamoxifen could reduce breast cancer risk by

half, and its implementation via the CCOP system, was a success that paved the way for other large-scale trials to take place. Tamoxifen became the first cancer prevention drug approved by the U.S. Food and Drug Administration. Today, the CCOPs provide about one-third of all the accrual to NCI's large-scale prevention clinical trials.

Summation

Twenty years after its founding, the CCOP Program has accomplished the early goals of including the community physicians in the research process and expanding the research focus of the Cancer Cooperative Groups and Cancer Centers to include cancer prevention and control.

More than 4,000 community physicians now participate in NCI clinical trials through the CCOP network. In addition, 50 CCOPs and 11 Minority Based CCOPs are funded across 34 states, the District of Columbia, and Puerto Rico, providing access to cancer clinical trials in 403 community-based hospitals.

The program established an integrated clinical trials research network that extends beyond medical oncologists, and serves as a first-class mechanism for implementing landmark cancer prevention clinical trials. Since 1989, over 74,500 people at risk



Breast Cancer Prevention Trial press conference, April 6, 1998

have been enrolled on cancer prevention clinical trials through this collaborative medium, making the CCOP network the premiere vehicle to conduct definitive phase III cancer prevention trials.

Through the dedication of the CCOP Research Base investigators, several novel and innovative cancer prevention clinical trials have been conducted. In 2003, over 90 cancer prevention and control protocols were open and actively accruing across 14 CCOP Research Bases. Just as they do with treatment research, each CCOP Research Base has tailored its cancer prevention and control research activities to its population and its scientific areas of interest.



*Diane Von Ostenberg, BS, RN,
Founding CCOP Administrator,
Grand Rapids, Michigan CCOP*

Since 1983, over 98,200 cancer patients have been entered onto cancer treatment clinical trials through the CCOP program. Consistently, CCOP sites account for one third of the accrual onto NCI sponsored treatment clinical trials, thereby ensuring that the results of these trials are applicable to patients in the community. Accrual takes less time, pressing questions are answered more quickly, and appropriate changes in clinical practice can be implemented faster.

Since 1986, the CCOPs have been a focal point of NCI research on supportive care, quality of life, and symptom management, which were orphan concepts in the 1980s. CCOP research over the past 17 years has been critical for pain management and the effective treatment of nausea and vomiting.

Because of its ongoing success, the CCOP program has been used as the prototype for other disease-specific clinical trials networks. In the late 1980's, the National Institute of Allergy and Infectious Diseases (NIAID) designed its AIDS clinical trials network after the CCOP approach. In 1999, the National Institute of Drug Abuse (NIDA) used the CCOP network to design and develop its network for community-based treatment centers to participate in clinical trials.



Charles Spurr, original founder of the Southeast Cancer Control Consortium, 1987

So, what is a CCOP?

Technically, a CCOP is a group of community hospitals and physicians funded by a peer-reviewed cooperative agreement to participate in NCI-sponsored cancer treatment, prevention and control clinical trials. But a CCOP is actually much more: it is an effective collaboration of

dedicated and committed people who give of their time, energy, and compassion to provide all aspects of care for cancer patients and their families, and for people at risk for developing cancer. CCOPs are people who firmly believe that advances in cancer care are the direct result of participation in clinical trials.

20-YEAR COMMUNITY CLINICAL ONCOLOGY PROGRAMS

CCOPs that have been continuously funded since 1983:

- Carle Cancer Center CCOP, Urbana, Illinois
- Columbus CCOP, Columbus, Ohio
- Dayton Clinical Oncology Program, Kettering, Ohio
- Duluth CCOP (previously Duluth Clinic CCOP), Duluth, Minnesota
- Evanston Northwestern Healthcare (previously Evanston Hospital), Evanston, Illinois
- Florida Pediatric CCOP, Tampa, Florida
- Geisinger Clinical Oncology Program, Danville, Pennsylvania
- Grand Rapids Clinical Oncology Program, Grand Rapids, Michigan
- Illinois Oncology Research Association CCOP (previously Methodist Medical Center CCOP), Peoria, Illinois
- Iowa Oncology Research Association CCOP, Des Moines, Iowa
- Kalamazoo CCOP, Kalamazoo, Michigan
- Kansas City Clinical Oncology Program, Kansas City, Missouri
- Marshfield CCOP, Marshfield, Wisconsin
- MeritCare Hospital CCOP (previously Fargo Clinic CCOP), Fargo, North Dakota
- Metro-Minnesota CCOP, St. Louis Park, Minnesota
- Northern New Jersey CCOP (previously Bergen-Passaic CCOP), Hackensack, New Jersey
- North Shore University Hospital CCOP, Manhasset, New York
- Northwest CCOP (previously Southwest Washington CCOP), Tacoma, Washington
- Ochsner CCOP, New Orleans, Louisiana
- Sioux Community Cancer Consortium CCOP (previously Sioux Falls Community Clinical Oncology Program), Sioux Falls, South Dakota
- St. Louis-Cape Girardeau CCOP (previously St. Louis CCOP), St. Louis, Missouri
- Southern Nevada Cancer Research Foundation CCOP, Las Vegas, Nevada
- Toledo CCOP, Toledo, Ohio
- Upstate Carolina CCOP (previously Spartanburg CCOP), Spartanburg, South Carolina
- Virginia Mason Research Center CCOP, Seattle, Washington
- Western Regional CCOP (previously Greater Phoenix CCOP), Phoenix, Arizona
- Wichita CCOP, Wichita, Kansas

SUCCESS OF THE MINORITY-BASED CCOPs

In 1990, NCI determined that in order to develop and implement effective treatment and cancer prevention and control strategies that applied to all populations, there was a need for racial and ethnic minorities to have broader access to clinical research protocols. The Minority-Based CCOP program became an important part of efforts to improve access to clinical trials and state-of-the-art care to minorities. MB-CCOPs can be any institution, organization or physician group that has more than 40% of their new cancer patients from minority populations – which opened the door for university hospitals and other minority-serving institutions not normally included in the CCOP program.

Minority-Based CCOPs are designed to:

- Bring the advantages of state-of-the-art cancer treatment and prevention and control research to minority individuals in their own communities by having practicing physicians and their patients participate in NCI-approved clinical trials.
- Provide a basis for involving a wider segment of the community in cancer prevention and control research and investigate the impact of cancer therapy and control advances in community medical practices.
- Increase the involvement of primary health care providers and other specialists with the MB CCOP investigators in cancer treatment, prevention, and control research, providing an opportunity for education and exchange of information
- Facilitate wider community participation among racial/ethnic minorities, women and other underserved populations in NCI-approved cancer clinical trials
- Provide an operational base for extending cancer control and reducing cancer incidence, morbidity and mortality in minority populations by accelerating the transfer of newly developed cancer prevention, early detection, treatment, patient management, rehabilitation, and continuing care technology to widespread community applications.



Dionne Thorne, MPH, of Howard University Cancer Center MB-CCOP

An assessment of the program was completed in 1992, and MB-CCOPs clearly demonstrated their ability to participate in clinical trials. More than 70% of MB-CCOP patients in clinical trials were from minority populations, and the 10 MB-CCOP programs contributed more than 10% of all the minority accrual to NCI sponsored treatment trials in these two years.

The MB-CCOPs demonstrate significant achievement in developing solutions to overcome participant and physician barriers to clinical trials, low literacy, limited education, and socioeconomic issues often endemic in minority and underserved communities. Many of the sites are celebrating more than 10 continuous years as CCOPs.

10-YEAR MB-CCOPs

MB-CCOPs that have been continuously funded for 10 years:

- Gulf Coast MB-CCOP, Mobile, Alabama
- San Juan MB-CCOP, San Juan, Puerto Rico
- South Texas Pediatric MB-CCOP, San Antonio, Texas
- University of Hawaii MB-CCOP, Honolulu, Hawaii
- Virginia Commonwealth University MB-CCOP, Richmond, Virginia

Why CCOP Physicians Participate in Prevention

CCOPs initially arose as mechanisms that would enable community oncologists to participate in cooperative group's cancer treatment studies. Often such protocols would include the investigation of a new drug. Some studies would redefine the standard of care for a particular disease.

Although these programs have been quite successful, community oncologists have come to recognize that the greatest reduction in the cancer burden will only arise from disease prevention. All of the advances in prolongation of survival and reduction of relapse pale in comparison to cancer prevention. CCOP investigators have learned this from their patients, their patient's families, and from their communities. CCOPs now view themselves as the best medium for chemoprevention studies at the local level.

Indeed, CCOPs are the ideal platform for such prevention studies because of the alignment of the principal investigator's recognition of the promise of chemoprevention and his/her local community's desire to participate in the research process to reduce the cancer burden

we all share. The successes of such cancer awareness events as the "Race for the Cure" and the "Walk for Life" are clues to how important local communities feel about doing their part to help. CCOPs then take this local interest and desire to participate to a higher level by enrolling at-risk individuals into studies designed to reduce cancer incidence.

The Cooperative Groups have a responsibility to harness their considerable expertise to design a national prevention program for all malignancies that are candidates for prevention strategies. When armed with good national large-scale prevention programs, the CCOPs can fulfill their initial promise of truly reducing the cancer burden.

*James L. Wade III, M.D.
Principal Investigator
Central Illinois CCOP
Decatur, Illinois*

ACCOMPLISHMENTS IN CANCER PREVENTION

In 1990, the Community Clinical Oncology Program turned a strong focus to prevention trials. Rather than pursuing traditional grants to conduct newly planned large-scale trials, the National Cancer Institute turned to the established CCOP clinical trials network.

Prevention trials require many more participants than treatment trials, because not all participants will develop cancer. The CCOPs, with their nationwide, broad reach, were considered an ideal focus for recruiting the thousands of people necessary for these trials. Working through established Research Bases, the network for prevention clinical trials was enhanced by the addition of university and outreach members of cooperative groups.

As was often the case, there was some skepticism that CCOPs could succeed in this new endeavor, but time has proven that they are up to the task.

Breast Cancer Prevention Trial

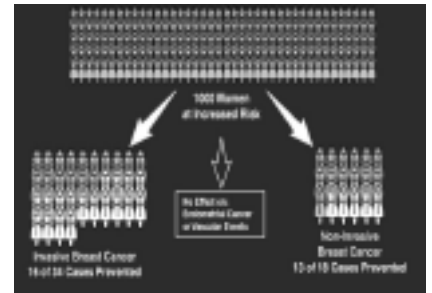
The first large-scale prevention trial to use the CCOP network was the Breast Cancer Prevention Trial (BCPT), in which tamoxifen was tested to prevent breast cancer in women at increased risk for the disease. The National Surgical Adjuvant Breast and Bowel Project (NSABP), led by Bernard Fisher, M.D., had more than 20 years of clinical trial experience with tamoxifen and successfully competed to conduct the study.

Tamoxifen is a selective estrogen receptor modifier -- it works like estrogen in some tissues, such as the uterus and bone, and against estrogen in others, like the breast. Previous NSABP research had shown that women with early stage breast cancer who took tamoxifen not only had fewer recurrences of their original breast cancer, but were also less likely to develop new breast cancers in the opposite breast. Tamoxifen was preventing new disease in these women at extremely increased risk for breast cancer.

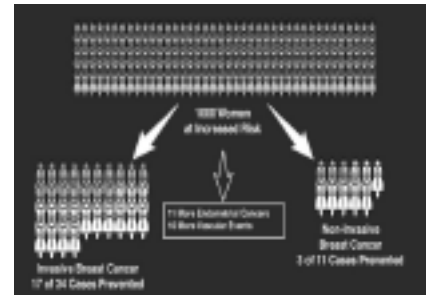
From this observation grew the Breast Cancer Prevention Trial, where 16,000 women age 35 and older, determined to be at increased risk of breast cancer, would be randomly assigned to take either tamoxifen or a placebo for 5 years. Throughout the trial, women would be evaluated not only for the development of breast cancer, but also for their likelihood of developing tamoxifen's rare, but serious side effects (blood clots and uterine cancer).

On April 29, 1992, the trial commenced at more than 270 centers across the United States and Canada, including nearly every CCOP. Recruitment was expected to take up to five years, but in September 1996 the BCPT study size was reduced from 16,000 to 13,000 because participants had a much greater underlying risk of breast cancer than anticipated. By September 1997, 13,388 women had joined the trial—4,092 from CCOPs (about 31%).

BREAST CANCER PREVENTION TRIAL BENEFITS & RISKS TO PARTICIPANTS AGE 35-49



BENEFITS & RISKS TO PARTICIPANTS AGE 50+



These graphics depict the risk of developing breast cancer in 1,000 women in two age ranges.

As part of the study design, the BCPT data were regularly reviewed by an independent Endpoint Review, Safety Monitoring and Advisory Committee. At the committee's meeting on March 24, 1998, the recommendation was made that the participants and their physicians be told what pills each participant had been taking because there was clear evidence that tamoxifen reduced breast cancer risk.

On April 6, 1998 initial results were released: BCPT had shown that tamoxifen reduced breast cancer incidence by 45% compared to women on placebo. In the study,

healthy women assigned to take tamoxifen developed 85 cases of invasive breast cancer compared to 154 cases in women assigned to the placebo. Due to the strong finding and the intense interest, NSABP researchers announced the trial results to investigators, participants, and the public immediately, without waiting for a journal to publish the data. There was a flurry of media coverage and an unprecedented attendance at a press conference to present trial data.

The data were subsequently further analyzed and published in the *Journal of the National Cancer Institute* in September 1998; the final analysis showed a 49% reduction in invasive estrogen-receptor positive breast cancer from tamoxifen. Additionally, tamoxifen increased the women's chances of developing uterine cancer, pulmonary embolisms (blood clot in the lung), and deep vein thrombosis (blood clot in major vein). Women under age 50, however, did not seem to suffer added risk of these adverse effects.

On October 29, 1998, the U.S. Food and Drug Administration approved tamoxifen for the reduction of breast cancer risk based on landmark BCPT data—the first cancer prevention indication for any drug.

Followup studies with the BCPT cohort continue to bring more critical information to light, such as the role of BRCA1/2 genes in breast cancer risk.

Reference: Fisher, B, Costantino JP, Wickerham DL, Redmond CK, et al. **Tamoxifen for Prevention of Breast Cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study.** *J Natl Cancer Inst* 1998; 90:1371-88

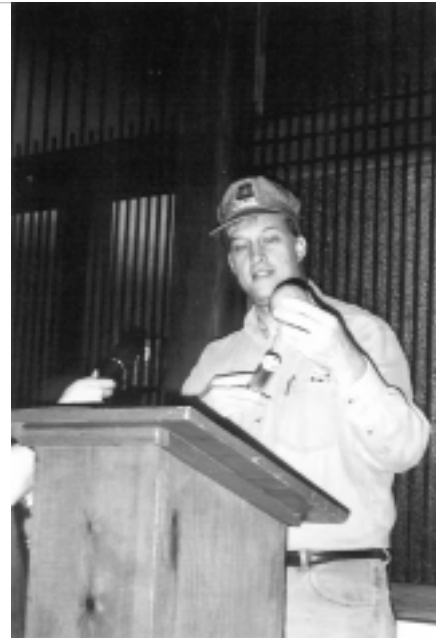
Prostate Cancer Prevention Trial

Shortly after the Breast Cancer Prevention Trial began, NCI joined with the adult cooperative groups, coordinated by Charles Coltman, M.D., of the Southwest Oncology Group, to design and implement a large-scale trial for the prevention of prostate cancer. The Prostate Cancer Prevention Trial (PCPT) was designed to determine if the drug finasteride would prevent prostate cancer in healthy men.

Research had shown that hormones played a key role in prostate cancer development. Men born with a rare deficiency in 5-alpha-reductase, an enzyme that converts testosterone to the more potent dihydroxy-testosterone, never develop prostate cancer. Finasteride inhibits 5-alpha reductase, shrinking the prostate. The drug was approved by the FDA in 1992 to treat benign prostate enlargement, and later, at a lower dose to treat male pattern baldness.

The Southwest Oncology Group designed a study where 18,000 men age 55 and older would take either finasteride or a placebo daily for seven years. Men would get yearly PSA tests and digital rectal exams to look for prostate cancer, and at the end of 7 years, participants would be asked to have a biopsy to truly determine if they had developed cancer.

In October 1993, the trial was kicked off at 221 sites, including 86 CCOPs (including MB-CCOPs). Despite concern that men would not be interested in such a long trial where the drug might have sexual side effects, the study accrued rapidly. More than 12,000 men joined within one year, and 18,882



*Scott and White CCOP, Temple, Texas
Michael Hermans, M.D., PI for PCPT,
demonstrates a core biopsy on an apple
during a luncheon held at a train depot.*

were randomized by May 1997, two years ahead of schedule. In total, 7,360 of these men were from CCOPs, or nearly 40% of all PCPT participants.

As part of the study design, the PCPT data were regularly reviewed by an independent Data and Safety Monitoring Committee (DSMC). On March 3, 2003, the DSMC notified the chair of SWOG that the primary goal of the trial had been met: finasteride reduced the risk of prostate cancer by 25 percent and it was extremely unlikely that continuing the trial would change that finding. The DSMC recommended that the trial be stopped early and that the men and their physicians be told what pills the participants had been taking.

To make the study findings available to the medical community, a report on the study findings was submitted to the *New England Journal of Medicine* on March 24 for expedited review. The report was published in the online version of the journal on June

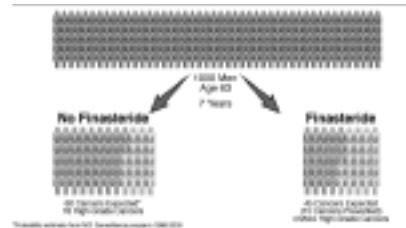
24, 2003, and in the print journal on July 17, 2003.

Finasteride is the first drug found to reduce the risk of prostate cancer in a prospective clinical trial with prostate cancer as the primary endpoint. The drug worked for men at low risk for prostate cancer, as well as those at high risk. Age, PSA level at enrollment, family history of prostate cancer, and race or ethnicity did not affect the drug's ability to prevent the disease.

There was a cautionary note: Although almost all of the men in the study who developed prostate cancer had early stage prostate cancer, those that were taking finasteride were more likely to have cancers that appeared to be high Gleason grade. High-grade cancers, when found in the general population, may spread quickly even if the tumors are small. The reason men on finasteride appeared to have more high-grade tumors is currently unknown, but the researchers are studying several possibilities. The drug may affect the architecture of the prostate gland, a well-known affect of androgen therapy, leading to a false estimate of tumor grade. Another possible explanation being examined is whether finasteride truly causes more aggressive tumors to develop.

Two types of follow up studies are already under way. All participants in the trial were encouraged to take part in a long-term follow-up study in which PCPT researchers continue to contact them to collect additional information about the effects of finasteride use, prostate cancer, and survival. Using the blood and tissue samples collected during the trial, a comprehensive program of translational research studies will look at the molecular biology of

ESTIMATED BENEFITS & RISKS FROM FINASTERIDE ON DEVELOPMENT OF PROSTATE CANCER



This graphic depicts the risk of developing prostate cancer in 1,000 men.

prostate cancer to try to determine who is at risk for developing this disease and who might benefit most from finasteride.

Reference: Thompson IM, Goodman PH, Tangen CM, Lucia MS, et al. **The Influence of Finasteride on the Development of Prostate Cancer.** *N Engl J Med* 2003;349:213-22

Colorectal Adenoma Prevention Study

Numerous epidemiologic studies have shown that people who regularly take aspirin and aspirin-like drugs to treat conditions such as arthritis have lower rates of colorectal adenomas (polyps), colorectal cancer, and colorectal cancer deaths. These drugs, known as non-steroidal anti-inflammatory drugs or NSAIDs, reduce levels of prostaglandins and decrease inflammation. Colorectal and other cancers are known to cause increased levels of prostaglandins.

Based on these promising epidemiologic data, as well as animal models and laboratory data, the Cancer and Leukemia Group B began the Colorectal Adenoma Prevention Study (CAPS) in 1993. The CAPS included men and women ages 30 to 80 diagnosed with an early stage colorectal cancer that was curatively treated with surgery

alone. These men and women were at increased risk of developing new colorectal adenomas or cancer.

Participants were assigned to take either 325 mg of aspirin or a placebo daily, and were stratified based on gender and stage of initial cancer. By January 2000, 635 men and women were enrolled on the trial .

At a regularly scheduled data and safety monitoring board meeting in late 2002, the recommendation was made to terminate the study early and release the statistically significant results of the interim analysis: daily aspirin use reduced the development of adenomas by 35% in patients with previous colorectal cancers. Aspirin treatment reduced the number of adenomas and the time to development of adenomas without causing significant adverse effects.

The results were presented at the American Society of Clinical Oncology meeting in May 2002, and published in the *New England Journal of Medicine* on March 6, 2003.

Reference: Sandler RS, Halabi S, Baron JA, Budinger S, et al. **A Randomized Trial of Aspirin to Prevent Colorectal Adenomas in Patients with Previous Colorectal Cancer.** *N Engl J Med* 2003;348:883-90.

13-cis Retinoic Acid for Upper Aerodigestive Cancers

Several of the leaders in clinical chemoprevention come from the University of Texas M.D. Anderson Cancer Center in Houston, Texas. Waun Ki Hong, M.D. pioneered the use of retinoids for prevention of both lung cancer and head and neck cancers in several critical clinical trials. Retinoids are one of the most intensively studied cancer

prevention agents; various laboratory and animal studies have shown that retinoids can destroy cancer cells and reverse premalignant tissues to normal. M.D. Anderson's first landmark trial of 13-cis retinoic acid in men and women with head and neck tumors was published in the *New England Journal of Medicine* in 1990 and showed a significant reduction in new cancers in patients treated with short-term, high-doses of 13-cis retinoic acid. This trial was the proof of principle that an agent could disrupt the progression of cells to cancer. However, another key principle of making prevention intervention viable is that the treatments have tolerable side effects and be applicable to a wide population. High-dose 13-cis retinoic acid did not fulfill this second principle.

Based on the data, as well as the very high incidence of second primary cancers in patients already diagnosed with head and neck cancer, a larger trial of long-term, low doses of the drug in men and women with early stage disease was begun using the CCOP network. The change to low dose 13-cis retinoic acid was made in the hope of translating the efficacy of the drug seen in the first trial into a tolerable treatment for larger populations. Beginning in 1991, 1,190 participants were randomized to receive either 13-cis retinoic acid or a placebo daily for 3 years, in addition to usual medical follow up appropriate for cancer survivors. Participants were then followed for an additional 4 years. The last patient was enrolled on the trial in September 2002.

Results presented at the American Society of Clinical Oncology meeting in May 2003 showed no significant difference in overall survival,

recurrence-free survival or, likelihood of developing new head and neck cancers (second primary tumors) between the groups. However, while participants were actively taking 13-cis retinoic acid, there seemed to be decreased likelihood of disease recurrence, although this disappeared once the drug was stopped.

Analysis of tumors found during the study will look at molecular characteristics to better distinguish new cancers from recurrent cancers, and to determine if and how the drug might be suppressing recurrence for some patients.

Also based on the same promising data published in 1990, M.D. Anderson began a CCOP trial of the retinoid 13-cis retinoic acid to prevent new lung cancers in 1,166 men and women who had surgery to remove an early stage, nonsmall cell lung cancer. These men and women were at extremely increased risk of having their lung cancers recur, and for developing new lung cancers. Beginning in February 1993, patients were randomized to take either low dose 13-cis retinoic acid or placebo daily for three years. The last person joined the study in June 1997.

Overall, 13-cis retinoic acid did not reduce the rate of disease recurrence or survival in the participants. However, subset analyses suggested that the drug is actually harmful to those who continue to smoke while taking the drug, but beneficial to those who have never smoked (a small minority of lung cancer patients).

Reference: Khuri F, Lee, JJ, Lippman SM, Kim ES, et al. **Isotretinoin effects on head and neck cancer recurrence and second primary tumors.** American Society of Clinical Oncology annual meeting, May 2003.

Reference: Lippman, SM, Lee JJ, Karp, DD, Vokes EE, et al. **Randomized Phase III Intergroup Trial of Isotretinoin to Prevent Second Primary Tumors in Stage I Non-Small-Cell Lung Cancer.** *J Natl Cancer Inst* 2001;93:605-18.

Ongoing Prevention Trials

Based upon the success of these initial studies, the CCOP network has proven the feasibility of implementing large-scale prevention trials in both individuals at increased risk for cancer and in those with early stage cancer at increased risk of second cancers.

Ongoing CCOP prevention trials include:

- Study of Tamoxifen and Raloxifene (STAR), the 19,000-woman trial to compare these drugs for the prevention of breast cancer. STAR is headed by NSABP;
- Selenium and Vitamin E Cancer Prevention Trial (SELECT), the 32,400-man prostate cancer prevention trial, coordinated by SWOG;
- a study of celecoxib, a selective NSAID, for the prevention of adenomas in early stage colorectal cancer patients at risk (NSABP); and
- selenium for the prevention of second tumors in people with early stage lung cancer, headed by the Eastern Cooperative Oncology Group.

In addition, novel agents are actively under development in other Division of Cancer Prevention programs for head and neck, lung, and other cancers, with the aim of leading to large-scale definitive CCOP trials.

ACCOMPLISHMENTS IN CANCER CONTROL

Charles L. Loprinzi, M.D., chairman of the North Central Cancer Treatment Group, credits the Community Clinical Oncology Program's emphasis on cancer control and symptom management as a facilitating factor in his ability to introduce a ground-breaking series of articles focused on symptom control into the *Journal of Clinical Oncology*. This series, titled "The Art of Oncology: When the Tumor is Not the Target," was reprinted as a special supplement to the journal in April 2002.

Loprinzi said, "It is through the CCOP program that I have been able to facilitate the development, conduct, and eventual publication of a large number of symptom control studies in patients with cancer." His introduction in the special supplement follows:

The CCOP Role in Cancer Control

As successful cancer treatment regimens resulted from clinical trials over time, questions emerged regarding treatment-related morbidity, symptom management, quality of life, and survivorship. Practicing oncologists found themselves being asked to address patient care situations that did not involve treating the cancer itself. Importantly for health care quality generally, the CCOP program was instrumental in reclaiming these "orphaned" patient care issues and moving them forward into the realm of clinical study.

The Art of Oncology INTRODUCTION

*Charles L. Loprinzi, Guest Editor
Division of Medical Oncology, Mayo Clinic,
200 First Street Southwest, Rochester, MN 55905*

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CANCER OVER the last century has consistently been amongst the most feared diagnoses. Oncologists, the physicians who classically have been most intimately involved with the care of patients with cancer, provide expertise with regard to surgery, radiation therapy, and cytotoxic chemotherapy. In addition to providing these anticancer therapies, oncologists are commonly called to care for patients with cancer in ways other than trying to directly kill/eliminate cancer cells.

How does an oncologist honestly, yet in a compassionate manner, tell patients and their families that things are not going well; that there is no good remaining anticancer therapy to give; that it is time to focus primarily on symptom control, not anticancer therapy; that resuscitation is not recommended in the event of a cardiopulmonary arrest; and about other end-of-life issues? How do oncologists deal with the emotional issues they themselves have when they deal with patients with end-of-life issues? These questions are addressed in this collection of manuscripts. In addition, this collection also addresses cancer survivorship issues and issues related to hospice care and symptom control.

The works in this collection were all published between January 2000 and December 2002 in a special section of the *Journal of Clinical Oncology* entitled, "The Art of Oncology: When the Tumor is Not the Target." This section of the journal was inspired by work done when the 1997-1998 President of the American Society of Clinical Oncology (ASCO), Dr. Robert Mayer, convened a task force to study how oncologists deal with end-of-life care for their patients. This task force concluded that there was room for improvement in the care of patients as they approached the end of their lives. An outcome recommendation from this task force was that this issue could nicely be highlighted in a special section of the *Journal of Clinical Oncology*.

Although the *Journal of Clinical Oncology* is primarily geared for oncology physicians, it was recognized, at the initiation of this section of the journal, that the issues addressed would be applicable for multiple other groups, including non-oncology physicians, nurses, other health care providers, and students.

In 1986, the CCOP scope of research was expanded to include patient management, continuing care, and rehabilitation. The CCOPs took on supportive care research, quality of life, and symptom management, which were orphan concepts in the 1980s. The past 17 years have demonstrated the success of this expansion: the landmark studies in pain management and the effective treatment of nausea and vomiting were achieved by CCOP research.

Despite the accomplishments, troublesome symptoms remain a problem for cancer patients. Two surveys of chemotherapy patients taken six years apart showed that more than half the latter group continued to experience the same five symptoms as the first. There remains a continuing and pressing need for research to better manage symptoms for cancer patients. The most common symptoms addressed in CCOP trials have been pain, anorexia, mucositis, and hot flashes.

Several Research Bases have made unprecedented contributions to this field:

- The North Central Cancer Treatment Group has had more than 75 cancer control protocols approved by NCI, the vast majority related to symptom control. They have conducted more cancer anorexia/cachexia trials than any other group in the world. Their work established megestrol acetate for anorexia and venlafaxine for hot flashes. NCCTG has extensively evaluated means of reducing or preventing mucositis from chemotherapy or radiation therapy.

- University of Rochester Comprehensive Cancer Center was the first research base to be approved for cancer control only. A major focus of their research efforts is on the reduction of treatment related morbidity to maximize the potential curative effect of cancer treatments and improve quality of life, concentrating in the areas of nausea, fatigue and hot flash control.
- The Radiation Therapy Oncology Group (RTOG) has completed several trials designed to prevent the acute complications of radiation therapy. One major finding was that prophylactic pilocarpine reduced the development of xerostomia (dry mouth) in head and neck patients: Pilocarpine has become utilized during radiation therapy to the head and neck.

Pain

Early in the development of cancer control research, ECOG conducted a landmark survey of oncologists and their patients. This report revealed cancer patients often had inadequate treatment for pain. This report and others lead to greater evaluation of patients' pain. Research has since focused on the efficacy of various routes of administration for pain medications, while other studies continue for identifying agents to treat postsurgical neuropathic pain.

Anorexia/Cachexia

CCOP studies have defined the role of megestrol acetate in the treatment of the severe weight loss and wasting associated with many cancers and known as anorexia and cachexia. Ongoing trials are evaluating the efficacy of other agents, such as infliximab (a monoclonal antibody to tumor necrosis factor), etanercept, and oxandrolone.

Mucositis

Mucositis, the inflammation of mucous membranes in the digestive tract, results from chemotherapy or radiation, and can cause pain and other symptoms from the mouth to the colon. This fundamental problem can lead to treatment delays or to a patient receiving reduced doses of effective drugs. CCOP studies have demonstrated that several treatments are not useful for this condition. Open trials are assessing the utility of L-glutamine for oral mucositis and octreotide to treat diarrhea resulting from radiation or chemotherapy affecting the colon.

Hot Flashes

A unique success of CCOP research has been the identification of a class of agents (serotonin and norepinephrine reuptake inhibitors) that provides nonhormonal relief for hot flashes. This finding has been particularly important for patients with a history of breast cancer, for whom estrogen replacement is contraindicated, but recent findings from the National

Institute of Health Women's Health Initiative (WHI) regarding the safety of hormone replacement therapy in healthy women suggest that these agents being studied in the CCOPs may be useful for other menopausal women suffering from hot flashes.

Smoking

Cigarette smoking causes 30% of all cancer deaths, and not smoking is the single most effective way for individuals to protect themselves from developing cancer – it is both prevention and control. The CCOP network has demonstrated its ability to recruit adults to three smoking cessation studies, which have assessed the effectiveness of nicotine replacement therapy (patch and nasal spray), bupropion, and behavioral interventions. These studies have shown modest effectiveness in the short term for nicotine replacement therapy. As new pharmacologic agents are developed for relieving nicotine addiction, the CCOP network can readily initiate studies to evaluate efficacy for these agents.

Complementary and Alternative Medicines

Cancer patients frequently use complementary and alternative medicines with or without the knowledge of their physicians. Most of these agents have little evidence to support their use. NCI has initiated evaluations of the efficacy of CAM agents, and CCOPs are a part of this focus. The safety of these agents in the setting of cancer and cancer treatment is critically important, as patients are already taking these agents for their symptoms.

Those agents with demonstrable efficacy and safety can find a legitimate role in cancer care, whereas those without proven benefit or those with safety concerns might fall into disuse. One study, for example, did not find that soy protein was effective for relief of hot flashes. Among agents currently under investigation are ginkgo biloba for cognitive function, St. John's Wort for depression, black cohosh for hot flashes, and ginger for chemotherapy-induced nausea.

Quality of Life

Improving quality of life is one of the primary goals of cancer care, and many CCOP trials are designed to include an assessment of general quality of life as part of evaluating an intervention. For example:

- The Children's Oncology Group (COG) completed a validation study for a comprehensive assessment of health/quality of life in survivors of childhood cancer. The data provide evidence for the validity and reliability of the MMQL-Adolescent Form as a comprehensive, multidimensional self-report instrument for measuring HRQL among survivors of childhood cancer.
- COG also completed a randomized comparison between antibiotics alone and antibiotics plus G-CSF in pediatric patients with chemotherapy induced febrile neutropenia. The results show that therapy containing G-CSF significantly reduces the time to recovery of febrile neutropenia and neutropenia.
- H. Lee Moffitt Cancer Center CCOP Research Base created a portfolio of studies in its first three years with the network that included quality of life studies in adults receiving radiation therapy and children experiencing cognitive loss from CNS therapy. Additional pediatric studies include interventions to overcome weight loss associated with chemotherapy.

CCOP CANCER CONTROL TRIALS* SINCE 1987

- 241 Total Cancer Control Trials
- 136 (56%) Symptom Management Trials
- 79 Closed
- 57 Ongoing

* The CCOP Network is the primary mechanism for conducting phase III clinical trials in symptom management, palliative care, and other cancer control issues.

Community Clinical Oncology History

EVENT DATE

December 1971



Nixon signs the National Cancer Act.

1974

President Nixon signs the National Cancer Act (P.L. 92-218), which increases responsibilities for the NCI director; initiates the National Cancer Program. This act establishes the President's Cancer Panel, the National Cancer Advisory Board, 15 research, training, and demonstration cancer centers, cancer control programs for cooperation with state and other health agencies to diagnose, prevent, and treat cancer, and extensive data collection, analysis, and dissemination efforts.

An estimated 85% of all cancer patients are being treated by community oncology practitioners, according to the Association of Community Cancer Centers.

November 1975



Former NCI Director Vincent DeVita, M.D.

1978

The Grand Rapids Michigan Clinical Oncology Program is formed under an NCI contract as a consortium of five community hospitals to develop a multi-institutional, multidisciplinary system for improving cancer management in the community setting.

Cooperative Group Outreach Program (CGOP) is created for community hospitals to participate in Cooperative Group cancer treatment clinical trials.

1981

Community Hospitals Program (CHOP), is started to disseminate patient management guidelines in the community setting.

1981

NCI Director Vincent DeVita, M.D. announces the intent to develop the Community Clinical Oncology Program.

May 19, 1982

The National Cancer Advisory Board gives final review and approval to CCOP.

July 16, 1982

NCI launches the Community Clinical Oncology Program (CCOP) to establish a cancer control effort that combines the expertise of community oncologists with NCI clinical research programs, and brings the advantages of clinical research to cancer patients in their own communities.

September 1983

The original CCOPs, spanning 34 states, are funded.

NIH GUIDE
supplement

REQUEST FOR RESEARCH GRANT APPLICATIONS:
COMMUNITY CLINICAL ONCOLOGY PROGRAM
NATIONAL CANCER INSTITUTE
Application receipt

I. PURPOSE

The Director of the National Cancer Institute (NCI) is interested in establishing a large scale cancer control effort which involves practicing community oncologists in the NCI clinical trials programs. The purpose of the program is to utilize as a resource the increasing number of highly trained oncologic specialists who have entered community practice in recent years. Combining the expertise of community physicians with ongoing clinical research projects will result in a dynamic development and exchange of the newest clinical treatment research findings at the community level. The Community Clinical Oncology Program (CCOP) should: (1) provide adequate support for the clinical research effort in the course of clinical investigation to

EVENT DATE



The estrogen receptor assay was a significant breakthrough.

1987 NCI issues the second Request for Applications, which requires treatment, prevention, and control accrual; and peer review of research base applications.

1987 First evaluation of CCOP, conducted by Fred Hutchinson Cancer Center and the University of Washington, finds the program effective in enrolling patients on clinical trials and getting physicians to adopt trial results as standards of care.

1989 The NCI's Board of Scientific Counselors approves the ongoing CCOP program with annual release of an RFA and 25 percent of awards under competitive renewal each year.

1989 Minority Based-CCOPs are established to focus on access to minority populations. Universities, as the primary health care providers for minorities, are permitted to apply to the program.

April 29, 1992

The CCOP network is used for the first time to conduct a large prevention trial that will evaluate the efficacy of tamoxifen to prevent breast cancer in women at increased risk of the disease. The National Surgical Adjuvant Breast and Bowel Project coordinates the trial, known as the Breast Cancer Prevention Trial (BCPT).

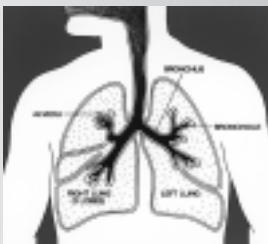


Patient receives blood test.

1992 The second evaluation of the CCOP program, conducted by the University of North Carolina at Chapel Hill and the University of Illinois-Chicago, finds there are key attributes of the treatment-oriented Cooperative Groups and community programs that would lead to the successful implementation of a community-focused, prevention-and-control clinical trials network.

August 1992

A study of 13-cis retinoic acid to prevent second primary cancers in survivors of stage I non-small cell lung cancers begins within the CCOP network. The study is headed by the University of Texas, M.D. Anderson Cancer Center.



June 1993

The Colorectal Adenoma Prevention Study is begun under the direction of the Cancer and Leukemia Group B, using the CCOP Network. The trial will evaluate whether aspirin will reduce the development of adenomas in people who have already had an early stage colorectal cancer.

EVENT DATE



October 1993

The Prostate Cancer Prevention Trial (PCPT), the second large-scale prevention trial to be conducted using the CCOP network, begins. PCPT will evaluate finasteride as a prostate cancer prevention drug, and is coordinated by the Southwest Oncology Group.

May 1997

Randomization of 18,882 men into the PCPT is completed two years ahead of schedule.

September 1997

Randomization of 13,388 women into BCPT is completed.

The 1996 Breast Cancer Awareness Stamp

April 6, 1998

Results of the Breast Cancer Prevention Trial (BCPT) are announced 14 months earlier than expected: women taking tamoxifen had 45 percent fewer breast cancer diagnoses than women on the placebo, proving that breast cancer can be prevented. Rare but serious side effects are shown to occur in some postmenopausal women on tamoxifen – endometrial cancer and blood clots. Final results were published in the *Journal of the National Cancer Institute* on September 16, 1998.

October 29, 1998

The Food and Drug Administration approves tamoxifen for reducing the incidence of breast cancer in women at high risk for developing the disease. This is the first drug ever approved by the FDA to reduce cancer risk.



1998

An Institute of Medicine report recommends that the National Institute on Drug Abuse use the NCI CCOP Model to conduct community-based trials of drug and alcohol treatments (Lamb, S., M.R. Greenlick and D. McCarty (eds) *Bridging the Gap Between Practice and Research: Forging Partnership with Community Based Drug and Alcohol Treatment*, National Academy Press, Washington DC, 1998.)

May 25, 1999

The Study of Tamoxifen and Raloxifene (STAR) one of the largest breast cancer prevention studies ever, begins recruiting volunteers. The trial will include 22,000 postmenopausal women at increased risk of breast cancer to determine whether the osteoporosis prevention drug raloxifene is as effective in reducing the chance of developing breast cancer as tamoxifen has proven to be.



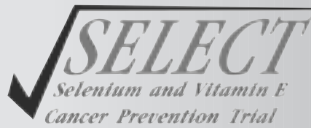
Tamoxifen is effective against estrogen-receptor positive breast cancer.

April 18, 2001

The trial of 13-cis retinoic acid to prevent new lung cancers is published in the *Journal of the National Cancer Institute*. The data show no reduction in the rate of disease recurrence or survival from the drug. Later subanalyses suggest that 13-cis retinoic acid is harmful to those who continue to smoke while taking the drug, but beneficial to those who have never smoked.

EVENT DATE

July 24, 2001



The largest-ever prostate cancer prevention study is launched by NCI and the Southwest Oncology Group (SWOG). The Selenium and Vitamin E Cancer Prevention Trial (SELECT) will determine if these two dietary supplements can protect against prostate cancer in 32,400 men.

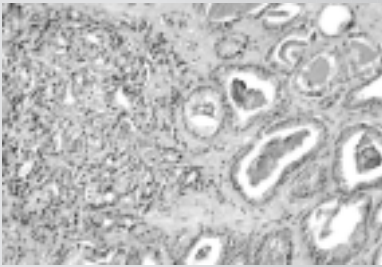
May 2002

Results from the Colorectal Adenoma Prevention Study are presented at the American Society of Clinical Oncology meeting: daily aspirin use reduced the development of adenomas by 35 percent in patients with previous colorectal cancers. The results were published in the *New England Journal of Medicine* in March 6, 2003.

2003

NCI funds 50 CCOPs across 34 states, 11 MB-CCOPs, and 14 Research Bases.

June 24, 2003



Histological slide showing prostate cancer.

September 2003

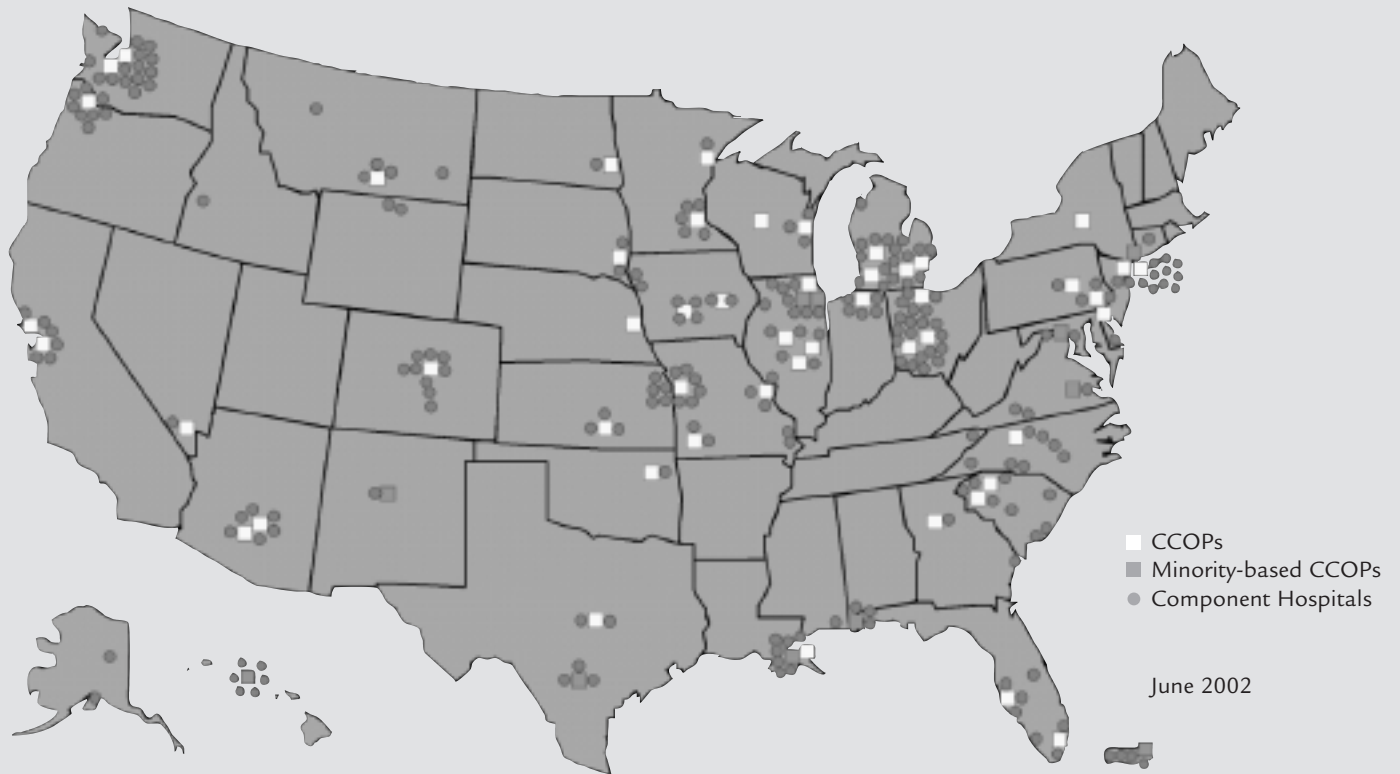
Results of the Prostate Cancer Prevention Trial, testing the effectiveness of finasteride to prevent the disease, are released almost a year earlier than expected. Men taking finasteride had 25 percent fewer prostate cancer diagnoses than men on the placebo, proving that prostate cancer can be prevented. There is a note of caution, however; the men who did develop prostate cancer while taking finasteride are more likely to have high-grade tumors. Results were published in the *New England Journal of Medicine* on July 17, 2003.

STAR participants are found to have a much greater underlying risk of breast cancer than the minimum projection, so the study size is reduced from 22,000 to 19,000.

2003

A followup evaluation of the CCOP program, led by the University of North Carolina at Chapel Hill, is launched to determine the extent to which cancer prevention and control activities and the CCOPs have been integrated into the operations of the clinical cooperative groups.

CCOPs and Minority CCOPs



CCOPs cover nearly every state in the U.S. and have regional impact throughout the country.

ALABAMA

The Gulf Coast MB-CCOP

(formerly the University of South Alabama MB-CCOP)

Mobile, Alabama

Principal Investigator

Marcel E. Conrad M.D.

Administrator

Marcia Grove Conrad RN,BSN,MSN,MPH

Size

4 hospitals, 33 physicians

The Gulf Coast MB-CCOP was established at the University of South Alabama (USA) following the inception of the MB-CCOP program by NCI in 1990-1. The oncology faculty believed that membership in a NCI-supported national research base was important for the cancer patients in the mid-gulf coast region and for the development of a viable oncology fellowship training program.

Affluent cancer patients frequently sought cancer care at large institutions distant from their homes and such state-of-the-art therapies were mostly unavailable for the poor and uninsured. Since almost 50% of our oncology patients were African American and Native American, the MB-CCOP program was a perfect fit. Fiscal support of personnel and travel permitted expansion of the program and allowed participation in a more comprehensive portfolio of research treatment, prevention and control trials.

In 2001, USA relinquished the MB-CCOP grant to the Mobile Infirmary Medical Center, the largest community hospital in the state. African Americans constitute 40% of oncology patients at MIMC.

ARIZONA

Scottsdale CCOP

Scottsdale, Arizona

Principal Investigator

Tom Fitch, M.D.

Administrator

Owen McClure

Size

1 hospital, 14 physicians

Mayo Clinic Arizona aspires to be the premier cancer center in the southwest United States and to provide the highest quality cancer care for its patients. Participation in NCI-supported cancer clinical trials is one of the most important and integral components of its Cancer Center programs.

Being a member CCOP has provided Mayo Clinic Arizona physicians access to innovative cancer therapies and has motivated them to constantly provide their patients state of the art, quality cancer care. It has also set the stage for Mayo Clinic Arizona physicians to become personally involved in the development of new cancer therapies. We are proud of the professional staff in our Cancer Clinical Research Unit/CCOP office and the growing success our cancer prevention, cancer treatment and cancer control clinical trials programs.

Challenges remain and participating as a CCOP has highlighted the importance to the institution of interacting with community physicians to involve them and their patients in cancer prevention strategies and trials and the need to recruit a diverse population of patients to participate in cancer clinical trials. We look forward to future growth and success and our continued participation in NCI supported cancer clinical research trials as a member CCOP.

Western Regional CCOP

(formerly the Greater Phoenix CCOP)

Phoenix, Arizona

Original and Current Principal Investigator	David K. King, M.D.
Original Administrator	Martin Hilger
Current Administrator	Cris Wells, RT, MBA, MHSA
Size	7 hospitals in 2 states, 80 physicians

In the early 1980s, the opportunity for cancer patients to enroll on clinical trials in the Phoenix area was very limited. The University of Arizona in Tucson was only place where clinical trials were available and many patients dreaded the “trip to Tucson.” When the CCOP concept was offered in the first RFA, it appeared to be the right option for clinical trial access in the Phoenix area. David King and his partners organized Greater Phoenix CCOP in tandem with 4 other private oncology practices and presented the concept to local Phoenix hospitals.

It was modeled as a centralized CCOP with all CCOP staff located on site. Nurses and data managers would travel to meet patients within physician offices or hospitals. The very thing that has made this CCOP a true community program, has offered it its biggest challenges. Western Regional CCOP accrues populations rich in demographic and geographic diversity, reflective of the Arizona/Colorado community. With that come the challenges associated with geographic distances, oncology practice and research market competition, economically challenged patients, and language barriers.

This CCOP’s biggest success remains its ability to overcome the above barriers and provide the Arizona and Colorado communities an opportunity to participate in clinical trials while being treated in their respective communities.

CALIFORNIA

Bay Area Tumor Institute CCOP
Oakland, California

Principal Investigator	James H. Feusner, M.D.
Administrator	Karen G. Egan
Size	35 physicians, 7 hospitals in 1 state

The BATI-CCOP was first funded in 1989 and has been in continual operation since. The CCOP has a pediatric and an adult component. Since the initiation of collaborative community-based protocol therapy, more than 1400 adult and 575 pediatric patients have entered trials of the national cooperative clinical trials study groups via the CCOP.

Perhaps the most gratifying accomplishment of the BATI-CCOP has been its success in reaching historically underserved patient populations. The CCOP accrues 100% of the eligible pediatric oncology patients in the region, screens all indigent patients at the county hospital for eligibility, and has demonstrated the ability to regularly accrue 75% of its patients from African American, Hispanic, Asian, pediatric, underserved, and female populations.

Access to the trials of the NCI-funded cooperative groups has been the most important contribution of the CCOP to the medical and patient communities in the service area. State of the art treatment would not otherwise be available in a region so heavily populated by patients who generally lack the resources to travel to a major medical center for comparable therapy.

Santa Rosa Memorial Hospital CCOP *Santa Rosa, California*

Principal Investigator	Wayne Keiser, M.D.
Administrator	Kris Hartigan, RN
Size	1 Hospital covering Northern California, 18 physicians

We are very proud of being an NCI funded CCOP for the last 9 years. Having clinical trials available to offer the patients we serve is extremely important to us. This not only allows patients to participate in clinical trials, but allows patients to stay in their own community to participate in clinical trials. Having to travel to an academic center to participate in a clinical trial can be a significant barrier.

Our community of oncologists and oncology nurses are dedicated to the advancement of cancer care through clinical trial research. Being involved in research stimulates us to stay current in diagnosis, staging and treatment. One of our greatest challenges to offering and providing cancer care under the guidelines of a clinical trial has been insurance coverage.

COLORADO

Colorado Cancer Research Program
Denver, Colorado

Principal Investigator	Eduardo R Pajon M.D.
Administrator	Tomiko Takeda
Size	10 hospitals in Colorado 100 affiliated physicians

The Colorado Cancer Research Program (CCRP) CCOP was created in 1983 as a vision of several community oncologists to have NCI-sponsored oncology research available to themselves and their patients.

The initial effort was supported by five local community hospitals. Thus, the CCRP was established as a hospital consortium. It is now expanded to 10 Colorado community hospitals and is expected to grow more in the coming months and years. CCRP is the only CCOP in Colorado. A major success is that our physicians want access to national trials to support their patients' needs. Physicians turn to CCRP as a community-based source. The Administrators Network (facilitated by Nancy Morton) is a most wonderful asset. It's a place to query and a sounding board.

DELAWARE

Christiana Care Health Services
(formerly the Delaware CCOP)
Wilmington, Delaware

Principal Investigator	Stephen S. Grubbs, M.D.
Administrator	Pauline E. Lauer
Size	6 affiliates in 3 states (Delaware, Maryland, New Jersey), 26 physicians

Christiana Care, through its practicing oncologists and hematologists, participated in NCI cooperative group research since the early 1970s. Because of limited resources within the institution and a commitment to improved patient care through research, a CCOP grant was successfully sought in 1987.

Affiliates have changed through the years, with the notable addition of Al duPont Hospital for Children and Cooper University in Camden, New Jersey. Cooper now complements our CCOP staff and their contribution to the cancer prevention trials is significant. Al duPont Hospital for Children also contributes significantly to our accruals through the Children's Oncology Group.

Working within the CCOP program has enabled us to have access to research trials which would otherwise not have been available. Having a CCOP also contributed significantly to the development and opening of the Helen F. Graham Cancer Center.

FLORIDA

Florida Pediatric CCOP
Tampa, Florida

Original and Current Principal Investigator James L. Talbert, M.D.
Original and Current Administrator Jamie Bayer, MSW, MPH
Size 7 hospitals in Florida and Puerto Rico,
104 physicians

Pediatric Oncology in the State of Florida was organized in 1970 as a coordinated program under the auspices of the Florida Association of Pediatric Tumor Programs, Inc., with the goal of ensuring access to high quality, state of the art cancer treatment for all children in the pediatric oncology centers throughout the State. In 1983, the CCOP provided an ideal vehicle for Florida’s community programs to obtain direct access to the benefits of clinical trials via the cooperative groups. The Florida Pediatric CCOP rapidly became the largest contributor to patient accrual for treatment and cancer-control studies.

The CCOP program also afforded opportunities for enhanced collaboration and joint educational programs, cementing a link between university and community centers. As the program matured, it expanded to include community programs located in Puerto Rico. Now, the CCOP investigators are active members of COG and contribute to the design of new clinical trials to improve the outcomes for children with cancer.

The CCOP mechanism has proved instrumental in fostering interaction amongst the centers that enhance access to care statewide while concomitantly ensuring that all new pediatric oncology cases are referred to treatment centers staffed by highly-qualified teams of multi-disciplinary specialists and are regularly monitored to maintain nationally-recognized standards of care.



Florida Pediatric CCOP's Dr. Emad Salman with a teenage patient.

Mount Sinai Medical Center CCOP

Miami Beach, Florida

Principal Investigator
Administrator
Size

Rogério Lilenbaum, M.D.
Janice Grimes, P.A.-C, CCRP
5 hospitals, 40 physicians

The Mount Sinai received its CCOP grant in 1987. Since the early 1990s, the Mount Sinai CCOP has been the only NCI-funded program in South Florida. From a humble beginning, struggling to place 50 patients each year on clinical trials, the program has emerged as the dominant clinical research center in South Florida.

The CCOP accrues over 200 patients per year to treatment and prevention studies, and is a leader in minority accrual with 31% Hispanic patients and 14% Black patients accrued for the year ending May 31, 2003. The Mount Sinai CCOP has provided a framework for collaboration and cooperation among the major community hospitals in South Florida and has succeeded in making cancer research studies available to a large diverse segment of the South Florida population. The MSCCOP is committed to building a stronger research network and providing increased access to appropriate clinical trials to our community.



Drs. Enrique Davila (left) and Michael Schwartz review an X-ray at Mount Sinai Medical Center CCOP.

GEORGIA Atlanta Regional CCOP

Atlanta, Georgia

Principal Investigator
Administrator
Size

Thomas Seay, M.D., Ph.D.
Margaret A. Riley, MN, RN, CNA
8 hospitals in metro Atlanta,
140 physicians

CCOPs raise the level of intellectual and scientific pursuit of excellence in cancer care for the community and for oncology professionals. In 1986, a small group of medical and gynecologic oncologists developed a plan to gain access to clinical trials for their patients. The Atlanta Regional CCOP has been continuously funded since June of 1987.

The major success as a CCOP is that we all feel a part of the larger effort to reduce morbidity and mortality from cancer in the USA. Also, being able to offer those with cancer and those at high risk for cancer an opportunity to participate in state of the art cancer care is both enriching and challenging. We are constantly learning the scientific process as well as all current treatment and prevention modalities, which allows us to be capable educators of our patients and the community.

Prevention trials have been a positive effort for the community because it has raised the issue of health prevention and offered a vehicle to do outreach education in our community. Articles, events and media information about the major prevention trials have created a broad-based awareness of breast and prostate cancer to the public. As a consortium of hospitals that compete in every other way, the CCOP mechanism has provided an opportunity to rise above the competitive nature of health care and come together to offer something for the greater good.

HAWAII
 University of Hawaii MB-CCOP
 Honolulu, Hawaii

Principal Investigator
 Administrator
 Size

Brian F. Issell, M.D.
 Dorothy Coleman, RN, MS
 9 hospitals in 1 state (3 islands),
 36 physicians

Hawaii's population of multiethnic minorities is unique within the United States. Over 70% of the population in Hawaii is comprised of non-Caucasian minorities making it an outstanding site to participate in the MB-CCOP program. The MB-CCOP award has brought unprecedented stability to NCI supported clinical trials in Hawaii and has given us the opportunity to participate with several cooperative groups, bringing more state-of-the art research to the islands.

There is no university hospital in Hawaii, and relationships among community physicians are of the utmost importance for high-quality care. The MB-CCOP has helped build constructive relationships among Hawaii's community physicians. In many ways, the CCOP has greatly impacted the way physicians conduct their office practices. Before the MB-CCOP, only a handful of physicians enrolled patients on studies and there was little active community physician support for a clinical trials program. Now, physicians are working together as an integral part of the MB-CCOP.

Community physicians actively participate in reviewing and selecting studies that fit best into their ongoing practice. Several community-based initiatives supported by the MB-CCOP and other NCI grants have resulted in an increased participation of the historically under-represented minorities, Native Hawaiians and Filipino. We believe that the MB-CCOP has facilitated a general improvement in the quality of cancer care in our state.

ILLINOIS

Central Illinois CCOP
Decatur and Springfield, Illinois

Principal Investigator	James L. Wade, III, M.D.
Administrator	Peggy Verrill, RN, BSN
Size	2 main and 1 affiliate hospital 30 investigators

The Central Illinois Community Clinical Oncology Program (CICCOP) was conceived in 1986 by a consortium of physicians and hospital administrators in central Illinois in order to enhance access for patients to clinical trials and to improve the quality of cancer care. We realized at the time that neither the Decatur medical community nor the Springfield medical community alone had the resources to compete for and implement a successful CCOP. If we could work together, we could reach enough critical mass to make the program productive.

That initial decision has enhanced the course of cancer care for the entire central Illinois region over the last 17 years. The CICCOP truly became a vector into the heartland for state-of-the-art cancer care and cancer control and prevention research. Our greatest strength lies in our ability to work closely with all medical professionals and lay people in our service area in order to implement cancer chemoprevention trials. We have been very strong accruals to the major prevention trials.

Our greatest challenge, one that we have successfully overcome, is to continuously insure that all studies are carried out efficiently and accurately across a widespread multi-site system. We look forward to the future, knowing that the journey toward the reduction of the cancer burden, in part, rests with all of us in the community of CCOPs.

Carle Cancer Center Urbana, Illinois

Original Principal Investigator	Alan Hatfield, M.D., FACP
Current Principal Investigator	Kendrieth M. Rowland, Jr., M.D.
Original Administrator	Joan Kamphaus or Linda Harder
Current Coordinator	Karen Cheek, RN, CCRP
Size	8 hospitals in Northern and East Central Illinois, Northern Indiana, and Mexico City, Mexico

The Carle Cancer Center has cherished its NCI CCOP designation over the last 20 years. Of greatest importance is access to NCI clinical trials, which provide the very best of care to those in our communities and raises the bar in our standards of oncology practice. Through NCI clinical trials, investigators learn to care for their patients “the right way,” which carries over to all patients, not just those in clinical trials. Offering new and exciting treatments to those in need close to home is a wonderful experience.

Advancing the science of oncology through clinical trials is also an extremely gratifying experience. Participating in the development of improved care and setting new standards is a lasting accomplishment that extends beyond our lifetime. The Carle Cancer Center has grown particularly because of our CCOP designation. Burnout is rare and medical oncologists moving on to other practices have been nonexistent since 1983. This same attitude is true for many of the clinical research associates and nurses that have worked at the Carle Cancer Center.

Sharing the opportunity to participate in CCOP activities with affiliate cancer centers in the states of Illinois and Indiana, as well as the ability to participate in a number of research bases has been a valuable aspect of the CCOP. Carle Cancer Center members have through the years had the opportunity to participate in protocol design, analysis, authorship and ASCO presentations. Such professionally enriching activities would not have occurred without the Community Clinical Oncology Program. No other program for health care providers funded by government resources or private industry offers the degree of academic stimulation, partnership in the advancement of medicine, or promotes the very best of care for large populations of individuals close to home, as does the NCI CCOP. The Carle Cancer Center as a 20-year CCOP has much to celebrate and be thankful for.

Evanston Northwestern Healthcare

(formerly Evanston Hospital)

Evanston, Illinois

Original Principal Investigator	Janardan D. Khandekar, M.D.
Current Principal Investigator	Gershon Y. Locker, M.D.
Original Administrator	Tim Block
Current Administrator	Dyon Kwan
Size	1 Hospital Corporation including 3 Illinois hospitals, 56 physicians

Participation in CCOP is beneficial to every constituent involved in this process. For patients who are the focal point of this activity, it translates into receiving state of the art therapy in their own community. Patients can also be involved in cancer prevention trials in an important emerging field.

For physicians, CCOP provides an opportunity to participate in clinical trials and thus contribute to the progress against cancer. Physicians can chair various protocols, head the subcommittee and thus participate in advancing the science. Physicians can also gain the latest knowledge through participation at meetings. This “diffusion” of knowledge is important for improving cancer care in the community and thus reduces mortality.

For nurses, data managers and pharmacies, CCOPs provide an opportunity to network with their peers and gain knowledge that can advance science and improve patient care. For the organization, CCOP provides a forum for bringing together multi-disciplinary teams, which include experts from all specialties: surgery, medicine, radiation, nursing and pharmacy to name a few. CCOP also promotes improved quality of care for cancer patients as it disciplines oncologists to practice evidence-based medicine.

Illinois Oncology Research Association CCOP

(formerly the Methodist Medical Center CCOP)

Peoria, Illinois

Original Principal Investigator	Stephen A. Cullinan, M.D.
Current Principal Investigator	John W. Kugler, M.D.
Original Administrator	Robert C. Sanderson
Current Administrator	Marsha L.B. Kutter
Size	19 hospitals, 7 clinics in 16 cities 20 accruing physicians

Being a CCOP allows participating physicians to better care for their patients. It brings new therapies to people who would otherwise go unserved or underserved. Patients do not have to travel far to get these therapies and can be accompanied by friends and family.

Being able to get their treatments close to home provides stability and control in their lives, which have been intensely disrupted by their diagnoses, and this convenience comes without sacrificing quality care. This translates into better stability within the family, less time from work for caregivers, less drain on patient budgets, increased income for local hospitals, clinics and pharmacies, and data for evaluating outcomes in national clinical trials. Primary care physicians are more involved and better informed about their patients; the promotion of health and cancer prevention for minority and underserved populations has a venue; participating physicians stay current in their knowledge to better serve their patients and communities.

Being a CCOP is not without myriad challenges. Why do we bother? The answer is simple: It makes a difference in patients' lives, which translates into increased knowledge about cancer which affects all people who have a cancer diagnosis or who are at risk for cancer, which means all of us.

University of Illinois at Chicago MB-CCOP

Chicago, Illinois

Original Principal Investigator	Jeffrey A. Sosman, M.D.
Current Principal Investigator	Thomas E. Lad, M.D.
Original Administrator	Consuelo Skosey, RN
Current Administrator	Judith L. Murray, MS
Size of CCOP	12 physicians, 3 inner city hospitals

The ultimate goal of any Community Clinical Oncology Program is to provide access to research treatments to all communities, including those with minority and underserved patients. Patients should be able to receive the latest treatment and prevention protocols at facilities that are familiar.

The components of the University of Illinois Minority Based CCOP make it an ideal example because of the locations and strengths of each of the individual units. While all 3 hospitals are within close proximity, they are inherently different and fill a specific niche. The CCOP program has ensured that there are research personnel to maintain the studies and quality data collection.

It is the goal of UIC to offer cutting edge research to all patients regardless of their economic status. With a state budget constricted by a difficult economy, UIC has been able to maintain its cancer research program with the assistance of the CCOP funding. The UICMB-CCOP has demonstrated success in enrolling minorities onto treatment protocols, including pediatric patients. The major success of this organization has been the large accrual of African American men to the SELECT prostate cancer prevention trial, currently the highest number in any participating SELECT center.

John H. Stroger, Jr. Hospital of Cook County MB-CCOP

Chicago, Illinois

Principal Investigator
Administrator
Size

Howard A. Zaren, M.D.
Erika K. Barth
1 hospital, 2 physicians

There are roughly 42 million people in the United States who are uninsured or underinsured. The mission of John H. Stroger Jr. Hospital of Cook County and the Department of Surgery is to provide a comprehensive program of quality health care with respect and dignity to the residents of Cook County, regardless of their ability to pay.

Breast cancer continues to be the most commonly diagnosed new cancer at JHSCC. Our MB-CCOP unit strives to address the shortage of accessible breast cancer healthcare resources for Chicago's poor and minority families. The community need for organized cancer care directed our efforts to establish a MB-CCOP. The MB-CCOP has provided the resources, both financial and medical, to deliver state-of-the-art cancer care to the medically underserved population in the Chicago-land area.

In the last few years, we have grown tremendously in terms of staff and resources. We now have a large enough staff to care for our patients' needs from navigation through the hospital system to giving adequate medical care. We are more successful at helping our patients become knowledgeable about treatment trials and helping them feel comfortable enough to participate in one.



The research team at Cook County MB-CCOP

INDIANA

Northern Indiana Cancer Research Consortium CCOP

South Bend, Indiana

Principal Investigator	Rafat H. Ansari, M.D.
Administrator	Mary Jean Wasielewski, RN OCN
Size	4 institutions in northern Indiana 23 physicians

The Northern Indiana Cancer Research Consortium CCOP was formed in 2000. The decision to become a CCOP was a long-standing goal of oncology clinical research in the South Bend, Indiana area. Oncology patients in northern Indiana have access to multiple clinical trials sponsored by the National Cancer Institute.

The greatest benefit yet challenge is to involve primary care physicians in the prevention and early detection research of the CCOP program. The greatest accomplishment of the NICRC has been bringing together four competing hospitals working in a cooperative effort to provide scientifically sound oncology clinical research.

The formation has been gratifying for all of the hospitals and has become a model for other community hospitals to consider. Working together has elevated the level of cancer care in the four communities served by the NICRC. The NICRC is growing and the future is bright for oncology clinical research.

IOWA

Cedar Rapids Oncology Project CCOP

Cedar Rapids, Iowa

Original and Current Principal Investigator	Martin Wiesenfeld, M.D.
Original Administrator	Mike Mohnsen
Current Administrator	Kathy Fleming MSN, RN
Size	3 hospitals, 2 states 9 physicians

The Cedar Rapids Oncology Project is pleased to celebrate the 20th anniversary of the CCOP program. The dedicated efforts of physicians, nurses and research associates over the years has enabled participants in our Heartland region to access cooperative group treatment and prevention trials.

We feel our CCOP participation has allowed close contacts to develop between community health professionals and regional cancer centers such as the Mayo Clinic, which has facilitated both technology transfer from the research base to the community as well helping our research bases “ground” their research studies to the realities of clinical practice.

We have been a major participant with all of the large chemoprevention studies and enjoy bringing these efforts to our communities. We are pleased to have been participants in trials leading to the development of multiple new anti-cancer drugs for adjuvant therapy of colon cancer, and are excited for future studies allowing us to bring the startling new developments of molecular biology to community practice. We thank the National Cancer Institute for its strong commitment to community-based cancer research.

Iowa Oncology Research Association CCOP

Des Moines, Ottumwa, Mason City, and Ames, Iowa

Original Principal Investigator	S. Fred Brunk, M.D.
Current Principal Investigator	Roscoe F. Morton, M.D., FACP
Original Administrator	Sharon Kubler
Current Administrator	Sherri Rickabaugh
Size	41 physicians

In 1979 the Iowa Oncology Research Association (IORA) was formed in Des Moines and first affiliated with the Mayo Clinic's North Central Cancer Treatment Group (NCCTG). This cooperative group was one of the Mayo Clinic responses to the National Cancer Act of 1971 for outreach.

Local visionary physicians, Drs. Louis Maher, Robert Strickler, John Green, and S. Fred Brunk, shared the passionate belief that high quality clinical cancer research could be conducted in the community. They desired a collaborative research effort that would supercede local and regional medical politics and bring the latest in cancer therapies to Des Moines.

The community-based research venue is the ultimate crucible in which to determine the effectiveness of new treatments. If a treatment works in Des Moines, Duluth, and Peoria, then it will be effective in any community. From Des Moines the IORA grew to include the central Iowa cities of Ames, Mason City, Ottumwa, and their surrounding rural communities. The CCOP's catchment area now reaches approximately a million Iowans.

KANSAS

Wichita Community Clinical Oncology Program Wichita, Kansas

Original Principal Investigator	Harry E. Hynes, M.D.
Current Principal Investigator	Shaker R. Dakhil, M.D.
Original Administrator	Gail Devun
Current Administrator	Marge Good
Size	3 hospitals, 14 affiliates across Kansas 37 physicians

In 1983, the Wichita CCOP was one of the first CCOPs funded by the NCI. Over the years the initial collaboration of hospitals and physicians that lead to the creation of the CCOP has continued.

Despite a relatively small patient base and long travel distances in an extended rural catchment area, the Wichita CCOP has consistently demonstrated successful accrual to cooperative group trials. Wichita, and much of the state of Kansas, has benefited by the CCOP presence, which has resulted in new therapies being available to cancer patients within their own communities, prevention opportunities for healthy and high risk individuals, and an increased rate of diffusion of new standards of care. There is increased opportunity for community collaboration that otherwise would not occur due to competition and/or political issues.

Participation with major cancer centers is a positive reflection on the community, and patients are both referred to the cancer centers for second opinions as well as referred from them to the CCOP to participate in clinical trials locally. Physicians, especially medical oncologists, view CCOP as an opportunity to participate in the “best of both worlds:” academically focused research, which offers the opportunity to publish, but also to experience community private practice. In 2000, the Wichita CCOP lost its founding Principal Investigator, Dr. Harry Hynes, to the very disease he and the CCOP were dedicated to eliminating. The foundation laid by Dr. Hynes remains and encourages us to continue.

LOUISIANA

LSU Health Sciences Center Stanley S. Scott Cancer Center MB-CCOP (previously LSU Medical Center MB-CCOP)

New Orleans, Louisiana

Principal Investigator	Jill Gilbert, M.D.
Administrator	Tasha Moore, RHIA
Size	6 sites in Louisiana, 49 investigators

Prior to the MB-CCOP award in 1994, the research staff for this program consisted of one part-time research nurse in Hematology/Oncology at LSU and one data manager at Children's Hospital. The grant award permitted the Cancer Center to hire more staff, thus increasing the number of patients who could participate in trials.

Community involvement has increased with the CCOP providing community physicians with access to national clinical trials. Perhaps the greatest value to the community is the MB-CCOP's participation in prevention trials. Prior to the MB-CCOP, the LSU Oncologists did not participate in prevention clinical research. Now over 170 people have enrolled on chemoprevention trials since the CCOP's inception.

Ochsner CCOP

New Orleans, Louisiana

Original and Current Principal Investigator	Carl G. Kardinal, M.D.
Original Administrator	Marilyn Bateman, RN, OCN
Current Administrator	Kate Rodger, RN, BSN
Size	6 sites in 2 states, Louisiana and Mississippi, 23 physicians

In 1982, the Ochsner Cancer Institute viewed the new-found research opportunity of CCOPs to be a great opportunity to expand involvement in clinical cancer research. Thus began the networking and forging of relationships with community oncologists in southern Louisiana and Mississippi.

Over the past 20 years, the Ochsner CCOP flourished and matured. Membership in the Ochsner CCOP has afforded the opportunity for rewarding interactions with our research bases and their entire memberships, as well as the local and regional oncology community. Long-lasting professional associations and friendships have developed which can be attributed directly to participation in the CCOP.

It is very exciting to have been involved actively in protocols that led to major changes in the clinical practice of medicine, such as the Breast Cancer Prevention Trial and the colon and breast cancer adjuvant therapy studies. The future of the CCOP program appears to offer unlimited opportunities with the development of gene profiling and the new-targeted therapies. The dedication of the CCOP program staff at the NCI, coupled with the dedication of the investigators, will ensure our continued success.



*Ochsner Cancer Institute CCOP
Dr. Carl G. Kardinal (standing at
whiteboard) addresses staff about
the Breast Cancer Prevention Trial
(BCPT).*

MICHIGAN

Kalamazoo CCOP
Kalamazoo, Michigan

Original Principal Investigator
Current Principal Investigator
Original Administrator
Current Administrator
Size

Phillip B. Stott, M.D.
Raymond Lord, M.D.
Eamar Curran
Joan Westendorp, BSN, OCN
2 Hospitals, 1 Cancer Center, 2
Private Practices, 11 physicians

The Kalamazoo CCOP has been a great asset to the Greater Kalamazoo area. Cancer patients have gone to some of the local large institutions only to be told “Go back to Kalamazoo, because they have it there.”



*CRA Team
Back row: Mary Charles,
Colleen Schwartz
Front row: Bonnie Witters,
Alison Holloway*



*First Principal Investigator Phillip Stott
and Director of Research and Education
Joan Westendorp*

The decision to become a CCOP was made because the oncologists wanted more access to clinical trials. Several of our physicians have been doing research via SWOG since 1974 and that is what brought the newer physicians to town. Having more clinical trials and access to new developments through the CCOP was a big benefit. The educational benefits offered by the CCOP have been a major achievement. Due to the Kalamazoo CCOP, new treatments have been brought to Kalamazoo that would not have been available without it or pursued on an individual basis.

The cooperative effort of the different specialties has been successful, but also very challenging. Changing the mindset of physicians from treatment to cancer control and prevention was not easy, but now it is a topic heard in conversation in the hall. Respect for national clinical trials has grown within the community due to the CCOP and during tumor conferences there are conversations about ongoing trials and the results of others.

Michigan Cancer Research Consortium CCOP

(formerly the Ann Arbor Regional CCOP)

Ann Arbor, Michigan

Principal Investigator
Administrator
Size

Philip J. Stella, M.D.
Linda L. Beekman, RN, MBA
8 Hospitals in central and southeastern
Michigan, 80 Physicians

The CCOP Program provided an excellent opportunity to bring clinical research to our community. It challenged our physicians to adopt a culture that demands access to state-of-the-art medical practices and gives them access to the work of some of the most renowned national and international researchers.

The program allows our physicians and health care professionals exposure to the exciting realm of cancer prevention and control and has provided us with an opportunity to work with and educate healthy people in the community that choose a proactive approach in their own health care. Over the years the emphasis has shifted from academic centers to the experienced community investigator allowing patient centered care to be provided in the communities where people live.

The CCOP Program brought clinical research to our institutions and our PI has made determined efforts to include a vast array of physicians in all aspects of the research process. Interest and commitment to clinical trials by our investigators is demonstrated by our ever growing and outstanding accrual. Our participating institutions have also encouraged our work to develop strong collaborative efforts among physicians.



*Michigan Cancer Research Consortium
CCOP Operations Staff*

Beaumont Community Clinical Oncology Program

Royal Oak and Troy, Michigan

Principal Investigator	David Decker M.D., FACP
Administrator	Veronica Decker RN, MS, CNS
Size	1 hospital (2 campuses), 55 physicians

William Beaumont Hospital is a recent recipient of CCOP status, which serves as the means by which clinical trials are now provided for a growing community of over two million lives. In 1999, Beaumont opened a cancer clinical trials office, providing the needed infrastructure to accelerate the number of clinical trials available to an ever-expanding patient population.

A primary goal of the office leadership has been improving patient care through clinical trials. This objective continues as an intense belief at Beaumont that promoting and conducting clinical trials, particularly NCI protocols, elevates the level of overall patient care. Beaumont physicians believe that NCI clinical trials ensure that physicians understand the standard of care, and our physicians challenge themselves to learn new prevention and treatment options.

An NCI CCOP designation is a promised standard of care provided to the entire community, for each patient that walks through our door. Yet, what most communities don't appreciate is that an NCI CCOP is not just about what is happening today but also what will happen tomorrow - and the hope that is being provided. Our Beaumont CCOP motto says it best - Today's clinical trial for tomorrow's standard of care.

Grand Rapids Clinical Oncology Program

Grand Rapids, Michigan

Original Principal Investigator	Edward L. Moorhead II, M.D.
Current Principal Investigator	Kathleen J. Yost, M.D.
Original Administrator	Diane VanOstenberg, RN,BSN
Current CCOP Administrator	Connie Szczepanek, RN,BSN
Size	9 hospitals and 1 basic science center 96 Investigators

Grand Rapids Clinical Oncology Program (GRCOP) is committed to community cancer research and education. Our mission is to assure that every person in the GRCOP service region has the opportunity to participate in national cancer prevention and treatment clinical trials.

Due to participation in the CCOP program, GRCOP has been able to make state-of-the-art clinical trials available to our patients, participate in landmark studies, contribute input to national research bases regarding community needs, offer strong research infrastructure to our community, and provide outstanding professional and community education.

One of the most meaningful aspects of this work has been the opportunity to customize approaches in our community so that patients receive maximum benefit. The GRCOP has served as a model CCOP by providing innovative access to cancer care and prevention in the community setting. Participation in clinical trials leads to integration of research findings into practice, and the utilization of cutting edge tools, such as breast cancer risk assessment. Grand Rapids Clinical Oncology Program is proud to be a pioneer, paving the road for strong community participation since the CCOP program was developed in 1983.



*Grand Rapids CCOP,
Edward L. "Ed" Moorhead, M.D.*

MINNESOTA

Duluth CCOP
(previously Duluth Clinic CCOP)
Duluth, Minnesota

Original Principal Investigator
Current Principal Investigator
Size

James Krook, M.D.
Robert Dalton, M.D.
One health system in 3 states,
11 physicians

Being a part of a federally designated CCOP has allowed us to function more independently than as simply an affiliate of an institution. (This was done for a period of time when the original local unit was set up.) In addition, it has allowed us to interact with other oncologists throughout the country.

We have been able to function in up to six major cooperative groups, and we've been able to fulfill most of our research needs through this mechanism rather than using pharmaceutical sources. It also has allowed us to be involved in some of the distal communities which we serve; we've been able to offer clinical protocols that have benefited both the participants involved and the national efforts in cancer control and cancer treatment research.

Through participation in federally sponsored research, we have been able to offer cutting-edge treatments to our patients who would otherwise need to travel 3-4 hours to an academic institution to participate on a research protocol.

Metro-Minnesota CCOP

(formerly West-Metro Minneapolis CCOP)

St. Louis Park, Minnesota

Original Principal Investigator	J. Michael Ryan, M.D.
Current Principal Investigator	Patrick (P.J.) Flynn, M.D.
Original Administrator	Pat Moylan
Current Administrator	Ann Deshler (started as a research nurse on day 1 in 1983 and has been with the CCOP the past 20 years!)
Size	9 hospitals in 1 state, 100 physicians

This consortium was originally formed under the NCI's Community Hospital Cancer Program ("CHOP"), and as that program was finishing its goals, this group of hospitals applied for and received one of the first CCOP grants in 1983.

The structure was already in place and provided a model to bring state-of-the-art treatment through participation in clinical trials into the community. As a result of the CCOP, oncology research has become a standard for the whole community. It provides a glowing example of cooperation and collaborative patient care at a time when the hospitals and practices would otherwise compete.

We are able to offer patients new treatments in their own community where they live and work. Having the CCOP keeps the level of care high across the community and improves care for all patients, whether enrolled on the trial or not (the "halo effect"). The knowledge gained working with new treatments and results of previous trials is shared across the group practice and is diffused more rapidly into practice patterns.



Metro Minnesota CCOP staff bowling at holiday party.



*Metro-Minnesota CCOP,
Dr. P.J. Flynn and Dr. Joseph
Cardamone in 1999*

MISSOURI

Kansas City CCOP
(formerly Kansas City Clinical Oncology Program)
Kansas City, Missouri

Original Principal Investigator	Robert J. Belt, M.D.
Current Principal Investigator	Jorge C. Paradelo, M.D.
Original Administrator	Cherry Reynolds
Current Administrator	Leslie Herst
Size	13 health care organizations in 2 states (Missouri and Kansas), 70 physicians

More than 80% of cancer patients receive their care in community settings. CCOP's provide oncologists access to important studies necessary to advance therapy. With the exception of a few scientific breakthroughs that drastically modify the treatment of some diseases, advances in oncology occur in small increments.

Participation in large randomized trials allows community physicians to contribute to the development of new standards of care and benefit their patients at the same time. Notable examples of this include the breast and prostate cancer prevention trials which have demonstrated the power of a coordinated community effort in completing a pivotal study in a very short time.

Community oncologists have an obligation to provide their patients with the best treatment available, and to advance the science of cancer care. The CCOP provides the venue to accomplish these goals. The availability of state-of-the-art, thoughtful, investigational treatments through collaborative research bases enables the community oncologist and radiation oncologist to participate in these advancements at a time when the science of oncology is progressing at a pace that prevents individuals from keeping current in every disease entity.

Cancer Research for the Ozarks
(formerly the Ozarks Regional CCOP)
Springfield, Missouri

Principal Investigator	J. Wendall Goodwin, M.D.
Current Administrator	Dean A. Matthews, MBA, J.D.
Size	6 hospitals, 4 states, 34 physicians

For the past 15 years Cancer Research for the Ozarks has been providing access to state-of-the-art NCI cancer research protocols to the people of the Ozarks. The cities of Southwest and South Central Missouri are growing and now represent a significant majority in the patient percentage that CRO serves; however, these cities exist in a vast land mass known as the Ozark Highlands with an overall low-density population.

The people of the rural Ozarks depend on the strength of CRO and its ability to present the opportunity to participate in advanced cancer therapies. Via networks with other facilities in the region, CRO can give the people of this area medical advances that otherwise could only be obtained by traveling great distances to major metropolitan centers.

To an Ozark native, being able to travel an hour to one of CRO's clinical trials sites rather than to a big city avoids a cultural shock that would greatly disrupt family life. Family members would likely not be able to successfully join their loved one if they had to travel to a large city for treatment. CRO's contribution to the well being of the cancer patients of the Ozark Highlands is significant.

St. Louis-Cape Girardeau CCOP

(formerly the St. Louis-CCOP)

St. Louis, Missouri

Original and Current Principal Investigator	Patrick H. Henry, M.D.
Administrator	Patrick H. Henry, M.D.
Size	6 component hospitals (5 in Missouri and 1 in Illinois)

A group of physicians decided to apply for a Community Clinical Oncology Program Grant in 1982 because they wished to participate in clinical trials. These physicians felt that the CCOP mechanism would allow their patients to have easier access to clinical trials research and that their own training in medical oncology had prepared them to participate effectively in such trials.

These premises have proven to be true as this CCOP has consistently produced high quality data for prevention and treatment trials of the Southwest Oncology Group and the NSABP. The physician investigators, their clinical research associates and their patients have participated in prevention and treatment trials that require large numbers of participants/patients to achieve answers to questions that could not be answered by single institution studies.

Participation in the CCOP Program allowed people to feel rather closely tied to certain programs of the National Cancer Institute and to the staffs and institutional members of the research bases.



Principal Investigator Patrick Henry and the operations staff of St. Louis-Cape Girardeau CCOP

MONTANA

Montana Cancer Consortium CCOP

(formerly the Billings Interhospital Oncology Project CCOP)

Billings, Montana

Principle Investigator
Administrator

Patrick Cobb, M.D.
Shirley Hall

The original primary objective of the Billings Interhospital Oncology Project as to bring state-of-the-art therapy to a community setting. In addition, other major objectives were to secure a funding source for doing clinical research, to create a common business plan among physicians and pool resources, to answer scientific questions within the network of the cooperative group mechanism, and to have recognition within the cooperative groups as a peer.

The Community Clinical Oncology Program gave us a mechanism by which to obtain our objectives. In 1993-1994, several physicians participating in clinical trials through a different mechanism joined the CCOP and created the Montana Cancer Consortium, a freestanding, not-for-profit, corporation.

NEBRASKA

Missouri Valley Cancer Consortium CCOP

Omaha, Nebraska

Principal Investigator
Administrator
Size

James A. Mailliard, M.D.
Mary Beth Wilwerding, RN
13 Hospitals in Nebraska and
western Iowa, 32 Physicians

Prior to the establishment of the Missouri Valley Cancer Consortium CCOP, some of the Omaha area hospitals were conducting clinical trial activities under the guidance and direction of Dr. Mailliard, with data management activities conducted at Creighton University. As clinical trial activities progressed, the need for additional staffing and funds became more apparent. The CCOP grant made sense, and in 1993, the application was submitted, with the first year of funding starting in July 1994.

The decision to become a CCOP did not initially impact clinical trial efforts in Omaha. Physicians continued to enroll at a steady rate, and data management activities were managed by each individual component. The biggest success we realize now as a program is the cohesive networking of physicians, nurses, and CRAs dedicated to improving the care our cancer patients receive.

Another success is being able to provide the best available treatment to our patients without them having to travel long distances, and leave the comfort of family and friends. Our program continues to develop in ways to provide quality cancer care, and quality research opportunities through our clinical trials program. The CCOP program has a profound and positive impact for our community, both for the patients we serve, and for the healthcare professionals who dedicate their efforts.

NEVADA

Southern Nevada Cancer Research Foundation-CCOP

Las Vegas, Nevada

Original Principal Investigators	John A. Ellerton, M.D. and Bruce B. Borgelt, M.D.
Current Principal Investigator	John A. Ellerton, M.D.
Original Administrator	Les Bolin
Current Administrator	Kathleen Van Wagenen, RN, BSN
Size	5 hospitals, 51 physicians

It all started at the Golden Steer Restaurant. The food was good and the camaraderie was excellent, but more importantly it was an opportunity for interested physicians to meet with Jerry Yates about the proposed CCOP program. The opportunity seemed “golden” to bring formal clinical trials to the citizens of Las Vegas. Geographically isolated from cancer centers, growing rapidly and imbued with well-trained cancer professionals, Las Vegas seemed the ideal location the new program was developed for.

From that meeting, the Southern Nevada Cancer Research Foundation was born; an event that created a successful project of enormous benefit to Nevada. The goal of the Foundation was and is to provide a service to the entire community. To that end, the Foundation was created to provide an independent organization that would serve as the CCOP base. The program has always felt that one of its strengths was its commitment to providing research into all types of cancer care; by creating a broad based membership that is open to any cancer professional who wishes to participate, the Foundation preserves its goal of being for the community.

The CCOP has been successful in bringing cancer clinical trials to Nevada and very importantly making the major prevention trials available to the citizens of Nevada. We have overcome the major obstacles of distance in the state and the independent delivery of medical care prominent in Nevada. Without the CCOP, the major prevention trials would not have been available in Nevada. As the next twenty years begins, the CCOP plans to expand its efforts in cancer control, expand the populations served and continue to function as an independent purveyor of the lifeblood of cancer research—clinical trials. All in all, it was quite a satisfactory meal.



Dr. John A. Ellerton, Principal Investigator for the Southern Nevada Cancer Research Foundation and his office nurse, Patricia Marshall, RN.

NEW JERSEY

Northern New Jersey CCOP
(previously Bergen-Passaic CCOP)
Hackensack, New Jersey

Original and Current Principal Investigator	Richard J. Rosenbluth, M.D.
Original Administrator	Debra Grammer, RN, MSN
Current Administrator	Laura Kudlacik, RN, BSN
Size	2 hospitals, 48 physicians

Our CCOP consists of The Cancer Center at Hackensack University Medical Center and Trinitas Hospital at Elizabeth General.

Our group chose to become a CCOP to provide our patients with the best possible care. Clinical trials allow our patients to have access to the newest drugs and treatment options. We believe that through the use of trials, we can offer our patients better options than the standard choices. The Cancer Center at Hackensack University Medical Center has grown tremendously.

We are now the 6th largest Cancer treatment provider in the country. We have achieved this by our outstanding physicians, nurses, community outreach, and access to innovative therapies. Our role in the community has been strengthened by the new approaches that we have been able to provide to them.

NEW MEXICO

University of New Mexico Cancer Research and Treatment Center
Albuquerque, New Mexico

Principal Investigator	Cheryl L. Willman, M.D.
Administrator	Monica Thompson
Size	7 hospitals, 46+ physicians

The State of New Mexico is characterized by ethnic diversity and unusual patterns of cancer incidence and mortality. A substantial number of New Mexicans are young, rural, poor, and medically uninsured and underserved; the highest percentage of Hispanics and Native Americans live in this state. In addition to English and Spanish, our Pueblo, Navajo, and Apache Indian Tribes speak over twenty different languages and dialects.

In this context, the mission of the UNM CRTC is to use its expertise in basic, population, translational, and clinical cancer research to reduce the incidence and mortality of cancer in New Mexico's multiethnic populations. Participation in cooperative cancer prevention and treatment trials sponsored by the National Cancer Institute's is a critical part of this mission. MB-CCOP funds and institutional support have enhanced our cancer clinical trials and treatment programs through the recruitment of 14 new oncology clinical specialists at UNM and through the development of a new expanded clinical trials infrastructure at UNM and Affiliate sites.

MB-CCOP support has been critical for the initiation of close partnerships with the leadership groups of the American Indian and Hispanic communities in our State to promote education, access, and participation in cancer prevention and treatment trials. Together, the UNM CRTC and its Affiliates serve 80% of the cancer patients in New Mexico. In close parallel with the State's ethnic diversity, 52% of the patients currently enrolled from our MB-CCOP program to NCI-sponsored treatment and prevention trials are ethnic minorities. Minority accrual has exceeded 50% for each year since 2000. As a result of the MB-CCOP program, the UNM CRTC is expanding its affiliate network and its outreach programs to minority populations and the medically underserved in our region and is increasing access and accrual of minority patients to cancer clinical trials.

NEW YORK

North Shore Community Clinical Oncology Program
(previously the North Shore University Hospital-CCOP)
Manhasset, New York

Original and Current Principal Investigator	Vincent Vinciguerra, M.D.
Original and Current Administrator	Terrence Moore, MSW
Size	4 system hospitals, 55 physicians

The North Shore University Hospital CCOP was initially developed because of a void in the area of clinical trials that existed in the Long Island communities. The first major cancer program on Long Island, which was based at North Shore University Hospital, was initially participating in the Cancer and Leukemia Group B research base. It became apparent that there was a need to develop a relationship with other research bases and the wide community of physicians, which included oncologists in Queens, Nassau, and Suffolk counties. Initially, this CCOP had two major portions, including both adult and pediatric oncology. The medical oncologists represented full-time academic physicians and community-based physicians on Long Island, while pediatrics was composed of major hospitals in the metropolitan New York area. Initially, there was a great deal of enthusiasm for this program because it offered a unique approach to the management of cancer patients through state-of-the-art clinical trials and access to protocols from research bases that were previously not available. It provided not only multi-disciplinary treatment options, but also major cancer chemoprevention studies.

Through the years, there have been many barriers to accruing patients because of resistance due to time requirements for physicians, limitations set by HMO and insurance companies, and skepticism on the part of the public and community members toward research protocols. By working together with many medical oncologists, surgeons, radiation therapists, oncology nurses, and community members and advocacy groups, there is now recognition of the importance of clinical trials in the Long Island area. The North Shore CCOP has been the focal point for a major merger of 14 hospitals for the North Shore-Long Island Jewish Health system. There has been a renewed interest and commitment on the part of the system to support clinical trials and to make the next 20 years of CCOP participation even more successful.

Our Lady of Mercy Comprehensive Cancer Center MB-CCOP

North Bronx, New York

Principal Investigator	Peter Wiernik, M.D.
Coordinator	Maria M. Serrano
Size	35 physicians

Our Lady of Mercy Comprehensive Cancer Center was established in October 1998 with the relocation of a group of experienced clinical and laboratory investigators as well as research nurses, oncology pharmacists, social workers, nurse practitioner, cytokine and BMT coordinator, and outpatient oncology nurses. The Cancer Center's treatment trial background was strong and a larger emphasis on prevention trials was desired and the MB-CCOP was the best mechanism.

As an MB-CCOP, the Cancer Center is dedicated to reducing the disparities in minority recruitment into clinical trials. We realize that the first step is to dismantle barriers and pre-conceived notions regarding participation in clinical trials by strengthening our connection with the community and the second is to increase physician involvement in accrual to clinical trials.

We have made progress in changing attitudes towards preventive care and hope that this increase will expand to help us overcome the continued challenge of increasing acceptance of preventive as well as treatment trial participation.

Syracuse Hematology-Oncology CCOP

Syracuse, New York

Principal Investigator	Jeffrey Kirshner, M.D.
Administrator	Marianne Hatch
Size	3 hospitals, 2 offices, 11 physicians

Our Hematology-Oncology practice decided to apply for a CCOP grant in order to better serve our patient base. The original partners had recently completed their fellowships and were very interested in continuing high quality clinical research. They also felt that patients would be best served in their own community.

Moreover, the inclusion of Cancer Control studies was very appealing to all of our physicians and nurses; we saw the symptoms that our patients were experiencing and wanted to take part in studies designed to prevent or ameliorate toxicity. Preventing cancer in the first place obviously makes a lot more sense than treating the disease once it is established; participation in Cancer Prevention trials is a high priority of our CCOP.

We felt that having access to these studies through our CCOP would be a valuable asset to our community. Our practice and CCOP has undergone many changes since the inception. We have expanded our CCOP staff and have recently moved into a state of the art cancer treatment facility, keeping three satellite offices as well. Our accrual keeps increasing and our commitment to high quality research remains as strong as ever. The experience we've gained through our CCOP has improved the overall quality of care we deliver to our patients throughout central New York.

NORTH CAROLINA

Southeast Cancer Control Consortium Inc.
Winston-Salem, North Carolina

Principal Investigator
Administrator
Size

James N. Atkins, M.D.
Belinda Butler, R.N., C.C.R.P.
24 hospitals in Georgia, North and South
Carolina, Tennessee, and Virginia, 126
physicians

In 1987, eleven community based medical oncologists joined together to apply to become a CCOP because CCOPs offered communities state-of-the-art, NCI approved treatment and prevention options at the local level. Through the years, the two greatest challenges have been recruitment of healthy subjects to participate in prevention studies and the recruitment of minorities.

The first two major prevention trials (BCPT & PCPT) provided learning curves requiring new recruitment strategies. A further challenge was minority recruitment, as a few communities have almost twice the national average minority population (45.2%). To overcome these barriers, the SCCC developed a minority recruitment plan approved by NCI as the “Gold Standard” and was very successful in minority recruitment. Despite the number of physicians and huge catchment area covered, the SCCC’s efforts alone would be minimal.

By collaborating in the CCOP program, the SCCC accrues significantly to clinical trials, providing stellar contributions to the eradication of cancer and equally important, its prevention.



Southeast Cancer Control Consortium, August 1994, preparation for continuing application.

NORTH DAKOTA

MeritCare Hospital CCOP
(previously Fargo Clinic CCOP)
Fargo, North Dakota

Original Principal Investigator	Lloyd Everson, M.D.
Current Principal Investigator	Ralph Levitt, M.D.
Original Administrator	Linda O'Halloran, RN, MS
Current Administrator	Connie Hoffman, RN, MS
Size	12 physicians

The most important aspect our CCOP is the opportunity to bring research and state-of-the-art cancer care to the rural population of our region in North Dakota, northwestern Minnesota and northeastern South Dakota.

The ability to provide clinical research trials to our patients has helped place MeritCare oncology on the cutting edge of treatments available for patients in these rural areas and to reduce the long distances that patients and their families must travel to receive oncology care. The ability to recruit talented physicians has improved due to the availability of clinical research trials. The audit process has helped to improve documentation, thereby improving the overall quality of our patient care. The high standards of the CCOP have encouraged our oncology department to remain current in oncology care, attend meetings and share new information with co-workers.

A strong emphasis has been placed on providing education regarding cancer prevention, screening and treatment at the community and professional levels. The opportunity to be involved with cancer prevention research, in the development of methods to someday prevent cancer entirely, is very exciting. The CCOP physicians and staff are honored to have been associated with the Community Clinical Oncology Program for 20 years!



MeritCare Hospital CCOP, Dr. Ralph Levitt, with staff member

OHIO

Columbus Community Clinical Oncology Program

Columbus, Ohio

Original Principal Investigator	Jerry Guy, M.D.
Current Principal Investigator	J. Philip Kuebler, M.D.
Original Administrator	Jennifer Guy
Current Administrator	Jacklyn Shaffer, RN, M.S.A.
Size	14 hospitals in Ohio and Kentucky 96 physician members

The focus of the Columbus CCOP remains the same as when it originated out of Grant Medical Center in 1983: to bring state-of-the-art cancer prevention and treatment programs to local physicians and the communities they serve. From its inception, the Columbus CCOP has offered national trials to our community physicians, bringing the most up-to-date cancer screenings, diagnostic care, and treatment plans to individuals in their own communities. Our “community of caring” now reaches from Columbus, to Central and Southern Ohio, and even into parts of Kentucky.

As members of the Columbus CCOP, our physicians are able to offer more clinical trial options to their patients, they play a vital role in the determination of new trials for our organization, and they are given educational and training opportunities that they would not have had available to them otherwise. As an organization, we are thrilled to see our purpose fulfilled in the communities we serve, with better access to national trials closer to home.

Dayton Clinical Oncology Program

Dayton, Ohio

Original Principal Investigator	James Ungerleider, M.D.
Current Principal Investigator	Howard Gross, M.D.
Original Administrator	Ann Martin, RN
Current Administrator	Sidney J. Pinkus, MBA
Size	10 hospitals in Ohio and Indiana 90 active physicians

Twenty years ago when the opportunity was presented by the National Cancer Institute to form a local, community-based organization to coordinate cancer research here in Dayton, Dr. James Ungerleider thought it was important to take advantage of this opportunity. Over the years DCOP has been very successful in maintaining its relationships with the original partnering hospitals and has formed a consortium that includes ten hospitals and a local university spread over two states.

Since its incorporation, DCOP has expanded its service area while continuing its high level of success with its prevention and control programs, minority recruitment and the development of a very competent follow-up program. One of the greatest challenges we

have faced as a CCOP has been to keep encouraging our partnering hospitals to support research in spite of the budget cuts they have faced over the years. Their invaluable support has come in the form of their in-kind contribution of the oncology research nurses in place at each hospital.

By working cooperatively with other groups, such as the Ohio Commission on Minority Health and the American Cancer Society, DCOP has been able to provide additional education, occasionally offer other health services such as prostate screenings and increase minority recruitment. In the beginning and continuing today, DCOP's goal has been to provide access to state-of-the-art cancer research for local physicians and the community.

Toledo Community Clinical Oncology Program

Toledo, Ohio

Original Principal Investigator	Charles Cobau, M.D.
Current Principal Investigator	Paul Schaefer, M.D.
Original Administrator	Mary Groff, RTT
Current Administrator	Diana Frie, Ph.D.
Size	13 institutions, 6 private medical practices, 47 participating physicians

The original Toledo Community Clinical Oncology Program (TCCOP) was funded in 1983 with a full cadre of investigators and an infrastructure already in place. With firm establishment of a successful operation, transfer in mid 1987 of the TCCOP central coordinating office was made to the Toledo Community Hospital Oncology Program, an independent not-for-profit corporation in Toledo, Ohio.

The subsequent track record of TCCOP, which has regularly grown to accrue over 100 patients on treatment related research trials annually, reflects this experience. TCCOP has also successfully met the challenge of conducting the Breast and Prostate Cancer Prevention Trials and other cancer control research protocols. The desire and ability of community physicians to participate in research protocols is constantly evident.

Looking back over the past 20 years, TCCOP is proud of its accomplishments. We recognize that during this same period, the community based oncology programs, as a group, have made a significant contribution to the National Cancer Institute, to the advancement of the science involved in research, and to the communities we serve by providing state-of-the-art cancer care. TCCOP looks forward to continuing this effort in the future.

OKLAHOMA

Oklahoma CCOP

(previously Natalie Warren Bryant Cancer Center CCOP)

Tulsa, Oklahoma

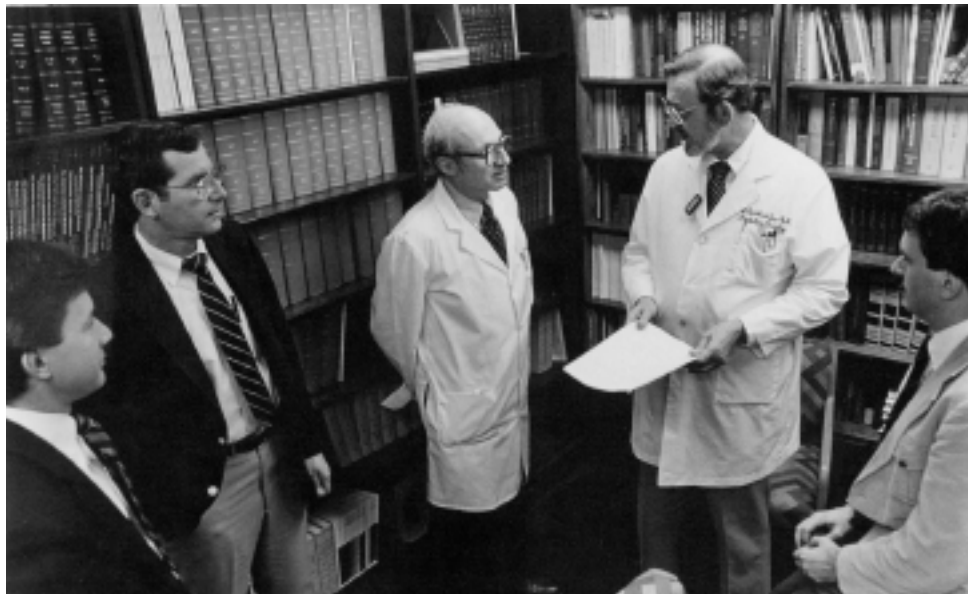
Principal Investigator
Administrator
Size

James B. Lockhart, M.D.
Michele A. Keeling, MPH
3 hospitals, 38 physicians

Although Saint Francis Hospital brought clinical trials to the community beginning in 1975, it was the CCOP mechanism that created an ongoing dialogue among community centers to identify improved methods for conducting clinical research with a focus on broadening the availability of trials to the cancer patient population.

Joining other cooperative groups was an important benefit of becoming a CCOP and broadened the nexus of medical oncologists initially involved in clinical research. Ultimately, the CCOP provided the groundwork for a multidisciplinary approach that has improved the overall quality of cancer care. Physician investigators philosophically believe they and their patients are contributing to the “greater good” by scientifically establishing the best way to treat cancer patients.

Participating in clinical research increases understanding of treatment options and improves patient education. The CCOP has also been vital in providing the needed resources for prevention and cancer control including minority outreach programs. Despite major financial, legal and political changes in healthcare, the Oklahoma CCOP has proven its sustainability for nearly two decades. Patient enrollment continues to grow and the Oklahoma CCOP has been distinguished as one of the highest enrolling single institutions in RTOG for two consecutive years. The CCOP program supports our continued success.



From the Oklahoma CCOP brochure, (L to R): Alan M. Keller, M.D., Principal Investigator; John M. Sexauer, M.D., Associate Principal Investigator; George W. Schnetzer, Associate Principal Investigator; T.J. Brickner, Associate Principal Investigator, (Radiation Oncology); James A. Young, M.D., Associate Principal Investigator

OREGON

Columbia River Oncology Program
Portland, Oregon

Principal Investigator	Keith Lanier, M.D.
Administrator	Mary Bruneti
Size	8 hospitals in 3 hospital systems in 2 states, 126 physicians

The Columbia River Oncology Program was founded in 1987 to serve the Portland, Oregon and Southwest Washington community. A commitment to the research process coupled with access to innovative therapies sparked the formation of this unique consortium known as CROP. The presence of our CCOP has strengthened rather than splintered the physician-patient relationship, enabling community oncologists to treat “on study” at their home hospital. The Columbia River Oncology Program consortium is composed of three large health care systems and their respective cancer programs. While competitive in many respects, these groups unite in the mutual goal of service to this community achieved through their cooperative effort and substantial financial support directed to this CCOP. Additionally, the oncologists have come together from various practice models (solo, small group and nationally affiliated US Oncology) to develop a strong investigator base with shared leadership and mutual respect.

The challenge to provide cancer prevention, control and treatment options to our citizens within an environment of increasing demands and dwindling resources remains a daunting challenge. We are committed to serving the need of an increasingly savvy consumer who comes to us armed with reams of Internet downloads. In the same respect, our mission to reach out to the most vulnerable and underserved remains a priority. We at the Columbia River Oncology Program CCOP embrace this opportunity with renewed enthusiasm as we celebrate the 20th anniversary of the CCOP development.

PENNSYLVANIA

Geisinger Clinical Oncology Program
Danville, Pennsylvania

Original and Current Principal Investigator	Albert M. Bernath, M.D.
Original Administrator	Peter M. Synoweiz, MHA
Current Administrator	Cindy Vought, RN
Size	2 hospitals in Danville and Wilkes-Barre 3 major group practice sites

As a funded CCOP since the inception of the program in 1983, we have enjoyed the development of a clinical culture which has cancer clinical trial research as a primary value. This has become embedded in our clinical life and for two decades has offered our patients treatment opportunities they could have found only in major cities at the very ends of our state.

We are gratified that the CCOP mechanism has permitted us to spread this culture to our group practice sites at Wilkes-Barre and at State College, widening our impact to a much larger region.

Main Line Health CCOP

Wynnewood, Pennsylvania

*Nurse Lisa O'Neil at
an educational program
in a local church.*



Principal Investigator
Administrator
Size

Paul B. Gilman M.D.
Rosemarie A. Tucci, MSN
3 hospitals, 25 physicians

One of the most important elements of a CCOP is providing the opportunity for patients to be offered state-of-the-art cancer care in our communities without the need to go into the city. The newest technologies and treatments are offered at the CCOP. Community hospitals throughout the country compete for CCOP federally funded awards.

To be able to tell a patient that their community hospital is participating in national and international research says a lot. To tell a patient that we are one of a select number of groups able to offer these studies through the NCI and NIH says more; it tells our community members that we are interested in not just caring for them one on one, but to be able to add to the body of knowledge in cancer prevention and treatment for all. Many patients are pleased to hear that the same studies being offered to them at the university hospitals are those offered in their community hospitals. We have found that the more people who know about the CCOP, the more who express interest in what we do.

Becoming a CCOP has completed the oncology program of the Main Line Health System, turning it from 3 good community hospital programs into a more unified program with its eye to the future of cancer care.

PUERTO RICO

San Juan- Minority-Based CCOP

San Juan, Puerto Rico

Principal Investigator
Administrator
Size

Luis Báez M.D.
Doris Cuadrado M.T.
3 institutions, 38 physician investigators

The San Juan MB-CCOP has been a member of the CCOP program since 1990. Our staff and investigators have managed to overcome or minimized barriers and challenges to clinical trial participation.

More than one-third of all cancer patients in Puerto Rico are cared for by our program. Over 50% of the patients enrolled in clinical trials are uninsured or government-sponsored managed care. These are indeed, minority populations with significant economic, social and medical needs.

Our clinical trials have helped to close the gap by offering our patients care that once before was only available to those able to visit major cancer centers on the U.S. mainland. Our clinical trial participation has helped our institution and staff update their services, by offering state of the art imaging and surgical services. Soon, the SJMB-CCOP will be able to offer clinical trial participation to all areas in the Island of Puerto Rico.

SOUTH CAROLINA

Greenville CCOP
Greenville, South Carolina

Principal Investigator
Administrator
Size

Jeff Giguere, M.D.
Lyndon Evans
6 hospitals, 27 physicians

The Greenville CCOP began in 1995, as a core of physicians in a private practice with an aptitude for research. The grant was unique in that it was not awarded to a hospital or medical center, but to a private practice. This relationship was tested repeatedly in the CCOP's first year of existence.

As the practice internalized its chemotherapy operations, the major hospital in the area became a competitor and impounded both study charts and research nurses so that accrual was halted. Legal action was required and rational thoughts and actions eventually prevailed. Rising from these ashes, the Greenville CCOP was more motivated than ever to succeed. Research has become a major priority and emphasis such that almost 10% of all new consults enter an investigational study.

We enjoy reviewing the innovative studies and participating in the trials that allow our patients to get state-of-the-art treatment close to home. Being a CCOP can be exasperating, but invigorating, tiring, but then stimulating. The thing that motivates us all is that this research is right for our practice and right for our patients.



*Left to right:
Julie Martin, RN,
Susan Webb, RN,
Lisa Leary, RN,
Nina Owens, RN,
Joanne Vergnole, RN*

Upstate Carolina CCOP

(previously Spartanburg CCOP)

Spartanburg, South Carolina

Original Principal Investigator	John McCullough, M.D.
Current Principal Investigator	James D Bearden, III
Original Administrator	Teresa Gillespie, RN, M.Ed
Current Administrator	Pam Williams, RN, M.S.N., CCRP
Size	4 hospitals in 3 states, 47 physicians

Since 1983 Spartanburg Regional Healthcare System has been a part of the NCI CCOP Program, as the founders felt that the endeavor was an important one the Spartanburg community should come together to embrace.

The availability of investigative studies and state of the art phase III protocols has been invaluable to ensure that patients do not have to travel great distances to participate in national trials, and they have the latest drugs made available to them in the community.

As a result of the CCOP program, a series of successful continuing medical education lectures and annual seminars have been developed to disseminate information to other colleagues including nurses, physicians, CRAs and patients within the community setting. The relationship with the NCI as well as the relationships enjoyed with NCI personnel over the past 20 years have been invaluable and help us to grow as an investigative and clinical research based institution offering state of the art cancer care to our community.



Seated, L-R: Dr. Eric Nelson, Dr. James Bearden, Dr Jim Brado, Susan Lemp, Oncology CNS and Debra Robbs, Resident Nurse; Standing, L-R: Dr. Al Stresing, Dr. Walt Kucaba, Pam Williams, Coordinator, Dr. John McCulloch, Principal Investigator, Dr. Julian Josey, Dr. Charles Webb, Denise Smith, Resident Nurse, Freida Spivey, XRT Nurse, and Susan Phillips, Secretary

SOUTH DAKOTA

Sioux Community Cancer Consortium

(formerly Sioux Falls Community Clinical Oncology Program)

Sioux Falls, South Dakota

Original Principal Investigator	Robert Marschke, M.D.
Current Principal Investigator	Loren Tschetter, M.D.
Current Administrator	Del Cinco
Size	5 Hospitals, 5 States, 34 physicians

The oncology community in Sioux Falls, South Dakota, became involved with the clinical trials program of the National Cancer Institute in 1977, but became a CCOP as soon as the awards were established.

We believe that the North Central Cancer Treatment Group and its community approach to clinical trials had some formative influence on the CCOP. Our involvement in clinical trials over the years, including some landmark trials, has demonstrated to us the importance of clinical trials in terms of making progress in cancer treatment, having current treatments available to patients, and being part of a cooperative effort that helps treat patients and answer questions regarding cancer therapies at the same time.

In more recent years we have been very active in the cancer prevention agents and have found that patients are quite interested in cancer prevention trials. Over the years we have educated community institutions on the value of the clinical trials program. We believe the biggest success of the CCOP has been the dissemination of clinical trials to the community setting where many patients are seen and treated. This enables patients to participate in clinical trials and makes available newer treatments and investigational drugs that would otherwise not be available to them.

We believe that as a CCOP and working cooperatively with other groups through the CCOP mechanism, we are much better prepared to help cancer patients in the preventative and treatment arenas. It has been a pleasure to be part of the Community Clinical Oncology Program since its inception in 1983.

TEXAS

Scott & White Community Clinical Oncology Program

Temple, Texas

Principal Investigator
Administrator
Size

Lucas Wong, M.D.
Lisa Keville, MHSM
2 hospital systems, 17 physicians

In 1996, the Center for Cancer Prevention and Care at Scott & White made the decision to apply for the CCOP grant in order to provide uniform administration of the cooperative group programs already in place and to allow for new cooperative group opportunities.

Scott & White believed that the administration of the cooperative groups within one grant mechanism would improve the efficiency and effectiveness of managing these trials by standardizing operations through one central office. Since the CCOP award in 1997, a cohesive, multi-disciplinary foundation has evolved at Scott & White resulting in enhanced patient care through collaboration of experts in oncology medicine.

With the CCOP grant and a priority on cancer control and prevention, our cancer program has an increased focus in providing community education and support, enhancing outreach efforts to underserved populations, and building our cancer control and prevention programs. In conclusion, the Scott & White CCOP has provided our community with quality cancer care through research and education, and new opportunities to enhance the availability of research, and improve cancer control and prevention.



Scott and White CCOP staff participate in Denim Day to raise money for cancer research.

South Texas Pediatric MB-CCOP

San Antonio, Texas

Principal Investigator	Anthony Infante, M.D., Ph.D.
Administrator	Margaret Lewis, MS, RN
Size	4 hospitals and 7 outreach clinics covering 65,000 square miles in South Texas. 14 pediatric hematologists/oncologists.

The CCOP program provides a critical mechanism to leverage existing strengths to build new relationships with area physicians and institutions. Additional sites, programs and protocols have been brought on-line to promote the CCOP mission of improving the quality as well as quantity of access to cancer clinical trials.

Participation in the CCOP program also provided an NCI “stamp of approval” for our program, which helped to attract additional funding for cancer research in San Antonio. Chief among these was an endowment for a Children’s Cancer Research Institute from the State of Texas tobacco settlement. The entrusting of this endowment to the University of Texas Health Science Center at San Antonio was helped immeasurably by the presence of NCI funding of the STP-MB-CCOP.

CCOP funding has been a tremendous boost for cancer research and treatment activities in San Antonio and South Texas. Congratulations and happy 20th anniversary to the NCI staff who make CCOPs possible.

VIRGINIA

Virginia Commonwealth University MB-CCOP

Richmond, Virginia

Principal Investigator	John D. Roberts, M.D.
Administrator	Martha D. Wellons
Size	5 hospitals, 30 physicians

The VCU Minority-Based CCOP was initially established in 1990 to serve a large minority patient population. The goal is to increase the availability of clinical trials to all patients in its catchment area.

Enrollment to NCI cooperative group clinical trials has more than doubled since becoming a CCOP institution. A major success in becoming a CCOP has been the enrollment of subjects to cancer prevention trials. VCU MB-CCOP has enrolled over 350 subjects on the two breast cancer prevention trials (BCPT and STAR) and the prostate cancer prevention trials (PCPT and SELECT).

Working cooperatively with other groups through the CCOP has enabled the VCU MB-CCOP to enroll large numbers of participants on cancer prevention trials. Without the funding mechanism of the CCOP, we would not have been able to maintain a cancer prevention clinical research program. In addition, as an MB-CCOP, we have been able to offer state-of-the art treatment to cancer patients in rural communities in central Virginia.

WASHINGTON DISTRICT OF COLUMBIA

D.C. United MB-CCOP
Washington, District of Columbia

Principal Investigator
Administrator
Size

Lucile L. Adams-Campbell, Ph.D.
Joan Pearson
2 hospitals, 30 physicians

Howard University Cancer Center (HUCC) serves a predominately African-American community, in which documented health disparities exist. Clinical trials are one means to address these disparities.

The MB-CCOP has afforded HUCC the opportunity to provide state-of-the-art treatment to cancer patients, particularly African-Americans and underserved populations. The decision to become a MB-CCOP was also based in part upon the need to enhance HUCC's clinical trials infrastructure. The MB-CCOP has enabled HUCC to increase the size of its clinical trials staff and, therefore, open additional protocols. Due to the wide selection of protocols, physicians are now considering options other than standard care. The MB-CCOP has also enhanced physicians' working relationships as they strive to enroll patients on clinical trials.

The MB-CCOP has had to overcome the challenge of lack of physician knowledge regarding clinical trials. Several steps have been taken to improve their knowledge and to remove barriers to physician participation, and improvements have been substantial. Another obstacle has been lack of patient awareness and fear of participating in clinical trials. The clinical trials staff has worked to provide information to patients through brochures, videos, posters, and presentations. Our educational efforts have enabled potential participants to make an informed decision. This remains an ongoing challenge.



*Howard University Cancer Center MB-CCOP
Urologist Dr. Bob Dewitty (left) and
Dr. Alfred L. Goldson, a radiation oncologist.*

WASHINGTON

Virginia Mason CCOP
Seattle, Washington

Original Principal Investigator	Albert Einstein, M.D.
Current Principal Investigator	Andrew Jacobs, M.D.
Original Administrator	Meredith Dawson, RN
Current Administrator	Beth Edelheit
Size	7 hospitals in 3 states (Washington, Idaho, Alaska), 25 physicians

The CCOP is valuable to both the physicians and patients involved with the program; it provides patients with the opportunity to participate in important phase II and phase III trials and in many cases gives them access to agents that might not otherwise be available to them. Additionally, CCOP investigators in outlying communities can provide their patients with access to the same trials as those patients being treated at the larger institutions without the travel requirement.

Northwest CCOP

(formerly the Southwest Washington CCOP)
Tacoma, Washington

Original Principal Investigator	Gale Katterhagen, M.D.
Original Administrator	Carolyn Miller
Current Principal Investigator	Lauren K. Colman, M.D.
Current Administrator	Karyn Hart
Size	12 hospital consortium 35 physicians in 3 states

Northwest CCOP was one of the original 52 CCOPs funded in September 1983 as a nine-hospital consortium in Washington State. In 1986, the CCOP changed its name to the Northwest CCOP to reflect a change in geographical representation

The specific aims of the Northwest CCOP since 1983 are: to focus on the patients, allowing them to remain in their communities and still participate in national clinical trials; to provide a strong community Cancer Program Base, one which will provide support to investigators involved in clinical therapeutic research; to involve primary care physicians in the cancer program and make them aware of the potential of existing clinical protocols and state-of-the-art cancer management; and to maintain a mechanism for protocol selection.

In addition the CCOP seeks to: enter patients onto clinical trials involving experienced investigators and maintain a mechanism for the data management and quality control of the protocols; maintain adequate pharmacy management procedures for investigative agents, and further develop the consortium's potential as a base for other NCI cancer control activities.

WISCONSIN

Marshfield Community Clinical Oncology Program

(formerly Community Clinical Oncology Program – Marshfield)

Marshfield, Wisconsin

Original and Current Principal Investigator	Tarit Kumar Banerjee, M.D., FACP
Original Administrator	Einard S. Haniuk, Ph.D.
Current Administrator	Kim Fuehrer, RN, BSN, MSM
Size	10 hospitals 34 Physician Investigators

Marshfield Clinic was awarded one of 20 Community Hospital Oncology Program (CHOP) grants in the country by the NCI in 1980. Upon receipt of funding by NCI in 1983 it was a natural progression from the Community Group Oncology Program to Marshfield CCOP.

Marshfield Clinic aspires to provide the highest quality patient care and to achieve and maintain excellence in its research initiatives. Sustained NCI funding of Marshfield CCOP from 1983 to the present helped the maintenance of excellence of the Cancer program. Up until 2002, Marshfield CCOP was the only CCOP in Wisconsin.

The greatest challenge for Marshfield CCOP to date has been the gradual establishment of a Cancer Prevention and Control program in an environment predominantly oriented to acute and chronic care of human illness in a large rural multispecialty group clinic setting where health insurance plans only reimburse acute and chronic illness costs. With NCI funding, Marshfield CCOP has now an excellent cancer prevention and control team. The Clinic administration has been very supportive of the CCOP program from its inception and closely monitors the impact of cost-sharing by the Clinic in order to maintain a high quality, successful CCOP program. The CCOP program also offers regional center cancer patients state-of-the-art cancer therapy. The Marshfield CCOP feels very proud by being a part of a national effort to decrease human suffering from malignancy by collaborative efforts with research bases and NCI.



Marshfield Community Clinical Oncology Program holds a video conference discussion with (Left to Far Left): Dr. Richard Mercier, Oncology Department Chair; Dr. Tarit K. Banerjee, CCOP PI; Laurie Feenstra, RN, Oncology Research Assistant Manager; Ione Miedema, RN; and Dr. Matthias Weiss (on video conference).

St. Vincent Regional Cancer Center CCOP
Green Bay, Wisconsin

Principal Investigator	Thomas J. Saphner M.D.
Administrator	Jolene Cheslock M.S. CCRP
Size	3 hospitals, 14 physicians

St. Vincent Regional Cancer Center CCOP in Green Bay, Wisconsin has just completed its first challenging and rewarding year as a CCOP. Our rewards have come from the pride and enthusiasm within our organization to be part of this program.

Our CCOP participation and desire to make it successful have led to common research objectives that have helped to integrate our adult oncology, radiation oncology and pediatric oncology research programs. Our challenge has been to transport this enthusiasm for cancer research beyond our walls. The St. Vincent physician investigators and research staff have worked very hard this first year as we have promoted the St. Vincent CCOP as a resource for cancer control and prevention information and have educated area physicians and the general public about cancer prevention and the importance of clinical trials as a treatment option for cancer.

The medical community and the general public have been very receptive and genuinely interested in our message and we are confident that this will translate into future clinical trial participation as our CCOP grows. Our physicians view the program as a means to bring new cancer treatment and prevention ideas to our community, to increase community awareness regarding cancer treatment and prevention trials, and an opportunity to make a valuable scientific contribution to the cancer knowledge base.

“To continue the progress of the last 20 years of cancer research, we must renew our commitment to cancer clinical trials. These trials are the key to identifying effective interventions to prevent and treat cancer. The gateway to these national clinical trials is through the community physician, and in particular, the neighborhood CCOP.”

DR. LORI MINASIAN, CHIEF, COMMUNITY ONCOLOGY AND
PREVENTION TRIALS RESEARCH GROUP,
NCI DIVISION OF CANCER PREVENTION

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Marcel Conrad, M.D. with wife, Marcia Grove-Conrad, displays Harry Hynes Award for 2003.

HARRY HYNES AWARD

The Community Clinical Oncology Program established the Harry Hynes Award in 2001, to honor Harry Hynes, M.D., principal investigator of the Wichita Community Clinical Oncology Program, for his commitment and dedication to community clinical research.

The Harry Hynes Award has been presented to the following investigators for their outstanding commitment to community clinical research:

2003

Marcel Conrad, M.D.

Gulf Coast Minority-Based Community Clinical Oncology Program

2002

Shaker Dahkil, M.D.

Wichita Community Clinical Oncology Program



Dr. Harry Hynes

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