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Two Successful Recruitment Strategies For Cancer Trials

Recruitment Strategies for a Chemoprevention Trial

by Linda A. Battiato, R.N., M.S.N., O.C.N.

Cancer control studies present a unique recruitment challenge for Community Clinical Oncology Programs (CCOPs). Potential participants for cancer treatment studies are found in the oncologist's office or the hospital, but CCOPs must look out into the community for participants for cancer control studies. Successful recruitment for cancer control studies requires innovative thinking, an intensive effort, and staff commitment.

Methodist Hospital of Indiana's (MHI's) CCOP recruited patients for a cooperative group oral leukoplakia chemoprevention trial. From January to December 1991, 30 patients were entered on this trial and an additional 40 patients were screened.

Several different recruitment strategies were used as part of an overall recruitment plan. These strategies included an advertisement in a dental journal, two statewide mailings to dentists and oral surgeons, a letter-to-the-editor in a dental journal, and an oral screening project. A group of head and neck surgeons affiliated with the hospital also served as a significant referral source. Each of the recruitment strategies was met with varying degrees of success, but overall, the recruitment plan produced positive results. The total cost of the recruitment efforts was approximately $1,500.

MHI CCOP placed a quarter-page advertisement in the Indiana state dental journal, requesting patients with oral leukoplakia. This bimonthly journal reaches all of the licensed dentists in the state. The advertisement was placed in four issues in 1991, and included study highlights and the name of a contact person for information. The total cost of the advertisements was $443.

In February 1991, MHI CCOP sent out letters about the study to approximately 3,000 dentists and oral surgeons in the state of Indiana. A computer printout with the names and addresses of these practitioners was obtained from the Health Professional Bureau at a cost of $37. The letter was a request for patients, and included highlights about the study, eligibility criteria, and the name of a study contact person. Volunteers were utilized to fold letters and to stuff and label envelopes.

An oral screening was conducted in March 1991 as part of the institution's comprehensive cancer screening programs. Although the screening was not conducted solely for the purpose of the study, it was recognized that it could be a potential recruitment source. This screening was free to the public and was conducted by physician volunteers on two consecutive Saturdays.

Of the 233 individuals screened, 13 (5 percent) were referred to the study and 9 (3.8 percent) were entered on the study. Costs for screening supplies totalled about $300.

A follow-up mailing was sent to the same list of dentists in August 1991. The letter included a reminder that the study was ongoing and thanked the dentists who had referred patients. It also presented some of the preliminary data about the study. The total cost of both of the mailings was $822.

In September 1991, the study's principal investigator sent a letter-to-the-editor of the state dental journal. It was similar in content to the follow-up letter and contained a plea for continued referrals and participation from dentists throughout the state.

A careful log was kept of all referrals, and each referral source was documented. Of the 30 patients entered on the study in 1991, 11 (37 percent) were recruited as a result of the initial mailing. Nine (30 percent) of the participants were recruited through the oral screening project. The group of head and neck surgeons referred 7 (23 percent) of the participants. The second mailing yielded one patient, and two patients were referred by miscellaneous sources. No direct referrals could be traced to the journal ad.

In addition to the 30 patients entered on study, 40 potential study candidates were evaluated, but were not entered because of eligibility or some other reason. Of these 40 referrals, 16 came from the initial mailing, 4 from the oral screening, 9 from the second mailing, 3 from the letter-to-the-editor, and 8 from the head and neck surgeons.

In 1991, MHI CCOP entered more patients on this oral leukoplakia study than any other cooperative group. MHI CCOP's initial recruitment plan was to rely solely on the group of head and neck surgeons affiliated with its cancer program. However, the majority of their patients had a diagnosis of oral cancer in the past two years, and this excluded them from the chemoprevention trial.

By expanding its recruitment efforts beyond this one source of patients, MHI increased its accrual to this study from 7 to 30 patients—an increase of 77 percent.

With the increased emphasis on cancer prevention studies by the National Cancer Institute (NCI), recruitment to these studies is going to become even more of an issue for CCOPs. CCOPs can meet the challenge of accrual through well-planned, innovative recruitment strategies. MHI CCOP learned that this requires time, effort, commitment, and administrative support of the costs involved.

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Enhancing Accrual To Clinical Research

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There is an NCI and American Cancer Society documented need for increased patient accrual onto clinical research trials. Patient accession to clinical trials is low, and total accrual to NCI-supported cancer treatment trials in adults represents a minute fraction—less than 10 percent—of the number of patients potentially available.* Only three to four percent of the more than 150,000 newly-diagnosed breast cancer patients, and less than two percent of the 160,000 patients with colorectal cancer, participated in clinical trials during 1991.** The slow accrual rates for clinical trials may have a direct effect on the acquisition of new knowledge regarding the biology of tumors and the treatment of these disease processes in a timely fashion.

The obstacles related to patient accrual onto clinical research trials are numerous and may relate to physician dislike for the clinical trial process, patient refusal to take part in these studies, and reimbursement difficulties related to investigational treatment. These factors are seen in the community setting and represent a microcosm of the national problem. The community health care provider must be cognizant of these problems and formulate strategies to attenuate the difficulties of accruing patients on clinical research trials.

The Cancer Institute of the Washington Hospital Center, located in Washington, DC, has committed its resources to enhancing community patient accrual onto clinical research trials. To that end, in the Fall of 1989, the decision was made to focus on institutionally-generated protocols which reflected the research interests of the Medical Director of the Institute and the clinical trials of the National Surgical Adjuvant Breast and Bowel Project (NSABP). The Medical Director and the Vice President for Nursing created the position of a clinical nurse specialist for clinical research protocol coordination. This position is responsible for protocol development in conjunction with the principle investigator, informed consent creation, and impact studies on all potentially affected health care professionals, both in the hospital environment and in affiliated satellite physician offices. This position is also responsible for all investigational review board approvals and yearly update activities, including educational programs for all nurses, pharmacists, physicians, social workers, and other appropriate care givers regarding available trials and their treatment rationales.

Patient screening for protocol eligibility is performed through the review of pathology reports and medical charts in conjunction with the Oncology Clinical Information Center. All data collection and follow-up evaluations for protocol patients is coordinated via the clinical research protocol nurse.

Numerous annual and monthly educational programs regarding clinical trials are available to all health care providers. The program directors of the Center for Cancer Research of The Cancer Institute are actively involved in this educational process. A clinical trials educational program for oncology nurses is scheduled on an annual basis and all oncology nurses at the Washington Hospital Center are introduced to the concept and process of clinical trials through the Cancer Chemotherapy Course—a required course for all oncology nurses who administer chemotherapy in the oncology units or the ambulatory infusion center.

The educational and administrative model for enhancing patient accrual onto clinical research trials that is being utilized by The Cancer Institute of the Washington Hospital Center has been effective and efficient in screening for all research-eligible patients. It has increased physician and nurse awareness of the research trial process. A firm foundation has been created to support the clinical research infrastructure at the Institute. This process is flexible and capable of change to incorporate new ideas that enhance both patient accrual and patient and clinician satisfaction with the clinical trials treatment option. ■

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