

A Demonstration Project to Increase the Awareness of Cancer Clinical Trials Among Community-Dwelling Seniors

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Purpose/Objectives: To describe the planning, implementation, and evaluation of an educational program to increase the awareness of cancer clinical trials among community-dwelling seniors in a southeastern metropolitan community.

Data Sources: Published articles, research findings, conference proceedings, government-issued educational materials, and clinical experiences with patient recruitment and enrollment.

Data Synthesis: The elderly are underrepresented significantly in cancer clinical trials. Often, patients and the lay public are not aware of clinical trials or have misconceptions about research. Community outreach efforts represent one viable strategy to close this knowledge gap.

Conclusions: Local communities can build partnerships to identify creative methods for disseminating materials about clinical trials.

Implications for Nursing: Oncology nurses can create and participate in partnerships that communicate information about cancer clinical trials within their local communities.

Although progress is being made in the treatment and prevention of cancer, it remains a significant disease of the elderly. Cancer control in seniors necessitates chemoprevention, early diagnosis, and timely, effective treatment (Balducci & Extermann, 2000). Patient enrollment in clinical trials is necessary for optimal cancer prevention and treatment modalities. Although a high percentage of children with cancer enroll in clinical trials, less than 3% of adults with cancer enroll in treatment trials sponsored by the National Cancer Institute (NCI). Recent studies have documented the substantial underrepresentation of older patients in studies of treatment for cancer (Hutchins, Unger, Crowley, Coltman, & Albain, 1999; Sateren et al., 2002). This is troubling particularly because of the high incidence of cancer in the elderly and the resulting anticipation of increased cases as the U.S. population ages (Edwards et al., 2002).

Guidelines for the inclusion of women and minorities in clinical research were published by the Federal Register, National Archives and Records Administration in March

Key Points . . .

- ▶ Older adults are underrepresented significantly in cancer clinical trials.
- ▶ The need to integrate aging and cancer research creates new challenges and opportunities for multidisciplinary, multi-institutional collaboration.
- ▶ A national-level partnership can result in a successful grassroots effort to promote awareness of clinical trials among community-dwelling seniors.

1994, and the participation of minorities and women in clinical cancer research continues to be addressed systematically (Ehrenberger, Allgood, Thomas, Wallace, & Licavoli, 2002; Underwood & Alexander, 2000). However, researchers must examine the issues surrounding the participation of the elderly in clinical trials. As patient advocates, nurses are in a unique position to give the public accurate information about these studies (Joshi & Ehrenberger, 2001). This article describes the planning, implementation, and evaluation of an educational program used to increase the awareness of cancer clinical trials among community-dwelling seniors in a southeastern metropolitan community.

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Background

Clinical Trials and the Elderly

Clinical trials participation remains low, hindering research progress and patient access to potentially beneficial therapy (Lara et al., 2001). Hutchins et al. (1999) examined enrollment data in 164 Southwest Oncology Group therapeutic trials from 1993–1996 and found that people aged 65 and older were underrepresented significantly. Saterén et al. (2002) examined participation in NCI-sponsored cancer treatment trials from April 1998 to April 1999 and found that, among adult patients with cancer, those aged 80 and older were least likely to be enrolled. Also, less than 1% of the estimated number of adults aged 70–79 with cancer were represented in these trials. Data from both of these studies are consistent with an earlier study by Trimble et al. (1994), which also found that older patients were underrepresented in NCI-sponsored cancer treatment trials.

Barriers to enrollment in clinical trials include physician and patient determinants, organizational issues, and healthcare system factors (Lara et al., 2001; Lengacher et al., 2001). Some physicians may believe that elderly patients with cancer will not tolerate some therapies and decide against entering them into clinical trials (Giovanazzi-Bannon, Rademaker, Lai, & Benson, 1994). Yet limited data support the idea that older patients cannot tolerate or benefit from treatment in clinical trials, particularly studies that test standard drugs for common solid tumors (Hutchins et al., 1999). As a partial response to this lack of information, clinical trials are examining cancer therapy in older patients, including the effects of aging and coexisting conditions on patients' responses and side effects to surgery, chemotherapy, and radiation therapy. These studies will help determine how to improve treatment in this segment of the population. In addition, NCI Cancer Centers recently were given the opportunity to use the information and research priorities created in a multidisciplinary workshop titled "Exploring the Role of Cancer Centers for Integrating Aging and Cancer Research" (NCI, 2002; National Institute on Aging & NCI, 2001). Although this opportunity addressed relevant issues for patients with cancer aged 65 and older, a significant barrier identified at the workshop was that "recruiting older patients into clinical trials and studying them is difficult, costly, [and] time-consuming" (National Institute on Aging & NCI, p. 79).

The public's misconceptions and unawareness of clinical trials compound the issue of recruitment. Focus groups conducted by NCI found that the public often did not understand the term "clinical trial" (NCI, Office of Cancer Communications, 1996). According to a Harris Interactive, Inc., survey (2000) of almost 6,000 patients with cancer, 85% of patients reported that they were unaware of possibly enrolling in a clinical trial for their treatment. Efforts to increase the understanding of clinical research must continue, and healthcare professionals are positioned to promote awareness of this practice. Through proactive education of the lay public, patients, and patients' families, oncology nurses can play an integral part in increasing understanding of cancer clinical trials among older adults and possibly increase patient participation in future clinical trials.

The National Cancer Institute's Cancer Clinical Trials Education Program

During the 1990s, NCI developed the Cancer Clinical Trials Education Program (CCTEP) with the assistance of

healthcare professionals and the Cancer Information Service (CIS) (Dean-Clower et al., 2000). CCTEP provided healthcare professionals with the knowledge and tools to educate the lay public, patients, and patients' families about clinical trials. The training program's intended audience was healthcare professionals and social workers. The training curriculum was a four-module notebook with interactive exercises, self-assessment tools, and slide presentations. The slide and script presentations in modules I, II, and III were aimed at the lay public with some college education and cancer knowledge and healthcare professionals who were not familiar with cancer clinical trials. Module IV, a stand-alone program that also used the slide and script format, was designed specifically to educate the lay public about cancer clinical trials.

For several years, a successful national partnership facilitated the promotion, dissemination, and implementation of CCTEP at regional and local levels. The Oncology Nursing Society (ONS), the Association of Oncology Social Workers, NCI, and Novartis Oncology joined forces to deliver educational programs across the country to increase awareness of cancer clinical trials among numerous targeted audiences. Although this national partnership no longer exists, it represented an innovative approach for delivering timely content and can be adapted by other healthcare professionals and organizations. Also, CCTEP has been re-engineered with the release of a new Clinical Trials Education Series. This new series contains basic and advanced educational materials, workbooks, brochures, slide shows, and videos about clinical trials for a variety of audiences (Michaels, Denicoff, Bright, Abrams, & Robinson, 2002), and many of the materials now are available on the Internet. A partial listing is given in Figure 1.

The Educational Program

At the local level, several individuals attended the CCTEP workshops at either regional or national meetings. A member of ONS, in partnership with NCI's regional cancer information specialist, local clinical research nurses, and a representative from Novartis Oncology, initiated planning efforts. Their goal

Cancer Clinical Trials: Basic Workbook

Self-modulated workbook designed for individuals developing a basic understanding of clinical trials

Cancer Clinical Trials: In-Depth Program

Textbook designed for healthcare professionals and others that expands on subjects outlined in the Basic Workbook

Cancer Clinical Trials: A Resource Guide for Outreach, Education, and Advocacy

Guide provides direction and guidance for developing clinical trial outreach and education activities.

Trainer's Guide for Cancer Education

Manual designed for planning and conducting educational sessions on cancer-related topics

Figure 1. National Cancer Institute's Clinical Trials Education Series

Note. This series is available from the National Cancer Institute Office of Education and Special Initiatives at <http://oesi.nci.nih.gov/series/cted/index.html>. Cancer Clinical Trials: In-Depth Program is approved as an independent study program by the Oncology Nursing Society's Approver Unit for 2.4 contact hours at no charge (www.oesweb.com/newce).

was to provide educational programming about cancer clinical trials in their local community. The southeastern metropolitan community was approximately 90% Caucasian, with more than 20% aged 55 or older. The community-dwelling seniors were the target audience, a lay public with an increased risk for cancer because of their age. An ONS member contacted a nonprofit healthcare organization in the community that had a well-established and highly publicized network of senior health centers. These centers provided primary health care, social services, health screenings, insurance assistance, and health and wellness education in seven neighborhoods. Each center provided the services of a primary care physician for patients aged 55 and older. The institution's administration approved the delivery of educational programming about cancer clinical trials.

Concurrently, several clinical research nurses within the community were contacted to gauge interest in an outreach effort. Most research nurses were affiliated with inpatient or outpatient clinical research programs and had little time or opportunity for community outreach. A select few were involved in coordinating prevention trials and already were engaged in various community outreach activities. Because of workload issues, each research nurse was asked to commit to delivering only one program. The time commitment was viewed as feasible, and six nurses agreed to participate in the project.

Modules I and IV were adapted slightly to follow the format of a "lunch and learn" seminar, where a 90-minute program included a light lunch, speaker presentation, short videotape, and question-and-answer session. Objectives for the "Lunch and Learn About Clinical Trials" program were obtained from module IV ("Educating the Public About Cancer Clinical Trials") and are listed in Figure 2. Each clinical research nurse was paired with a CIS specialist and assigned to at least one senior center. The program series and scheduled dates were advertised by hospital marketing personnel who regularly published announcements about their senior center programs and activities via various media channels (e.g., local newspaper, newsletters, television). Seating was limited at each center, and those interested in attending the program were required to make a reservation. During three months, six clinical research nurses and a CIS specialist presented programs at seven senior centers. A final program was held at the parent institution.

The program's primary financial consideration was the cost of the luncheon. The educational materials were obtained essentially at no charge from CIS. In addition, the senior centers provided the meeting space at no charge, and speakers volunteered their time and effort. The marketing and program promotion were included as part of a larger, existing hospital-based program and were less costly. An educational grant from Novartis Oncology helped underwrite the expenditures and was essential to the implementation of the program.

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- Learn what cancer clinical trials are and their key role in producing better care.
 - Understand the importance of consumer knowledge about cancer clinical trials and the two types of information they may need.
 - Become familiar with some of the prevention and treatment approaches that current clinical trials are evaluating.
 - Appreciate the negative public health effects of low public and patient participation in cancer clinical trials.
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Figure 2. "Lunch and Learn About Clinical Trials" Program Objectives

Program Evaluation

A brief program evaluation questionnaire consisted of 11 items. Six items used a Likert-format response set ranging from one (strongly agree) to five (strongly disagree.) These items addressed the literature and clinical experiences with patient recruitment and enrollment. The remaining five items established demographic information (gender, age, and educational level), previous awareness of clinical trials, and interest in further programming about clinical trials. The anonymous evaluation was distributed at the completion of each educational seminar.

Results

Demographics

Data were collected from 60 seniors; however, four questionnaires were incomplete and not evaluated. The adjusted total sample was 56 for the analyses and composed of 43 (77%) women and 13 (23%) men. The mean age of the respondents was 73 years (range = 55–84, SD = 7.3). Thirty-four percent (n = 19) of the respondents indicated their highest level of education as completion of high school, and 57% (n = 32) had attended some college. Nine percent (n = 5) had some high school or grade school education.

Awareness and Attitudes Toward Clinical Trials

Of the respondents, 95% (n = 53) agreed or strongly agreed that clinical trials provide high-quality and up-to-date care for patients with cancer, and 84% (n = 47) thought that they would be able to provide family members or friends with general information about clinical trials. Eleven percent (n = 6) were undecided, and 5% (n = 3) did not think they could provide this information. Eighty-eight percent (n = 49) believed that they would be comfortable asking their doctors about clinical trials, but 12% (n = 7) were undecided; 96% (n = 54) agreed that the option of participating in a clinical trial should be discussed with most patients with cancer. Finally, 88% (n = 49) indicated they would like to have more programs about clinical trials and medical research, 11% (n = 6) were undecided, and one respondent did not want more programming on the topic.

Discussion

The national partnership served as a model for this grassroots effort to promote the awareness of clinical trials among community-dwelling seniors. The implemented "Lunch and Learn About Clinical Trials" program was received well by the seniors. Identifying an established network of senior health centers clearly facilitated program planning. In addition, the institution's promotion of the series was key in ensuring program visibility. When developing a marketing plan for an individual clinical trial, the study's parameters and marketing strategies should define the targeted population (Adams, Silverman, Musa, & Peele, 1997; Meadows, 2000).

The small-group format at each senior center allowed interaction between the speakers and the audiences. Studies have reported that recruitment efforts are more successful if presentations are made directly to older adult audiences; this allows potential participants to identify the study with an individual, voice concerns, and receive answers in a personalized format (Adams et al., 1997). Most participants were eager to learn about

clinical research and wanted more opportunities to learn about research. Perhaps the most encouraging feedback was that the majority of respondents (88%) believed that they could ask their doctors about clinical trials, and 84% indicated that they would feel comfortable sharing information about clinical trials with family members or friends. Anecdotal reports indicate that a few respondents later spoke to research nurses about participation in a chemoprevention trial. Although this feedback is encouraging, only long-term evaluation can determine the relationship between educational programming and clinical trials participation.

In addition, the clinical research nurses, who were employed at local institutions or physician practices that participate in clinical trials, reported valuing the opportunity to present information related to their daily practice. The ability to use a prepackaged program with slides and a script enhanced program delivery. Clinical research nurses could bring their own institutional perspective to a "Lunch and Learn About Clinical Trials" program, but the overall presentation remained standardized.

Limitations of the demonstration project included the lack of a formalized baseline assessment. Although the program evaluation ascertained the participants' previous awareness of clinical trials, it did not account for exposure to promotional materials prior to the program. A small percentage of the seniors may have learned about clinical trials through the promotional materials about the upcoming program series. Because the demonstration project was deemed logistically feasible with overall encouraging results, more rigorous evaluation strategies are recommended. In addition, ethnically diverse populations should be targeted.

Conclusion

Public education in cancer clinical trials continues to be paramount, particularly among the elderly population. NCI's Cancer Clinical Trial Education Series provides oncology nurses and other healthcare professionals with tangible tools to disseminate this important information. A professional partnership can serve as a vehicle for program planning and implementation locally, regionally, and nationally. As Sateren et al. (2002) stated, ongoing partnerships with professional societies may be an effective approach to increase enrollment in clinical trials. The current study's authors recommend that local communities create partnerships and identify senior centers or other established networks to use the readily available NCI materials to disseminate information about clinical trials. As the need for integrating clinical research in aging and cancer heightens, increasing the awareness and knowledge of clinical trials among seniors is an important initial step.

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References

- Adams, J., Silverman, M., Musa, D., & Peele, P. (1997). Recruiting older adults for clinical trials. *Controlled Clinical Trials, 18*, 14–26.
- Balducci, L., & Extermann, M. (2000). Cancer and aging: An evolving panorama. *Hematology/Oncology Clinics of North America, 14*, 1–16.
- Dean-Clower, E., Scheytt, J., Harley, K., Aikin, J., Axelrod, A., Graves, C., et al. (2000). Cancer Clinical Trials Education Program: A training program to reach patients and the public. *Health Promotion Practice, 1*, 90–101.
- Edwards, B.K., Howe, H.L., Ries, L.A., Thun, M.J., Rosenberg, H.M., Yancik, R., et al. (2002). Annual report to the nation on the status of cancer, 1973–1999, featuring implications of age and aging on the U.S. cancer burden. *Cancer, 94*, 2766–2792.
- Ehrenberger, H.E., Alligood, M.R., Thomas, S.P., Wallace, D.C., & Licavoli, C.M. (2002). Testing a theory of decision-making derived from King's system framework in women eligible for a cancer clinical trial. *Nursing Science Quarterly, 15*, 156–163.
- Giovanazzi-Bannon, S., Rademaker, A., Lai, G., & Benson, A.B., III. (1994). Treatment tolerance of elderly patients with cancer entered onto phase II clinical trials: An Illinois cancer center study. *Journal of Clinical Oncology, 12*, 2447–2452.
- Harris Interactive, Inc. (2000, October 28). Misconceptions and lack of awareness greatly reduce recruitment for cancer clinical trials [Press release]. Retrieved June 22, 2002, from http://www.harrisinteractive.com/news/newsletters/healthnews/HI_HealthCareNews2001Vol1_iss3.pdf
- Hutchins, L.F., Unger, J., Crowley, J., Coltman, C., & Albain, K. (1999). Underrepresentation of patients 65 years of age or older in cancer-treatment trials. *New England Journal of Medicine, 341*, 2061–2067.
- Joshi, T.G., & Ehrenberger, H.E. (2001). Cancer clinical trials in the new millennium: Novel challenges and opportunities for oncology nursing. *Clinical Journal of Oncology Nursing, 5*, 147–152.
- Lara, P., Higdon, R., Lim, N., Kwan, K., Tanaka, M., Lau, D., et al. (2001). Prospective evaluation of cancer clinical trial accrual patterns: Identifying potential barriers to enrollment. *Journal of Clinical Oncology, 19*, 1728–1733.
- Lengacher, C.A., Gonzalez, L.L., Giuliano, R., Bennett, M.P., Cox, C.E., & Reintgen, D.S. (2001). The process of clinical trials: A model for successful clinical trial participation. *Oncology Nursing Forum, 28*, 1115–1120.
- Meadows, B. (2000). Recruitment and promotion strategies for clinical trials. In A. Klimaszewski, J. Aikin, M. Bacon, S. DiStasio, H. Ehrenberger, & B. Ford (Eds.), *Manual for clinical trials nursing* (pp. 73–75). Pittsburgh, PA: Oncology Nursing Society.
- Michaels, M., Denicoff, A.M., Bright, M.A., Abrams, J., & Robinson, D. (2002). Current initiatives at the National Cancer Institute. *Oncology Issues, 17*(2), 33–35.
- National Cancer Institute. (2002). *Integrating aging and cancer research in NCI cancer centers*. Retrieved July 22, 2002, from <http://deainfo.ncl.nih.gov/concepts/AgingCancerRFA.htm>
- National Cancer Institute, Office of Cancer Communications. (1996). *The public's perception of medical and cancer research: Results of a focus group study*. Bethesda, MD: Author.
- National Institute on Aging & National Cancer Institute. (2001). *Workshop report: Exploring the role of cancer centers for integrating aging and cancer research*. Retrieved July 22, 2002, from <http://nia.nih.gov/health/nianci>
- Sateren, W.B., Trimble, E.L., Abrams, J., Brawley, O., Breen, N., Ford, L., et al. (2002). How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *Journal of Clinical Oncology, 20*, 2109–2117.
- Trimble, E., Carter, C., Cain, D., Freidlin, B., Underleider, R., & Friedman, M. (1994). Representation of older patients in cancer treatment trials. *Cancer, 74*(Suppl. 7), 2208–2214.
- Underwood, S.M., & Alexander, G.A. (Eds.). (2000). Participation of minorities and women in clinical cancer research. *Annals of Epidemiology, 10*(Suppl. 8), S1–S112.