

Empowering Natural Clinical Trial Advocates: Nurses and Outreach Workers

Diane B. Mitschke, PhD*

Kevin Cassel, MPH**

Paula Higuchi, MSW***

Partnership Program Coordinator, Cancer Information Service, dmitschke@gmail.com **Partnership Program Coordinator, Cancer Information Service, kevin@crch.hawaii.edu *Partnership Program Manager, Cancer Information Service, paulah@crch.hawaii.edu. Primary Contact Author: Kevin Cassel, MPH, Cancer Information Service, Pacific Region, Cancer Research Center of Hawai'i, 1236 Lauhala Street, Room 502, Honolulu, HI 96813, Ph: (808) 564-5916, Cell Ph: (808) 284-9097, Fax: (808) 586-3009, Administrative Asst: Shirley Nishiyama, Ph: (808) 586-5853*

Abstract

Cancer clinical trials are essential to advancing the prevention and treatment of cancer, yet adult participation rates in clinical trials remain abysmal. Despite the essential contributions of clinical trials to science and medicine, adult participation in clinical trials remains exceedingly low, with only 2%-4% of all adult patients with cancer in the U.S. participating in clinical trials. Clinical trials accrual rates in Hawai'i follow this national trend of less than 3% of eligible patients participating in trials. Recognizing the need to increase awareness about clinical trials, the National Cancer Institute's Cancer Information Service-Pacific Region, through the Hawai'i Clinical Trials Education Coalition, has employed strategic dissemination plans to train and educate key target audiences, including registered nurses, nursing students, and community outreach workers about the availability of over 90 cancer clinical trials in Hawai'i. Previous research suggests that nurses often play a vital role in increasing a patient's understanding of clinical trials and may also act as a patient advocate in regards to participation in a clinical trial. A train-the-trainer model curriculum was developed using the Clinical Trials Education Series (CTES), a collection of multi-level resources designed by the National Cancer Institute, to educate various constituents about clinical trials. The training curriculum and workshop format is adapted based on both formal and informal needs assessments conducted with audiences prior to the planned training, yet key elements remain central to the training model. In addition, an interactive, internet-based case study was developed using local place names and cultural cues to allow training participants to engage in realistic and practical methods for locating and sharing information about clinical trials with patients and the public. This training model has been implemented in a variety of settings including three statewide nursing conferences, two college campuses, and a community-based workshop. Evaluation results consistently indicate statistically significant increases in participants' knowledge and awareness related to clinical trials, and a cadre of trained clinical trials advocates is developing. Health professional advocacy towards adult participation in clinical trials is gaining momentum, with plans to expand the training model throughout the Pacific region. (PHD 2007 Vol 14 No 1 Pages 57 - 65)

Background

A number of studies have attested to the important roles of registered nurses in educating and recruiting cancer patients on clinical trials.[1-3] In fact, a randomized trial that compared registered nurses and surgeons recruitment of patients to a prostate cancer treatment trial, indicated that nurses were equally effective in recruiting patients to the study as surgeons. Further, cost-benefit analyses indicated that utilizing nurses to recruit patients to the study was more cost effective than urologic surgeons.[4] For this reason, registered nurses often fulfill the role of clinical trial coordinators,

with duties ranging from; overseeing recruitment of trial participants, serving as patient advocates, and evaluating outcomes of trials.[1,3] As medical research clinical trial sites shift from academic medical centers to community-based clinical practice settings,[3] the role of nurses in clinical trials coordination may continue to grow in both magnitude and importance. In response to the increasing need for nurses to engage in clinical trials education and implementation efforts, several U.S. universities; including the Institute for Johns Hopkins Nursing, Boston University, Duke University, and George Washington University among others, have established formal certification and training programs for nurses. These programs prepare registered nurses for certification by the Association of Clinical Research Professionals, the Society of Clinical Research Associates, or the Center for Clinical Research Practice as Clinical Research Coordinators. Certification by these bodies involves formal recognition of the nurses as clinical research professionals who have met

professional eligibility requirements and demonstrated job-related knowledge and skills required to support clinical research. These programs emphasize research design, nursing ethics, and outcome measurement, among related topics. CRC training is also available to nurses in the form of continuing education credits through these programs, most employers prefer at least two years of acute-care nursing experience for CRCs.[5]

Although registered nurses can vary in their education and training regarding medical research, several common factors contribute to the unique role that all types of registered nurses can serve in educating and recruiting patients to clinical trials. First, nurses “comprise the largest single component of hospital staff, are the primary providers of hospital patient care, and deliver most of the nation’s long-term care.”[6] Practically speaking, nurses outnumber physicians in the U.S. four to one[6]; hence, the reach and scope of registered nurses to patients far exceeds that of physicians, in terms of sheer numbers alone. Finally, nurses communicate with patients in important, and qualitatively different ways than do other members of the healthcare team.[7] Communication between nurses and patients can be instrumental or affective, depending on the needs of the patient and the comfort level of the nurse. Instrumental communicative behaviors are typically associated with addressing a patient’s need to comprehend an aspect of their disease or treatment regimen, while affective communicative behaviors address a patient’s need for emotional support.[7] A review of the literature in the area of nurse-patient communication found that emphasis on affective behaviors is characteristic of nurses’ relationships with oncology patients. This includes “facilitating behaviors such as empathy, touch, comforting, and supporting”,[7] all of which are key to communicating with and educating patients about their potential involvement in a research study. Recognizing the key role that nurses and other healthcare providers play in communicating with cancer patients about prevention, screening, treatment, and follow-up care, the National Cancer Institute created a unique and comprehensive set of educational resources called the Clinical Trials Education Series (CTES).[8] Designed to influence and increase adult participation in cancer clinical trials by targeting and training a cadre of trained health professionals to serve as advocates for clinical trials participation, the Series was distributed to organizations throughout the U.S. to infiltrate local

communities and disseminate clinical trial awareness and educational messages throughout the ranks of health professionals in local communities. This article describes the efforts of the National Cancer Institute’s Cancer Information Service, Pacific Region, to increase awareness and accessibility of clinical trials information and resources among registered nurses, nursing students, and outreach workers across the state of Hawai’i.

Training Components

Didactic PowerPoint

A basic lecture provides an introduction to clinical trials and ensures that participants have a general understanding of core concepts that are central to understanding cancer research. The CTES slide program provides a core set of PowerPoint slides and lecture notes that can be adapted based on the learning needs of the audience. The didactic portion of the training stresses the importance of clinical trials participation as key to advancing cancer research. It provides information about the phases and types of trials, while also refuting common myths about trial participation related to participant protection measures and institutional review boards. This portion of the training is useful in ensuring that training participants have accurate, up-to-date information about clinical trials in their own communities.

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Interactive Case Study

A detailed case study follows the fictional experience of Maria, a 62-year-old Filipina woman, living in Honolulu, Hawai’i, as she becomes the caregiver for her sister, Cora, who is diagnosed with Stage II breast cancer. The story line follows the women through a series of exercises that encourage the learner to complete a series of tasks such as searching for applicable clinical trials, locating relevant publications from the National Cancer Institute, and finding accurate answers to typical questions that patients have regarding clinical trials on the National Cancer Institute’s website, <http://cancer.gov>. The excerpt below exemplifies the multi-faceted features of the case study including: 1) introducing actual cancer treatment centers and trial locations; 2) acknowledging different types of clinical trials, for healthy people who are interested in cancer prevention, as well as for people with cancer that are interested in treatment trials; 3) the concept of advocacy, and sharing knowledge and enthusiasm about clinical trials

with others; and 4) skills in finding accurate information about clinical trials and in locating specific trials within a geographic region.

Case Study Excerpt A. Maria has an appointment to meet with a research assistant at the City of Hope Comprehensive Cancer Center about a breast cancer prevention trial that is testing the effects of grape seed in preventing breast cancer in postmenopausal women who are at high risk for the disease. She has been so enthusiastic about all she has learned about clinical trials that some of her excitement has rubbed off on her sister, Cora, who was diagnosed with Stage II breast cancer. Maria would like your help in finding resources to educate her sister about cancer treatment trials, and also in locating a few specific trials for which she might be eligible.

In addition to prevention and treatment trials, information and resources about survivorship are also woven into the case study. In the excerpt below, breast cancer survivor Cora assumes the role of advocate in assisting a friend with prostate cancer in locating information about supportive care studies in Hawai'i that explore the management of treatment side effects. By incorporating fluidity and flexibility in the types of trials, roles of fictional characters, and geographic locale, the case study is accessible and relevant for a variety of audiences.

Case Study Excerpt B. Cora has joined a local church where she participates in a cancer survivors' support group that meets once a month. At the support group, Cora has become close friends with Melvin, a handsome, gentlemen who is currently undergoing hormone therapy for prostate cancer. Melvin seems to have handled his initial treatments well, but now talks about awful hot flashes he's been having consistently over the past few weeks. Cora wonders if she might be able to suggest a clinical trial in which Melvin could participate to help him with the side effects he's been experiencing.

Other Training Elements

While the PowerPoint presentation and the interactive case study are the core components of a clinical trials training workshop for nurses and outreach workers, a number of other elements are also incorporated on a case by case basis, depending on the interests, needs, and time constraints of a particular audience. As is the case with any successful training model, a willingness to adapt and change the

structure of the training while maintaining the core messages and intent of the curriculum is key to the ability of the training to achieve its goals. Incorporating the use of role play generated an enthusiastic response from nursing students, who appreciated the opportunity provided within the training workshop itself to practice sharing the information they learned about clinical trials with mock patients.

Other CTES Materials

A number of other materials including publications, workbooks, videos, and CD-ROMs have also been helpful supplements to the core training curriculum. While the ideal setting for a typical clinical trials workshop for nurses would include small group access to computers for use in the interactive case study, this is not always possible. In some circumstances, training workshops can be adapted to incorporate print, rather than online resources, and clinical trial searching can be accomplished through the use of a single presenter in a more didactic approach.

Interactive Discussion

Collaborative discussion is often a key piece of the training workshop, and can help to promote a deeper understanding of the issues involved in talking with potential participants about clinical trials. Because barriers to participation in trials vary by culture, age, socioeconomic status, geographic location, and other factors, providing training participants the opportunity to generate barriers to their specific population group by facilitated brainstorming activities and interactive discussions is necessary and important at the onset of a training workshop. Table 1 displays a list of barriers to clinical trials participation by Native Hawaiians that were

Table 1. Barriers to Clinical Trial Participation Identified by Outreach Workers (N=20)

Barrier	Ranking
Lack of awareness/information	1
Fear, distrust, or suspicions of medical research	1
Cultural beliefs and values	2
Lack of access to trials	2
Lack of insurance	3
Lack of money	4
Language barriers	4
Not informed/referred by physician	4

generated by a group of outreach workers who attended a clinical trials training workshop. These barriers were ranked by the outreach workers in order from 1 (most serious impediment to trial participation) to 5 (least serious impediment to trial participation). The results of this ranking clearly indicate a need for education and training regarding the availability of clinical trials and the purpose and procedures associated with medical research in Hawaii.

Results

To date, over 300 nurses, nursing students, and outreach workers across the state of Hawai'i have participated in an educational workshop or seminar that has implemented the core clinical trials curriculum described in the previous section. Workshop participants individually and anonymously completed a short (10-item) written assessment of their knowledge and awareness regarding clinical trials prior to and immediately following the education workshop or session. Because the training workshops are tailored to address the specific needs of each audience, these assessments were specifically tailored to the group being trained as well.

which identify and stage cancers more accurately: (multiple choice)

2. Identify 2 barriers patients face when considering participating in a clinical trial. (short answer)
3. <Blank> is a method used to prevent bias in research. (multiple choice)
4. List 2 types of clinical trials. (short answer)
5. Only people who have cancer are eligible to participate in a cancer clinical trial. (True/False)
6. Informed Consent is a process where potential participants learn the details of the study before deciding whether they wish to participate. Once a person signs the consent form, they are not permitted to leave the study until its conclusion. (True/False)
7. List two sources of information about clinical trials. (short answer)
8. The Cancer Information Service is a public service of the National Cancer Institute and provides the latest, most accurate information about cancer to which group(s) of people? (multiple choice)

Table 2. Training Evaluation Feedback: Graduate Nursing Students (N=17)

All students agreed that:

- < Content of the course matched the stated learning objectives
- < Speakers were knowledgeable about the subject matter
- < The course made them more familiar with the resources available through the National Cancer Institute and Cancer Information Service
- < They now have a better understanding of why clinical trials are important in the progress against cancer
- < They now have a better understanding of how clinical trials participants' rights and safety are protected
- < They now have a better understanding of the clinical trials process and why clinical trials may be a viable treatment option
- < They would recommend the training to other nursing students
- < The information was presented in an easily understood manner
- < They are now willing to talk with others in their respective communities to increase awareness about clinical trials
- < They now plan to use the tools they had been provided to educate others about clinical trials

As a result, the evaluation data is difficult to condense and report in aggregate form. Below is a sample list of questions that required either, multiple choice, short answer, and true/false responses.

Sample Questions

1. This type of clinical trial tests new procedures

Through an examination of the evaluation data from each individual training, results indicate that the training model is successful in engaging training participants in an active learning process that increases their knowledge about clinical trials. All participants completed a written evaluation of the training following their participation in a workshop or session. Table 2 provides a sample of

the type of written feedback typically given from a group of trainees. These particular data were collected from a group of advanced practice nursing students (N=17) who participated in a training session in Spring 2006.

In addition to the consistently positive feedback that is generated regarding the structure of the clinical trials training workshops and specific components within the training model, significant differences in knowledge are observable when comparing written pre- and post-workshop knowledge assessments. Again, a set of 10 multiple choice questions that assess knowledge were developed specifically for each training. To examine the difference from pre-test to post-test, we used the McNemar test for nonparametric statistics and ran CrossTabs to attain levels of significance and a chi-square for each item.

Topics that consistently produce significant gains in knowledge include: 1) identifying the approximate percentage of adult cancer patients currently participating in clinical trials; 2) identifying specific barriers that inhibit participation in cancer clinical trials; and 3) identifying at least two types of clinical trials (e.g., prevention, screening, treatment, and supportive care, etc.). For example, data from a workshop held for undergraduate nursing students (N=71) in the fall of 2005 indicated that students significantly increased their knowledge related to the percentage of adult cancer patients currently participating in clinical trials due to their participation in the clinical trials education workshop ($\chi^2=45.021$, $p<.05$). In a workshop with undergraduate nursing students (N=32) held in Spring 2006, students were significantly more likely to understand that participation in clinical trials was not limited to cancer patients ($\chi^2=6.125$, $p<.05$). Questions that were commonly administered at trainings for undergraduate and graduate nurses that did not show significant improvement in correct responses included: "randomization is a technique to reduce bias" (98% correct responses in pre-tests in one sample), and "people who do not have cancer are eligible to participate in trials" (87% correct in pre-tests in one sample). Clearly, baseline knowledge about these issues was high among the nurses trained.

While clinical trials participation rates are low across all population groups in Hawai'i, participation also varies by ethnicity. Historically, clinical trials in Hawai'i have been unsuccessful in attracting Native Hawaiian and Pacific Islander participants. For example, although Native Hawaiians comprise approximately 12% of

Hawai'i's cancer cases,[9] less than 7% of all clinical trial participants are from this ethnic group.[10] Some of the specific barriers for Native Hawaiians include a cultural bias towards western medicine, feeling uncomfortable with medical providers, and clinical trials are not being offered by medical providers as an option.[11] In working with outreach workers within the Native Hawaiian community, the standard training model was adapted to incorporate discussion regarding the application and relevance of traditional values such as *kokua* (to help, aid, and assist), *malama* (to take care, provide a service), and *lokahi* (to be in agreement, harmony). Twenty-two (22) Native Hawaiian outreach workers were trained using the culturally-tailored version of the model curriculum.

Significant differences from pre- to post-assessment were seen in the outreach workers' ability to name four different types of clinical trials ($\chi^2=4.9$, $p<.05$).

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Questions that did not demonstrate a significant change from pre-test to post-test in a particular training included:

1. Ability to explain how CTES contributes to progress against cancer (90% correct pre-test, 95% post-test).
2. Ability to define clinical trials (85% pre-test, 90% post-test).
3. Ability to explain how trainee might utilize CTES in the future (65% pre-test, 85% post-test).

This result indicates a high baseline level of initial knowledge about clinical trials and CTES among this group of outreach workers.

During the year following the initial training, the trained outreach workers educated a total of seventy-four (74) individuals on each of the state's five major islands about clinical trials, and eight (8) of these individuals enrolled in a clinical trial, for a 9.25% success rate. In addition, the trained outreach workers also assisted in conducting a clinical trials training sponsored by 'Imi Hale, the Native Hawaiian Cancer Awareness, Research, and Training Network, for outreach workers from the Hawai'i Breast and Cervical Cancer Control Program.

Discussion

Raising awareness about clinical trials among registered nurses and outreach workers who are in direct communication with cancer patients and their friends and families, is an important step in developing a cadre of clinical trials advocates that may influence participation rates. It is clear that health professionals have a unique influence on the choices that their patients make regarding participation in clinical trials;

yet, efforts to systematically educate nurses about core concepts in clinical trials research have lagged behind the focus on clinical research included in medical education.[3] Now, as growing numbers of nurses and other health professionals find themselves tasked with various responsibilities in the area of study coordination, patient education, and outcome evaluation, the need for clinical trials education in the nursing work force is clear. Nurses and other allied health professionals are often primary providers of patient care and education in many settings. As such, they have a unique perspective on ways to improve patient outcomes. Today, clinical trials research has expanded beyond treatments to encompass broader patient outcomes including building family support, managing the side effects of therapy, and improving quality of life. Clinical trials trainings for nurses and other health professionals may have the added effect of empowering this group to have an increased role in the development of new areas for clinical trials research. Finally, patients today have unprecedented access to medical and health information due to the diffusion of the internet.[12] Clinical trials trainings develop healthcare providers' competency in accessing credible resources on medical information, and can enable nurses and other allied health professionals to respond to the increasing demands for health information from patients.

Conclusions

It is expected that the clinical trials training of nurses and allied health professions will ultimately improve the adult participation rates in cancer clinical trials. The tremendous advances seen in the treatment of childhood cancers are attributed to the total integration of clinical trials research as part of a routine care protocol for children.[13] A paradigm shift is necessary in adult oncology so that clinical trials become a part of the standard of care in oncology. Training and education of nurses and outreach workers is a first step in pushing forward this new paradigm.

The impact of clinical trials training for nurses and other health professionals serves to increase familiarity and comfort for these professionals to include clinical trials as part of a patient's healthcare options. In turn, this increased awareness of trials and the subsequent boost in trial accrual rates can result in an improved ability to manage cancer. The clinical trials trainings for registered nurses, nursing students, and outreach workers revealed that the interactive train-the-trainer model curriculum increased participants' knowledge

and awareness about clinical trials. However, follow-up evaluations are needed to determine if knowledge gained is retained, and whether trainees have discussed clinical trials with potential participants. Clinical trials training and continuing education is important for health professionals and community outreach staff who are responsible for reaching those experiencing the greatest cancer health disparities, including Native Hawaiians, Pacific Islanders and Asians.

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