
Training Community Nurses & Administrators to Implement Cancer Clinical Trials

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Death from cancer in the U.S. declined 20 percent from 1991 to 2010, from 214.1 deaths per 100,000 to 171.8 deaths per 100,000, respectively.[1] This dramatic improvement in cancer survival is directly attributable to the remarkable findings coming out of clinical trial research,[2] which serves to highlight the need for the continued creation, support, and completion of cancer clinical trials. While today's clinicians recognize the value clinical trials offer in conquering cancer and improving quality of life of cancer patients undergoing treatment,[2] many community cancer programs have not been able to improve clinical trial accrual for their cancer patients.[3]

To help in the effort to improve access to clinical trials in the community setting, the American College of Surgeons Commission on Cancer (CoC) established new accrual goals as part of its *Cancer Program Standards 2012: Ensuring Patient-Centered Care*.[4] Standard 1.9 requires "a percentage of patients be accrued to cancer-related clinical trials each year. The clinical trial coordinator or representative reports clinical trial participation to the cancer committee yearly."[4] The standard states that the community cancer program must accrue 2 percent of their annual analytic cases to clinical trials by 2015 to meet the standard; it requires 4 percent of the analytic cases for commendation. The comprehensive community cancer program requires a minimum of 4 percent accrual, with 6 percent necessary for commendation.

Implementation of this CoC standard requires that community cancer programs build an adequate clinical trials infrastructure staffed by qualified administrative, nursing, and data management personnel. Unfortunately, many community cancer programs do not have the infrastructure, institutional resources, or qualified personnel to carry out the myriad tasks involved in accruing and maintaining patients on cancer clinical trials. Accordingly, the National Cancer Institute (NCI), among other organizations, is looking to provide support for these programs. For example, in 2012, nurse researchers from the Hospital of the University of Pennsylvania, City of Hope, and the Mount Sinai Hospital received an NCI-funded R25 grant to support the education of both clinical trial nurses and administrators to meet CoC Standard 1.9, through a two-day curriculum that would be provided twice a year for three years, with an additional course in year four. Courses began in 2013 and continued through the spring of 2016, with a total of seven courses held. This article describes the program curriculum and participant evaluations for courses one through three; Course 1 was held May 18-19, 2013, Course 2 was held October 5-6, 2013, and Course 3 was held June 5-6, 2014.

The Program

The aim of the program, *Training Community Nurses & Administrators to Implement Cancer Clinical Trials*, was to develop and administer a curriculum that can be used to train community-based nurses and administrators to implement clinical trials and increase accrual to meet CoC accreditation standards. The curriculum was built on the foundations of the:[5-7]

- Oncology Nursing Society (ONS) Clinical Trials Nurse Competencies
- International Conference on Harmonization Good Clinical Practice
- Institute of Medicine report on building a clinical trials system for the 21st Century
- Code of Federal Regulations.

Participants were recruited through a variety of approaches. For example, researchers collaborated with CoC leadership to obtain email contact information for cancer program administrators from accredited programs. Researchers also contacted the ONS special interest group for clinical trials nurses, as well as other multicultural focused nursing groups: the American Black Nurses Association, the National Association of Hispanic Nurses, and the Philippine Nurses Association of America. The participant application included demographic and professional information, statements of interest, and a list of three goals to be implemented by participants when returning to their care setting.

Historically, the education of clinical research nurses and those administratively responsible for the conduct of clinical trials was often limited to "on the job" training experiences.[3] In the current research environment, this approach is less than optimal. The increased complexity of trial design, the exponential increase in regulatory demands, advances in informatics, and the need for patient protection make a compelling case for a more formal,

systematic approach to the education and skill maintenance of cancer clinical research personnel.

Quality cancer research requires highly competent clinical research personnel with knowledge of:

- Research methods
- Regulatory and compliance issues
- Oncology-specific reimbursement and patient management.

The framework identified in Figure 1 (below) shaped the development of the content presented in the educational program and identified the teaching strategies to be used.

The two-day curriculum was developed by investigators and content experts from around the country, using teaching methods that were based on adult learning principles and performance improvement strategies, including lectures, discussion, small group work, and individual participation activities.[8] Table 1, below, describes the education approaches used to apply the conceptual framework to the education program. A sample of the two-day agenda is provided in Table 2, right.

Separate workshops were held simultaneously for administrators and nurses, and focused on specific aspects of their roles in cancer clinical trials. Additionally participants were asked to submit three goals that they planned to implement in their own cancer programs over the 18 months post course. Evaluation of

Figure 1. Conceptual Framework for Curriculum Planning

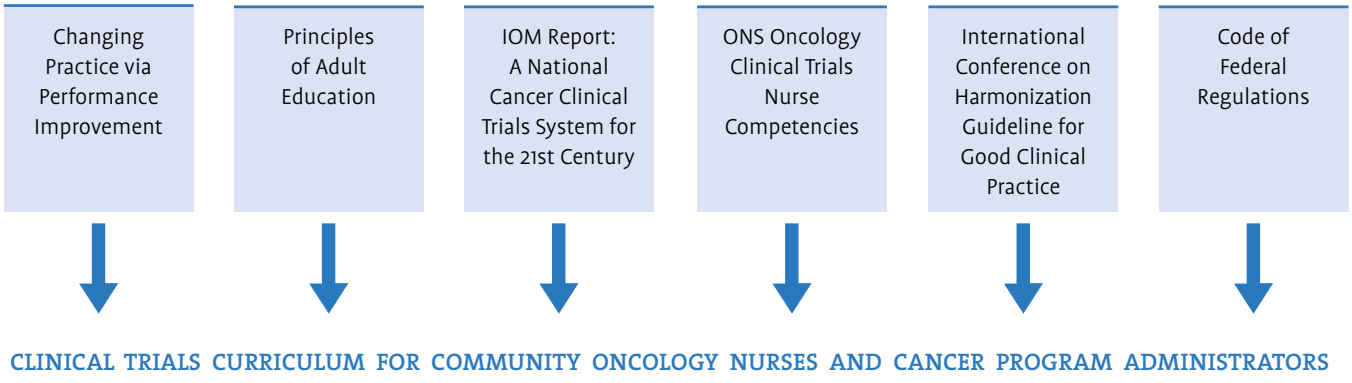


Table 1. Application of Conceptual Framework to Curriculum Development

Changing Practice via Performance Approval	• Pre- & post-clinical trials knowledge test • S.M.A.R.T. goal follow-up
Principles of Adult Education	• Mixed didactic presentations • Small group breakouts • Conference call follow-up
IOM Report: A National Cancer Clinical Trials System for the 21st Century	• Presentations: Why do Clinical Trials?, Overview of History and Background of Clinical Trials Research, Ensuring Quality in Clinical Trials, and Keys to Success in the Community Setting
ONS Oncology C.T. Competencies	• Didactic lectures to improve knowledge and prepare for competency exam
International Conference on Harmonization Guideline for Good Clinical Practice	• Presentations: Overview of Protocol Development, Regulatory & Legal Issues, Roles & Responsibilities, and Patient Management
Code of Federal Regulations	• Presentations: Responsible Conduct of Research and Why do Clinical Trials?

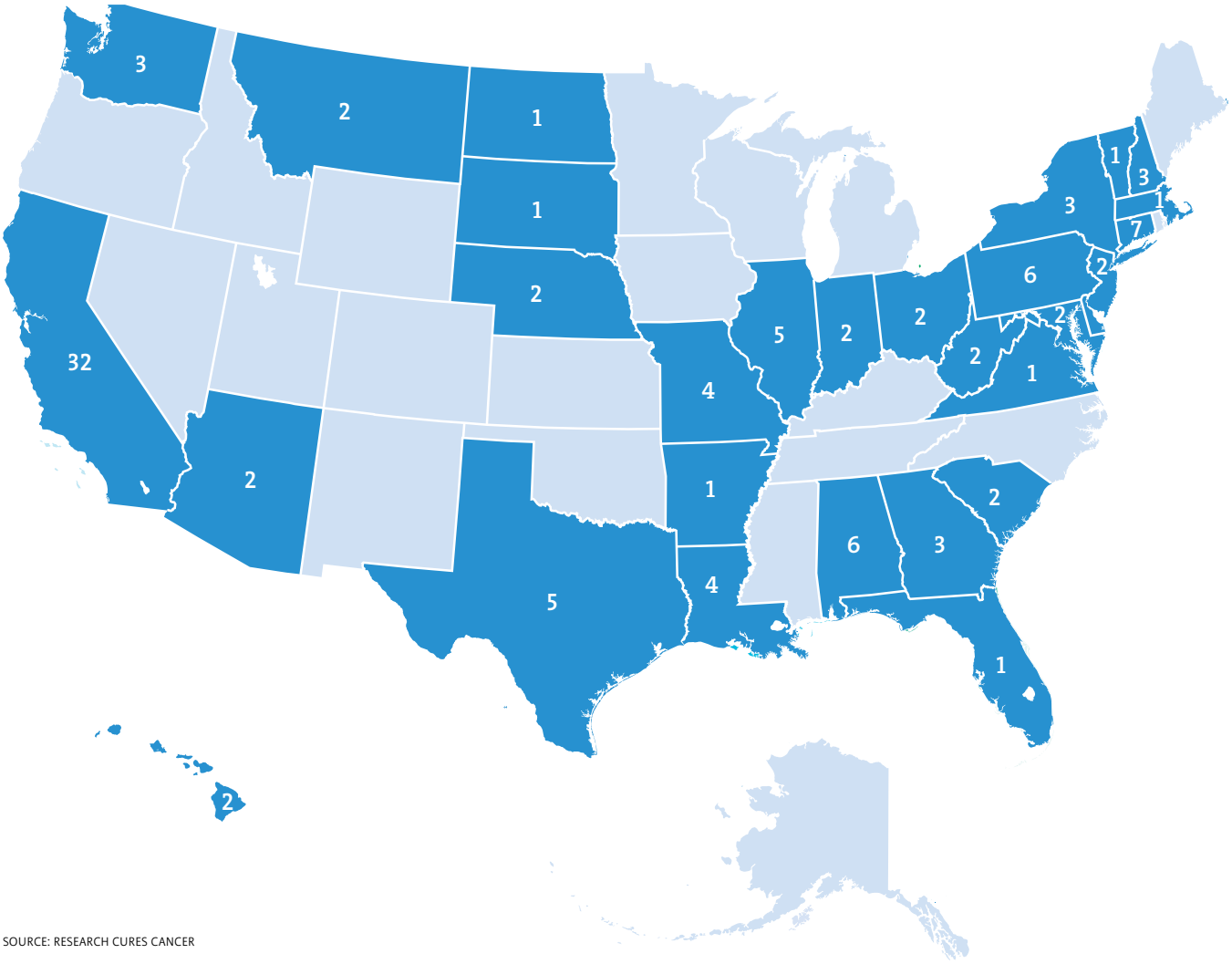
Table 2. Training Community Nurses & Administrators to Implement Cancer Clinical Trials

AGENDA: DAY 1	
Welcome & Overview	All
Pre-Test & Completion of Involvement in Clinical Trials Survey	All
Why Do Clinical Trials? Research Cures Cancer	All
Overview of the History & Background of Clinical Research	All
Break	All
Overview of Clinical Trials Designs	All
Overview of a Clinical Trial Protocol	Clinical participants
Protocol Development	Administrative participants
Regulatory & Legal Issues	All
Lunch	All
Roles & Responsibilities of the Research Team	All
Clinical Trial-Related Communication	All
Break	All
Goal Refinement, Completion of Day 1 Course Evaluation	All
Networking & Poster Session	All
AGENDA: DAY 2	
Barriers to Recruitment & Retention of Subjects in a Culturally Diverse World	All
Clinical Trials Patient Management: Pre-Study, Active, and Follow-Up Phases	Clinical participants
Clinical Trials: Administrative Workshop	Administrative participants
Break	All
Data Management	Clinical participants
Working with Sponsors	Administrative participants
Lunch	All
Ensuring Quality in Clinical Trials: Good Clinical Practices, SOPs, Audits	All
Capitalizing on Clinical Trials: Keys to Success in the Community Setting	All
Q&A, Post-Test, Goal Finalization, Completion of Day 2 Course Evaluation	All

goal achievement provided a way to document changes in practice patterns. Goals were reviewed by program staff and principal investigators at 6, 12, and 18 months post course. An additional mechanism to allow for interaction among participants and principal investigators included monthly conference calls over the four months following the two-day course. During these calls, participants discussed their goal-focused activities, as well as asked for and shared additional resources and information related to clinical trials program development barriers and facilitators. Faculty participated in the calls to provide support for participants' individual questions or concerns.

Program resources included a binder with the syllabus content consisting of an overview, objectives, a content outline, slides, references, and resources for each agenda topic. Additional resources such as the NCI Clinical Trials Booklets and other clinical trials-focused resources were available for participants

Figure 2. Course Participants by State



SOURCE: RESEARCH CURES CANCER

to review and obtain if relevant to their settings. A program participation announcement letter allowed attendees to share their course completion with hospital leadership. Participants also received a CD with overview slides and statistics to help them deliver an in-service session on clinical trials and marketing strategies at their individual cancer programs.

Results

The first three courses had 108 participants, including 56 nurses and 52 administrators from 29 states (Figure 2, above). Participant credentials, positions, setting characteristics, patient culture, and ethnicity were documented, see Table 3, pages 63–64.

Pre- and post-knowledge tests were used to evaluate administrators and nurses before and immediately after the course. The knowledge scores of nurse participants showed a statistically significant increase from pre- to post-testing (p=0.01) with a change in score from 65.49 percent to 70.03 percent. The same approach was used to evaluate administrator knowledge scores, which also showed a statistically significant increase from pre- to post-testing (p=0.00) with a change in score from 71.47 percent to 76.77 percent.

Overall course evaluations (range 1=lowest to 5= highest) for day 1 and day 2 were as follows:

- What was your overall opinion of this conference? Ranged from 4.5 to 4.89.
- Was the information stimulating and thought provoking? Ranged from 4.53 to 4.94.
- To what extent did the course meet the objectives and your expectations? Ranged from 4.22 to 4.85.

Descriptions of faculty average evaluations (range 1=lowest to 5=highest) for day 1 and day 2 are provided in Table 4, page 65.

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Table 3. Participant Demographics

POSITION DESCRIPTION	N=108	%
Administrators	52	48.1
Nurses	56	51.8
GENDER OF PARTICIPANTS	**N=95**	**%**
Female	86	90.5
Male	9	9.5
ETHNICITY OF PARTICIPANTS	**N=90**	**%**
Not Hispanic or Latino	82	91
Hispanic	8	8.9
RACE OF PARTICIPANTS	**N=90**	**%**
American Indian or Alaskan Native	0	0
Asian	7	7.8
Black or African American	2	2.2
Native Hawaiian or Pacific Islander	0	0
White	80	88.9
More than one race	1	1.1
Other	0	0
TYPE OF INSTITUTION	**N=96**	**%**
Academic Medical Center	15	15.6
Community Hospital	64	66.7
Integrated Health System	12	12.5
Community Cancer Center/Ambulatory Care	1	1
VA	4	4.2
Pediatric Hospital	0	0
Other	1	1.1
ACCREDITED BY AMERICAN COLLEGE OF SURGEONS	**N=95**	**%**
Yes	89	93.6
No	6	6.3
ACCREDITATION DESIGNATION	**N=92**	**%**
Academic Comprehensive Cancer Program	17	18.9
Community Cancer Program	18	20.0
Comprehensive Community Cancer Program	43	47.8
Freestanding Cancer Center Program	1	1.1
Integrated Network Cancer Program	1	1.1
NCI-Designated Comprehensive Cancer Program	4	4.4
Pediatric Cancer Program	2	2.2
Veterans Affairs Cancer Program	2	2.2
Other	1	1.1

table continued on page 64

Table 3. Patient Demographics, *continued from page 63*

ETHNICITY OF PATIENT POPULATION	%
Not Hispanic or Latino	81.36
Hispanic	16.55
RACE OF PATIENT POPULATION	**%**
American Indian or Alaskan Native	1.04
Asian	5.29
Black or African American	12.28
Native Hawaiian or Pacific Islander	1.95
White	73.43
Other	5.93

Attendees at the two-day course, *Training Community Nurses & Administrators to Implement Cancer Clinical Trials*, participate in a breakout session.

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Going Forward

Education for cancer professionals is one approach to addressing the challenges of increasing participation in cancer clinical trials. Based on these data, the *Training Community Nurses & Administrators to Implement Cancer Clinical Trials* curriculum was well received by attendees. Further, participants had the opportunity to interact with peers from across the country—both during the workshop and in the months following the workshop.

During the interactive sessions, participants indicated that this education was needed because many were new to their role or their departments were new to clinical research. When attendees left the two-day program, they had the support and mentorship of the faculty. Faculty made four monthly phone calls to participants immediately after the course; long-term follow-up involved evaluating achievement of individual goals at 6, 12, and 18 months post course. As goals are followed up and analysis is completed, faculty will be able to identify any institutional changes that have occurred and whether this professional education has made an impact on increasing accrual and retention of patients to cancer clinical trials—the ultimate outcomes of this program. Currently post-course goal analysis is in progress, and results will be submitted for publication once follow-up is completed. (NCI funding-1R25CA 168551-01). OI

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Table 4. Overall Course & Faculty Evaluations

COURSE EVALUATIONS OVERALL	RANGE (1=Lowest to 5=Highest)		
	COURSE 1	COURSE 2	COURSE 3
Overall opinion of this course	4.50	4.85	4.50
Was the information stimulating and thought provoking?	4.50	4.94	4.52
To what extent did the course meet the objectives and your expectations?	4.20	4.85	4.20
FACULTY EVALUATIONS OVERALL	**RANGE (1=Lowest to 5=Highest)**		
	COURSE 1	COURSE 2	COURSE 3
Clarity of presentation	3.78–4.95	3.59–4.86	4.71–4.96
Quality of content	3.72–4.95	3.81–4.79	4.69–5.00
Value to you as a clinician	3.94–4.95	3.91–4.75	4.70–4.95