

Initiative to Standardize a Clinical Trial Educational Program

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Inconsistencies in how clinical trial information is disseminated and what information is given can adversely affect the number of patients enrolled (Avis, Smith, Link, Hortobagyi, & Rivera, 2006; Cox, 2002; Cox & McGarry, 2003; Ellis, Butow, & Tattersall, 2002; Ellis, Butow, Tattersall, Dunn, & Houssami, 2001; Hutchison & Campbell, 2002; Stevens & Ahmedzai, 2004; Wright et al., 2004), patient compliance with trial expectations (Kornblith et al., 2002; McTiernan, 2003; Oppenheim, Georger, & Hartmann, 2005; Stevens & Ahmedzai, 2004), and the validity of trial results (Beskow, Sandler, Millikan, & Weinberger, 2005). Additionally, inconsistencies can compromise patients' ability to make informed decisions about whether to participate in clinical trials (Barrett, 2005; Menikoff, 2005; Weinfurt et al., 2005).

Providing clinical trial information at a major comprehensive cancer center can be a challenge. At the start of the project described in this article, the University of Texas MD Anderson Cancer Center had few clinical trial educational resources, no standard clinical trial education program, and no systematic way to communicate such information to patients, staff, and the public. Patients reported being offered clinical trials as treatment options but having no tools to help them make decisions. In this article, the authors describe a needs assessment and a process survey to determine the clinical trial education needs of patients and the education practices of nursing research staff. The authors then discuss how a standard clinical trial education program was developed and implemented.

Methods

To begin, the authors informally asked staff what resources they used to educate patients about clinical trials and what information they deemed necessary to include in their teaching materials. Us-

ing that information, the authors developed a 13-item needs assessment. With institutional e-mail groups, the authors identified all cancer center research nurses, research nurse supervisors and managers, advanced practice nurses, and research data coordinators, for a total of 262 prospective survey participants, who received the needs assessment via Lotus Notes (IBM Software Group) and a reminder two weeks later.

Although the needs assessment captured the resources staff used to teach patients about clinical trials, it did not clarify who was using them, when they were using them, or how they were using them. The needs assessment did not identify the process by which staff identified patients for a particular trial, enrolled them, or educated them about clinical trials, and it did not clarify the role of those involved in the process. Therefore, the authors developed a 12-item follow-up process survey based on the results of the needs assessment. They administered it to the same 262 individuals using SurveyMonkey™ (www.surveymonkey.com). The survey sought to elucidate which patients were educated about clinical trials and at what point they received education about clinical trials (e.g., before or after signing the informed consent). The questions addressed who introduced and matched patients to clinical trials, who educated them about clinical trials and the informed consent process, and when and how each step happened.

Results of the Needs Assessment

Of the 262 people surveyed, 109 (42%) responded to the needs assessment. Respondents included research nurses (62%), data coordinators (21%), research nurse supervisors (10%), advanced practice nurses (5%), and other personnel (3%) (i.e., two research nurse managers and one clinical research program coordi-

nator) (because of rounding, percentages do not total 100). The needs assessment revealed that respondents came from a variety of clinical areas: blood and marrow transplantation (4%), brain and spine (6%), breast (7%), cancer prevention (7%), child and adolescent (2%), gastrointestinal (13%), genitourinary (7%), gynecologic (2%), head and neck (5%), leukemia (10%), lymphoma and myeloma (5%), melanoma and skin (5%), palliative care and rehabilitation medicine (2%), plastic surgery (3%), radiation treatment (10%), sarcoma (2%), thoracic (4%), and other (9%).

The needs assessment revealed the topics most often included when participants educated patients about clinical trials: the benefits of participating in a clinical trial (88%), where patients can find information about clinical trials (85%), the informed consent process (79%), phases of clinical trials (77%), the cost of clinical trials (70%), and placebos (29%). In addition, most of the respondents' (72%) comments indicated that they would like all of the topics to be included in an educational booklet on clinical trials, emphasizing compliance.

Most referrals for more information about clinical trials were made to the institution's Web site (62%). Fewer referrals were made to the National Cancer Institute (48%), the cancer center's learning centers (40%), the cancer center's information phone line (25%), and videos available through a closed-circuit television system (6%) (see Table 1).

Results of the Process Survey

Of the 262 surveyed, 115 (44%) responded to the process survey. Survey results indicated that clinical trial information was introduced most often by a physician (87%), research nurse (82%), data coordinator (10%), other (10%), or clinic nurse (9%) (see Table 2). Respondents also reported that clinical trial

Table 1. Needs Assessment Results

Variable	%
Topics covered	
The benefits of participating in a clinical trial	88
Where patients can find information about clinical trials	85
Informed consent process	79
Phases of clinical trials	77
Cost of clinical trials	70
Placebos	29
Resources used	
Cancer center's Web site	62
National Cancer Institute resources	48
Cancer center's learning centers	40
Cancer center's information line	25
Videos available through a closed-circuit television system	6
N = 109	
Note. Respondents could choose more than one answer.	

information was introduced most often when a patient met eligibility criteria (83%), when a patient's treatment failed (47%), or when a patient was new (22%) (see Table 3) (responders could check all possible answers for each question). Other respondents (12%) reported that they introduced the information when they believed a patient would be a good candidate or when a patient was referred by his or her primary physician.

Participants used a variety of methods to match patients to clinical trials (see Table 4). Before a patient signed an informed consent, the research nurse (96%) or physician (75%) explained the form to the patient. Others who explained the form included the data coordinator (12%); physician assistant, advanced practice nurse, or pharmacist (6%); and clinic nurse (2%). A patient's understanding of informed consent was validated most often by a question-and-answer discussion about the new information (62%) or by staff asking patients to restate the new information in their own words (58%). Other validation methods included using a translator, keeping it

simple (using graphics or cartoons), and asking patients whether they understood or had any questions or concerns (19%). If patients had questions after signing the informed consent, their main contact was the research nurse (81%) or doctor (12%). Seven percent responded that other staff (e.g., data coordinator, physician assistant, advanced practice nurse, pharmacist, a combination of research nurse, doctor, and data coordinator) answered patient questions or concerns once they signed the informed consent.

The data coordinator role varied throughout the institution; they performed all or some of the following responsibilities.

- Assist the research nurse.
- Screen for trial eligibility.
- Obtain signed consent forms.
- Enroll patients in clinical trials.
- Coordinate appropriate tests per protocol.
- Collect data (e.g., laboratory specimens, tissue samples, medical record information).
- Document adverse events and responses to drugs.
- Enter patient information in a computer database or case book report.
- Ensure that all aspects of regulatory compliance are met.
- Prepare for and assist during monitoring visits and audits.
- Provide quality assurance.

The results were reviewed by executive staff in the patient education office, who determined that an institutional clinical trial education initiative should be implemented to address the inconsistencies in clinical trial education and develop a standard approach to patient education.

Program Planning and Implementation

An interdisciplinary team was assembled, including physicians and staff from the areas of clinical research, patient education, public education, clinical nursing and research nursing, nursing professional development, physician relations, and community oncology. A core group of individuals were approached and asked to participate based on their educational foci. After much discussion regarding inconsistencies in clinical trial education and factors contributing to the inconsistencies (e.g., limited knowledge of available educational resources, role variation among clinical areas regarding patient teaching about clinical trials), the team identified its goal: to establish

processes that would ensure consistency in clinical trial education for patients, staff, and the public. The objectives established to achieve the goal were (a) to develop and implement consistent staff training, patient teaching guidelines, and educational resources; (b) to identify opportunities for increasing patient awareness of clinical trials; and (c) to assess patient and public access to information about specific clinical trials at the cancer center. To accomplish the objectives, the team divided into three subcommittees: the patient and family committee, the staff and community committee, and the institutional committee. Each committee met at least monthly for about one year to identify specific issues and to outline an action plan to address the issues. In addition, each of the committee chairs cross-collaborated to ensure that each group was developing strategies to support a consistent message and similar language during clinical trial education for patients, families, staff, and the community.

The Patient and Family Committee

The patient and family committee discussed how to standardize patient and family education by enhancing current clinical trial educational resources or developing new resources (e.g., videos, orientation class content, learning center resources, booklet). In addition, the committee reviewed the literature for patient and family education to see how others had addressed the issue.

The committee surveyed patients and families (N = 25) from the genitourinary,

Table 2. Who Provides Clinical Trial Information to Patients?

Provider	%
Physician	87
Research nurse	82
Data coordinator	10
Clinic nurse	9
Other ^a	10

N = 115

Note. Respondents could choose more than one answer.

^a Physician assistant, advanced practice nurse, pharmacist, data analyst, research manager or assistant, business center, surgery scheduler, or phase I staff

gastrointestinal, and breast centers about the MD Anderson Cancer Center clinical trial booklet. They reported being very satisfied with the booklet; all said it was easy to use and helped them know what questions to ask their doctors and nurses. Most (89%) also said that the booklet was easy to understand and had just enough information. Eighty-five percent said the booklet answered their questions and concerns about participating in a clinical trial, 12% said they still had more questions, and 3% said they did not have any questions before reading the booklet but did after reading the booklet. The questions that remained, however, generally were not those the booklet could answer; they related to, for example, prognosis, data on specific treatments, or payment on specific protocols. Sections of the booklet that respondents found most helpful were the description of phases, discussion of benefits and risks, suggested list of treatment-specific questions for patients to ask themselves, and decision-making suggestions. Finally, the survey asked how patients felt about clinical trials before and after reading the booklet. The survey revealed that before reading the booklet, 23% were anxious, 23% were undecided, 39% were optimistic, and 15% had more questions. After reading the booklet, the percentages changed to 4%, 8%, 72%, and 16%, respectively.

From the survey results and the literature review, the committee identified several strategies to enhance the proposed patient and family clinical trial education program. The strategies included developing a decision aid that would support a patient's choice to enroll or not enroll in a clinical trial; developing specific pediatric and phase I resources (e.g., video, print); revising the booklet and video content to include information regarding tissue banking, cancer registries, and the significance of population-based research; and including information on why patients may or may not want the results of a research study in which they participated.

The Staff and Community Committee

In reviewing the clinical trial educational resources for staff and community, the committee identified those that already were available and those that needed to be updated or developed. First, the committee updated the cancer center's Web site with current clinical trial information based on the clinical

Table 3. When Are Clinical Trials Most Often Introduced to Patients?

Introduction Criteria	%
When a patient meets eligibility criteria	83
When a patient's treatment fails	47
When a patient is new	22
Other	12

N = 115
Note. Respondents could choose more than one answer.

trial booklet. Second, the committee investigated the operational aspects of the public education office's clinical trial education program, including (a) the distribution of articles about research and clinical trials that targeted people in minority cultures and media, (b) the development of educational and promotional materials for clinical trial awareness and recruitment, (c) the schedule for presenting clinical trial information at events and health fairs, (d) the ways the institution showcases its role in research and clinical trials when conducting institutional tours, and (e) the materials used to present the National Cancer Institute's "Clinical Trials Education Series" training to healthcare providers, community-based organizations, and community health liaisons. From the information obtained, the committee saw an opportunity to incorporate clinical trial information into the CancerWise Community Speakers Bureau. The bureau educates more than 6,000 people each year in worksite, school, and community settings. Third, the committee spent some time learning about the clinical trial educational efforts of the volunteer services department. The department's contributions included publishing clinical trial articles in a quarterly patient newsletter and coordinating special programming focused on clinical trials and survivorship awareness.

The committee also reviewed how staff was educated about clinical trials. The committee recognized that the physicians and nursing research staff who enroll patients in clinical trials are required to attend monthly training classes on the history and ethics of clinical

research, federal regulations, clinical practice guidelines, and institutional policies for the protection of human subjects. They also are required to review online information about clinical ethics and research. Upon closer review, however, the committee realized that no patient teaching and learning principles and application of such principles were part of the curriculum. As a result, the committee collaborated with the Office of Research Education and Regulatory Management to incorporate a teaching and learning principles section into the training classes. The committee also suggested the development of a clinical trials e-learning module to complement the class content. To augment the effectiveness of the curriculum addition, the committee developed and implemented clinical trial teaching plans—standardized patient education and preprinted medical record forms to assist staff with documenting patient and family teaching about clinical trials.

The Institutional Committee

Members of the institutional committee looked at the big picture—whether an institution-wide communication plan was in place to ensure consistent clinical trial education for patients, staff, and the public. First, the committee communicated with the other two committees to determine what resources already were in place and what resources were needed to fill the gaps. The institutional committee also reviewed other comprehensive cancer centers' Web sites to benchmark how they posted their clinical trial information. Second, the committee devised a communications plan to highlight the institution's clinical trial efforts and promote the use of the clinical trial resources. To accomplish that goal, the committee outlined face-to-face communication tactics (e.g., presentations to senior management, executive councils, clinical operations management, physicians, research staff, supportive care staff, and patients); electronic communication tactics (e.g., clinical operations newsletter, patient education newsletter, nursing news and information update, monthly e-mail reminders to research staff about available patient education resources, closed-circuit television programs, clinical trials home page link, online live chat with senior leadership); publications and print tactics (e.g., employee and faculty online newsletters, alumni newsletter, weekly patient and caregiver newsletter, volunteer newsletter); and finally,

external communication tactics (e.g., continuing to work with Internet services to create additional content and explore opportunities to further highlight clinical trial education).

Discussion

The needs assessment and process survey provided data that were helpful in clarifying how clinical trial education was implemented at the cancer center. The needs assessment and process survey were sent to all research staff involved in the daily operations of clinical trial education and enrollment. The needs assessment revealed inconsistent delivery of clinical trial education and, more specifically, inconsistency in the type of patient education resources used by staff to teach patients. In turn, the process survey revealed inconsistency in how patients were matched, educated, and enrolled in clinical trials, and it revealed inconsistency in staff roles across clinical areas and disciplines. One limitation to the findings was that physicians were not included in the survey; however, research staff reported the major role that physicians play in matching, educating, and enrolling patients in clinical trials. Future efforts will include promoting the clinical trial education program to physicians and soliciting their feedback.

Once the executive staff reviewed the findings, an institutional clinical trial education initiative was launched. Through the initiative, the institutional committee was able to solicit the staff support and commitment needed to establish processes that would ensure consistency in clinical trial education for patients, staff, and the public. Through the work of the committee and subcommittees, specific clinical trial education issues affecting patients and families, staff and the community, and the institution were identified, and a variety of changes were implemented over a two-year period.

- Development and implementation of clinical trial teaching plans that standardized the patient education information to be used
- Development and implementation of preprinted medical record forms to assist staff with documenting their clinical trial teaching
- Collaboration with the Office of Research Education and Regulatory Management to incorporate teaching and learning principles into research training classes
- Development of a communication plan to highlight the institution's clinical

Table 4. Methods for Matching Patients to Clinical Trials

Method	%
Physician awareness of clinical trials	77
Protocol notebook	41
Computer database	38
Other ^a	27

N = 115

Note. Respondents could choose more than one answer.

^a A multidisciplinary or treatment planning meeting, priority protocol lists, screening tools, or clinic schedules that are checked daily with clinic station to determine patient eligibility

trial efforts and promote the use of clinical trial resources

- Work with Internet services to ensure content consistency between the new clinical trial patient education booklet and the clinical trial information posted on the Web site
- Incorporation of the clinical trial information into a public education office program—the CancerWISE Community Speakers Bureau
- Publication of clinical trial articles in a quarterly patient newsletter and coordination of special programming focusing on clinical trials and survivorship awareness

Although much was accomplished, each of the three committees continues to move forward with planning the development and implementation of more strategies that will lay the groundwork for consistent clinical trial education. For example, some members of the patient and family committee are in the process of developing a decision aid and adding it to the new clinical trial booklet. Other members are working with the phase I clinical trial program to develop educational resources (e.g., video, print) specifically targeting experimental therapies. In addition, members of the staff and community committee are working with nursing education and professional development to create an e-learning module to complement the teaching and learning principles class content. The institutional committee continues to work with Internet services to create additional content and explore opportunities to further highlight clinical trial education.

With the exception of the new clinical trial booklet, no formal evaluation of the program has taken place. This limits the authors' ability to report the effectiveness or impact of the program. With the new program structure in place, however, each committee has a means for analyzing which components would best lend themselves to evaluation and devising a plan to do so.

Practice Implications

Healthcare providers who are required to address clinical trial education for patients, staff, and the public are challenged to address inconsistencies in who provides clinical trial education, how clinical trial information is disseminated, and what information is given. Some of the challenges are providing consistent clinical trial information, involving the collective efforts of many, and securing resources to meet the needs of patients, staff, and the public. Thus, providers can be instrumental in developing tools that assist patients in making informed decisions about whether to participate in a clinical trial. Patients' decisions ultimately will have an impact on the number of patients enrolled in trials, patient compliance to trial expectations, and the validity of trial results.

Conclusion

Assessing, planning, and implementing a standardized clinical trial education program for patients, staff, and the public at a major comprehensive cancer center involved the cooperation and collective efforts of many. It required the support and commitment of everyone involved. Recommendations for a successful clinical trial education program include securing executive sponsorship for the program and ensuring that all stakeholders are involved (e.g., senior management, executive councils, clinical operations management, physicians, research and supportive care staff). From the collective efforts, the authors learned that healthcare providers have the ability to develop the necessary tools to assist patients in making informed decisions about clinical trials. Thus, providers not only can be instrumental in helping patients and families overcome barriers to participation in clinical trials, but also can affect the clinical trial community by increasing the number of patients enrolled, patient compliance to trial expectations, and the validity of trial results.

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Leadership & Professional Development

This feature provides a platform for oncology nurses to illustrate the many ways that leadership may be realized and professional practice may transform cancer care. Possible submissions include, but are not limited to, overviews of projects, accounts of the application of leadership principles or theories to practice, and interviews with nurse leaders. Descriptions of activities, projects, or action plans that are ongoing or completed are welcome. Manu-

scripts should clearly link the content to the impact on cancer care. Manuscripts should be six to eight double-spaced pages, exclusive of references and tables, and accompanied by a cover letter requesting consideration for this feature. For more information, contact Associate Editor Mary Ellen Smith Glasgow, PhD, RN, ACNS-BC, at Maryellen.smith.glasgow@drexel.edu or Associate Editor Judy Schreiber, RN, PhD, at judy.schreiber@louisville.edu.