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The Role of Oncology Nurses in Discussing Clinical Trials

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Abstract

Purpose/Objectives—To describe oncology nurses' experiences with discussing clinical trials with their patients, and to assess barriers to these discussions.

Research Approach—A qualitative study designed to elicit narratives from oncology nurses.

Setting—Community and academic-based oncology clinics throughout the United States.

Participants—Thirty-three oncology nurses involved in direct patient care in community-based and large hospital-based settings. The sample was drawn from a national oncology nursing professional society.

Methodologic Approach—In-depth interviews were conducted and analyzed using a crystallization-immersion approach to identify themes and patterns. The analyses highlight specific issues, examples, and contexts that present challenges to clinical trial discussions with patients.

Findings—Oncology nurses view their roles as patient educators and advocates to be inclusive of discussing clinical trials. Barriers to such discussions include lack of knowledge and strategies for addressing patients' common misconceptions, and uncertainty with regard to timing of discussions.

Conclusions—Having a systematic approach to initiating discussions of CTs, a clarification of ONs' roles and expectations, and additional training and education on this topic could assist patients with consideration of their treatment options.

Interpretation—These data indicate that enabling nurses to fulfill a central role in actively engaging patients in discussions of clinical trials will require educational interventions to build self-efficacy and close gaps in knowledge.

1. Oncology nurses recognize that they have a central role in assuring their patients have information about and access to clinical trials.
2. There are both challenges and barriers that can hamper discussions with patients about clinical trials.
3. Educational programs that provide both factual information about clinical trials and guidance on how to hold discussions with patients about trials are needed to address existing challenges and barriers.

Keywords

clinical trials; cancer; research; communication

Cancer clinical trials (CTs) are the cornerstone for demonstrating effectiveness of new ways to prevent, diagnose, and treat patients with cancer, and to provide effective supportive interventions for them and their families. Studies of new treatment regimens can provide participants with early access to promising interventions. While clinical trials provide the evidence base for clinical practice, less than 10% of cancer patients participate. (Al-Refaie et al., 2011; *Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary*, 2010; Murthy, Krumholz, & Gross, 2004; Unger et al., 2013). There are a variety of reasons why enrollment in trials is so low, but a common reason people give for not taking part in a clinical trial is that they did not know the studies were an option for them (American Cancer Society, 2014). In addition, we have previously categorized a variety of patient knowledge gaps and attitudes, including concerns about risks that may impede their participation (Manne et al., 2015; Meropol et al., 2007; Meropol et al., 2016).

A recent National Cancer Institute-American Society of Clinical Oncology symposium focused on clinical trial accrual identified provider communication with patients as an important target to improve patient participation. Oncology nurses are routinely involved in the care of patients who are eligible for enrollment in clinical trials. The Oncology Nursing Society's (ONS) 2016 specification of competencies for the generalist oncology nurse begin with the statement, "Regardless of employment setting, comprehensive knowledge and skills regarding cancer pathophysiology, treatment options, and symptom management are required elements of practice." Specific competencies include providing education to address the needs of the patient and family caregivers, as well as identifying resources available to people with cancer and their family caregivers. (Oncology Nursing Society, 2016) The ONS Core Curriculum for Oncology Nursing confirms the relevance of these competencies as they relate to clinical trials. Nursing interventions addressed in the Core Curriculum include providing information related to clinical trial participation, reinforcing the voluntary nature of trial participation, and assisting and encouraging the patient and family to ask questions of the research team. (Klimaszewski, 2016) As the highest rated in honesty and ethics among professions (Gallup, 2015), oncology nurses are in a key position to engage patients and increase awareness and accurate understanding of clinical trials

through patient education, counseling, and support for informed decision making. (Jenerette & Mayer, 2016)

Despite unanimity regarding the important role of oncology nurses in supporting patient awareness of and decisions about trial participation, little is known about the involvement of oncology nurses in clinical trials decision making beyond those nurses who work within specific clinical trials support units. While there has been some investigation of the role of nurses as clinical trial coordinators (Hastings et al., 2012; Haugen et al., 2015; Ocker & Plank, 2000; Spilsbury et al., 2008; Sun & Borneman, 2007), much less is known about attitudes and behaviors of nurses who serve in traditional patient care roles. From one of the few surveys of nurse activities, Arrigo and colleagues' (Arrigo, Gall, Delogne, & Molin, 1994) study of European nurses reported that the availability of information about trials varied among centers and that nurse respondents believed that their responsibilities related to clinical trials were primarily oriented towards direct care of the patients. Little is known about contemporary nursing practice and attitudes about clinical trials in the United States.

Burnett and colleagues (2001) interviewed 250 nurses working at one National Cancer Institute (NCI)-designated Comprehensive Cancer Center. The great majority (96%) believed that patient participation in trials is important, although only 56% believed patients should be encouraged to participate. A survey of 455 primary care nurse practitioners in Pennsylvania revealed that less than half felt comfortable discussing clinical trials with patients and that nearly 75% reported 3 or more ethical concerns with research. However, nurses also said that they were willing to recommend clinical trials, but needed more education (Ulrich et al., 2012). Schutta and Burnett (2000) conducted a qualitative study with 22 patients who were enrolled in trials. These patients were unable to describe any influence of nurses on their decision to take part in the trials. These findings raise the possibility that nurses are not routinely engaging in discussions about this potential treatment option.

Oncology nurses have an opportunity to play a central role in assuring that patients are educated about the option of taking part in a clinical trial, have questions and concerns addressed, and receive support for making an informed decision. However, we lack data regarding the extent to which practicing nurses see this as part of their role, what their attitudes and beliefs are, and what challenges may exist to fulfilling these important responsibilities. In order to explore and evaluate the potential for engaging nurses to be key actors in providing timely information to patients about clinical trials, a better understanding of current practice and an effective means to provide nurses with preparation for this role is needed.

As a first step towards this aim, we conducted a study of how practicing nurses perceived their roles related to clinical trials. The purpose was to explore the attitudes and beliefs about clinical trials, the nurse's role, and perceptions of influential personal or environmental factors.

Research Approach

This study employed a qualitative design and analysis, using in-depth interview methods to generate new understanding about oncology nurses' experiences and perceptions of their role in discussing clinical trials with patients. The development of the interview guide (described below) was based on a tradition of phenomenology (Giorgi, 1997; Holstein & Gubrium, 1998). The goal was to elicit lived experiences around a specific issue, in this case, experiences discussing clinical trials with patients. The interview also sought to elicit perceptions and understandings of the contexts that promote or inhibit that activity, and perceptions of role, attitudes, and beliefs towards discussing clinical trials with oncology patients.

Participants

Participants were drawn from a national sample of oncology nurses. We used a purposive sample of 33 Oncology Nursing Society (ONS) members, stratified by practice setting. This strategy maximized variation across a characteristic that was expected to affect nurses' attitudes and subjective norms for discussing clinical trials with patients. Using this approach, we anticipated reaching saturation of new information about initiating discussions with patients about clinical trials. Based on ONS experience with prior research studies, a 10% response rate was expected. Therefore, three hundred ONS oncology nurses, chosen by random from the ONS membership, were invited by email to participate in an in-depth phone interview regarding their experience with discussing clinical trial therapies with patients.

Methodological Approach

An email invitation included the study information sheet for preview and an individualized link to a website that included a prescreening survey. Inclusion criteria were 1) currently practicing nurse, 2) currently involved in direct patient care, 3) self-identification in a primary practice role, and 4) having an available email address. Nurses who were interested contacted the study staff and if they met the inclusion criteria, a time to conduct the interview was scheduled. Informed consent was required of all participants. Study participation was incentivized by offering a \$50 Amazon.com e-gift card. The study protocol was approved by the Institutional Review Board of University Hospitals Case Medical Center, Cleveland, Ohio.

Telephone interviews took place between October and December, 2014, lasted between 30–40 minutes, and were audio-recorded. Verbal consent was collected at the beginning of each interview. The semi-structured interview guide featured open-ended questions regarding the ways that nurses help cancer patients learn about the opportunity to participate in clinical trials (CT), as well as specific questions around the presence and extent of CTs at their primary work location. Interviews also explored nurses' perceptions of barriers to discussing clinical trials with patients, their attitudes about having such discussions, and their perceptions of the subjective norms for nurses engaging in these discussions. Finally,

demographic data were collected at the end of the interview, along with opportunities for further questions or thoughts.

Qualitative data were analyzed in several stages using an immersion-crystallization process (Crabtree & Miller, 1999). This is an iterative approach involving cycles of concentrated review of the data combined with reflection and intuitive insights. The first phase of analysis occurred during data collection. After half of the interviews were completed, the initial set of interviews were analyzed for emerging themes and to identify areas where additional probing questions would facilitate understanding. Subsequently, the second round of interviews was conducted using a modified interview guide that incorporated probing questions about the emerging themes detected in the initial interviews. The analysis team found that saturation of concepts was reached at 24 interviews. The team continued to conduct interviews and analyses with the individuals who had already responded to participate in the study and did not accept any new participants, resulting in a sample size of 33 interviews.

Upon completion of the interviews, transcripts of one third of the interviews were read and discussed by two of the co-authors, who began to identify emergent themes and patterns. Next, the remaining two-thirds of interviews were independently analyzed by these co-authors, who compiled detailed notes to build on identified themes and note patterns of variation. Finally, a third co-author read and analyzed all 33 transcripts and recordings, providing additional insights and a synthesis of interpretations. The use of multiple perspectives to independently interpret data and compare similarities and differences is a strategy for corroborating and legitimating the analysis. The final synthesis and description of themes was developed and then reviewed for clarity and completeness by all co-authors and the results are presented below.

Demographic information was entered and stored using a REDCap database (Harris et al., 2009). Descriptive statistics were used to summarize nurses' demographic characteristics and primary work setting.

Findings

Thirty-five of the 302 nurses invited to participate (12%) responded and were eligible for the study. Thirty-four nurses successfully scheduled interviews, and 33 interviews were completed. Table 1 shows the demographic characteristics and primary work environments of participating nurses. The majority were female and white, with a mean age of 46 years. Over half (64%) worked in an outpatient setting and 70% in a community setting. On average, respondents had 18 years of nursing experience and 13 years specifically within oncology nursing.

The Role of Oncology Nurses in Discussing Clinical Trials

Context of CT team vs. no team—Current practices for discussing clinical trials with patients varied with certain features of the practice setting (Table 2). In settings where on-site CTs are available, a designated clinical research nurse is often on staff. This person plays a central role in initiating discussions with patients regarding their eligibility for

specific clinical trials. In some locations there is a CT team, including the research nurse as well as an oncologist, who discuss CTs with the patient. In contexts where there is a CT nurse or team, respondents were very clear that these individuals initiate and discuss trials with patients. In cases where there is no dedicated clinical research nurse or team, respondents indicated that it is the patient's oncologist who usually raises the subject of participation in a clinical trial for which the patient might be eligible. However, only one participant noted that discussions of clinical trials systematically occurred with nearly all patients within her practice setting. Participants in this study also reported the perception that supervisors and oncologists were generally supportive of the idea of oncology nurses discussing clinical trials. However, it was very uncommon for the oncology nurse to *initiate* a general discussion of clinical trials. Further, most respondents were unsure whether doing so would be supported by supervisors and oncologists.

For most respondents working in an in-patient setting, the initial contact with a patient occurs after a CT has started, thus there was no perceived opportunity to initiate a discussion of a CT. Discussions about CTs in this context focused on treatment issues, such as side effects, rather than decision making.

Perceived Primary Role—Most of the respondents described the primary role of the oncology nurse as providing information, supporting, and assisting the patient after this initial discussion had taken place. Once a patient has had time to digest what they have been told by their oncologist or the research nurse, they often have further questions and concerns. The respondents reported that they were often called upon to provide clarification or elaboration of CT information, helping the patient and his/her family to understand the purpose and what might be involved with the CT.

Many oncology nurses also emphasized their role in providing the emotional support often needed by patients who find themselves facing an important decision. Patients and their families may experience a range of emotions, including hope, apprehension, and confusion. Nurses noted spending time listening to patients, offering compassion, empathy, and reassurance, and helping patients to feel empowered about their decision. Respondents reported that, particularly when they have a preexisting relationship with the patient, patients feel comfortable asking them questions that they might not feel comfortable asking the CT nurse, or may be embarrassed to ask their doctors.

While it is most common for research staff or the patient's oncologist to initiate discussion of CTs, sometimes the patient initiates the discussion with his/her nurse, particularly if CTs are not offered on site. While respondents generally felt comfortable discussing CTs in general terms in this context, they often referred a patient to other resources to determine eligibility for CTs at other sites. Some nurses were also able to point patients to on-line resources.

Overall, the roles described by oncology nurses with regard to their involvement in CT discussions fit within their more general role as patient advocate. Nurses want to support their patients to make an informed decision and appreciated that CTs could offer hope, and empower patients to feel like they are exploring every option available to them. CT

discussions can build on and strengthen a nurse-patient relationship based on trust, compassion, and advocacy. However, such discussions can also present an array of challenges.

Barriers to Discussing Clinical Trials

Throughout our interviews with oncology nurses, several themes emerged regarding barriers to discussing clinical trials (Table 2). The most common challenge expressed by respondents was a lack of information. While most felt comfortable discussing CTs in general terms with their patients, patients often asked specific questions for which the nurse did not have an answer at hand. These questions often centered on the specifics of a CT with regard to the study protocol and logistics, eligibility, financial burden, or to the nuances of their specific cases. In such situations, the oncology nurse would contact the research nurse or oncologist for answers. However, this could prove frustrating if neither was available. For example, a nurse who worked on the night shift felt that patients often relaxed and talked with the nurse during this time, but others were not readily available to answer questions.

In other cases, respondents reported a lack of confidence in their ability to explain CTs correctly and communicate effectively about CTs in general terms. This lack of self-efficacy was apparent, for example, when they felt unsure about how to debunk common myths about CTs, or how to explain the benefits of CTs and why they are important. Many patients and their families have done their own investigating into cancer treatments, and asked challenging questions.

Another example where nurses may feel they do not have the necessary information concerns the appropriate timing of discussing CTs with patients within the care trajectory. It is not always clear when and with whom these discussions should take place. For example, a patient may be eligible for a specific trial only before starting treatment. If the nurse is responsible for administering the treatment, he/she might feel unclear about how to proceed with such discussions. Many oncology nurses were unsure if oncologists would be supportive of them introducing the subject of CTs. Much of this uncertainty seems related to the fact that for nurses, norms for a clear process or protocol for having these discussions are lacking. Further, very few respondents reported receiving any training about clinical trials.

Another area in which oncology nurses reported barriers to discussing CTs is in the managing of the expectations, perceptions, and emotions of patients and their families. Several scenarios were described by nurses as requiring sensitivity, knowledge about CTs, and the ability to communicate effectively. In one such situation, the patient (or family member) feels that he/she is being experimented upon, not necessarily for his own benefit but for that of the researchers. Related to this is the expression of anger or frustration if the patient is assigned to the “standard of care” rather than the experimental group in a randomized clinical trial. Another commonly reported assumption is that patients feel that participating in a CT means that there is no more hope for them, and that the CT is a “last resort” that is unlikely to provide any benefit. Taken further, concern was expressed that this may imply to patients that current treatments are not working and that they should not be satisfied with their current treatment plans and/or physicians. Alternatively, nurses indicated that patients may feel that a CT provides a certain expectation of a cure. In such instances,

nurses raised concern that patients' hopes may be raised to such an extent that the oncology nurse is in a challenging position to help balance expectations with the reality of the CT's likely or potential benefit.

Finally, as advocates for their patients, respondents reported feeling at times a sense of conflicting priorities. For example, if an oncology nurse works in a practice that does not offer CTs, then referring a patient to another site that does offer CTs may conflict with his/her loyalty to the physician, who would be losing business if the patient leaves. A further implication in this scenario is the potential interpretation that the current physician's care was somehow less than optimal, requiring the move to another location where a CT is offered. At the other extreme, a few nurses reported feeling some discomfort prioritizing patient advocacy in settings where there was an expectation regarding clinical trials volume.

Discussion

In summary, the oncology nurses who participated in these interviews perceived that they played an important role in supporting patients who were considering participation in clinical trials. Although others (research nurses or oncologists) most often were the persons to introduce the topic to patients, nurses were actively engaged in answering questions or helping the patient obtain access to a source for answers. They also provided emotional support to patients and families, sometimes correcting misinterpretations or clarifications of what the patient had been told by others.

While reporting positive attitudes towards clinical trials and the nursing role, respondents also described common challenges. Some of these were the perception of a knowledge deficit, some related to uncertainties about the appropriateness of raising the topic before the patient asked, and many described the need for advanced skills in recognizing and responding to patient and family emotional concerns.

Study Limitations

Our study was designed to conduct in-depth interviews with a sample of about 30 oncology nurses, but the participation rate among those who were eligible was low. ONS projected a 10% response rate, we engaged just over 11% with a hand written invitation letter, email reminder, and remuneration for completing the interview. The low response rate could be due to the method of inviting individuals drawn from an organization membership list, and we cannot confirm if emails were opened in order to calculate a participation rate among those who at least viewed the invitation. Nonetheless, the process of collecting interviews and probing more deeply about new issues raised generated data for which patterns of responses were readily identified. Saturation of new information was reached after the first 24 interviews. These qualitative interview data are not intended to generate the frequency of responses; additional data collection with larger samples and alternative data collection methods, such as survey, could yield data to inform the frequency of behaviors and attitudes and should be the focus of additional study.

Implications for Nursing Practice and Research

These data confirm that oncology nurses recognize the central role they play in assuring patients have access to the newest therapies as well as supporting the discovery of new and improved therapies for patients through clinical trials. While many of the barriers reported by oncology nurses are an unavoidable part of discussing an important topic in the context of a life-threatening disease, potential facilitators were suggested by the respondents. Continuing education and/or guidelines for these patient/family discussions could prove helpful, as could resources, such as training videos. Similar to the findings by Ulrich et al. (2012), many of the respondents in this study expressed an interest in further training and education in this topic, and seemed driven to learn ways to improve their roles as patient advocates. However, the data from this study further suggest that interventions will require modifying the norms around nurse roles to effect change. This effort will require not only delivering educational interventions to close gaps in knowledge, but also building self-efficacy and positive attitudes that his/her role of engaging patients in discussions of clinical trials can advance cancer care through discovery of improved therapies. Such training could provide specific suggestions for how to negotiate complex situations with both patients and with other healthcare providers. This may be particularly important in light of the findings from this study that participants reported the perception that supervisors and oncologists were generally supportive of the idea of oncology nurses discussing clinical trials, but were less sure regarding the idea of initiating these discussions.

Providing practicing nurses with increased, targeted education and preparation for holding general discussions about clinical trials with patients might increase the nurse's confidence in his/her ability to provide accurate information to patients. Increasing self-efficacy can contribute to the nurse's intention to consistently raise the topic of trials with her/his patients or respond to unsolicited questions, assess patient understanding, and thus respond to either misunderstandings or emotional concerns. Ultimately, increasing timely conversations about clinical trials with patients can contribute to quality decision making and access to clinical trials as a therapeutic opportunity.

Conclusion

This study highlights that oncology nurses perceive that they play an important role in supporting patients who are considering participation in clinical trials but that this support is predominately after the patient has made a decision to participate in a trial. Enabling nurses to fulfill a central role in actively engaging patients to initiate general discussions of clinical trials will require educational interventions to build self-efficacy and close gaps in knowledge.

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References

- Al-Refaie WB, Vickers SM, Zhong W, Parsons H, Rothenberger D, Habermann EB. Cancer trials versus the real world in the United States. *Ann Surg.* 2011; 254(3):438–442. discussion 442–433. DOI: 10.1097/SLA.0b013e31822a7047 [PubMed: 21775882]
- American Cancer Society. Why do we need clinical trials?. Oct 31, 2014 Retrieved from <http://www.cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/whatyouneedtoknowaboutclinicaltrials/clinical-trials-what-you-need-to-know-why-do-we-need-clin-trials>
- Arrigo C, Gall H, Delogne A, Molin C. The involvement of nurses in clinical trials. Results of the EORTC Oncology Nurses Study Group survey. *Cancer Nurs.* 1994; 17(5):429–433. [PubMed: 7954391]
- Burnett CB, Koczwara B, Pixley L, Blumenson LE, Hwang YT, Meropol NJ. Nurses' attitudes toward clinical trials at a comprehensive cancer center. *Oncol Nurs Forum.* 2001; 28(7):1187–1192. [PubMed: 11517851]
- Crabtree, B., Miller, W. *Doing Qualitative Research.* Thousand Oaks, CA: Sage Publications; 1999.
- Gallup. *Historical Trends.* 2015. Honesty/ethics in professions.
- Giorgi A. The theory, practice, and evaluation of the phenomenological method as a qualitative research procedure. *Journal of Phenomenological Psychology.* 1997; 28(2):235–260.
- Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics.* 2009; 42(2):377–381. <http://dx.doi.org/10.1016/j.jbi.2008.08.010>. [PubMed: 18929686]
- Hastings CE, Fisher CA, McCabe MA, Allison J, Brassil D, Offenhartz M, ... Turbini V. Clinical research nursing: a critical resource in the national research enterprise. *Nurs Outlook.* 2012; 60(3): 149-156.e141–143. DOI: 10.1016/j.outlook.2011.10.003 [PubMed: 22172370]
- Haugen M, Kelly KP, Leonard M, Mills D, Sung L, Mowbray C, Landier W. Nurse-led programs to facilitate enrollment to children's oncology group cancer control trials. *J Pediatr Oncol Nurs.* 2015; doi: 10.1177/1043454215617458
- Holstein, J., Gubrium, J. *Phenomenology, Ethnomethodology, and interpretive practice.* In: Lincoln, INDY., editor. *Strategies of Qualitative Inquiry.* Thousand Oaks, CA: Sage; 1998. p. 137-157.
- Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. *Transforming clinical research in the United States: Challenges and opportunities: workshop summary.* Paper presented at the 6, *Clinical Trials in Cancer;* Washington (DC). 2010.
- Jenerette CM, Mayer DK. Patient-provider communication: The rise of patient engagement. *Semin Oncol Nurs.* 2016; 32(2):134–143. DOI: 10.1016/j.soncn.2016.02.007 [PubMed: 27137470]
- Klimaszewski, AD. *Research protocols and clinical trials.* In: Itano, JK., editor. *Core Curriculum for Oncology Nursing.* 5. St. Louis, MO: Elsevier; 2016. p. 62-70.
- Manne S, Kashy D, Albrecht T, Wong YN, Lederman Flamm A, Benson AB 3rd, ... Meropol NJ. Attitudinal barriers to participation in oncology clinical trials: factor analysis and correlates of barriers. *Eur J Cancer Care (Engl).* 2015; 24(1):28–38. DOI: 10.1111/ecc.12180 [PubMed: 24467411]
- Meropol NJ, Buzaglo JS, Millard J, Damjanov N, Miller SM, Ridgway C, ... Watts P. Barriers to clinical trial participation as perceived by oncologists and patients. *J Natl Compr Canc Netw.* 2007; 5(8):655–664. [PubMed: 17927923]
- Meropol NJ, Wong YN, Albrecht T, Manne S, Miller SM, Flamm AL, ... Schluchter MD. Randomized trial of a web-based intervention to address barriers to clinical trials. *J Clin Oncol.* 2016; 34(5): 469–478. DOI: 10.1200/jco.2015.63.2257 [PubMed: 26700123]
- Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. *JAMA.* 2004; 291(22):2720–2726. DOI: 10.1001/jama.291.22.2720[pii] [PubMed: 15187053]
- Ocker BM, Plank DM. The research nurse role in a clinic-based oncology research setting. *Cancer Nurs.* 2000; 23(4):286–292. quiz 293–284. [PubMed: 10939176]

- Oncology Nursing Society. Clinical Care. Pittsburgh: Oncology Nursing Society; 2016. Oncology nurse generalist competencies.
- Schutta KM, Burnett CB. Factors that influence a patient's decision to participate in a phase I cancer clinical trial. *Oncol Nurs Forum*. 2000; 27(9):1435–1438. [PubMed: 11058975]
- Spilsbury K, Petherick E, Cullum N, Nelson A, Nixon J, Mason S. The role and potential contribution of clinical research nurses to clinical trials. *J Clin Nurs*. 2008; 17(4):549–557. DOI: 10.1111/j.1365-2702.2006.01872.x [PubMed: 17419791]
- Sun VC, Borneman T. The oncology nurse's role in the informed consent process. *Oncology (Williston Park)*. 2007; 21(8 Suppl):11–14. discussion 15.
- Ulrich CM, Zhou Q, Ratcliffe SJ, Ye L, Grady C, Watkins-Bruner D. Nurse practitioners' attitudes about cancer clinical trials and willingness to recommend research participation. *Contemporary clinical trials*. 2012; 33:76–84. [PubMed: 21983623]
- Unger JM, Hershman DL, Albain KS, Moinpour CM, Petersen JA, Burg K, Crowley JJ. Patient income level and cancer clinical trial participation. *J Clin Oncol*. 2013; 31(5):536–542. DOI: 10.1200/jco.2012.45.4553 [PubMed: 23295802]

Table 1

Characteristics of participating nurses (n=33)

Demographic characteristics	n (%)
Female	31 (94)
Age mean (SD)	46 (11)
Race	
White	29 (85)
Black/African American	1 (3)
Asian	1 (3)
Native Am/Hawaiian	1 (3)
Bachelor degree	20 (59)
Primary work context and experience	n (%)
Setting	
Community	23 (70)
Academic	10 (30)
Patient care setting	
Inpatient	10 (30)
Outpatient	21 (64)
Both	2 (6)
Treatment	
Infusion	19 (56)
Radiation	5 (15)
Years in Nursing, mean (SD)	18 (12)
Years in Oncology, mean (SD)	13 (10)

Table 2

Perceived roles and barriers to discussing clinical trials

Roles in discussing clinical trials
Setting matters
In settings with CT nurse on staff, oncology nurses have a clear understanding of who initiates discussion of CTs
In other settings, the default is that the oncologist is the one to initiate the discussion of CTs
Primary Role
Provide informational assistance to the patient <i>after</i> an initial discussion had taken place
Provide emotional support
Serve as patient advocate in context of family and clinical team to support patient's decision
It is someone else's role to initiate the discussion of clinical trials
Barriers to discussing clinical trials
Lack of information
Lack information on details, logistics, protocol, nuances of patient's case, scope of trial
Lack of self-efficacy for explaining CTs
Uncertain of appropriate timing of discussion in care trajectory
No clear norms for process or protocol in these discussions
Managing emotions/expectations of patients and their families
Patient may feel disempowered, like they're being experimented on
Patient may feel in denial of their condition, and offended by "last ditch effort"
Patient may have false hope that CT will cure them
Conflicting priorities
May lose business for practice if patient leaves for CT elsewhere
Mitigating conflicts of opinion within family or between patient and family
Discomfort in settings where there is an expectation regarding clinical trial volume