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Nurse Practitioners' attitudes about cancer clinical trials and willingness to recommend research participation

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Abstract

Background—Recruitment and retention of human participants in cancer clinical trials remains challenging for all investigators. Nurse Practitioners (NPs) are in a prime position to discuss, educate and refer patients to clinical trials as many NPs work in ethnically and geographically diverse primary care settings in the U.S., yet they remain an untapped resource. We examined NPs' general attitudes toward cancer clinical trial recommendations and assessed their willingness to recommend such trials.

Methods—We randomly surveyed 455 primary care NPs in the state of Pennsylvania during 2008 with an adjusted response rate of 55.3%. Descriptive statistics were used to characterize NPs' demographic and practice characteristics, and logistic regression was used to assess the relative influence of the various attitudes and beliefs on the likelihood that the NP would bring up clinical trials as a treatment option.

Results—NPs were more likely to bring up the topic of clinical trials with at least some patients if they were comfortable discussing treatment options with their cancer patients (OR = 4.29, $p = 0.001$), were comfortable discussing options of entering a clinical trial for treatment (OR = 3.54, $p = 0.003$), had adequate time during patients' visit to explain clinical trials (OR = 3.40, $p = 0.008$), and if they believed that patients in clinical trials were receiving the best medical treatment (OR = 3.34, $p = 0.019$). NPs who were comfortable discussing cancer clinical trials were almost 5 times

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more likely to think clinical trials were useful (OR = 4.70; 95% CI = 1.81–12.19; $p = 0.001$). Nearly three-quarters (72.6%) of the entire responder sample reported three or more ethical concerns associated with clinical trials, including issues of randomization, informed consent, and patient burden.

Conclusions—NPs are willing to recommend clinical trials but need more education about the benefits and burdens of clinical trials, the associated ethical concerns, and evidence regarding the translatability of research to clinical practice to increase their knowledge and comfort level with discussing clinical trials.

Keywords

Clinical trials; Nurse Practitioners; Recruitment; Retention

1. Background

Difficulty in recruiting subjects to participate in research remains an ongoing concern for biomedical researchers, hampering the completion of clinical trials, translation of research into practice and ultimately effective treatments for human diseases. Unfortunately, it is well documented that only 3–5% of the U.S. public participates in cancer clinical trials although nearly a quarter of the U.S. population are diagnosed with some form of cancer and an astounding number (562,875 in 2007) die from the disease [1–3]. Additionally, minorities share an unequal burden of disease and for example, African Americans in the state of Pennsylvania have significantly higher age adjusted cancer mortality rates than Caucasians in the United States for all cancers and lung/bronchus cancers and may have limited access to the latest healthcare services [4]. This limited access to care may also extend to access to information regarding the availability of clinical trials.

Minorities are often hesitant to participate in research due in part, to past ethical lapses in the conduct of research and a generalized mistrust of the research enterprise [5–7]. One analysis suggested that African Americans are less frequently invited to participate in research, contributing to the lower rate of African American participation in research [8]. Adequately conveying the benefits and burdens of research participation during the patient-provider encounter and communicating this information with confidence and in a timely manner adds a burden on the health care community. Yet, healthcare providers' research recommendations may be an important factor in their patients' decision-making process as many patients receive their preventative and primary care from primary healthcare providers, including Nurse Practitioners (NPs). NPs, in particular, work in ethnically and geographically diverse communities and are licensed independent practitioners who care for individuals, families, and groups with acute and chronic care illnesses. Today, in the state of Pennsylvania, there are over 7000 certified NPs and over 30 nurse-managed centers that provide primary care to individuals of all age and racial/ethnic minority groups, and for those who might be living in poverty or with limited access to healthcare services [9]. Thus, they are in a prime position to discuss, educate and refer patients to clinical trials as over 80% of the U.S. population express trust in nurses [10]. Regrettably, NPs have not been part of this conversation; national clinical trials and other multi-site research consortiums have generally focused on physician and clinical research associate education and training in clinical trials. Currently,

there is limited information about the attitudes and beliefs of NPs regarding recommending clinical trial participation to patients. The objectives of this survey were to examine NPs' general attitudes toward cancer clinical trial recommendations and to assess their willingness to recommend such trials.

2. Methods

2.1. Sampling and subjects

We randomly selected 455 primary care NPs in the state of Pennsylvania to respond to a mailed, self-administered survey. NPs were identified from the state membership lists from Medical Marketing Services (MMS), an independently owned organization that manages medical industry lists [11]. The MMS includes NPs' demographic variables and basic practice information (e.g., family health, primary care, adult health). Inclusion criteria consisted of active participation in patient care (at least 10 h/week) and currently certified and licensed to practice in the state of Pennsylvania. Sample size was determined by statistical power analysis for descriptive designs. Based on our previous research with the NP population, the study was powered to detect a small to medium effect size, assuming 80% eligibility and 55% response rate [12]. Of the 455 questionnaires mailed, one hundred forty-two participants were not eligible. This included questionnaires returned for an insufficient address (n = 10), non-practicing/retired NPs (n = 27), those who self-identified as not qualified to participate (n = 99) and others (n = 6, i.e. death). Of the potentially eligible 313 NPs, 16 refused to participate. A total of 173 usable questionnaires were obtained for the study representing an adjusted response rate of 55.3%.

2.2. Survey questionnaire and procedures

To measure NPs' beliefs about cancer clinical trials and willingness to recommend research participation, we used items from the surveys of Crosson, Eisner, Brown, and TerMaat's [13] study of primary care physicians' attitudes, knowledge, and practices related to clinical trials and the questionnaire developed by Burnett, Koczwara, Pixley, Blumenson, Hwang, and Meropol [14] to assess cancer nurses' attitudes. The final data collection questionnaire included the (1) demographic and practice characteristics and (2) scales/items that measure attitudes, beliefs, and practices toward clinical trials, including ethical concerns.

Following approval by the Institutional Review Board at the University of Pennsylvania, Dillman's [15,16] Tailored Design Method (TDM) was used to guide the data collection. Our procedures included: 1) a small pilot study to address any issues of concern prior to the full study; 2) four mailings in 2008 with an initial complete survey packet sent to the full sample, postcard follow-up 10 days after the initial mailing, replacement questionnaires and a final appreciation postcard for completing the survey; and 3) a financial incentive of \$5 affixed to the initial cover letter [12,17,18].

2.3. Measures

2.3.1. Demographic information—Data were collected on a number of socio-demographic and practice-related variables, including age, gender, ethnicity, income, years as a practitioner and years in current position, practice setting, employment status, for-profit

and/or not-for-profit designation and percent of the population in the provider's practice covered by healthcare insurance.

2.3.2. Attitudes towards clinical trials—Attitudes towards clinical trials were measured by seven individual items adapted from Crosson and colleagues [13] and measured on a Likert scale from strongly disagree to strongly agree. These items reflected how comfortable NPs were in discussing treatment options with cancer patients as well as discussing the option of entering a clinical trial. Items also asked respondents if they had adequate time to spend with patients during their office visit to explain clinical trials and whether they would leave the decision for clinical trial enrollment to an oncologist or someone who they perceived to be more knowledgeable about the protocol. In the analysis, these items were recoded into dichotomous values with 1 indicating agree/strongly agree, and 0 indicating strongly disagree/disagree/neutral.

We also assessed NPs' perceptions about possible obstacles to patients' enrolling in clinical trials for their cancer treatment. For example, this included items such as “patients tend to lose confidence in their provider when they recommend a clinical trial for their cancer therapy”; and “patients assume that the intervention or treatment in a clinical trial is more invasive than the standard treatment.” Each perceived obstacle item is scored on a scale of 1 (not a barrier) to 3 (large barrier). Cronbach's alpha for this scale was 0.72.

2.3.3. Ethical concerns—Eight descriptive items were developed by the research team, including concerns related to randomization to the non-active arm, patient's understanding of randomization, confidentiality in recruitment, scientific value of clinical trials, burden to patient, informed consent, enrollment of “high risk” (pre-disease) rather than diseased subjects, and concerns about the risk/benefit ratio. Each item was scored from strongly disagree to strongly agree with a higher value indicating stronger ethical concerns. In this study, these items showed high internal consistency ($\alpha = 0.88$). Factor analysis extracted one factor explaining 55.7% of the variance. The factor loadings ranged from 0.62 to 0.81, supporting the cluster of ethical concerns. The total number of ethical concerns of a responder was calculated as the sum of eight items coded as (1) agree/strongly agree and (0) strongly disagree/disagree/neutral.

2.3.4. Beliefs regarding clinical trials—Beliefs regarding clinical trials were measured by 5-items adapted from Crosson et al. [13]. Each item has five response categories from strongly disagree to strongly agree with higher scores reflecting favorable beliefs toward clinical trials. The scale had an acceptable internal consistency (0.69) and exploratory factor analysis supported construct validity explaining 46.7% of the variance in one factor (factor loadings range from 0.48 to 0.80). Example of items in this scale included: “Patients with cancer who are participating in a clinical trial are receiving the best medical treatment available”; “Clinical research improves patient care for the patient involved”; and “Conducting patient research is an important role of oncologists and/or nurse researchers who specialize in cancer care.” In analysis, the responses were classified into (1) agree (agree/strongly agree) and (0) disagree (strongly disagree/ disagree/neutral).

2.3.5. Recommending clinical trials—The practice of recommending clinical trials was measured by three practice-related statements. First, we asked providers how often they bring up the topic of clinical trials when discussing treatment options with patients and grouped the responses into (1) bringing up the topic with a few patients versus (0) not any patients. Second, we ascertained the level of support NPs would convey to patients who specifically asked about participation in clinical trials. Responses to this question were classified as (1) supportive, or willing to recommend a clinical trial when asked by the patient if the responses included somewhat or very supportive; and (0) non-supportive if participants reported not supportive or neutral. Finally, we used a hypothetical case vignette developed by Crosson et al. in their survey of primary care physicians. This vignette asked respondents to suppose there was a clinical trial that randomized women with a positive family history of breast cancer to groups receiving either an anti-estrogen drug or a placebo. The drug was reported to have few side effects and the regimen proposed was one tablet twice a day for 5 years. If you had a patient who had a positive family history because her mother was diagnosed with breast cancer at age 47, “how likely would it be that you would recommend this prevention trial?” Respondents were classified as (1) likely (willing to recommend clinical trial to high risk patients) if they answered somewhat likely or very likely, and as (2) unlikely if they answered somewhat unlikely or very unlikely.

3. Data analysis

Data were analyzed using SPSS 15.0. Descriptive statistics included frequencies and percentages (for categorical variables) or median and ranges (for continuous variables). Relationships between variables were assessed using Fisher's exact tests, chi-square, or Mann–Whitney U-tests (due to non-normality of continuous variables), as appropriate. For all analyses, a two-sided significance level of $\alpha = .05$ was used. Logistic regression was used to assess the relative influence of the various attitudes and beliefs on the likelihood that the NP would bring up clinical trials as a treatment option, their willingness to recommend one when asked by a patient, and on their hypothetical willingness to recommend the preventive clinical trial for the high risk patient. Logistic regression models were adjusted for responder age, gender, years as an NP, practice affiliation with a university or medical school, and whether the practice participates in clinical trials.

4. Results

4.1. Demographic and practice characteristics of Nurse Practitioner sample

The descriptive and practice characteristics of the sample are presented in Table 1. The sample ($N = 173$) was primarily female (91.9%), Caucasian (95.2%) and non-Hispanic (99.4%). Respondents ranged in age from 28 to 65 with a median age of 51. Ninety-four percent of NP respondents were prepared at the master's level. Years as a practitioner ranged from 2 to 32 with a median of 9 years. Also, more than two-thirds were employed full time and were employed in their current positions a median of 5 years.

More than a third (38.8%) were currently practicing as family NPs in a group practice of 3–10 providers (35.7%) with a for-profit status (51.2%). About a third of the practitioners' client population was privately insured (35%) with others being Medicaid participants

(15%), Medicare enrollees (28%), and the uninsured (5%). 27% of respondents indicated that their office participated in clinical trials and nearly a quarter indicated they refer patients to National Cancer Institute sponsored studies.

When asked about usual treatment practices with patients who are diagnosed with cancer (Table 1), over fifty percent of NPs (54.3%) refer patients to a specialist and do not stay involved in their care for cancer while 36.4% refer the patient but remain involved in their care. Respondents described the remaining involvement in patients' cancer care as including: treating side effects of the cancer or treatment (28%), providing pain management (34.4%), providing or referring to psychosocial support or counseling (43.6%) and hospice (33.7%), ordering follow-up lab work (36.8%), treating other health problems (74.8%), and managing the chemotherapy (2.5%).

4.2. Attitudes toward clinical trials

Less than half of respondents felt comfortable discussing treatment options with their cancer patients (47.8%) and discussing the option of entering a cancer clinical trial for treatment (47.2%) (Table 2). Moreover, only a third of NPs reported having enough time to spend with patients during their office visits to explain clinical trials (34.4%) and slightly more than half (53.4%) felt the level of communication they have with other providers about the patients they refer is sufficient to ensure the delivery of high quality care. Most NP respondents (86.7%) would leave the decision for clinical trial enrollment to an oncologist or others. However, they still felt it was possible to remain involved (77.3%) with patients while they were participating on clinical trials. Close to 30% of the NP respondents would recommend a clinical trial as a treatment option only when conventional therapy has failed.

4.3. Beliefs and perceived usefulness of clinical trials

The majority of respondents agreed that clinical research improves patient care for the patient involved (74.4%) and that conducting research is an important role of oncologists and/or nurse researchers who specialize in cancer care (97%). However, less than half of respondents (43.8%) perceived that patients with cancer who are participating in a clinical trial are receiving the best medical treatment available; this could reflect the fact that some respondents were cognizant of the differences between clinical care and clinical research. When asked the question, "if I had cancer, I would prefer to be treated as part of a CT", 45.6% agreed with the statement and a similar percentage were neutral (45.6%) (Table 2).

Some NP respondents did not find clinical trials useful to their own practice (34.9%), another third (36.4%) said research was useful sometimes, and 27.3% reported it as often to extremely useful. The most common explanation for the limited usefulness of cancer clinical trial research was the difficulty of translating research results into clinical practice (53%).

An open-ended question on the survey asked what organizations (e.g., National Cancer Institute, American Cancer Society) could do to encourage NPs to bring up the topic of clinical trials when they discuss treatment options with their cancer patients. A majority of the 105 who responded reported that they needed more information and education regarding available studies and the effectiveness of current treatments versus new options. NP responses included the following: "access to easy to utilize databank for providers, easy to

read/understandable patient information;” “benefits of clinical trials for my patients;” “demonstrate that the primary purpose is to improve patient's outcome/quality of life rather than making a large amount of money; and discuss/make available options and end-points of treatment, costs, follow-up.”

4.4. Ethical concerns regarding clinical trials

Many of the respondents reported ethical concerns related to clinical trials. In fact, nearly three-quarters (72.6%) of the entire responder sample reported three or more ethical concerns. Noted were concerns about patients' understanding of randomization (76.8%), potential burden to the patient (69.9%), patient randomization to the non-active arm (65.5%), informed consent (46.7%), the scientific value of the trial (42.2%), patients being used as “guinea pigs” in clinical research (39.2%), and confidentiality in recruitment (29.8%) [19]. Indeed, 69% of NPs thought that patients' fear of being a clinical research subject or “guinea pig” was a large barrier to participation in clinical trials. Interestingly, those NPs who said they were willing to bring up the option of a cancer clinical treatment trial or support their patients' interest in clinical trials if asked reported more ethical concerns in every category than those who would not bring clinical trials up or would be less supportive if asked.

Two-thirds of NPs perceived that patients' fear of being used as “guinea pigs” was a large barrier to their participation (69%). Other barriers included “undesirable side effects” (32.7%) and “patients' beliefs that a particular treatment or intervention is ineffective” (37.1%). Nearly half of NPs (48.2%) said they thought that patients believe their well-being is secondary to the research and that a barrier to research participation may be a loss of confidence in the provider when he or she recommends a clinical trial to the patient (45.8%).

4.5. Recommending clinical trials

Table 3 summarized the association between NPs opinions about and ethical concerns with clinical trials and their willingness to *bring up clinical trials as a treatment option*. More than a third (n = 61, 38.9%) would bring up clinical trials as a treatment option with a few to every patient. In adjusted models, NPs were more likely to bring up the topic of clinical trials with at least some patients if they were comfortable discussing treatment options with their cancer patients (OR = 4.29, p = 0.001), were comfortable discussing options of entering a clinical trial for treatment (OR = 3.54, p = 0.003), had adequate time during patients' visit to explain clinical trials (OR = 3.40, p = 0.008), and if they believed that patients in clinical trials were receiving the best medical treatment (OR = 3.34, p = 0.019). The ethical concern about patient's understanding of randomization was associated with bringing up the topic of clinical trials as a treatment option, in that those with the concern were more likely to bring up the topic of clinical trials for treatment (OR = 7.51, p = 0.006).

Table 4 summarized the associations between NPs opinions about and their ethical concerns with clinical trials and their willingness to *recommend clinical trials when asked by patients*. The majority of the respondents (n = 135, 80.8%) would recommend clinical trial participation if asked by a patient. The adjusted models showed that NPs who felt comfortable discussing the option of entering a clinical trial for treatment (OR = 2.71, p =

0.049) were also those who perceived they had a sufficient level of communication with other providers (OR = 3.11, $p = 0.017$), believed in the importance of clinical trials in improving the future standards of care ($p < .001$), and were willing to participate in clinical trials if diagnosed with cancer him- or her-self (OR = 3.98, $p = 0.044$) and were more willing to recommend clinical trials when asked by patients. Additionally, NPs who would recommend a clinical trial only when conventional therapy fails were less likely to recommend clinical trials when asked by patients (OR = 0.38, $p = 0.045$). NPs who have ethical concerns about the potential burden to the patient ($p = 0.026$), and who were concerned that the patient was being used as a “guinea pig” in clinical research (OR = 3.39, $p = 0.024$) were more likely to recommend clinical trials if asked by patients. This is a conflicting finding, but could in part be a reflection of their understanding of clinical research and the ethical concerns that could potentially arise as part of research participation.

For the hypothetical vignette regarding *willingness to recommend a clinical trial for the high risk patient*, 127 (78.4%) of NPs were willing to recommend participation in the clinical trial. In adjusted models, NPs who believed “patients with cancer who are participating in a clinical trial are receiving the best medical treatment available” were more likely to be willing to recommend the clinical trial (OR = 3.96, $p = 0.011$). Further, NPs who would recommend a clinical trial only when conventional therapy fails were less likely to recommend clinical trials when asked by patients (OR = 0.36, $p = 0.043$). Interestingly, NPs with expressed concerns for the “scientific value of the clinical trial” (OR = 3.24, $p = 0.039$) were also more likely to be willing to recommend clinical trial participation for the high risk patient (Table 5).

4.6. Usefulness of clinical trials

In adjusted models, NPs who were comfortable discussing cancer clinical trials were almost 5 times more likely to think clinical trials were useful (OR = 4.70; 95% CI = 1.81–12.19; $p = 0.001$). NPs who believe patients are used as “guinea pigs” in clinical research are 3 times less likely to think clinical trials are useful (OR = 3.12; 95% CI = 1.01–9.64; $p = 0.048$), while NPs with ethical concerns about informed consent are almost 4 times less likely to think clinical trials are useful (OR = 3.57; 95% CI = 1.03–12.40; $p = 0.046$). However, when these ethical concerns were included in a model with the NPs comfort discussing clinical trials, only the comfort level remained significantly associated with their belief in the usefulness of cancer clinical trials ($p = 0.012$).

5. Discussion

This is one of the first studies to examine the role of primary care NPs in recommending cancer clinical trials. Many authors have recognized the importance of the patient-provider relationship in communicating about clinical trials; [20,21] however, no research has focused on NPs. Primary care NPs are in a unique position to discuss research opportunities and present clinical trial information to newly diagnosed cancer patients because they practice in ethnically and geographically diverse communities and can present an opportunity to

patients who might not otherwise have access to new drugs available in research trials. Unfortunately, NPs remain an untapped resource.

We found that almost all of the NPs who responded agreed that oncology clinical research is important to improving the future standard of care and an important role for oncologists and nurse researchers. The majority, however, felt somewhat uncomfortable with the topic of clinical research in their clinical practice and 86.7% would leave discussion of clinical trials with the patient to an oncologist. In that regard, our findings are similar to but go beyond those of Crosson and colleagues' who found that 40% of the U.S. primary care physicians' who they surveyed would leave the clinical trial discussion to oncologists. Additionally, there was a general lack of awareness about clinical trials available to patients and limited discussions surrounding these issues. Importantly, Joffe and Weeks [22] reported that even oncologists can be misinformed about the purpose of clinical trials.

Although the majority of our respondents did not discuss clinical trials with their patients, our data indicate that NPs are receptive to these discussions. It is understandable that concerns about the scientific value of the study, time pressures, and other patient-related priorities may inhibit conversations about clinical trials. Yet, although the majority of NPs said they would be positive and supportive if a patient asked them about clinical trial participation, only one of three participants reported that they had enough time to explain clinical trials during the patient's office visit. Chen, Miller, and Rosenstein [23] argue that integrating a conversation about research participation into clinical practice represents "good clinical practice." On the other hand, more than a quarter of respondents said they would only be somewhat positive and nineteen percent neutral if a patient asked them about clinical research. NPs indicated a need for more education and general knowledge about the benefits and burdens of clinical trials as well as more discussion about the ethical implications of research participation. Additionally, they reported needing more information on institutional review board regulations, results of ongoing and past research, and access to contacts for available trials.

Tensions often exist between clinical practice and clinical research as clinical practice is meant to directly benefit individual patients whereby clinical research addresses a specific research question with the intent of advancing our scientific understanding of a particular disease entity and may or may not individually benefit those patients who enroll in the trial [23]. This tension was evident by the number of ethical concerns raised by the NPs on the usefulness of clinical research. Two-thirds were concerned about randomization of the patient to the non-active arm of the trial along with other ethical concerns (i.e., informed consent, burden to patient) that could potentially influence whether they approach a patient about enrollment onto a trial. Of note, of those NPs who would discuss clinical trials as an option with their patients or support their patients when asked about clinical trials, the frequency of concern was higher. Certainly, these concerns are justifiable in some situations. In a meta-analysis and systematic review of both qualitative and quantitative research focused on patient-reported barriers to participation in cancer clinical trials, assignment to a placebo arm and the dislike of randomization were significant concerns for patients [24]. It is interesting to note that we found similar results with clinicians. Further study is required

to address the aspects of randomization and the use of placebos that are troubling to both patients and clinicians.

Many NPs agreed that research is useful in the abstract, but that it is not necessarily relevant to what they do clinically. Several issues might account for this finding. First, we did not distinguish between treatment trials and symptom management trials in this study. NPs may indeed find more clinical utility for evidence based practice of symptom management that they are involved in rather than cancer treatments thought to be in the realm of the oncologist, since many of our respondents treated the side effects of cancer and provided psychosocial and other types of support to patients. Second, it could possibly reflect the inability of researchers to disseminate how their research improves patient outcomes and why research would be beneficial to discuss with clinical patients. Third, it is possible that limited training and education about clinical trials and research in general could bias NPs perspectives on the value of research; and given the exploratory nature of our study, it is not clear how many NPs who responded were formally trained in clinical research or research methods. Fourth, our results suggest a possible divide between academic researchers and clinicians that warrants further discussion about academic-clinical practice partnerships. Academic-clinician partnerships could improve communication about clinical trials within primary care settings as well as address the most salient ethical concerns of each stakeholder group. Additionally, these partnerships could work together to identify important researchable topics that impact clinical practice and address issues of access, quality, and cost.

There are several limitations to our study. First, although this is one of the first studies to explore the role of NPs in discussing and recommending research to patients in primary care, it was conducted in only one northeastern state. NPs who practice in different states and geographical regions might respond differently, and further research is needed to describe any differences that might exist. Second, this study specifically focused on cancer clinical trials, it would be instructive to investigate these issues more broadly. Are NPs generally uncomfortable with clinical research within their practice setting and the practical issues they face in discussing the importance of research with their patients, or are there features unique to cancer clinical research? Third, although we achieved a strong response rate (> 50%), it leaves some room for non-response bias; however our findings are within the expected range of response rates for healthcare professionals [25].

Finally, improving access to research participation requires innovative thinking and collaborations among diverse groups. The recruitment and retention literature does not address the importance of NPs in clinical practice as a factor that might influence access to and attitudes about research participation. Nonetheless, we recommend a call to action to increase the level of NP communication about clinical trials based on our results. As this group of providers continues to grow and to meet the healthcare needs of a diverse group of people across the U.S., they need education about the benefits and burdens of clinical trials and the availability of research in their communities as well as encouragement to recommend research participation when it is an appropriate option for their patients. In addition, there are some data that suggest that patient-provider concordance in clinical interactions increase trust and communication patterns [26]. Future research should examine

best practices for communicating in concordant or discordant patient-provider dyads regarding clinical trials. Finally, we need to develop innovative system-based networks to increase communication between primary care providers and cancer centers or an efficient means to follow-up with oncologists to discuss and establish clinical trial options for patients. With such information, they will be able to recommend research to their patients and more importantly, engage in honest dialog with patients about their views on research participation.

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Table 1

Practice characteristics of the Nurse Practitioner sample.

Characteristic	Freq (%)	Total n
Current practice setting		168
• Solo office/Group practice: 2 providers	26 (15.5)	
• Group practice: 3–10 providers	60 (35.7)	
• Group practice: 11+ providers	15 (8.9)	
• Hospital based practice	37 (22.0)	
• Other	30 (17.9)	
Area current practice in		152
• Counties of 1 million or more people	31 (20.4)	
• Metropolitan areas of <1 million people	43 (28.3)	
• Urban area	59 (38.8)	
• Rural area	19 (12.5)	
Current practice for-profit	86 (51.2)	168
Has privileges with hospital or medical center	91 (54.2)	168
Affiliated with hospital or medical center	62 (41.1)	151
Office participates in clinical trials	47 (27.2)	173
Usual practice for treating cancer patients		173
• Treat	6 (3.5)	
• Refer, not involved	87 (50.3)	
• Refer, remain involved	63 (36.4)	
• Don't know	17 (9.8)	
Percentage of insured patients		160
• 0–10%	119 (74.4)	
• 11–20%	19 (11.9)	
• 21–30%	10 (6.2)	
• >=31%	12 (7.5)	
Large (.=31%) white patient population	138 (83.6)	165
Large (.=31%) African American patient population	27 (16.4)	165
Large (.=31%) Hispanic patient population	15 (9.1)	164

Table 2

Attitudes and beliefs of Nurse Practitioners toward clinical trials.

	Agree/strongly agree (%)	n*
<i>Attitudes</i>		
Comfortable discussing treatment options with my cancer patients	77 (47.8)	161
Comfortable discussing the option of entering a clinical trial for treatment of cancer patients	76 (47.2)	161
Have adequate time to spend with patients during their office visit to explain clinical trials	55 (34.4)	160
The level of communication with other providers about patients I referred to them is sufficient	86 (53.4)	161
Possible to maintain a continuing relationship with patients while they are participating on clinical trials	119 (77.3)	154
Would leave the decision for CT enrollment to an oncologist or someone who is more knowledgeable about the protocol	144 (86.7)	166
Would recommend a clinical trial as a treatment option for cancer patients only when conventional therapy has failed.	47 (29.2)	161
<i>Beliefs</i>		
Clinical research in oncology is important in improving future standards of care in oncology	160 (97%)	165
Conducting patient research is an important role of oncologists and/or nurse researchers who specialize in cancer care	159 (97.0)	164
Clinical research improves patient care for the patient involved	119 (74.4)	160
Patients with cancer who are participating in a clinical trial are receiving the best medical treatment available	63 (43.8)	144
Hospitals that conduct clinical research have better standards of clinical care than hospitals that do not	52 (34.4)	151

n varied due to missing data.

Table 3

NPs opinions and ethical concerns in relation to bringing up clinical trials as a treatment option to patients.

	All (n=157)	Bring up topic of clinical trial with at least some patient		P- value	Adjusted OR ^a (95% CI)
		Yes (n=61)	No (n=96)		
<i>NP opinions; n(%)</i>					
Comfortable discussing treatment options	69 (46.9)	37 (61.7)	32 (36.8)	0.001	4.29 (1.83, 10.06)
Comfortable discussing option of entering a clinical trial for treatment	68 (46.3)	37 (61.7)	31 (35.6)	0.003	3.54 (1.53, 8.15)
Have adequate time during visits to explain clinical trials	49 (33.6)	27 (45.0)	22 (25.6)	0.008	3.40 (1.37, 8.45)
Level of communication with other provider sufficient to ensure high quality care	79 (53.4)	34 (56.7)	45 (51.1)	0.600	1.23 (0.56, 2.71)
Possible to maintain relationship with patients participating in clinical trials	110 (78.0)	51 (85.0)	59 (72.8)	0.019	3.34 (1.22, 9.10)
Patients in clinical trials receive best medical treatment available	58 (44.3)	32 (56.1)	26 (35.1)	0.092	2.11 (0.88, 5.05)
Would leave decision for clinical trial to oncologist or someone more knowledgeable about the protocol	135 (89.4)	51 (83.6)	84 (93.3)	0.328	0.51 (0.13, 1.95)
Would recommend a clinical trial only when conventional therapy fails	44 (30.1)	13 (21.3)	31 (36.5)	0.097	0.47 (0.19, 1.15)
Conducting patient research is important role of oncologists/nurse researchers specializing in cancer care	144 (96.6)	59 (96.7)	85 (96.6)	0.032	1.10 (0.12, 10.07)
Clinical trials improves patient care	107 (73.8)	46 (79.3)	61 (70.1)	0.287	1.82 (0.61, 5.46)
Hospitals conducting clinical research have better standards of clinical care	47 (34.1)	21 (36.2)	26 (32.5)	0.346	1.51 (0.64, 3.59)
Clinical research is important in improving future standards of care	147 (97.4)	60 (98.4)	87 (96.7)	0.648	NA ^b
If I had cancer, I would prefer being in a clinical trial	52 (46.0)	27 (57.4)	25 (37.9)	0.516	1.35 (0.54, 3.39)
<i>Ethical Concerns with</i>					
Randomization of the patient to the non-active arm of the trial.	22 (14.8)	12 (20.3)	10 (11.1)	0.141	2.26 (0.76, 5.72)
Patients' understanding of randomization.	17 (11.4)	11 (18.6)	6 (6.7)	0.006	7.51 (1.78, 31.59)
Confidentiality in recruitment.	59 (39.3)	24 (40.7)	35 (59.3)	0.990	1.00 (0.45, 2.20)
Scientific value of the clinical trial.	52 (35.6)	21 (36.8)	31 (34.8)	0.745	1.15 (0.50, 2.63)
Potential burden to the patient.	17 (11.6)	9 (15.8)	8 (8.9)	0.164	2.40 (0.70, 8.24)
Informed consent	52 (35.9)	22 (38.6)	30 (34.1)	0.308	1.54 (0.67, 3.56)
Enrollment of "high risk" patients rather than subjects with a disease.	24 (16.8)	13 (54.2)	11 (45.8)	0.120	2.24 (0.81, 6.22)
Patients being used as a "guinea pig" in clinical research.	56 (37.8)	24 (42.1)	32 (35.2)	0.478	1.34 (0.60, 3.01)

^a %s based on non-missing data.
Significant results are bolded.

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Logistic regression adjusted for age, gender, years as a Nurse Practitioner, affiliation with a university/medical school, and whether clinical practice participated in clinical trials.
p not analyzed due to lack of variance. Fisher's exact p-value shown.

Table 4

NPs opinions and ethical concerns in relation to recommending clinical trials to patients.

	All (n=167)	Willing to recommend clinical trial when asked by patient		P- value	Adjusted OR ^a (95%CI)
		Yes (n=135)	No (n=32)		
<i>NP opinions; n(%)</i>					
Comfortable discussing treatment options	75 (48.4)	65 (51.6)	10 (34.5)	0.214	1.79 (0.71, 4.48)
Comfortable discussing option of entering a clinical trial for treatment	75 (48.4)	68 (53.5)	7 (25.0)	0.049	2.71 (1.00, 7.30)
Have adequate time during visits to explain clinical trials	54 (35.1)	45 (36.0)	9 (31.0)	0.784	1.14 (0.44, 2.99)
Level of communication with other provider sufficient to ensure high quality care	84 (54.2)	74 (58.7)	10 (34.5)	0.017	3.11 (1.22, 7.92)
Possible to maintain relationship with patients participating in clinical trials	115 (77.2)	96 (76.8)	19 (79.2)	0.615	0.74 (0.22, 2.42)
Patients in clinical trials receive best medical treatment available	61 (43.9)	54 (47.0)	7 (29.2)	0.085	2.53 (0.88, 7.29)
Would leave decision for clinical trial to oncologist or someone more knowledgeable about the protocol	138 (86.3)	113 (86.3)	25 (86.2)	0.678	1.31 (0.36, 4.77)
Would recommend a clinical trial only when conventional therapy fails	44 (28.4)	31 (24.4)	13 (46.4)	0.045	0.38 (0.15, 0.98)
Conducting patient research is important role of oncologists/nurse researchers specializing in cancer care	153 (96.8)	127 (97.7)	26 (92.9)	0.209	3.43 (0.50, 23.5)
Clinical trials improves patient care	114 (73.5)	95 (75.4)	19 (65.5)	0.141	2.16 (0.78, 6.00)
Hospitals conducting clinical research have better standards of clinical care	49 (33.8)	41 (34.5)	8 (30.8)	0.456	1.48 (0.53, 4.20)
Clinical research is important in improving future standards of care	154 (96.9)	130 (100.0)	24 (82.8)	< .001	NA ^b
If I had cancer, I would prefer being in a clinical trial	55 (45.1)	51 (50.0)	4 (20.0)	0.044	3.98 (1.04, 15.3)
<i>Ethical concerns with</i>					
Randomization of the patient to the non-active arm of the trial.	24 (15.0)	20 (15.6)	4 (12.5)	0.539	1.52 (0.40, 5.85)
Patients' understanding of randomization.	20 (12.5)	18 (14.1)	2 (6.3)	0.259	2.50 (0.51, 12.3)
Confidentiality in recruitment.	64 (40.0)	54 (42.2)	10 (31.3)	0.598	1.27 (0.52, 3.08)
Scientific value of the clinical trial.	54 (34.4)	46 (36.2)	8 (26.7)	0.770	1.15 (0.45, 2.97)
Potential burden to the patient.	19 (12.0)	19 (15.0)	0 (0.0)	0.026	NA ^b
Informed consent	56 (35.9)	45 (36.3)	11 (34.4)	0.653	1.23 (0.49, 3.08)
Enrollment of "high risk" patients rather than subjects with a disease.	27 (17.7)	24 (19.5)	3 (10.0)	0.275	1.10 (0.55, 7.93)
Patients being used as a "guinea pig" in clinical research.	60 (37.7)	53 (41.7)	7 (21.9)	0.024	3.39 (1.17, 9.81)

^a%s based on non-missing data.
Significant results are bolded.

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Logistic regression adjusted for age, gender, years as a Nurse Practitioner, affiliation with a university/medical school, and whether clinical practice participated in clinical trials.
Not analyzed due to lack of variance. Fisher's exact p-value shown.

Table 5

NPs opinions and ethical concerns in relation to recommending clinical trials to high risk patients.

	All (n=162)	Willing to recommend clinical trial to high risk patients		P-value	Adjusted OR ^a (95%CI)
		Yes (n=127)	No (n=35)		
NP opinions; n(%)					
Comfortable discussing treatment options	72 (47.7)	55 (47.0)	17 (50.0)	0.790	0.88 (0.35, 2.21)
Comfortable discussing option of entering a clinical trial for treatment	72 (47.7)	57 (48.7)	15 (44.1)	0.694	0.83 (0.33, 2.09)
Have adequate time during visits to explain clinical trials	51 (34.01)	38 (32.5)	13 (39.4)	0.659	0.81 (0.31, 2.08)
Level of communication with other provider sufficient to ensure high quality care	80 (53.0)	64 (53.8)	16 (50.0)	0.660	1.23 (0.49, 3.09)
Possible to maintain relationship with patients participating in clinical trials	112 (76.2)	89 (76.1)	23 (76.7)	0.769	1.18 (0.39, 3.52)
Patients in clinical trials receive best medical treatment available	60 (44.1)	53 (50.5)	7 (22.6)	0.011	3.96 (1.36, 11.51)
Would leave decision for clinical trial to oncologist or someone more knowledgeable about the protocol	135 (86.5)	106 (86.9)	29 (85.3)	0.417	1.71 (0.47, 6.25)
Would recommend a clinical trial only when conventional therapy fails	44 (29.1)	31 (26.3)	13 (39.4)	0.043	0.36 (0.14, 0.97)
Conducting patient research is important role of oncologists/nurse researchers specializing in cancer care	149 (96.8)	117 (96.7)	32 (97.0)	0.661	0.58 (0.05, 6.59)
Clinical trials improves patient care	109 (72.7)	88 (75.2)	21 (63.6)	0.322	1.72 (0.59, 5.04)
Hospitals conducting clinical research have better standards of clinical care	49 (34.8)	39 (35.8)	10 (31.3)	0.512	1.40 (0.51, 3.80)
Clinical research is important in improving future standards of care	150 (96.8)	119 (97.5)	31 (93.9)	0.774	1.50 (0.09, 24.0)
If I had cancer, I would prefer being in a clinical trial	54 (45.8)	46 (49.5)	8 (32.0)	0.255	1.98 (0.61, 6.50)
Ethical concerns with					
Randomization of the patient to the non-active arm of the trial.	23 (14.7)	21 (17.2)	2 (5.7)	0.094	4.09 (0.79, 21.31)
Patients' understanding of randomization.	20 (12.7)	18 (14.8)	2 (5.7)	0.099	4.31 (0.76, 24.42)
Confidentiality in recruitment.	64 (40.8)	56 (45.5)	8 (23.5)	0.059	2.65 (0.96, 7.27)
Scientific value of the clinical trial.	55 (35.7)	49 (40.8)	6 (17.7)	0.039	3.24 (1.06, 9.90)
Potential burden to the patient.	19 (12.3)	18 (14.8)	1 (3.03)	0.140	NA ^b
Informed consent	54 (35.3)	45 (37.2)	9 (28.1)	0.539	1.35 (0.52, 3.52)
Enrollment of "high risk" patients rather than subjects with a disease.	27 (18.0)	23 (19.8)	4 (11.8)	0.418	1.68 (0.48, 5.88)
Patients being used as a "guinea pig" in clinical research.	58 (37.2)	50 (41.0)	8 (23.5)	0.282	1.71 (0.64, 4.53)

^a %s based on non-missing data.
Significant results are bolded.

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Logistic regression adjusted for age, gender, years as a Nurse Practitioner, affiliation with a university/medical school, and whether clinical practice participated in clinical trials.
Not analyzed due to lack of variance. Fisher's exact p-value shown.