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ORIGINAL RESEARCH

Understanding Attitudes and Roles of Oncology Advanced Practitioners in the Setting of Cancer Clinical Trials: A Pilot Study

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Abstract

Purpose: Oncology advanced practitioners (APs), including nurse practitioners, physician assistants, clinical nurse specialists, and pharmacists, are skilled health-care providers who contribute significantly to quality cancer care. However, little is known about how APs function within the clinical trials arena. With low rates of clinical trial enrollment among the adult oncology patient population, APs could play an important role in improving clinical trial enrollment. **Methods:** A descriptive cross-sectional study was conducted based on a 57-item survey of oncology APs' attitudes, beliefs, and roles in relation to cancer clinical trials. **Results:** To assess validity and internal consistency of the survey, a pilot data collection was completed on 14 respondents from Hawaii. The survey's internal consistency across the subscales was moderate to very high, with Cronbach's alpha ranging between 0.55 and 0.86. The majority of oncology APs were interested in being more involved in the clinical trials process, and many are registered as investigators through the National Cancer Institute (NCI). However, few respondents reported being involved in recruitment, consenting, protocol development, or being actively involved with a research base. **Conclusions:** This survey was found to be a valid tool to measure APs' attitudes and roles in regards to clinical trials. This survey is just the beginning of data collection in regards to clinical trials among this group of health-care professionals. **Recommendations:** To gain further insight into oncology APs and their roles in clinical trials, it is recommended that this survey be implemented on a national level as a first step in moving this issue forward.

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Nurse practitioners, physician assistants, and pharmacists, known collectively as advanced practitioners (APs), are highly trained and skilled health-care providers who contribute significantly to quality cancer care. They have been identified multiple times as part of the solution to the projected shortage of oncologists. In 2015, over 70% of the American Society for Clinical Oncology (ASCO) census practices reported employing nurse practitioners and physician assistants. There are over 5,000 nurse practitioners and physician assistants practicing in oncology nationwide (Bruinooge et al., 2018).

Oncology APs are valuable contributors within the oncology workforce, with the potential to expand into roles in clinical trials. However, little is known about their current roles in clinical trials. A search of the literature, the community, research base memberships and organizations such as the Oncology Nursing Society (ONS) and Advanced Practitioner Society for Hematology and Oncology (APSHO), returns little evidence of an established programmatic connection with these groups and oncology research. With clinical trial enrollment estimated to be between 2% to 8% among the adult oncology population (American Cancer Society, 2018; Hallquist Viale, 2016; Murthy et al., 2004; Rimel, 2016), AP participation in clinical trials recruitment and management is a potential expansion of the clinical trials workforce and could facilitate higher enrollment in oncology clinical trials.

When it comes to clinical research and clinical trial accrual, oncology APs have the potential to connect the oncologist and the patient. Advanced practitioners have a deep understanding of treatment along the disease trajectory and are experts in symptom management. Because of these strengths, they can discuss trials with patients more easily than their research nurses and coordinator counterparts. They not only have the knowledge and skills to help a patient understand what is involved in the trial, but also why the trial is being done and why it is being offered to them (Ulrich et al., 2012).

In addition, APs are independent practitioners and can serve as sub-investigators and even principal investigators on protocols. In this role, they serve as the primary provider for patients on clinical trials. As clinical trials are supported by evidence that provides clear guidance for treatment, toxicity, and dose modification, the trial protocol also serves as a learning tool for the AP.

Pharmacists are another group of APs identified as key oncology advanced practitioners. They could also serve as a crucial link to clinical trials. They are practitioners trained to address many aspects of patient care, including treatment assessment, monitoring for potential adverse drug reactions and interactions, dosing, and patient education (Board of Pharmacy Specialties, 2018).

To propose any intervention among this group of health-care providers in an attempt to increase clinical trial accrual and clinical trials management, one must first understand current practice. We currently have limited information about the attitudes, beliefs, and roles in relation to clinical trials among these practitioners. The present study aimed to develop a survey of APs' attitudes, knowledge, and involvement in clinical trials, in order to gain knowledge in this area as a basis for a potential intervention.

METHODS

Study Design

The survey was developed based on a review of published oncology AP data sets and other clinical trials literature. Cognitive interviewing was then performed on key informants, including three medical oncologists, two oncology advanced practice registered nurses (APRNs), two behavioral scientists, and a biostatistician. The survey questions were divided into three categories: background, attitudes/beliefs, and roles/involvement in clinical trials. The survey protocol was submitted to and approved by the University of Hawaii Institutional Review Board.

Survey Procedures

The intent of the Hawaii pilot survey was to assess the feasibility, validity, and reliability of the tool. In addition, this pilot helped to gain insight into oncology APs' clinical trial practice in Hawaii. The eligibility criteria for respondents included nurse practitioners, clinical nurse specialists, physician assistants, and pharmacists who practice in the oncology setting as APs in the state of Hawaii. We

disseminated the survey to 16 oncology APs representing all four counties in Hawaii. A brief introduction to the survey was sent via e-mail with a link through SurveyMonkey. A statement of implied consent was embedded into the introduction with a link to full consent.

On average, it took participants 8 minutes to complete the survey. Fourteen of the 16 invited APs participated in the survey, of which 13 completed the full survey. After the survey, 6 of the 14 respondents participated in a focus group and 8 participants took the survey again 2 months later to assess its test-retest reliability.

Statistical Analysis

The construct validity and reliability of the survey was assessed using 14 responses from the first run. For all quantitative (Likert's scale or yes/no) questions, the range of responses was examined to assess the range of offered answer choices. To identify the dimensionality (the number of subscales) of the survey, principal components (subscales) were identified using factor analysis and scree plot, with minimum eigenvalue of 1. In each subscale, survey questions with loadings of 0.5 or higher were marked for inclusion. No factor rotation was applied due to the small number of responses in the pilot run. Cronbach's alpha was computed for all subscales to assess the internal consistency of the survey. The adequacy of the subscales was examined by computing Cronbach's alpha with one question deleted at a time, which resulted in the deletion of one question from one of the subscales (Figure 1). To assess test-retest reliability, the repeat run of the survey was compared with the first run. Pearson's correlation coefficient was computed for each quantitative question, using answers from the respondents who completed both runs of the survey and whose responses could be uniquely matched between the two runs (n = 4; Figure 2).

RESULTS

Survey Validity, Interval Consistency, and Repeatability

Five subscales were identified among the quantitative questions of the survey. The survey's internal consistency across the subscales was moderate to very high, with Cronbach's alpha ranging between 0.61 and 0.86 (Figure 1). Pearson's correlation coefficient between the two runs of the survey ranged between –0.57 and 1.0, with a mean of 0.84 and median of 1.0. Correlation could not be computed for 12 questions due to no variability in the answers. Out of the remaining 31 questions, 24 (77%) had correlation 1.0 between the runs, and 28 (90%) had correlation > 0.8 (Figure 2). Two questions with negative correlation were reviewed and revised in the final version of the survey.

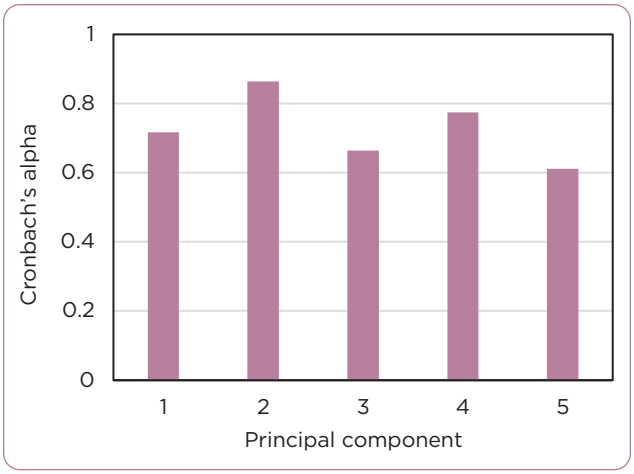

Figure 1. Cronbach's alpha for the five identified principal components (subscales). Principal component (PC) 1 comprises questions 7, 8, 9, 10; PC 2 comprises questions 17, 22, 23, 26, 29, 30, 37, 38, 39, 43, 44, 46, 49, 51, 54; PC 3 comprises questions 16, 18, 20, 31, 40; PC 4 comprises questions 34, 47, 48, 53; PC 5 comprises questions 15, 24, 25.

APs' Background

The oncology APs who participated in the pilot surveys included seven nurse practitioners, one clinical nurse specialist, one physician assistant, and five pharmacists. All respondents worked as oncology APs in the community, except for two who were employed by the government. All reported fewer than 10 oncology APs and oncologists in their practice. The respondents reported multiple duties, such as direct patient care (including chemotherapy checks), procedures, patient education, and clinical research. The majority of respondents worked in medical oncology and hematology, with a minority working in surgery and other areas (gynecologic oncology, pediatric hematology/oncology, surgical oncology, adolescent/young adult, survivorship care). Almost all

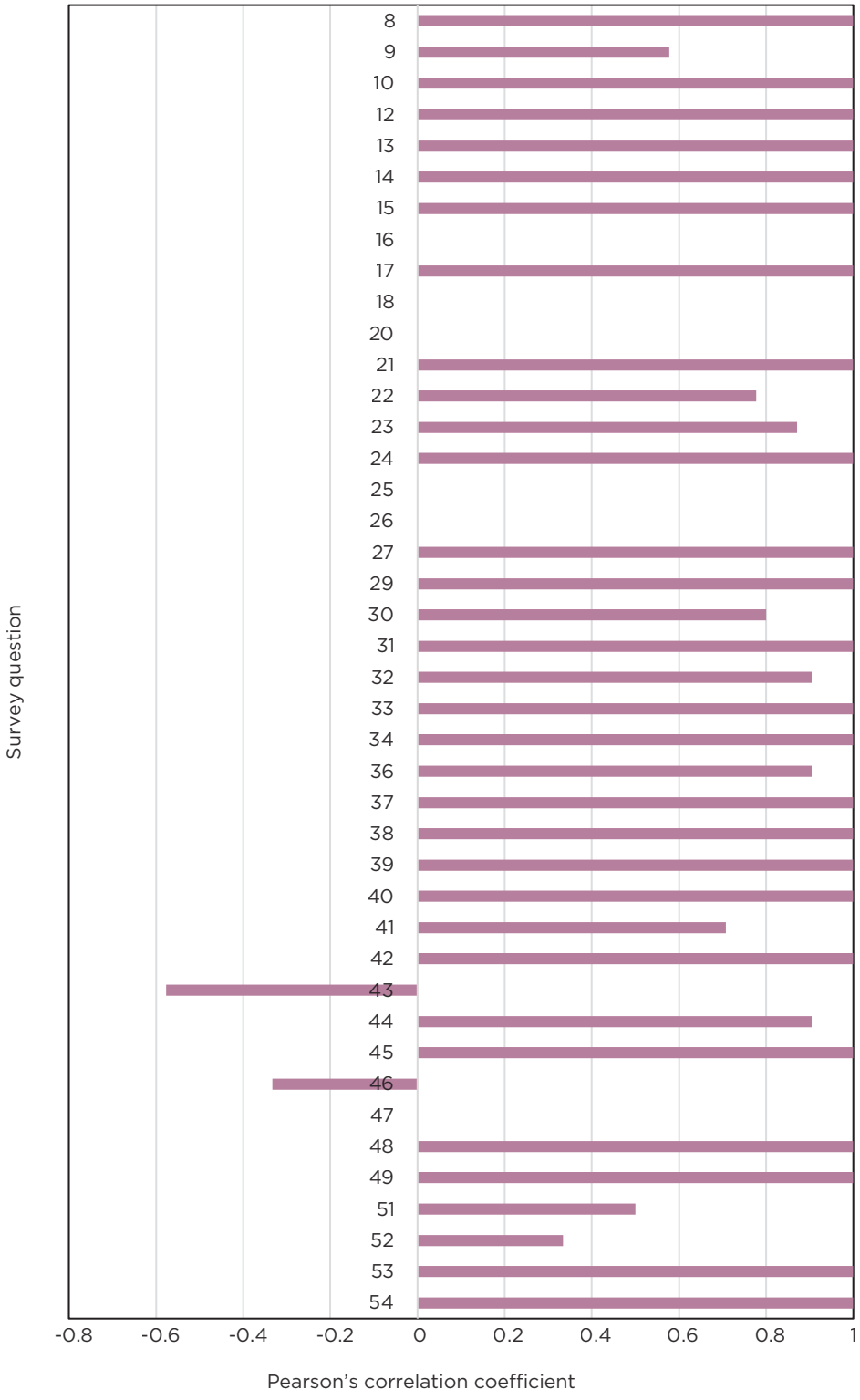

Figure 2. Test-retest correlation between two runs of the survey. Questions 12, 13, 14, 21, 27, 32, 33, 36, 41, 42, 45, and 52 had no variability in responses on at least one of the two survey runs. The Pearson's correlation coefficient could not be computed.

(n = 13) respondents reported that clinical trials were available at their practice setting. Over 30% (n = 5) were not aware of all the different types of trials that they participated in, such as National Cancer Institute (NCI), industry, or investigator-initiated trials. Six of the 14 respondents did not know whether they belonged to a NCI Community Oncology Research Program (NCORP), despite 13 of the 14 being members of the Hawaii Minority/Underserved NCORP or the Kaiser Permanente NCORP (Table 1).

APs' Attitudes and Beliefs

The majority of oncology APs surveyed felt comfortable discussing available clinical trials with their patients (n = 11). Fifty percent (n = 7) believed they had adequate time to spend with patients to explain a clinical trial and 50% (n = 7) would leave the recommendation for clinical trial participation to someone else, but the answers to these questions did not strongly correlate. All but one (13 of 14), felt conducting clinical research was an appropriate role for oncology APs. Twelve of the 14 respondents believed

Table 1. Study Sample Distribution by Practice Setting and Advanced Practitioner Role

Characteristic/question	No.	%
AP type		
Nurse practitioner	7	50.0
Physician assistant	1	7.1
Clinical nurse specialist	1	7.1
Pharmacist	5	35.7
Currently employed as an AP		
Yes	12	85.7
No	2	14.3
Primary practice setting		
Hospital-based clinic	7	50.0
Physician-owned or group practice	3	21.4
Practice owned by hospital or health system	2	14.3
Government	2	14.3
Clinical focus		
Hematology/oncology	11	78.6
Gynecologic oncology	3	21.4
Pediatric hematology/oncology	2	14.3
Surgical oncology	1	7.1
Adolescent and young adult	1	7.1
Survivorship	3	21.4
Other	1	7.1
Number of physicians and oncology APs in the practice		
< 5	2	14.3
5–10	12	85.7
Number of oncologists in the practice		
< 5	6	42.9
5–10	8	57.1

Note. AP = advanced practitioner; NCI = National Cancer Institute; NCORP = NCI Community Oncology Research Program.

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Table 1. Study Sample Distribution by Practice Setting and Advanced Practitioner Role (cont.)

Characteristic/question	No.	%
Percentage of time AP typically spends on direct patient care		
100%	2	14.3
75%–99%	7	50.0
50%–74%	4	28.6
25%–49%	1	7.1
How many patient visits do you have in a typical week?		
< 25 visits per week	5	35.7
25–50 visits per week	4	28.6
> 50 visits per week	5	35.7
What types of duties do you perform in a typical week (answer as many as apply)?		
Direct patient care: chemotherapy checks, follow-up visits, urgent visits	12	85.7
Procedures: bone marrow biopsy, intrathecal chemotherapy, lumbar punctures, paracentesis, thoracentesis	2	14.3
Patient education/coordination of care	6	42.9
Clinical research	4	28.6
Other	2	14.3
There are clinical trials are available at my practice setting.		
Yes	13	92.9
No	1	7.1
Don't know	0	0
Does your practice site participate in NCI-sponsored trials?		
Yes	13	92.9
No	1	7.1
Don't know	0	0
Does you practice/participate in pharmaceutical trials?		
Yes	11	78.6
No	3	21.4
Don't know	0	0
Does your practice setting participate in investigator-initiated trials?		
Yes	8	57.1
No	2	14.3
Don't know	4	28.6
Is your practice setting a member of an NCORP?		
Yes	8	57.1
Don't know	6	42.9

Note. AP = advanced practitioner; NCI = National Cancer Institute; NCORP = NCI Community Oncology Research Program.

that patients enrolled in clinical trials receive the best possible care; however, less than half reported that they routinely explore a clinical trial for each patient they see (n = 6). Finally, the majority (n = 9) of oncology APs were interested in becoming more involved in the clinical trials process (Table 2).

Table 2. Advanced Practitioners' Attitudes Regarding Clinical Trials

Question	No.	%
I am comfortable discussing treatment options with my cancer patients.		
Strongly agree	7	50.0
Agree	4	28.6
Neither agree nor disagree	2	14.3
Disagree	1	7.1
I am comfortable discussing the available clinical trials with my patient.		
Strongly agree	5	35.7
Agree	6	42.9
Neither agree nor disagree	2	14.3
Disagree	1	7.1
I have adequate time to spend with patients during their office visit to explain clinical trials.		
Strongly agree	1	7.1
Agree	6	42.9
Neither agree nor disagree	5	35.7
Disagree	2	14.3
I would leave the decision for clinical trial recommendation to the oncologist or someone more knowledgeable about the protocol.		
Strongly agree	2	14.3
Agree	5	35.7
Neither agree nor disagree	1	7.1
Disagree	4	28.6
Strongly disagree	2	14.3
I believe that patients enrolled in clinical trials get the best possible care.		
Strongly agree	8	57.1
Agree	4	28.6
Neither agree nor disagree	2	14.3
Clinical research outcomes improve patient care.		
Strongly agree	11	78.6
Agree	3	21.4
Participating in clinical research enhances my knowledge about the subject being studied.		
Strongly agree	10	71.4
Agree	4	28.6
Conducting clinical research should be a role for advanced practitioners in oncology.		
Strongly agree	10	71.4
Agree	3	21.4
Neither agree nor disagree	1	7.1

Note. Answer choices with zero responses are not shown.

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Table 2. Advanced Practitioners' Attitudes Regarding Clinical Trials (cont.)

Question	No.	%
Cancer clinical trials are important to improve the standards of oncology care.		
Strongly agree	13	92.9
Agree	1	7.1
I explore whether there is a potential clinical trial for each patient I see.		
Usually	6	42.9
Sometimes	4	28.6
Rarely	2	14.3
Never	1	7.1
I only look for clinical trials for my patients if all standard therapy has failed.		
Strongly agree	1	7.1
Agree	2	14.3
Neither agree nor disagree	4	28.6
Disagree	4	28.6
Strongly disagree	3	21.4
I have a good understanding of the different phases of cancer clinical trials (phases I–IV).		
Strongly agree	6	42.9
Agree	8	57.1
I have a good understanding of the different types of clinical trials.		
Strongly agree	5	35.7
Agree	6	42.9
Neither agree nor disagree	3	21.4
I know where to look for available clinical trials at my institution for a patient.		
Yes	13	92.9
No	1	7.1
I know where to look for available clinical trials at an outside institution for my patient.		
Yes	10	71.4
No	4	28.6
My cancer care team sees the oncology advanced practitioner as having an important role in clinical trials.		
Strongly agree	4	28.6
Agree	8	57.1
Neither agree nor disagree	2	14.3
I am interested in becoming more involved in the clinical trials process.		
Yes	9	64.3
No	1	7.1
Don't know	3	21.4

Note. Answer choices with zero responses are not shown.

APs' Roles

The final section of the survey assessed AP roles in relation to clinical trials (Table 3). The majority of respondents reported that they were involved in identifying, recruiting, and coordinating patients on trial (n = 11). In addition,

Table 3. Advanced Practitioners' Roles in Clinical Trials

Question	No.	%
In my practice setting, the following individuals are involved identifying, recruiting and coordinating the clinical trials process.		
Physician	14	100.0
Research nurse/coordinator	12	85.7
Oncology advanced practitioner	11	78.6
Clinic or chemotherapy nurse	6	42.9
Navigator	4	28.6
Other	2	14.3
Which, if any, of the following roles do you play in the clinical trials process?		
Primary person who consents patient	0	0.0
Helps with consent process	5	35.7
Identify patients	8	57.1
Recruits patients	4	28.6
Coordinates patients	3	21.4
Follows patients on trials	9	64.3
Toxicity management	10	71.4
Other	2	14.3
None of the above	1	7.1
I am registered with the NCI as a non-physician investigator.		
Yes	8	57.1
No	6	42.9
I recruit patients to clinical trials at my practice setting		
A great deal	1	7.1
A lot	1	7.1
A moderate amount	2	14.3
A little	4	28.6
None at all	6	42.9
I consent patients for clinical trials at my practice setting.		
A few times a week	1	7.1
Less than once a month	11	78.6
I follow patients on clinical trials at my practice.		
Every day	2	14.3
A few times a week	2	14.3
A few times a month	6	42.9
Less than once a month	3	21.4
I am the primary provider for patients on clinical trials at my practice setting.		
Yes	1	7.1
No	12	85.7

Note. Answer choices with zero responses are not shown. NCI = National Cancer Institute.

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Table 3. Advanced Practitioners' Roles in Clinical Trials (cont.)

Question	No.	%
I am an enrolling provider for patients on cancer clinical trials.		
Yes	4	28.6
No	8	57.1
Don't know	1	7.1
In regards to the patients you see on trial, did you play a part in recruiting them on the trial?		
Yes	6	42.9
No	6	42.9
N/A	1	7.1
I am a principal investigator at my site on at least one clinical trial.		
No	13	92.9
I am a sub-investigator at my site.		
Yes	7	50.0
No	6	42.9
I am able to order investigational drugs.		
Yes	3	21.4
No	6	42.9
Don't know	4	28.6
Are you involved in reviewing clinical trials at your practice setting?		
Yes	7	50.0
No	6	42.9
Are you involved in the process of selecting appropriate trials for your practice setting?		
Yes	7	50.0
No	6	42.9
What role, if any, do you play in protocol development?		
Study team	5	35.7
Co-investigator	1	7.1
No involvement in protocol development	7	50.0

Note. Answer choices with zero responses are not shown. NCI = National Cancer Institute.

the majority of respondents followed patients on trial (n = 9) and performed toxicity management (n = 10). Eight of the fourteen respondents were registered with the NCI as a nonphysician investigator. Half of these investigators (n = 4) were able to enroll patients independently of an oncologist. In addition, 50% (n = 7) reported being involved in reviewing trials for their site. Multiple respondents indicated that they had been involved in protocol development (n = 6). However, no one reported being a principal investigator.

DISCUSSION

To our knowledge, this is the first attempt to gain insight into this group of oncology clinicians (APs) in the setting of cancer clinical trials. As there are increasing numbers of oncology APs entering the workforce every day, we have the opportunity to engage this important group of providers in the practice of clinical trials. However, one must first understand current practice. The present study attempted to develop, validate, and refine a survey tool to assess oncology APs' background, attitudes/beliefs, and roles in regards to clinical tri-

als. Overall, the results showed that this tool has adequate psychometric properties. Knowledge gained from the use of this tool can facilitate better understanding of the current practice of oncology APs in clinical research.

In addition to validation of the instrument, this study begins to add data in this area. One of the themes that emerged from this research is that oncology APs act as both coordinators and providers for patients on clinical trials. Whether it is identifying and coordinating patients or direct patient care, it is clear that this group of providers has an important role in clinical trials. Both Bevans and colleagues (2011) and Schramp and colleagues (2010) reported similar findings; however, there is almost a decade-long dearth in the literature in discussing the role of the oncology AP in clinical trials. During this time, the impact of oncology nurse practitioners and physician assistants in the United States has exploded (Bruinooge et al., 2018).

The importance of oncology pharmacists cannot be overlooked either. Interestingly, one publication reported pharmacists' critical role in drug interaction screening when reviewing eligibility criteria as an area of patient safety. This is another arena that could incorporate the oncology AP's expertise in the clinical trials realm, but only about 17% of pharmacists reported being routinely involved (Goodin, 2018). Five respondents of this survey were pharmacists, and all reported being engaged in the clinical trial process; however, the issue of drug interactions and eligibility assessment was not addressed. This is an additional area where oncology APs can add value to the coordination of patients on trial.

Another theme that emerged is research involvement. The majority of oncology APs surveyed reported being sub-investigators. They also indicated being involved in the research process at their institution. However, few reported being comfortable recommending trials or routinely exploring available trials for their patients. The reason for this observation is unclear, but one may allude that time constraints may be of concern. Other disciplines have reported time constraints as being a significant barrier to clinical trial accrual (Ford et al., 2011), and oncology APs may not be any different.

Finally, this survey found that oncology APs are interested in becoming more involved in the clinical trials process. This is an exciting finding, as the group surveyed already appears engaged. However, there are still more opportunities. For instance, despite a majority of respondents being sub-investigators, none reported being a principal investigators. At present, non-physician investigators can be principal investigators on NCI-sponsored trials that do not involve medications and for certain industry trials, which depends on the sponsor. There are also oncology APs developing investigator-initiated treatment-based protocols with the support of a physician colleague (Jameson et al., 2020). Just as the scope of oncology AP practice has expanded in standard-of-care practice, there is opportunity to grow in the clinical trials arena.

Oncology APs can add to physicians and other PhD researchers doing clinical research, since they are a significant part of the oncology workforce that continues to grow. We need to create opportunities for all oncology providers to participate in research. This will be crucial as oncology care continues to become more complex. In addition, survivorship and cancer care delivery issues are becoming more relevant and important research domains. Oncology APs are well positioned to add value to these types of trials and could play a key role in protocol development. Oncology APs run many survivorship clinics and perform much of the care coordination for these clinics (Bruinooge et al., 2018).

This study has a number of limitations. First, although this survey is valid and reliable, this conclusion is based on a small sample and a homogenous set of respondents. Second, all oncology practice sites in Hawaii are community based, which may show bias. Third, the majority of respondents are employed at sites that are part of an NCORP either through the Hawaii Minority/Underserved NCORP or the Kaiser Permanente NCORP. Hawaii is known for its strong community research program; therefore, respondents may not be fully representative of community oncology APs nationally.

CONCLUSION

Overall, this survey is a valid tool to gain a better understanding of oncology APs' knowledge, attitudes toward, and involvement in clinical re-

search. Despite this study's limitations, it is the beginning of developing a data set for oncology APs in the realm of cancer clinical trials. Since this pilot study, the survey has undergone additional refinement. We invited the pilot respondents to participate in a focus group and worked with additional national key informants to refine the survey. Recently, a national pilot was completed, as well as a larger national study.

As oncology APs are becoming increasingly important in the landscape of oncology care, it is time that this group of providers become more involved in the research that will shape oncology practice for the years to come. As oncology APs are well positioned to have a positive effect on cancer care and outcomes, they can also make significant contributions to cancer clinical research. However, more information is needed regarding the best ways to utilize their skills.

Disclosure

The authors have no conflicts of interest to disclose.

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