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ORIGINAL RESEARCH

Role of Oncology Advanced Practitioners to Enhance Clinical Research

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Abstract

Background: Oncology advanced practitioners (APs), including nurse practitioners, clinical nurse specialists, physician assistants, and clinical pharmacists contribute significantly to quality cancer care. Advanced practitioners enhance value across the spectrum of cancer care. Research is an underdeveloped component of quality care, as well as an underdeveloped component of AP practice. Understanding research-related attitudes and roles of APs could lead to enhanced clinical trial accrual, conduct, and protocol development. **Methods:** A nationwide survey addressing attitudes, beliefs, and roles of APs regarding clinical research was distributed by the Association of Community Cancer Centers (ACCC) and Harborside in early 2020. **Results:** 408 oncology APs completed the survey. Thirty-five percent practice in an academic setting and 62% in the community. Nearly all respondents believe clinical trials are important to improve care, and over 90% report clinical trials are available at their practice. About 80% report being comfortable discussing the topic of clinical trials with patients and are involved in the care of trial participants. Sixty percent are comfortable discussing available trials, and 38% routinely explore available trials with patients. While 70% report approaching eligible patients about trials, only 20% report doing so "a great deal" or "a lot." Ninety percent report that APs should play a role in clinical research, and 73% want to be more involved. Barriers identified to greater AP clinical trial involvement include lack of time, inadequate awareness of trial specifics, and a lack of a formal role in protocol development and leadership. **Conclusions:** Advanced practitioners are engaged and interested in clinical trials and believe clinical research is important to improve cancer care. Multidisciplinary team integration, trials-related education, and policy change are needed to employ APs to their full potential within cancer clinical trials.

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Oncology advanced practitioners (APs), including nurse practitioners, clinical nurse specialists, physician assistants, and clinical pharmacists, contribute significantly to quality cancer care. Advanced practitioners enhance value across the spectrum of cancer care. Research is an underdeveloped component of quality care, as well as an underdeveloped component of AP practice. In 2015, the American Society of Clinical Oncology (ASCO) identified APs as part of the care delivery solution to the projected shortage of oncologists (ASCO, 2015). It was noted then that there were about 3,000 oncology APs, and recently that number is estimated to be over 10,000 (The JADPRO Podcast, 2021; Vogel, 2016). Services that oncology APs provide include, but are not limited to, treatment counseling, side-effect monitoring and management, coordination of care, disease surveillance, supportive care, long-term follow-up, survivorship, palliative, and end-of-life care (Hylton & Smith, 2017). However, little documentation exists about the AP role in clinical trials.

A search of the literature and professional organizations, including the Oncology Nursing Society (ONS), the Advanced Practitioner Society for Hematology and Oncology (APSHO), the American Academy of Physician Assistants (AAPA), and the Hematology/Oncology Pharmacy Association (HOPA), returns little evidence of specific education or advocacy regarding oncology APs and clinical trials. Current estimates are that only 2% to 8% of the adult oncology population enrolls in a clinical trial, with more than 20% of trials failing to meet accrual goals (American Cancer Society Cancer Action Network, 2019; Hallquist-Viale, 2016; Murthy et al., 2004; Rimel, 2016). Understanding current attitudes and research responsibilities of oncology APs will identify opportunities to leverage this capable workforce to enhance the accrual, conduct, and development of clinical trials.

Clinical trials can be time-consuming for clinicians and research staff, potentially expensive for facilities, and even burdensome on patients (Fogel, 2018). The time required to introduce and educate a patient about a clinical trial is a recognized barrier to accrual (Unger et al., 2020). Oncology APs are uniquely trained and positioned to facilitate these discussions with patients. The majority of APs have a thorough understanding of treatment paradigms along the disease trajectory, and many are experts in symptom management. Their knowledge and expertise can lead to a more thorough discussion augmenting specific trial information provided by other members of the research team (Ulrich et al., 2012). In addition, oncology APs are more often serving as subinvestigators to assist in the conduct of clinical trials and perform study-related procedures. In some instances, APs have conducted clinical trials as the primary investigator (PI).

Highlighting AP capabilities may expand their role in research. It is difficult to discern the true number and extent of oncology AP researchers and scholarship. Development and expansion of this role should be an academic and practice priority that ensures an adequate supply of oncology APs who make substantial and meaningful research contributions (Burton et al., 2010).

The present survey describes current oncology APs' attitudes, beliefs, and roles within this realm, identifying practice opportunities from which initial recommendations can be made.

METHODS

Setting and Subjects

We conducted an online survey of oncology APs through the Association of Community Cancer Centers (ACCC) and Harborside (APSHO's management company). We sent out 14,601 emails requesting survey participation from January 22, 2020, through March 6, 2020, to oncology APs within these organizations. The email consisted of an initial message followed by a reminder email 3 weeks later. The University of Hawaii institutional review board (IRB) approved all procedures.

Survey Development

The 65-item survey was developed and validated in two prior pilot studies. The initial survey was piloted in Hawaii using a mixed-methods approach (Braun-Inglis et al., 2021). The survey was then revised based on national expert input. To assess the validity and internal consistency of the national survey, pilot data collection was completed on 28 respondents across the United States. The survey's internal consistency across subscales was moderate to very high (Cronbach alpha rang-

ing between 0.59 and 0.88). Analysis of test-retest repeatability using 23 pairs of responses yielded Pearson correlations among two responses between 0.32 and 1.0, with a median of 0.77, further verifying significant strength of association between responses nationally.

Survey Procedures

Respondent eligibility criteria included nurse practitioners, clinical nurse specialists, physician assistants, and pharmacists practicing as oncology APs in the US. The email contained a brief introduction with a link to the survey through SurveyMonkey. A statement of implied consent was embedded into the introduction, with access to the full consent via a hyperlink. Four hundred eight participants finished the survey, with an average completion time of 9 minutes. Data analysis was performed using SurveyMonkey.

Measures

Sociodemographic variables included respondent age, sex, and ethnicity. The survey was divided into three main sections: demographics and background, attitudes and beliefs, and roles.

RESULTS

AP Demographics and Background

Respondents are primarily white (83%) and female (92%), with a median age of 45 years. Participants practice in 43 US states and the District of Columbia, representing a broad cross section of the country (Figure 1). The majority of respondents are nurse practitioners (70.6%), followed by physician assistants (12.3%), pharmacists (9%), and clinical nurse specialists (7%). Thirty-five percent practice in an academic setting and 62% in the community (Figure 2), with significant variation in practice size. Over 92% report current employment as an AP in oncology, with average time in practice of 11 to 15 years (Table 1). The vast majority (80%) work in the outpatient setting, identify their specialty as medical oncology (75%), and report their primary role is direct patient care (> 80%). In addition, approximately 25% report clinical research as a focus. More than 45% of respondents report

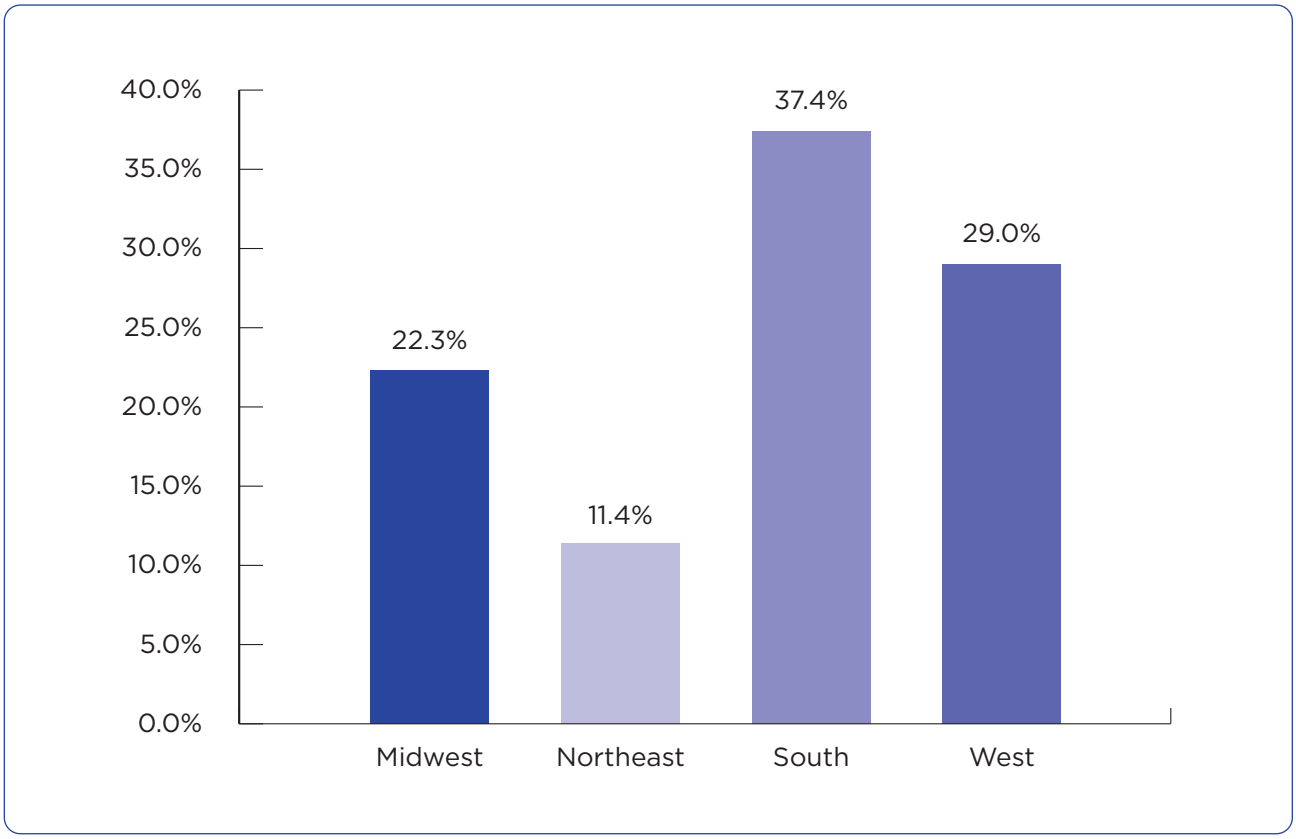

Figure 1. Survey respondents' geographic location, by US geographic region.

an average of 25 to 50 patient visits per week, with direct patient care (chemotherapy checks, follow-up visits, urgent visits) and patient education/care coordination among the most common duties performed (84.8% of respondents). Over 90% report that clinical trials are available at their practice, and more than 70% report participation in NCI, industry, and investigator-initiated sponsored trials. Over half of respondents (57%) report seeing 1 to 5 patients enrolled in clinical trials weekly.

APs' Research Attitudes and Beliefs

Most oncology APs surveyed feel comfortable discussing treatment options with their patients, including clinical trials, and indicated knowing where to find information on specific trials (84%; Table 2). Nearly all respondents (98%) believe clinical trials are important to improve oncology care standards and that oncology APs should participate in clinical research (91%). Furthermore, over 80% report having a good understanding of the different phases (phases I–IV) of clinical trials; however, fewer report having a good understanding of the different types of clinical trials. Greater than 60% believe that their cancer care teams see them as having an important role in clinical trials. Seventy-three percent report they are interested in

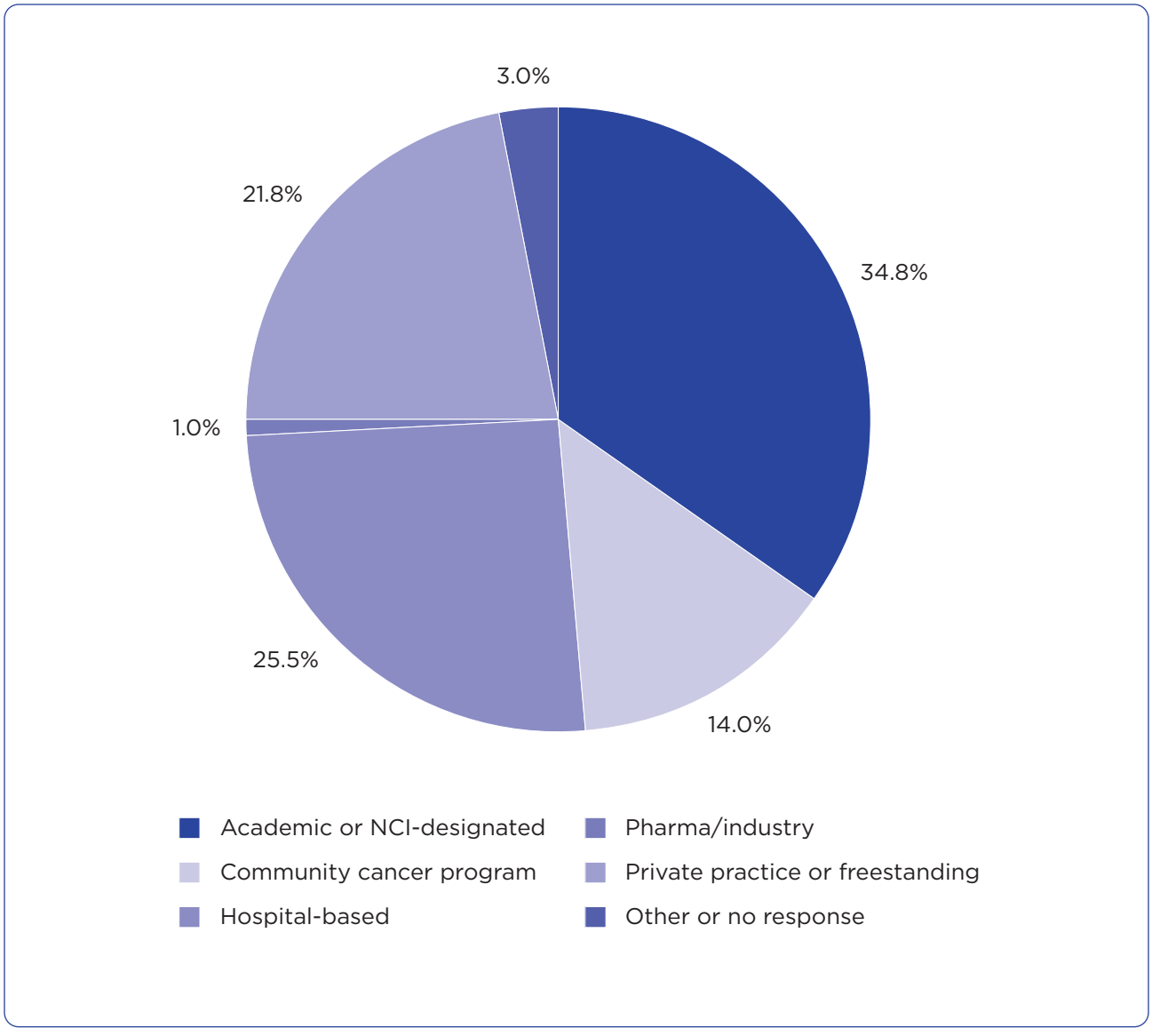

Figure 2. Oncology advanced practitioners' cancer program settings.

becoming more involved in the process. Thirty-seven percent routinely explore whether a clinical trial is available for their patients; however, more than half reported deferring clinical trial discussion(s) to another team member.

APs' Roles

Of the 408 respondents, 80% report participation in the care of patients enrolled in clinical trials (Table 3). Seventy percent of respondents are involved in identifying, recruiting, and coordinating patients for clinical trials, and 60% refer potentially eligible patients for trials. Over 50% conduct clinical trial patient visits, standard of care visits, Common Terminology Criteria for Adverse Events (CTCAE) toxicity visits, and assist research coordinators. While most APs report approaching eligible patients about clinical trials at their practice (70%), only 20% report doing so "a great deal" or "a lot." Less than half (43%) report seeing patients on trials at least once per week, but some oncology APs report being the primary provider for patients enrolled on clinical trials at their practice setting (11%). Furthermore, 15% report being an enrolling provider for patients on trials, and 10% serve as principal investigator on at least one clinical trial. About 50% of respondents are subinvestigators. Thirty-five percent are registered with the NCI as investigators. A minority report being further involved in clinical research, specifically IRB participation (14%), trial selection (20%), protocol development (34%), or research committee participation locally (24%) or nationally (5%).

DISCUSSION

To our knowledge, this is the first comprehensive study that reports national insight into oncology APs' current practice in cancer clinical trials. As the oncology AP workforce is estimated to be 10,000 (The JADPRO Podcast, 2021), there is an opportunity for this capable group to expand engagement in clinical research. Due to the demand for oncology services, oncology APs have become integral members of the multidisciplinary care team for cancer patients and positively impact the quality of cancer care (Bruinooge et al., 2018; Kurtin et al., 2015; Martin-Misener et al., 2015). National guidelines recommend clinical trial participation as a requisite for best clinical

Table 1. Oncology Advanced Practitioners' Demographics and Practice Settings

Question	N	%
What is your age?		
No response or prefer not to answer	3	0.7
21–29	18	4.4
30–39	103	25.3
40–49	118	28.9
50–59	98	24.0
60 or older	68	16.7
What is your gender?		
(No response)	2	0.5
Female	373	91.4
Male	31	7.6
Other	1	0.3
Prefer not to answer	1	0.3
Which race/ethnicity best describes you?		
(No response)	2	0.5
American Indian or Alaska Native	2	0.5
Asian or Asian American	21	5.2
Black or African American	11	2.7
Hispanic or Latino	16	3.9
Native Hawaiian or Other Pacific Islander	3	0.7
White or Caucasian	336	82.4
Other (please specify)	9	2.2
Prefer not to answer	8	2.0
What type of advanced practitioner are you?		
(No response)	5	1.2
Clinical nurse specialist	28	6.9
Nurse practitioner	288	70.6
Pharmacist	37	9.1
Physician assistant	50	12.3
What is your primary practice setting?		
(No response)	2	0.5
Inpatient	28	6.9
Outpatient	326	79.9
Both	52	12.8
What is your clinical focus? Please select all that apply.		
Medical oncology	304	74.5
Hematology	201	49.3

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Table 1. Oncology Advanced Practitioners' Demographics and Practice Settings (cont.)

Question	N	%
Clinical trials	100	24.5
Survivorship	91	22.3
Gynecologic oncology	52	12.7
Palliative care	44	10.8
Other	38	9.3
Radiation oncology	29	7.1
Prevention	27	6.6
Investigational drug services	22	5.4
Surgical oncology	17	4.2
Urologic oncology	16	3.9
Pediatric hematology and oncology	7	1.7
Adolescent and young adult (AYA)	7	1.7
Hospice care	5	1.2
How many years have you been in practice as an oncology advanced practitioner?		
(No response)	4	1.0
< 1 year	23	5.6
1–5 years	117	28.7
6–10 years	91	22.3
11–15 years	59	14.5
> 15 years	114	27.9
How many advanced practitioners are in your practice?		
(No response)	3	0.7
< 5	172	42.2
5–10	81	19.9
11–15	31	7.6
> 15	121	29.7
How many oncologists are in your practice?		
(No response)	6	1.5
< 5	106	26.0
5–10	98	24.0
11–15	48	11.8
> 15	150	36.8
What percent of your time do you spend on direct patient care?		
(No response)	3	0.7
< 25%	38	9.3
25%–49%	27	6.6
50%–74%	85	20.8
75%–99%	174	42.7
100%	81	19.9
How many patient visits do you have in a typical week?		
(No response)	3	0.7
< 25 visits	130	31.9
25–50 visits	186	45.6
51–75 visits	60	14.7
> 75 visits	29	7.1
What types of duties do you perform in a typical week? Please select all that apply.		
Direct patient care: chemo checks, follow-up visits, urgent visits	346	84.8
Patient education/coordination of care	346	84.8
Clinical research	180	44.1
Procedures: bone marrow biopsy, intrathecal chemotherapy, lumbar punctures, paracentesis, thoracentesis	96	23.5
Other	79	19.4
There are cancer clinical trials available at my practice setting.		
(No response)	2	0.5
Yes	371	90.9
No	32	7.8
Don't know	3	0.7
Does your practice site participate in NCI-sponsored trials?		
(No response)	5	1.2
Yes	284	69.6
No	57	14.0
Don't know	62	15.2
Does your practice site participate in industry/pharmaceutical-sponsored trials?		
(No response)	2	0.5
Yes	296	72.6
No	46	11.3
Don't know	64	15.7

practice (National Comprehensive Cancer Network, 2021). Therefore, it is essential that clinical research is an element of oncology AP practice and barriers to utilization of APs in clinical research are removed.

Oncology APs are involved in many aspects of care delivery, and the frequency of AP follow-up visits facilitates many requirements of clinical trials, including introducing trials, confirming participant eligibility, and enrolling independently (as permitted). In addition, APs can assist with study coordination, investigation, ordering tests, identifying adverse events (AEs), evaluating imaging, and reviewing and signing treatment orders (where applicable), thus enhancing patient accrual and retention. Oncology APs are well trained and positioned to assist with protocol development and coordination of cancer care delivery (CCD) and implementation science studies, which is a new area of focus (Geiger et al., 2019; Good et al., 2020). We hypothesize that oncology APs could positively influence cancer research in multiple ways by increasing accrual, improving trial conduct, as well as contributing to protocol review and development.

Table 2. Oncology Advanced Practitioners' Attitudes Toward Clinical Trials

Question	N	%
I am comfortable discussing treatment options with my cancer patients.		
(No response)	3	0.7
Strongly agree	208	51.0
Agree	138	33.8
Neither agree nor disagree	39	9.6
Disagree	20	4.9
I am comfortable discussing clinical trials in general with patients I see.		
(No response)	6	1.5
Strongly agree	162	39.7
Agree	157	38.5
Neither agree nor disagree	45	11.0
Disagree	34	8.3
Strongly disagree	4	1.0
I would leave the decision for clinical trial recommendation to the oncologist or someone more knowledgeable about the protocol.		
(No response)	4	1.0
Strongly agree	85	20.8
Agree	127	31.1
Neither agree nor disagree	102	25.0
Disagree	74	18.1
Strongly disagree	16	3.9
Cancer clinical trials are important to improve the standards of oncology care.		
(No response)	4	1.0
Strongly agree	299	73.3
Agree	96	23.5
Neither agree nor disagree	9	2.2
I have a good understanding of the different phases of cancer clinical trials (phases I–IV).		
(No response)	5	1.2
Strongly agree	174	42.7
Agree	159	39.0
Neither agree nor disagree	42	10.3
Disagree	27	6.6
Strongly disagree	1	0.3

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Accrual

We asked respondents what they believed they needed to increase accrual at their institutions. Common responses included further defining roles, receiving more trial-related education, creating increased research-specific expectations, and providing adequate time to discuss trials with patients. Only 37% of survey respondents routinely explore trials for patients and even fewer (20%) routinely approach patients about trials.

Many studies address barriers and some offer solutions (Durant et al., 2014; Hillyer et al., 2020; Lee et al., 2019; Unger et al., 2019). However, only one (Lee et al., 2019) mentions APs as a resource. Many of the reported barriers to date are common issues that oncology APs address in daily practice. Hillyer and colleagues (2020) report on structural barriers to trial participation, which include lack of awareness of eligibility criteria and lack of time to discuss a trial. Oncology APs can ease the burden on physician colleagues by staying abreast of protocol requirements and taking the time to introduce and discuss a clinical trial. All front-line providers, including APs, must share the responsibility of identifying eligible patients. Therefore, institutions and professional

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

Question	N	%
I have a good understanding of the following types of clinical trials. Please select all that apply.		
Cancer treatment	339	83.1
Supportive care	275	67.4
Screening/prevention	263	64.5
Diagnostic	205	50.2
Basket vs. umbrella	100	24.5
Cancer care delivery research (CCDR)	76	18.6
None of the above	48	11.8
I know where to look for available clinical trials at my institution for a patient.		
(No response)	8	2.0
Yes	341	83.6
No	59	14.5
I am comfortable discussing the available clinical trials at my practice setting with patients I see.		
(No response)	4	1.0
Strongly agree	126	30.9
Agree	127	31.1
Neither agree nor disagree	78	19.1
Disagree	68	16.7
Strongly disagree	5	1.2
I explore whether there is a potential clinical trial for each patient I see.		
(No response)	7	1.7
Always	55	13.5
Usually	97	23.8
Sometimes	99	24.3
Rarely	98	24.0
Never	52	12.8
My cancer care team sees the oncology advanced practitioner as having an important role in clinical trials.		
(No response)	7	1.7
Strongly agree	143	35.1
Agree	114	27.9
Neither agree nor disagree	88	21.6
Disagree	46	11.3
Strongly disagree	10	2.5

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

Question	N	%
I approach potentially eligible patients about clinical trials at my practice setting.		
(No response)	11	2.7
A great deal	48	11.8
A lot	36	8.8
A moderate amount	84	20.6
A little	116	28.4
None at all	113	27.7
Participating in clinical research should be a role for advanced practitioners in oncology.		
(No response)	5	1.2
Strongly agree	221	54.2
Agree	146	35.8
Neither agree nor disagree	35	8.6
Disagree	1	0.3
I am interested in becoming more involved in the clinical trials process.		
(No response)	9	2.2
Yes	299	73.3
No	100	24.5

organizations must train and empower oncology APs to approach, educate, and enroll eligible patients onto clinical trials.

In our survey, over 80% of respondents report providing patient education and coordination of care to patients. This AP role offers a platform to discuss options in depth, including available clinical trials, with a focus on shared decision-making. Visits with oncology APs provide opportunities for patients to discuss trial-related questions and help them understand how the trial fits into their treatment options. The development of a workflow between the oncologist and an AP could address the patient-physician barrier highlighted by Unger and colleagues (2019) due to clinic time/reimbursement constraints. For example, many APs provide follow-up visits, which enable patients who are initially undecided about a clinical trial, to clarify any remaining questions. The time that APs spend on additional education and informed consent to increase patients' understanding of the research protocol and process

could lead to increased accrual, protocol compliance, and trial retention. In addition, in the context of patient follow-up, APs gain patients' trust and a good understanding of the patient's disease status and symptoms, enabling them to identify patients for additional trials not identified at initial screening.

Conduct

Over 80% of respondents report that they participate in the care of patients on trial. Currently, routine clinical care is where APs are most utilized in clinical trials (Patterson & Barber, 2020; Welch et al., 2017). As experts in symptom management (Bruinooge et al., 2018; Mason et al., 2013; Sivendran et al., 2016), APs serve as key subinvestigators on trials. In addition, APs are a clinical resource to research staff, as over half of our respondents reported that they assist the research coordinator by providing clinical information and documentation for patients on trial.

Oncology APs have the skills to identify AEs promptly and provide feedback to the research sponsor, particularly in early-phase clinical trials in which side effects are unknown and provider visits are frequent. Advanced practitioners performing toxicity evaluations adeptly identify changes from patient baseline, which may be attributed to an investigational agent(s). Such timely clinical data is crucial to the accuracy of AEs when the agent becomes approved. Advanced practitioners are qualified to identify, grade, and attribute AEs (Barber et al., 2020; Patterson & Barber, 2020). Importantly, only about half of the survey respondents reported being subinvestigators at their site, with fewer reporting registration with the NCI as non-physician investigators. Additionally, AP involvement in protocol conduct enhances patient-focused, safe, and reliable practice that ensures compliance with regulatory requirements.

Protocol Review and Leadership

Survey respondents report a high rate of direct patient care, care coordination, and education of patients in their daily practice. Many APs have leadership, care coordination, and training responsibilities within their clinics and organizations. Unfortunately, only a minority of survey respondents are involved in trial selection, proto-

Table 3. Oncology Advanced Practitioners' Roles in Clinical Trials

Question	N	%
Which, if any, of the following roles do you play in the clinical trials process? Please select all that apply.		
Refer potential patients to the research coordinator/staff	254	62.3
Assist research coordinator by providing clinical information/ documentation for patients on trial	231	56.6
See patients on clinical trials for standard of care (SOC) visits	230	56.4
CTCAE toxicity visits	218	53.4
Clinical trial patient visits	217	53.2
Discuss available trial(s) with potential patients	201	49.3
Review consent form with patient	114	27.9
Coordinates patients (scheduling of visits, scans, etc.)	73	17.9
Other	49	12.0
None of the above	47	11.5
Primary person who consents patient	36	8.8
How many patients per week do you see that are enrolled in a clinical trial?		
(No response)	3	0.7
0	72	17.7
1–5	232	56.9
6–10	59	14.5
> 10	42	10.3
I am registered with the NCI as a non-physician investigator.		
(No response)	14	3.4
Yes	139	34.1
No	169	41.4
Don't know	86	21.1
I am the primary provider for patients on clinical trials at my practice setting.		
(No response)	10	2.5
Yes	46	11.3
No	352	86.3
I am an enrolling investigator for patients on cancer clinical trials.		
(No response)	8	2.0
Yes	61	15.0

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

Question	N	%
No	304	74.5
Don't know	35	8.6
I am or have been a principal investigator at my site on at least one clinical trial.		
(No response)	7	1.7
Yes	42	10.3
No	359	88.0
I am or have been a subinvestigator at my site.		
(No response)	7	1.7
Yes	200	49.0
No	201	49.3
I am involved with the institutional review board (IRB) at my institution.		
(No response)	9	2.2
Yes	56	13.7
No	343	84.1
I am involved in the process of selecting appropriate trials for my practice setting.		
(No response)	7	1.7
Yes	83	20.3
No	318	77.9
Are you involved with any research committee at a cooperative group or research base (SWOG, Alliance, NRG, COG, ECOG-ACRIN, Wake Forest, URCC)?		
(No response)	10	2.5
Yes	19	4.7
No	379	92.9
Are you involved in a research committee at your institution or practice?		
(No response)	15	3.7
Yes	99	24.3
No	294	72.1
What, if any, role do you play in protocol development? Please select all that apply.		
No involvement in protocol development	261	64.0
Study team	69	16.9
Co-investigator	52	12.7
Other	23	5.6
Principal investigator	18	4.4

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

Question	N	%
I think I could increase clinical trial accrual at my institution if (please answer all that apply):		
It was an expected part of my role	161	39.5
I had more education regarding clinical trials	155	38.0
I was more aware of potential trials available for my patient	153	37.5
I had more time to discuss trials with my patient	135	33.1
I had access to trials more appropriate to my role	112	27.5
I had more time to help coordinate patients getting on trial	98	24.0
I had more support from the research personnel	94	23.0
I was involved in picking appropriate trials for my patient population	89	21.8

col development, and research committees. Even fewer report that they are enrolling investigators or primary investigators for trials.

On a systems level, APs can review, develop, and lead protocols that are meaningful for patients and feasible in their practice. Huang and colleagues (2018) report on a framework for strategic recruitment that identifies trial design, site selection, and communication planning as key components. Oncology APs as key stakeholders in three identified areas would effectively strengthen this framework, as APs are experts in symptom management, survivorship, and cancer care delivery.

Future Directions

Survey respondents indicate awareness of the various phases of treatment trials; however, they report less familiarity with the different types of trials (e.g., basket vs. umbrella, screening, cancer treatment, CCD research, etc.). Oncology APs need to be aware of different types of trials in order to educate patients appropriately. Clinical trial education can be included as part of formal program training, onboarding, and/or subsequent training. For oncology APs to be successful in the roles discussed above, professional support and education is imperative. Experienced research team members can further help with training and mentorship.

Providing opportunities for oncology APs to attend research lectures, professional meetings, and webinars that are pertinent to their practice is crucial. Ideally, learning should be bidirectional, with APs sharing clinical expertise and research-trained personnel sharing clinical trial management knowledge.

Policy changes at the federal, state, and institutional levels are necessary to optimize the inclusion of oncology APs in trial recruitment and management. Recently, the NCI changed its policy and guidelines to allow APs to order anti-neoplastic drugs on treatment trials and medication on supportive care trials on NCI-sponsored trials (Good, 2020; NCI, 2021). In addition, APs can now serve as enrolling investigators on supportive care and cancer care delivery trials (Good, 2020). Advanced practitioner advocacy through the NCI and research bases had a major impact on these changes.

Furthermore, institutions and industry-sponsored trials many times limit investigators to physicians, perhaps due to Good Clinical Practice (GCP) guidelines that specify MD investigators but do not indicate investigators of other disciplines. The clinical trial role of the AP is often left up to the industry or institutional sponsor. Furthermore, many state boards limit APs from prescribing investigational drug(s), and institutions may further restrict AP practice. Barriers such as these must be removed to fully leverage AP practice contributions to clinical research.

Finally, the majority of our respondents are Caucasian, which is representative of current AP practice composition (Bruinooge et al., 2018). The lack of diversity in AP practice can inhibit our ability to enhance enrollment of minority participants in clinical trials. Research shows a racially and ethnically matched workforce improves equity in cancer care delivery, which must include clinical trials (American Association for Cancer Research, 2020). Therefore, greater diversity among oncology APs is required. Patients from marginalized groups are more likely to reside in medically underserved areas that lack an adequate supply of health-care providers, preventing timely access to high-quality care (Barrett, 2019; Poghosyan & Carthon, 2017). Such settings feature more prominent roles for APs and provide opportunities for their contribution to clinical trial enrollment. A recent systematic review and meta-analysis of patient participation in clinical trials showed that Black, Hispanic, and Asian patients enrolled at rates comparable to White patients when offered a trial (Unger et al., 2020).

Limitations

We acknowledge that this study has limitations. This was a convenience sample, and the response rate was low. Although the survey was sent to over 14,000 emails, it is unclear how many emails were correct and nonduplicative, and how many were opened. Unfortunately, the platform we used did not track this. This is a significant flaw in our methodology. We used both ACCC and Harborside listservs, which are overlapping, and explains why the survey was sent to more emails than estimated APs.

Second, although the exact percentages vary, the geographic region distribution of our sample matches with that from ACCC and Harborside in terms of the most represented (South) and least represented (Northeast) geographic regions. However, unlike in these data sources, our survey had a smaller proportion of respondents from the Midwest and a higher proportion from the West as compared to our listserv.

Third, given that 25% of the respondents state clinical research was their focus, and 35% report being academically employed, these results may be biased towards APs already engaged in research, and therefore may not be fully representative of oncology APs nationally. Regardless, we are still able to identify improvement is needed in this group and can be generalized to the greater community. Additional data analysis is ongoing to look at the differences between community vs. academic APs, and research vs. non-research APs who answered our survey.

CONCLUSION

This study reports current roles, attitudes, and beliefs of oncology APs in the practice of cancer clinical trials. To our knowledge, this study is the first description of what this group of skilled oncology providers currently contributes to clinical cancer research in the US. Oncology APs are already an essential part of oncology care, and expanding their roles will significantly enhance

trial accrual, conduct, protocol development and improve the standard of care. Successful models of team-based care should include APs in clinical trial enrollment and execution. Based on APs' current expertise and role in clinical practice, APs can remove barriers that limit participation in clinical research. We recommend action steps that include enhancing AP clinical trial training both for those in practice today and within graduate training programs, organizational support for the AP role in clinical trials, changes in clinical trial design and conduct by NCI research bases and other sponsors, and regulatory changes that expand the AP role in research. ●

Disclosure

The authors have no conflicts of interest to disclose.

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