

Role of the Advanced Practitioner in Clinical Research

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Abstract

Advanced practitioners are key members of the oncology care team, and their numbers and significance continue to expand. While the role of the AP has become well defined in everyday clinical practice, there is still space to define the AP role in clinical research. In accordance with its mission, the Advanced Practitioner Society for Hematology for Oncology (APSHO) recognizes the significance of addressing the role of the AP in clinical research. This article discusses three key projects related to APs and clinical research (a 2020 benchmarking survey, a 2021 summit, and a 2023 collaboration) and addresses how APSHO is working to continually support the AP role in clinical research through advocacy, committees, formal education, publications, and mentoring.

Advanced practitioners (APs) are key members of the cancer care team. They include nurse practitioners (NPs), physician assistants (PAs), clinical nurse specialists (CNS), and pharmacists. The number of APs who practice in cancer care and research in the United States continues to increase from approximately 5,000 in 2018 to an estimated 10,000 in 2021 (Bruinooge et al., 2018; Vogel, 2016). Advanced practitioners provide patient care in a variety of settings, including academic centers, community settings, and private practices. Advanced practitioners in clinical roles or who support clinical programs work in

a variety of cancer care specialties, including oncology, hematology, radiation, surgical oncology, high-risk cancer and genetics, clinical research institutes, palliative care, and other specialty programs. Responsibilities of the AP are broad, largely driven by the individual role and practice type, but encompass the full scope of clinical management of patients, prescribing treatment, managing adverse events, patient education, survivorship, and end-of-life care (Hylton & Smith, 2017; Kurtin et al., 2015). While the role of the AP in the standard care of cancer patients has been well defined, the description of the AP role in cancer clinical trials and research is lacking.

Since the establishment of the National Cancer Institute (NCI) Act of 1937, cancer clinical trials have led to significant drug discovery (Parascandola et al., 2022). This act subsequently led to the development of the NCI whose mission is “to lead, conduct, and support cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives” (NCI, 2018). Additionally, the National Comprehensive Cancer Network (NCCN), which provides guidance on cancer care, recommends clinical trial participation for all patients with cancer when possible. The Advanced Practitioner Society for Hematology and Oncology (APSHO) has incorporated AP involvement in research and quality improvement (RQI) in the society’s strategic plan, which will be further discussed in this article.

As research is the backbone of cancer care, it is important that AP involvement in this be well defined and inclusive. Most recently, the NCI changed their policy on the AP role in managing patients participating in clinical trials, including a change in prescriptive authority for antineoplastic agents and increased autonomy for supportive care trials. This has been a major step forward in the inclusion of APs in cancer clinical trials. Beginning September 2021, the NCI allows APs to sign for cytotoxic agents for cancer patients enrolled on NCI-sponsored clinical trials, significantly increasing AP independence and improving continuity of care for patients on clinical trials. In addition, the policy expands AP roles in supportive care trials, allowing them to enroll their own patients and serve as primary investigators on these trials (NCI, 2021; Good, 2020).

There is still work to be done to fully integrate APs into the clinical research process. APSHO in collaboration with other organizations is moving the ball forward to increase AP involvement in research. This article highlights three key projects/initiatives that address the role of APs in clinical research and discusses APSHO’s response to these findings and continued commitment to AP involvement in RQI.

APSHO COMMITMENT TO CLINICAL RESEARCH

APSHO has a strong commitment to clinical RQI, reflected in the APSHO vision and mission state-

ments that emphasize a commitment to quality of care through optimizing the role of the AP (Table 1). Timely and clinically relevant integration of clinical research findings is essential to effective implementation of new drug approvals, improvement in symptom management strategies, and optimization of the AP role in maintaining a practice that reflects best practice. Strategies to support this initiative reflect this commitment and include numerous resources for APs as a benefit of membership. The APSHO RQI Committee maintains and continually updates a portal on the APSHO website (<https://www.apsho.org/page/research-and-quality-improvement>). Resources on the site include Educator Modules (slides and speaker notes on a variety of topics), podcasts, and peer-reviewed articles on topics such as clinical trial design, applied statistics, and the AP role in clinical trials. There is also a forum in the APSHO online community that facilitates collaboration among APs interested in research. The APSHO Mentorship Program provides support for APs involved in research, publication of RQI projects, and presentation through abstracts, posters, publications, or live programs.

The *Journal of the Advanced Practitioner in Oncology* (JADPRO), the official journal of APSHO, is a peer-reviewed journal that includes a dedicated column for research and scholarship that highlights AP-led RQI initiatives. JADPRO Live, the annual meeting for APSHO, the JADPRO Workshop, a mid-year educational and networking event that provides expanded sessions for selected topics, and other special projects conducted in collaboration with other organizations feature sessions dedicated to RQI. Three specific collaborations will be described here.

2020 BENCHMARKING SURVEY

In 2022, Braun-Inglis and colleagues published the first national survey examining the attitudes, beliefs and roles of oncology APs related to clinical trials. This was a collaboration between the University of Hawaii Cancer Center (UHCC), the Association of Community Cancer Centers (ACCC) and Harborside (now BroadcastMed, as the management company for APSHO). The survey, disseminated nationally through Harborside and ACCC, was built on a local and national pilot

Table 1. APSHO Strategic Goal for Research and Quality Improvement

To promote the integration of research, including AP-led research and quality improvement initiatives, into practice goals through:

1. Support of AP-led research and quality improvement
2. Integration of AP-led research and quality initiatives into APSHO and JADPRO activities
3. Aligning the JADPRO Research and Scholarship column, JADPRO Live sessions, JADPRO Workshop sessions, the APSHO Industry Council, and other APSHO initiatives to promote effective integration of research into practice.

validating the survey (Braun-Inglis et al., 2021, 2022). Among the 408 APs completing the survey, most were nurse practitioners (71%), followed by physician assistants (12%), pharmacists (9%), and clinical nurse specialists (7%). The majority reported practicing in the community setting (62%), with 35% reported practicing in an academic setting. All regions of the United States were represented. Over 90% reported clinical trials being available in their practice setting and felt that APs should play a role in clinical research. Almost 50% reported serving as a sub-investigator. Over 70% reported wanting to be more involved in research.

However, this study also found that only a minority (37%) of APs explored clinical trials for their patients routinely and even fewer (20%) approached their patients about clinical trials. In addition, only 24% of APs reported being involved in research-related committees both locally and nationally, and very few reported serving as a primary investigator (4%) or involved with protocol development (30%).

This study also identified barriers to clinical trial participation, including lack of education, policies limiting AP scope of practice, lack of time, and not incorporating clinical trial involvement in the AP role. Surveyed APs made recommendations to increase their role in clinical trials through multidisciplinary team integration, clinical trials-related education, and policy change.

2021 SUMMIT ON THE ROLE OF THE ONCOLOGY AP IN EQUITABLE CANCER CARE

In 2021, ACCC and Harborside, in collaboration with Pfizer Oncology, hosted A Virtual Summit to Define the Role of Oncology Advanced Practitioners in Equitable Cancer Care Delivery, which included the role of the AP in clinical trials. The collaborators for this initiative collectively recognized that APs have a significant role in promoting equitable cancer care delivery through positions

as educators, trainers, clinicians, program managers, researchers, authors, administrators, and quality improvement leaders.

The impetus for this program came from the COVID-19 public health emergency, which sparked national attention on the devastating real-world consequences of health inequities in the United States and provided a sense of urgency to identify effective strategies for unbiased health-care delivery. The virtual summit took place in 2.5-hour sessions over 3 days. Day 1 focused on equity in the context of care coordination and communication, Day 2 explored equity in cancer clinical trials, and Day 3 centered on acknowledgment and mitigation of implicit bias. Participants included APs, as well as other key stakeholders such as patients, advocates, physicians, and researchers.

During the clinical trials conversation on Day 2, participants identified current barriers in the research setting, including a lack of standardization of AP involvement in individual organization clinical trials programs, institutional policies or procedures that disincentivize AP participation in research, lack of available information on clinical trials within institutions and across health systems, insufficient training for APs regarding clinical trials, studies that do not reflect the patient population of the community in which the facility is located, and overly restrictive trial eligibility requirements that present barriers to diversity and inclusion.

Participants' responses to a question asking them to define the desired future state, where cancer clinical trials are inclusive, diverse, and equitable, included study designs based on the population of those who are most affected by the disease, a consistent message about clinical trials, strong navigation programs to reach underserved minority patients and diverse communities in ways that are culturally relevant, accountable reporting of aggregate trial results, broader access to clinical trials, including the setting where the patient is

getting their care, inclusion of AP perspectives in all aspects of clinical trials, and proactive incorporation of community partners in research so that they then become advocates in the community on behalf of clinical research.

To achieve this desired future state, summit participants committed to several attainable actions that APs could integrate into their roles to support equitable cancer clinical research (Table 2; ACCC, 2021). An executive summary was developed and made available on ACCC, APSHO, and Pfizer platforms. Additionally, Pfizer created a 1-page summary of the initiative to share as a printed resource. Advanced practitioners have continued to keep these conversations and initiatives top of mind through further dissemination in sessions at JADPRO Live and continued partnerships in 2023.

SOCIETY FOR IMMUNOTHERAPY OF CANCER COLLABORATION AND WORKSHOP

In August 2022, the Society for Immunotherapy of Cancer (SITC) convened over 600 attendees and 30 panelists for the Crisis in Clinical Research virtual summit. The impetus for this meeting was an identified slowing of clinical research due to staffing shortages, administrative burden, outdated clinical trial business models, and the impact of COVID-19. Stakeholders acknowledged the impending risk to novel drug development and refinement of cancer care with widespread consequences to the clinical landscape. The 5.5-hour session focused on four key efforts to address the identified risk: (1) standardization and centralization of clinical research resources, (2) cross-

institutional data availability, (3) maximizing efficiency across clinical research operations, and (4) diversification of clinical research sites.

As an attending organization and key research stakeholder, APSHO recognized the need to synthesize the findings from this initial summit with expert AP investigators to understand the key role that APs will play in addressing this research crisis. The follow-up conversation took place at the JADPRO Workshop meeting on May 6, 2023, in Houston, Texas, at a session called “Crisis in Clinical Research: Solutions From the AP Perspective” jointly hosted by SITC and JADPRO. Faculty presenters included Michael S. Gordon, MD, and Gayle Jameson, MSN, ACNP-BC, AOCNP®, from HonorHealth Research Institute, F. Diane Barber, PhD, APRN, ANP-BC, AOCNP®, from The University of Texas MD Anderson Cancer Center, and Christa Braun-Inglis, DNP, APRN, FNP-BC, AOCNP®, from University of Hawaii Cancer Center. Panelists discussed unique perspectives from their research roles in private clinics, academic centers, and community facilities, respectively. Attendees learned about APs as principal investigators, sub-investigators, research team managers, cooperative research group participants, educators, and advocates. Discussants noted the key role APs play in clinical trial recruitment, conduct of trials, adverse event monitoring, patient education, leadership, and result dissemination. An executive summary summarizing key learnings from this live meeting was published August 2023 (APSHO, 2023). APSHO and SITC have continued to partner in attaining follow-up goals and next steps.

All three key projects identified similar themes in terms of AP involvement in clinical research: APs

Table 2. Ten Opportunities for Oncology Advanced Practitioners to Play a Role in Equitable Cancer Care Delivery

1. Encourage and engage in active shared decision-making.
2. Identify existing data collection metrics and equity screening tools.
3. Deliver a consistent message about clinical trials.
4. Step into research.
5. Advocate for inclusive cancer clinical research.
6. Support and engage in research publication.
7. Ask for training resources for APs related to diversity, equity, and inclusion in clinical trials.
8. Create a checklist to support a top-of-mind focus on equity.
9. Call for equity in medical professional curricula.
10. Request that your professional societies reserve space at events and in publications for discussion of implicit bias education and equity in cancer care delivery.

Note. Information from ACCC (2021).

add value to clinical research, but barriers such as time, education, integration, and policies that limit APs' scope and involvement in clinical research remain. In an ongoing response to address these barriers, APSHO has embarked on initiatives to support AP involvement in clinical research through the development of committees, courses, online resources, lectures, workshops, and publications in effort to educate on, advocate for, and integrate the role of the AP in clinical research.

DEVELOPMENT OF THE RQI COMMITTEE

In 2020, APSHO recognized the need to address the AP role in RQI and created the APSHO RQI Task Force. The task force included six APs working in oncology and knowledgeable about RQI. Based on the group's findings and the strategic plan, the APSHO Board of Directors recommended the group become the RQI Committee in early 2022 and established five key charges: (1) develop programs to support AP involvement in RQI, (2) provide mentorship and opportunities to present and publish professional projects, (3) provide mentorship to support the AP's involvement in research, (4) engage other APSHO committees and task forces to integrate RQI into broader initiatives, and (5) include a column on RQI in each issue of the quarterly member newsletter, the APSHO Advance.

Recent initiatives to meet the first charge include the committee co-sponsoring the previously discussed session with SITC at the JADPRO Workshop called "Crisis in Clinical Research" in May 2023. In addition, RQI committee members have developed RQI toolkits that are accessible to APSHO members on the society website. The committee also keeps up the resource center to provide quick links to resources and articles from APSHO and JADPRO.

Almost in tandem with the initiation of APSHO's task force, like-minded APSHO members were coming together to form a research cooperative group. This cooperative group grew out of a clinical investigator course hosted by HonorHealth in 2020 and discussion sessions at JADPRO Live in 2020 and 2021. This cooperative provides value to practicing oncology APs interested in research and now serves as an ad hoc subcommittee of the RQI committee. This coopera-

tive provides a space for APs to share and discuss research projects, best practices, and barriers to research. To sustain the continued engagement of this group, the APSHO RQI committee has committed to provide speakers for two meetings per year. This group meets via Zoom quarterly and hosts a guest speaker on a research topic followed by an open discussion on best practices and barriers. This is an invaluable resource in partnership with APSHO to further support professional growth of the AP in clinical research.

APSHO is also supporting professional growth in RQI through mentorship to support APs interested in exploring research and learning more about how to be involved but not sure how to take the first steps. With APSHO's Mentorship Program, interested APs can be matched with a committee mentor and develop a mentoring relationship based on their own personal goals.

The committee continues to host a column in each edition of the APSHO Advance highlighting pertinent RQI topics or projects. The committee works with other committees to assure RQI is addressed across APSHO initiatives. One such example is the Cancer Therapy Prescribing Course (CTPC) launched in 2022 sponsored by the Education Committee. The CTPC includes 19 modules and one specifically dedicated to clinical trials. Recognizing that the role of the oncology AP is constantly expanding, especially in the field of clinical research, APSHO felt it imperative to include a module on clinical trials in this course. The clinical trials module, developed by members of the RQI committee, addresses the key elements of clinical trials, trial sponsors, clinical trial endpoints, the FDA approval process, investigator training, the role of the AP in clinical trials, and the importance of diversity equity and inclusion in clinical trials. This module goes beyond cancer therapy prescribing in clinical trials to give the AP an excellent basic education about clinical research. This course is described in a separate publication in this supplemental issue (Archana et al., 2023).

FUTURE DIRECTIONS

The importance of APs in the field of oncology cannot be emphasized enough. With the increasing population of cancer survivors and the shortage of oncologists, APs are vital to the oncology

workforce. Institutions such as the US Food and Drug Administration, the NCI, and pharmaceutical partners have begun to recognize the importance of AP involvement in clinical research. However, many barriers to AP scope of practice, education, and integration in the conduct of clinical trials remain. There are few AP educational programs that prepare the AP for participation in clinical research, yet there are increasing expectations for AP involvement in managing patients participating in clinical trials, including reviewing and signing orders, adverse event attestation and reporting, and documentation to support clinical trial requirements for reporting (Kurtin & Taher, 2021).

Advanced practitioner participation in clinical research has been recognized as rewarding and part of professional development (Nandwani et al., 2022). APSHO, as the leading professional organization for APs in hematology and oncology, is committed to a diverse strategy to support these identified needs, including publications, presentations, courses, and workshops that address APs' involvement in clinical research and ultimately work to improve the quality of care and access to clinical trials for patients with cancer. ●

Disclosure

The authors have no conflicts of interest to disclose.

References

- Advanced Practitioner Society for Hematology and Oncology. (2023). Crisis in Clinical Research: Solutions from the AP Perspective. https://www.apsho.org/resource/resmgr/resource_center/Executive-Summary_JAD-PRO-Wor.pdf
- Association of Community Cancer Centers. (2021). A Virtual Summit to Define the Role of Oncology Advanced Practitioners in Equitable Cancer Care Delivery: Executive Summary. <https://www.accc-cancer.org/docs/projects/health-equity/oncology-advanced-practitioner-summit-executive-summary-07-23-21.pdf>
- Archana, A., Boehmer, L., Braun-Ingليس, C., Hoffner, B., Matta, M., & McKay, R. (2023). Understanding advanced practitioner prescriptive privileges for anticancer therapies: A national survey. *Journal of the Advanced Practitioner in Oncology*, 14(7), 28–34. <https://doi.org/10.6004/jadpro.2023.14.7.12>
- Braun-Ingليس, C., Boehmer, L. M., Zitella, L. J., Hoffner, B., Shvetsov, Y. B., Berenberg, J. L.,...Benson, A. B., 3rd. (2022). Role of oncology advanced practitioners to enhance clinical research. *Journal of the Advanced Practitioner in Oncology*, 13(2), 107–119. <https://doi.org/10.6004/jadpro.2022.13.2.2>
- Braun-Ingليس, C., Shvetsov, Y. B., Springer, A., Ferguson, V., Workman, T., Omatsu, D. A.,...Rhee, J. (2021). Understanding attitudes and roles of oncology advanced practitioners in the setting of cancer clinical trials: A pilot study. *Journal of the Advanced Practitioner in Oncology*, 12(5), 465–476. <https://doi.org/10.6004/jadpro.2021.12.5.2>
- Bruinooge, S. S., Pickard, T. A., Vogel, W., Hanley, A., Schenkel, C., Garrett-Mayer, E.,...Williams, S. F. (2018). Understanding the role of advanced practice providers in oncology in the United States. *Journal of the Advanced Practitioner in Oncology*, 9(6), 585–598. <https://doi.org/10.6004/jadpro.2018.9.6.2>
- Good, M. (2020). NCI DCP & DCCPS NCORP Guidelines: Advanced practice nurse roles in DCP trials & DCCPS studies. Presented at NCORP Administrator Webinar.
- Hylton, H. M., & Smith, G. L. (2017). Collaborating with advanced practice providers: Impact and opportunity. *American Society of Clinical Oncology Educational Book*, 37, e1–e7. https://doi.org/10.1200/EDBK_175654
- Kurtin, S. E., & Taher, R. (2020). Clinical trial design and drug approval in oncology: A primer for the advanced practitioner in oncology. *Journal of the Advanced Practitioner in Oncology*, 11(7), 736–751. <https://doi.org/10.6004/jadpro.2020.11.7.7>
- Kurtin, S. E., Peterson, M., Goforth, G., May, M., Viale, P. H., Smith, W. J.,...Bishop, C. S. (2015). The advanced practitioner and collaborative practice in oncology. *Journal of the Advanced Practitioner in Oncology*, 6(6), 515–527. <https://doi.org/10.6004/jadpro.6.6.2>
- Nandwani, M., Blacker, A., Shanafelt, T. D., Harshman, J., & Kuriakose, C. (2022). Promoting professional fulfillment for advanced practice providers. *NEJM Catalyst*, 3(10). <https://doi.org/10.1056/cat.22.0183>
- National Cancer Institute. (2018). About NCI - overview and mission. <https://www.cancer.gov/about-nci/overview>
- National Cancer Institute. (2021). Investigator's handbook. Cancer Therapy Evaluation Program (CTEP). https://ctep.cancer.gov/investigatorResources/investigators_handbook.htm
- National Comprehensive Cancer Network. (n.d.). Home. <https://www.nccn.org/>
- Parascandola, M., Pearlman, P. C., Eldridge, L., & Gopal, S. (2022). The development of global cancer research at the United States National Cancer Institute. *Journal of the National Cancer Institute*, 114(9), 1228–1237. <https://doi.org/10.1093/jnci/djac104>
- Vogel, W. H. (2016). Oncology advanced practitioners bring advanced community oncology care. *American Society of Clinical Oncology Educational Book*, 36, e97–e100. https://doi.org/10.14694/edbk_158751