CRISIS IN CLINICAL RESEARCH: SOLUTIONS FROM THE AP PERSPECTIVE

A PANEL DISCUSSION AT THE JADPRO WORKSHOP 2023 MEETING

Presented in collaboration with the Advanced Practitioner Society for Hematology and Oncology (APSHO) and with the Society for Immunotherapy of Cancer (SITC)
Background

Due to a convergence of factors over the past 3 to 4 years, clinical oncology research has slowed on both national and global scales. The 2023 JADPRO Workshop Panel Discussion, "Crisis in Clinical Research: Solutions from the AP Perspective," was developed in partnership with the Society for Immunotherapy of Cancer (SITC) and the Advanced Practitioner Society for Hematology and Oncology (APSHO) to examine the reasons for the research crisis, illustrate how it has continued to manifest, and highlight the myriad ways advanced practitioners (APs) are crucial to solution engineering and implementation.

SITC is a member-driven organization specifically dedicated to professionals working in the field of cancer immunology and immunotherapy. In August 2022, SITC convened 30 expert panelists across several discussions as part of the free, public, virtual SITC Crisis in Clinical Research Virtual Summit. More than 600 attendees participated, including physicians, APs, administrators, patient advocates, patients, caregivers, and representatives from pharmaceutical companies, contract research organizations, and government agencies such as the U.S. Food and Drug Administration (FDA) and the National Cancer Institute (NCI). APSHO and SITC extended the discussion to the JADPRO Workshop session in order to provide this vital information to more of those involved in clinical trial research, not just physicians and trial sponsors but APs and other staff who are involved with clinical trial conduct through daily patient care.

APSHO is a society comprised of APs in oncology: nurse practitioners, physician assistants, clinical nurse specialists, advanced-degree nurses, and pharmacists. Through its peer-reviewed journal, JADPRO, and other educational offerings, APSHO aims to support APs in conducting clinical research by spotlighting their research findings in JADPRO, offering live educational sessions at professional society meetings, and providing virtual educational resources, such as the CE-accredited Cancer Therapy Prescribing Course in the society’s AP Academy. The JADPRO Workshop meeting is one of two academic meetings hosted by JADPRO each year. The Workshop meeting is meant to be an intimate environment facilitating discussion and interaction, with no more than 200 participants. By contrast, the JADPRO Live meeting is a large comprehensive learning event with 1,500 to 2,000 attendees each year.

Executive Summary Goals

Although the number of APs in the oncology workforce continues to grow, only a small percentage are known to be routinely involved in clinical research. Through its dedication to the ultimate goal of the highest-possible quality care for patients, APSHO recognizes the intersection of need and opportunity that this unique moment in time provides for APs regarding research involvement and is committed to aiding in the removal of barriers through education and advocacy.

This Executive Summary aims to increase awareness about the ways in which APs can and should contribute to clinical research, as well as to encourage sharing of best practices for overcoming barriers to participation. To facilitate further education on the topics discussed, links throughout the content and in references are clickable. APSHO encourages you to share this product within your practice and professional networks using #APSHOinResearch to more easily follow related conversations on your favorite social media platforms.
Attendee Demographics

The panel discussion was the most well-attended session of JADPRO Workshop 2023, with more than 135 professionals currently involved with or interested in clinical research in oncology attending. Of the total attendees:

- 38% were nurse practitioners
- 15% were physician assistants
- 11% were advanced practice nurses

Attendee practice settings also were diverse and included:

- Academic Medical Center/University: 31
- Pharmaceutical/Biotech/Manufacturing Company: 55
- Private Practice: Hospital-Based: 9
- Private Practice: Office-Based: 40
- Training Program: 0

Panel Discussion Learning Objectives

- Explain what is meant by "crisis in clinical research," including the multifaceted stressors that have led to the current environment.
- Identify the ways in which interactions between key stakeholders involved in clinical research can be optimized.
- Discuss the role of the oncology AP in alleviating the current research crisis through improved engagement, understanding, and inclusion.
The Clinical Research Crisis in Oncology: An Opportunity for Systemic Evolution

- The business of clinical research suffered tremendous losses during the COVID-19 pandemic. Interruptions in regular care and treatment, a massive fall-off of clinical trial involvement, and cancellations of costly elective procedures resulted in extreme financial losses for clinical trial sponsors—hospitals and academic-based systems to pharmaceutical companies and contract research organizations—that caused numerous clinical trials to be closed due to lack of funding. Research-focused staff also experienced layoffs.

- There were dramatic shifts in the workforce driven, in part, by remote working and elimination of travel. APs performing face-to-face patient care moved to remote positions that offered greater personal safety. The “Great Resignation” resulted in a loss of institutional knowledge regarding trial protocols and individual patient history.

- The clinical research industry is adapting slowly to the evolving demands caused by the pandemic and by the ever-increasing complexity of trials:
  - 45% of investigators participate in only one trial
  - 68% of sites fail to meet enrollment targets and timelines
  - 80% of clinical trials are delayed

- Potential solutions
  - Use a value-based assessment of your research goals—think about your patient population and your practice's strengths
  - Foster retention by making education and advancement a critical component of your program—make research participation accessible to APs
  - Use APs as the front-line for clinical trial enrollment
  - Be transparent with your internal communications to ensure understanding at all levels
APs as Clinical Investigators: Enhancing Patient Care and Career Satisfaction

- There are many opportunities for APs in clinical research. Some roles and would require additional education and physician mentoring, such as that of a primary investigator (PI) or sub-investigator (SI), and some are informal and are already known well to APs, such as providing patient education and managing adverse events.
- The U.S. Food and Drug Administration does not mandate that a physician serve as a PI of a clinical trial, but if an AP is the PI, it is recommended that a physician serve as SI for assistance with medical decision-making if needed. It is the trial sponsors that often require a physician to be PI.
- There is a lack of formal training for APs regarding how to initiate a clinical trial or even become familiar with the formal processes of trials.
- Despite obstacles, APs can be their own best advocate for clinical trial participation and leadership by:
  ◇ Becoming an expert in a chosen topic
  ◇ Finding a physician mentor
  ◇ Networking
  ◇ Presenting trial data at meetings

GAYLE JAMESON, MSN, ACNP-BC, AOCN
Nurse Practitioner and Associate Clinical Investigator
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The AP Perspective on Participation in Academic Institution-Based Research Trials

- Because of the challenges faced regarding patient accrual to trials, community APs are well positioned to become more involved as SIs.
- Some of the SI duties are tasks that APs already perform, such as identifying, grading, and managing symptoms for trial-related adverse events.
- Although state regulations vary regarding limitations to AP responsibilities, APs can still be valuable resources regarding clinical trial protocols. Having APs perform certain trial-related tasks not only benefits the trial but also benefits the practice in terms of increased efficiency and decreased time to train new staff. APs are also well positioned to learn on the job.
- APs and physicians who are involved in research should work together to:
  ◇ Remove policies and regulations that limit AP practice
  ◇ Develop and provide formal AP clinical trial training
  ◇ Encourage sponsors and investigators to include APs when designing trials

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The AP Perspective on Participation in Community-Based Research Trials

- There must be a paradigm shift in the way clinical research is conducted and promoted. APs can and should be knowledgeable about the clinical trials available in their communities, within their practices, and beyond. This is crucial to this shift. APs must understand that offering a clinical trial to their patients should be the standard of care.
- APs spend a lot of time educating patients about treatment options, so it is logical that they would be able to discuss clinical trial options with their patients as well. However, APs must be aware of current trials in order to be able to educate their patients.
- APs can be part of the supportive care and disease-site working groups that review and approve trials at their practice sites, and they can serve on the regulatory and compliance committees. These types of activities can further engage and educate APs about clinical trials.
- APs can serve as enrolling investigators and site PIs for supportive care trials sponsored by the NCI and SIs for NCI-sponsored treatment trials. APs are also able to sign for cancer therapy on all types of NCI-sponsored trials if they are able to do so at their institution. APs must be aware of what they are able to do in compliance with a clinical trial research protocol and its sponsor.
- Diversity, equity, and inclusion (DEI) goes beyond race and ethnicity; it can also be reflected in professional roles. A research team does not have true equity unless there are equitable opportunities for APs. Likewise, diversity of a research team should also be represented in roles and knowledge.

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APs IN THE ONCOLOGY/HEMATOLOGY WORKFORCE

- A shortage of between 21,000 and 77,100 of specialty care physicians is expected by 2034.¹
- 22% of oncologists are nearing retirement (aged 64 and older).²
- 66% of rural counties in America have no oncologist and 32 million Americans live in counties without an oncologist.³
- More than 80% of US oncology practices reported employing APs across practice settings by 2017.⁴
- 80% of APs are involved in treatment and symptom management, including follow-up visits.⁴
- 90% of APs are involved in patient counseling and prescribing.⁴

GEOGRAPHY MATTERS

There are 22 states in which NPs have full medical practice privileges, including the ability to be an autonomous principal investigator (shown on the map below). Although similar autonomous roles are rolling out in some states for advanced practice registered nurses, physician assistants must still work under the supervision of a physician.

In 2021 APSHO launched a research and quality task force to identify needs within the AP community, with a goal to develop curricula that APs can access. Although there are several existing Educator Modules on topics such as clinical trial design and drug approval in oncology, APSHO is working to provide more CE-accredited modules in the new AP Academy, such as the existing APSHO Cancer Therapy Prescribing Course. Through its provision of both online and live education, as well as its relationships with SITC and other organizations, APSHO hopes to continually address this topic over the next several years.

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THE CLINICAL RESEARCH CRISIS IN ONCOLOGY: AN OPPORTUNITY FOR SYSTEMIC EVOLUTION

A hematology and oncology specialist of more than 30 years, Dr. Michael S. Gordon has juggled daily patient care and clinical research for decades and is no stranger to the peaks and valleys of clinical trial funding, enrollment, and results reporting. As the Chief Medical Officer of the HonorHealth Research Institute, a component of HonorHealth, Dr. Gordon was able to successfully navigate the COVID-19 pandemic without staff layoffs. Research programs based on elective procedures in bariatric, gastrointestinal, and cardiovascular health were suspended, and research staff was reassigned to one or more of approximately a dozen COVID-related clinical trials. In his panel discussion, Dr. Gordon provided an overview of clinical trial stakeholders, the financial requirements of research programs, and the unfortunate intersection of events that has led to a sea change in oncology research and care delivery. He also provided advice for weathering the next research storm.

UNDERSTANDING RESEARCH AS A BUSINESS

The majority of clinical trials are sponsored by pharmaceutical or biotechnology companies with the primary focus on development of novel therapies. These types of clinical trials are often designed in phases that will be reported over several years. These trials are often expensive due to their size, scope, and duration, with average drug development costs of $1.7 billion per agent.¹ For these types of sponsors, money and speed are crucial, as a single day of delay in getting a new product to market can result in $1 million to $13 million in lost revenue.¹

Contract research organizations (CROs) are for-profit entities that manage the oversight of the trials across a mix of academic-based and community-based sites. CROs handle all of the administrative and reporting aspects including budgets, good clinical practice, regulatory compliance, and data compilation, and they serve as the interface between the large pharmaceutical or biotechnology research sponsors and the individual sites.

In addition to research sponsors, there are regulatory agencies and groups tasked with research oversight, such as the U.S. FDA and Institutional Review Boards, as well as boards of directors, ethics committees, and lawyers—all of whom have key roles to play but can also delay the progress of trial startup, contributing to overall costs.

I think we too often forget that we're in the business of providing care to our patients. That business may be standard of care, where chemotherapy costs could be a quarter of a million dollars or more every week, or it could be research and investigational therapies. Regardless, we have to be able to bring in business to pay our bills.

—DR. GORDON
Outside of trial sponsors and regulators—the 50,000-foot perspectives of a research trial or topic—there are two sides to the research enterprise, according to Dr. Gordon. There is the patient-facing side, which comprises everyone who contributes to the care of a patient on trial, from infusion nurses who are tasked with protocol compliance to pharmacists who manage the actual products to laboratory technicians who process a range of required specimens. The other, perhaps larger, side comprises all of those who work on the project-management aspects of a trial, including those involved with budgets, contracts, regulatory affairs documentation, data transfer, accounts payable, and billing.

DEFINING THE CRISIS

Over the past few years, there has been a “cataclysmic conjunction of events,” according to Dr. Gordon, exacerbated by, if not beginning with, the worst pandemic in modern medical history. It has been previously established that even a 4-week delay in treatment can be associated with increased mortality across all three treatment modalities for bladder, breast, colon, rectum, lung, cervix, and head and neck cancers, so the treatment delays experienced during the pandemic due to fear of exposure or actual exposure to COVID have undoubtedly contributed to decreased survival rates. In addition, screening of cancers drastically declined, leading to later-stage diagnoses and treatment initiation. Predictably all of this translated to considerable disruption to clinical trials. Although clinical trial enrollment prior to the pandemic, especially for targeted therapies, was estimated to be less than 40% of accrual goals for phase III and IV trials, trial enrollment and participation experienced a massive falloff, leading to a global hiatus of non-COVID-related research and extensive redirection of funding and staffing.

In addition to enrollment, clinical trial funding also dried up. Although increased patient admissions due to COVID-19 might have partially offset lost revenue from surgical and other procedures, the American Hospital Association estimated a total loss of $202.6 billion between March and June of 2020 for American hospitals so future research dollars disappeared. As spending decreased throughout the pandemic, the economy suffered in general. Research funding became harder to secure for small companies, opening more of them to acquisition. As the larger companies acquired more and more smaller companies, research pipelines were culled, cutting off patients from investigational therapies and narrowing research fields even further.

The problems we will discuss are not new, but facing them all at once, in a dire setting, is unique. It is the proverbial blind men and the elephant. One man grabs the tail, but it feels like a rope. Another man touches the side of the elephant, and it feels like a wall. The ear is described as a fan, the leg is a tree trunk, and the trunk is a snake. Like the elephant, the crisis is perceived individually—what you do defines your crisis.

—DR. GORDON
As increased numbers of healthcare providers and staff transitioned to remote work, staffing shortages began to arise—dubbed “the Great Resignation.” For example, CRO employees transitioned to roles at pharmaceutical companies where trial monitoring was remote and no travel was required. Data management staff at research centers transitioned to CROs, where their responsibilities were expanded and, again, they were able to work in a remote setting more of the time. Perhaps the staffing shortages with the most impact on clinical trials and patient care, however, were the medical assistants on the front lines who were leaving to find jobs that offered more personal safety. To compound the issue, staff members most likely to resign were those with the most seniority and experience.
HITTING THE RESET BUTTON

As devastating as this crisis has been for so many, Dr. Gordon is adamant that there are lessons to be learned.

- **Use a value-based assessment of your research goals.** Build pillars of care in a longitudinal manner based on both your patient population's needs and your organization's strengths. For example, a drug in phase I development must match your organization's patient population, or a clinical trial will not be able to complete accrual.

- **Foster retention.** This has been an area of focus for the corporate world outside of healthcare since the pandemic as well. For those staff who do not have patient-facing responsibilities, flexible working hours or environments should be allowed as much as possible, such as through remote trial monitoring.

- **Make education and advancement a critical component of your program.** For those staff directly involved in patient care, such as APs, career opportunities in the form of research participation should be provided. Physicians involved in trials should make an AP a subinvestigator also known as a co-principal or co-primary investigator, (co-PI) or even a PI and provide mentoring regarding research tasks and goals.

- **Play to your strengths to achieve your goals.** More complete and rapid trial enrollment logically leads to less cost. Physicians running trials should play to the natural strength of APs, who are already helping patients with symptom and medication management, and enlist them to aid with trial enrollment.

- **Be transparent and flexible.** Transparency of communication ensures that everyone in the program understands priorities and how to adjust when faced with sudden challenges. This will not only help your organization thrive through natural ebbs and flows, but it will also allow you to offer high-quality care regardless of the circumstances.

1. Gordon MS. The “crisis” in clinical research. Presented at: JADPRO Workshop; May 7, 2023; Houston, TX.
APs AS CLINICAL INVESTIGATORS: ENHANCING PATIENT CARE AND CAREER SATISFACTION

A nurse practitioner and associate clinical investigator, Gayle S. Jameson, MSN, ACNP-BC, AOCN, has been with the HonorHealth Research Institute since its infancy in 2006. Ms. Jameson specializes in pancreatic cancer and supportive care research and has worked on more than 100 pharma-led, foundation-sponsored, and investigator-initiated trials as an SI or PI. During the panel discussion, Ms. Jameson walked APs through the steps it takes to become a clinical research investigator, providing insights into how best to navigate barriers.

THE FIRST STEP

There are numerous potential roles for APs in clinical research. Some of these are responsibilities that APs perform during daily patient care without formal “research participation” acknowledgment. Some research-related roles are:

- Serve as a referring provider
- Participate in study review and selection based on knowledge of the patient population
- Communicate with study teams and medical monitors regarding adverse-event grading and safety
- Comply with all federal regulations and good clinical practice guidelines in study participation and leadership
- Follow patients closely regarding symptom prevention and management

- Educate patients, caregivers, and staff regarding trial protocols and experiential data
- Participate in community outreach
- Present research findings at local, national, and international meetings
- Participate on creation and revision of journal publications
- Participate on an Institutional Review Board (IRB)

MANY OPPORTUNITIES FOR APs IN CLINICAL TRIALS

An SI, or a co-investigator, is a very important role, albeit limited in scope. At the HonorHealth Research Institute, SIs are encouraged to be very active partners to medical monitors on the various studies and to really engage on safety calls about dose escalation and adverse events.
FILLING A VOID, SEIZING AN OPPORTUNITY

Unfortunately, trial sponsors often impose limitations on the role of PI for APs, mandating that this role be filled by a physician. However, the FDA Code of Federal Regulations in Section 312.53 and Section 812.43 states that sponsors of clinical trials are required to select investigators who are qualified by education and experience in the context of the study, regardless of whether the focus is an investigational product or device. This means, very clearly, that APs can be PIs, with a physician as an SI for support, for best overall patient care. Should more trial sponsors allow this as part of trial protocols, not only would this increase the pool of investigators for clinical research, advancing scientific innovation more quickly, but it may also enhance the quality of the execution of clinical trials due to the holistic training of APs.

For those APs who are interested in serving as PIs, it is important to become familiar with the Statement of Investigator, Form FDA 1572. The form is an agreement between the PI and the study sponsor regarding compliance with FDA regulations. This form provides all of the relevant information about the PI to the sponsor, allowing the sponsor to determine whether the PI is qualified and the site is an appropriate location for the trial, and to communicate expectations regarding trial conduct with the PI. The 1572 does not mandate that a PI be a physician, but it does state that if the PI is a nonphysician, the SI should be a physician, who will be responsible for all trial-related medical decisions.

In this world of pharma-driven studies, we need strong physician mentorship. You need to see a lot of patients. You need to know the subject matter well. You need to be passionate about being a researcher, be confident, and be persistent. You need to network, present, and publish. And you need a supportive institution—that really is so important to maximizing research opportunities as an AP.

—MS. JAMESON

BECOMING FAMILIAR WITH FORM FDA 1572

The Statement of Investigator, Form FDA 1572 is available as a downloadable PDF, complete with a Frequently Asked Questions section that may prove useful when first becoming familiar with clinical trial-related roles.

TIPS FOR TAKING THE LEAD

It can be challenging for an AP to find formal education regarding clinical trial requirements, roles, and reporting. In 2019, the HonorHealth Research Institute and City of Hope Cancer Center joined forces to create the Oncology Nurse Practitioner Clinical Trialist Intensive Course. This bootcamp-like course provided 30 hours of CME and aimed to empower participants with the knowledge regarding how to develop a concept into a clinical trial protocol synopsis that could be shared with the attendee’s home institution. The course was paused during the pandemic, but there are plans to reinstitute it in 2024.

In addition to the clinical research spotlighted in JADPRO, APSHO also offers an educational module, “Clinical Trial Design and Drug Approval in Oncology: A Primer for the Advanced Practitioner.” Other resources are currently in development with the newly created Research and Quality Improvement Committee, which currently authors a regular column in APSHO’s quarterly newsletter that focuses on clinical research.
We have to be creative in terms of how we get ourselves out there. If you have a good relationship with a physician, it’s okay to say, ‘I have contributed to this study, and I really want to be on this manuscript and get my name out there as an investigator.’ It sounds impossible to people, but it’s about persistence.

—MS. JAMESON

A portion of Ms. Jameson’s panel discussion focused on several studies on which she was or is the lead PI. To prepare for your own journey into clinical research, Ms. Jameson advises APs to:

- Know your chosen topic and patient population very well—become an expert
- See as many patients as possible
- Partner with physicians who will support and mentor you
- Be willing to accept constructive criticism
- Network
- Be reliable and always meet timelines
- Present and publish
- Be confident and thank often


TOP 5 JADPRO ARTICLES ON CLINICAL RESEARCH

1. Role of Oncology Advanced Practitioners to Enhance Clinical Research (2022)

2. Phase 1 Clinical Trials in the Elderly: Enrollment Challenges (2020)

3. Clinical Trial Design and Drug Approval in Oncology: A Primer for the Advanced Practitioner in Oncology (2020)

4. Understanding Attitudes and Roles of Oncology Advanced Practitioners in the Setting of Cancer Clinical Trials: A Pilot Study (2021)

5. Management of Adverse Events in Early Clinical Trials by Advanced Practice Providers in the Outpatient Setting: The University of Texas MD Anderson Cancer Center Experience (2022)

Please note that the items on this list are in order of readership score, with the highest score listed in first place. Abstracts from JADPRO Live meetings are not included. You must be logged in to JADPRO to access the full articles. If you are not a JADPRO subscriber, registration is free. Visit advancedpractitioner.com to register.
PARTICIPATION IN ACADEMIC INSTITUTION-BASED RESEARCH TRIALS: THE AP PERSPECTIVE

An advanced-degree oncology nurse herself, F. Diane Barber, PhD, APRN, ANP-BC, AOCNP, has developed a clinical practice framework for oncology NPs who serve as SIs in early-phase clinical trials. Dr. Barber’s own personal research interest is focused on evaluating the role of APs in the care of patients with cancer who are enrolled on early-phase trials and how that care translates into patient outcomes. During the panel discussion, Dr. Barber talked about her unique experience in the Department of Investigational Cancer Therapeutics, which is a phase I clinical trial program, at the University of Texas MD Anderson Cancer Center. Home to more than 300 employees all active in clinical research, resulting in a tremendously wide array of multispecialty resources, from finance to social workers, her institution provides Dr. Barber with a comprehensive perspective.

THE ESSENTIAL ROLES OF A SUB-INVESTIGATOR

Although MD Anderson does not allow APs to serve as PIs, there are numerous essential roles for them as SIs. Patient-facing responsibilities include:

- Screen new patients and consult with them regarding trial eligibility
- Perform trial-related physical examinations
- Perform trial-related procedures such as skin-punch biopsies and intratumoral injections
- Review, interpret, and act on diagnostic and laboratory results
- Manage symptoms for trial-related adverse events
- Identify and grade trial-related adverse events
- Provide trial-related patient and caregiver education
- Participate in trial team weekly meetings

Research NPs in the SI role in Dr. Barber’s department report all adverse events, trial violations, trial amendments directly to the Institutional Review Board. They facilitate and coordinate all of the daily clinical trial activities, such as meeting with sponsors and monitors, and they assist with the collection, compilation, documentation, and analysis of trial data. They also create trial-related in-services for both the inpatient and outpatient nursing staffs, as well as participate in periodic quality assurance audits of the trials.

APs in the inpatient unit manage the trial-related care of the patients, such as adverse events and disease progression identification and monitoring. Some specific immunotherapy trials require patients be admitted, so they will be managed in this area of the department. The APs in the outpatient section work in a co-managed clinic with an oncologist for clearance and restaging. There is an independent AP “Fast Track Clinic” that falls under the outpatient umbrella in which APs perform all of the protocol-related physical examinations, adverse-event assessments, and laboratory reviews. The infusion center, or Clinical and Translational Research Center, also is part of the outpatient
center, so APs working on clinical trials will visit patients in the center if there is monitoring needed for a specific adverse event- or physical exam-related task.

**BARRIERS AND SOLUTIONS**

As there is no formal education for APs in clinical research at her institution, Dr. Barber noted that learning happens on the job. As SIs, the connectivity between patient care and clinical trial data collection is taught informally by more senior staff and colleagues. Because of the high volume of trials dealt with at any one time, APs are unable to retain all of the details about each and every one. Coupled with frequent turnover of research staff and study coordinators, SIs are unable to know each protocol by rote, which slows decision-making and, ultimately, patient care. Onboarding of new trial staff also can be a burden regarding AP time and can lead to confusion in decision making when protocol information is first being learned.

In addition, based on state policies, there are limitations to the responsibilities of APs in clinical trials. For example, APs were able to conduct virtual visits during the pandemic, but that has since been rescinded, which adds a layer of complexity for both the APs and the patients. Outside of state policies, some sponsors mandate that a physician perform the physical examinations, which can create bottlenecks in data compilation and puts an unnecessary burden on a trial-related physician’s time.

Dr. Barber suggests several solutions to overcoming these barriers:

- Remove policies and regulations that limit AP practice
- Develop and provide formal AP clinical trial training
- Explore use of AI to identify and recruit patients for clinical trials
- Encourage sponsors to include APs as PIs of supportive care trials
- Encourage sponsors and investigators to include APs when designing trials
PARTICIPATION IN COMMUNITY-BASED RESEARCH TRIALS: THE AP PERSPECTIVE

Christa Braun-Inglis, DNP, MS, APRN, FNP-BC, AOCNP, is one of the few oncology-certified nurse practitioners (NPs) in the state of Hawaii and has a unique dual role of AP and part-time faculty member supporting clinical research at the University of Hawai’i Cancer Center, which is National Cancer Institute (NCI)-designated community oncology research program (NCORP). Since 2018, she has helped to train more than 10 oncology APs in clinical research, all of whom are registered as non-physician investigators through the NCI. In her panel presentation, Dr. Braun-Inglis talked about how conducting of clinical trials in a community-based setting post-pandemic requires a paradigm shift.

DETAILED AWARENESS, SPECIALIZED KNOWLEDGE

Not enough emphasis can be put on the workforce challenges faced by APs who are interested in participating in clinical research. From the Great Resignation, which caused a deficit of knowledgeable staff across positions, to the increasing complexity of trials, which results in mounting staff burden due to duplicative procedures and unwieldy data management, clinical trial research is challenging. Now add the lack of clinical space and the nuances that come with conducting clinical research in a community-based setting. Instead of focusing on the challenges, however, Dr. Braun-Inglis emphasized a necessary paradigm shift, to which APs are crucial.

APs can be knowledgeable about the clinical trials available in the community outside of those that may or may not be available within any given practice. APs spend time educating patients about their routine care, so it is a logical extension that they would be useful in trial enrollment and patient education. In addition, APs are fully immersed in patient care every day, learning about patients’ anxieties, goals, and overall health. For example, a medication may be listed on a patient chart as “active” when in fact it has been discontinued. The AP, knowing the patient as well as they do, would recognize that that specific medication was stopped 6 months or more ago, but a clinical trial coordinator would not have that information and could deem the patient as ineligible for the trial. This type of detailed involvement in care of patients on trial not only enhances the trial process, but it also enhances safety for the patients involved.

In addition, APs are in tune with the clockwork of the clinic, especially in the community. Dr. Braun-Inglis provided the example of a patient who needs a 12-hour pharmacokinetic blood draw, and you only have an 8-hour nurse there that day—where will the patient go for the blood draw? A specific example, yes, but also a common barrier when delivering care to patients on trial—just the simple matching of protocol to logistics and feasibility.
Diversity, equity, and inclusion go beyond race and ethnicity. It applies to whether a research team is diverse according to roles and knowledge, as well as to whether there are equitable opportunities for APs.

—DR. BRAUN-INGLIS

CLINICAL RESEARCH IS BEST-AVAILABLE CARE

The NCI does allow APs to be PIs on clinical trials. All of the APs within Dr. Braun-Inglis’ institution are registered as at least SIs, and a handful serve as site PIs on supportive care trials. In addition, more than 80% of the University of Hawai‘i NCORP’s supportive care trial enrollments are done by APs in the community. Inclusive participation means that APs are part of the supportive care and disease-site working groups that review trials, are voting members of the community research advisory board, and serve on the regulatory and compliance committees.

Dr. Braun-Inglis likens AP involvement to following National Comprehensive Cancer Network (NCCN) guidelines in that the NCCN always recommends clinical trials for patients if one is available. Clinical research and standard of care should be treated as one in the same, and having APs involved in research ensures that trial treatments are being offered and accepted. In addition, involvement in clinical trials often energizes APs, allowing for more professional satisfaction.

NCORP AND APs: EXPANDING THE REACH, SPEED, AND QUALITY OF TRIALS¹-³

The National Cancer Institute (NCI) Community Oncology Research Program (NCORP) is a national clinical trials network that uses community-based centers to design and conduct clinical trials to allow larger and more diverse patient populations treated in a variety of healthcare delivery settings. Although academic centers play a vital role in cancer research, community-based research reflects the complexity of care delivery while encouraging community oncologists, advanced practitioners, and non-oncology specialists to develop real-world solutions. NCORP studies focus on the following areas:

- Cancer prevention
- Screening
- Supportive care and symptom management
- Surveillance
- Health-related quality of life
- Cancer care delivery

NCORP is composed of 7 Research Bases and 46 Community Sites, 14 of which are designated as Minority/Underserved Community Sites.¹

Since 2021, NCORP and the NCI Cancer Therapy Evaluation Program (CTEP) have allowed qualified APs—as defined as nurse practitioners (NPs), physician assistants (PAs), clinical nurse specialists, advanced degree nurses, and pharmacists who are qualified per institutional policy and local and state laws—to write patient orders for study agents, including both investigational new drugs (INDs) and standard-of-care agents, without a physician cosignature.² In addition NCORP protocols funded by the NCI Divisions of Cancer Prevention (DCP) and Cancer Control and Population Sciences (DCCPS) have developed a guideline outlining enhanced roles for APs who have have Master’s level educational degrees or a PhD, DNP, or PharmD.³ When developing and implementing NCORP Research-funded trials, qualified APs may:

- Serve as chairs (PhD required)
- Serve as co-chairs
- Serve as a local investigator to consent and enroll patients
- Prescribe/write orders (in accordance with the CTEP policy)

An important caveat to these allowances is that state and local law must be in concordance. State and local laws supersede and NCORP and/or CTEP guidelines. Also, clinical trial site institutional policies must include information about³:

- The processes for AP credentialing
- The process for AP-written study orders
- How APs are meeting the Guidelines for Good Clinical Practice (GCP)