The Advanced Practice Role in Clinical Trials: Past, Present, and Future

PRESENTED BY COLLEEN LEWIS, MSN, ANP-BC, AOCNP®

From Winship Cancer Institute of Emory University, Atlanta, Georgia

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Abstract

At JADPRO Live Virtual 2021, Colleen Lewis, MSN, ANP-BC, AOCNP®, discussed the trajectory of the advanced practitioner role in clinical research, including the historical experience, potential barriers to practice, and future possibilities to advance patient care and maximize the role of the advanced practitioner in research.

Although enrollment has increased slightly in recent years, it is estimated that only 8% of patients with cancer in the United States enroll in a clinical trial (Hillyer et al., 2020). According to Colleen Lewis, MSN, ANP-BC, AOCNP®, Director of Clinical Operations, Phase I Program, Winship Cancer Institute of Emory University, there are key opportunities for advanced practitioners (APs) to enhance the clinical trial experience.

At JADPRO Live Virtual 2021, Ms. Lewis described the past and present role of APs in clinical trials as well as future possibilities for APs in clinical research. Ms. Lewis also discussed ways to overcome barriers limiting AP practice in clinical research and improve trial participation.

"As APs, we are integral to the care team and are some of the primary points of contact for patients, who inherently trust the discussions that we have with them," said Ms. Lewis. "Every discussion we have with our patients can move the needle on enrollment into trials."

CLINICAL TRIAL PLANNING

As Ms. Lewis explained, there are numerous phases and components to trial preparation, from site evaluation and site activation to site initiation and study closeout, and many of those steps are historically performed by trial sponsors (Welch et al., 2017).

"We typically think about the role of the AP being in patient enrollment and study conduct, which consists of taking care of patients on trial, ensuring accuracy of the conduct of patient care and accuracy of data collection," said Ms. Lewis. "However, it's important to look at all areas of trial conduct to consider where APs can have a larger role."

According to Ms. Lewis, scientific review committees, which evaluate the scientific merit, feasibility, and logistics of proposed clinical tri-

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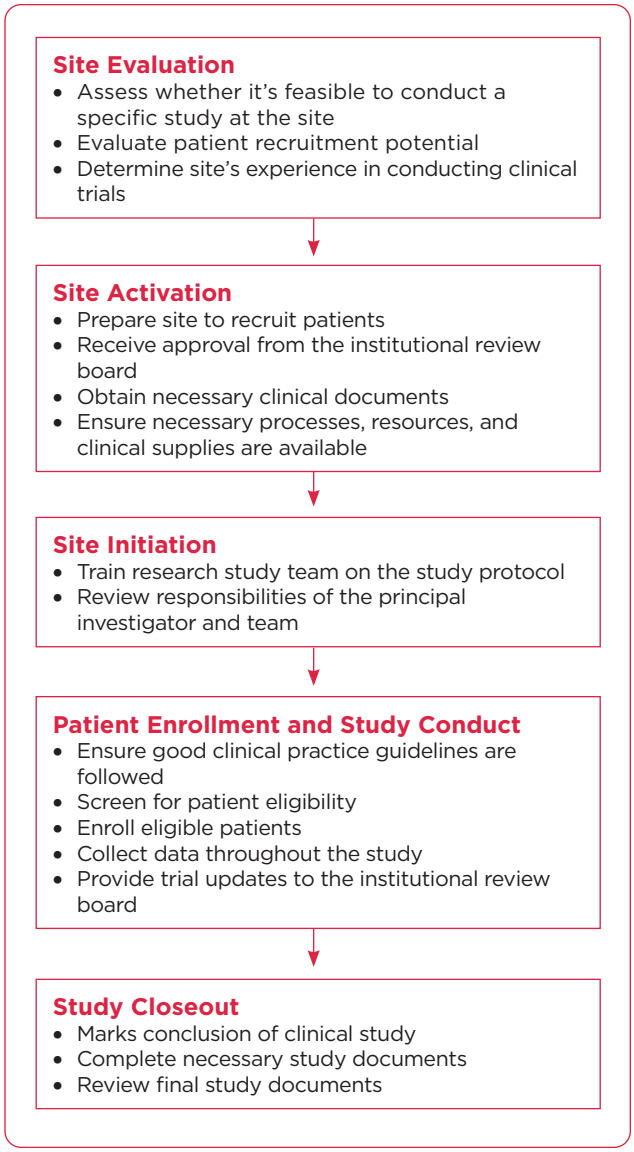

Figure 1. Planning and conducting a clinical trial: Role of the advanced practitioner. Reprinted from Welch et al. (2017).

als, represent a great opportunity for APs to think outside the box of patient care. Other opportunities for involvement include the evaluation of trial portfolio needs at a site based on population served and operational planning through collaboration with research and clinical teams (Figure 1).

"Being a part of those discussions on the front end, before trials are even brought into your care center, can be incredibly impactful," said Ms. Lewis.

PAST ROLE OF AP IN TRIALS

The role that APs play in the management of patients on clinical trials has changed significantly over the years. In the past, protocols specified that a physician must perform trial-related visits, and there were no research-specific job descriptions for APs.

"Job descriptions did not even mention taking care of research patients, even at large academic medical centers," said Ms. Lewis. "APs were less involved with discussing clinical trials with patients, and in many instances, were not listed as coinvestigators."

A 2008 survey of APs about clinical trials reflects these former perspectives and attitudes (Ulrich et al., 2012). When asked whether they would leave the decision for clinical trial enrollment to an oncologist or someone more knowledgeable about the protocol, 87% of respondents said yes.

"At the time, APs did not have the ability to make a recommendation independently or even collaboratively about trial selection for a patient, even though they recognized the importance of clinical research in oncology," Ms. Lewis explained.

CURRENT EVOLUTION

Current data evaluating AP perspectives, however, confirm that APs are now much more comfortable discussing clinical trial recommendations. One recent survey showed that 97% of APs recognize the importance of trials in advancing the standard of care, and more than 70% expressed interest in more clinical trial involvement (Braun-Inglis et al., 2021).

"APs are well positioned to leverage knowledge and interest in trials to increase patient enrollment on oncology trials," said Ms. Lewis. "It's a good sign that many have more comfort and awareness of their ability to identify trial options."

In support of this evolution, research-specific AP job descriptions have become more common, especially at larger academic centers, and APs frequently serve as subinvestigators managing patients on trial. There is also a strong interest across professional organizations to understand and promote a more comprehensive role for APs in clinical research. In fact, Ms. Lewis noted that APs already have an ability to sign orders and consent patients at some practice sites, although this varies by state.

"For APs to fully integrate into the clinical trial team, it's important that they are given the opportunity to practice at the top of their ability, which includes signing treatment orders and consenting

patients," she said. "Handling reconsents is a critical role that APs can play, especially in those areas where they truly are content experts on protocols."

"Expanding some of the responsibilities of APs can help increase the accuracy of trial conduct as well as our ability to comply with the regulations more thoroughly," she added.

OVERCOMING IMPLICIT BIAS

According to Ms. Lewis, clinical trials represent a standard of care for many patients; they are not the historical, last-ditch effort that many patients and some providers may still have in mind. Although every patient with cancer should be considered for clinical trial participation, however, Ms. Lewis noted several barriers to patient enrollment.

One major barrier is discordant perceptions about cancer clinical trial participation between physicians, research staff, and cancer patients (Hillyer et al., 2020). When compared with interviews of adult cancer patients, an online survey of physicians and research staff (physician assistants, nurse practitioners, staff and research nurses, clinical assistants, and program coordinators) involved in clinical research at a comprehensive cancer center showed a wide gap in physician/staff and patient attitudes and beliefs.

Specifically, 63% of the care team said that a lack of understanding led patients to decline a trial, while only 9% of patients claimed lack of understanding as a reason. Similarly, while nearly 25% of the care team thought that religious reasons influenced patient decisions, none of the patients interviewed agreed.

"The disconnect between clinical-team and patient-cited reasons for declining a trial may contribute to fewer patients being approached about trial options," said Ms. Lewis, who noted that reconciling these differences will require tailored education to reduce implicit biases and dispel misperceptions.

"It's important for us to understand that when we're seeing patients, we cannot make assumptions about their interest in trials or their readiness to have some of these conversations," she continued. "We certainly want to meet people where they are and with their preferred communication style, but it's important that we include information about clinical trial enrollment at every opportunity we can."

LOOKING AHEAD: KEY OPPORTUNITIES FOR APs

One way to improve patient enrollment is for APs to leverage technology to allow more time to discuss trials. According to Ms. Lewis, telemedicine may be especially impactful in this area by promoting prompt trial evaluation.

"AP-led clinical trial consults have been around for a while, but historically, they were always in person," she said. "Recently, however, we've seen increased use of telemedicine. This is a great way for our internal referrals who are established at the cancer center and have probably had recent labs to receive information about potential trial options and get a recommendation."

Another opportunity is regional community and academic partnerships among APs. According to Ms. Lewis, many physicians already have a pipeline where they refer each other patients, and a similar model could be adopted by APs.

"APs in the community who are close to an academic center could have an AP resource at an academic center to quickly tap into information about new trial offerings for patient populations they commonly serve," she said.

PHARMACISTS IN CLINICAL RESEARCH

As Ms. Lewis explained, pharmacists can also play a critical role in clinical research, which includes patient education, trial selection, oral drug adherence, multi-drug regimen dose modification, and concomitant medication review.

Although clinically relevant drug interactions have been identified in more than 50% of early-phase oncology clinical trials, one survey of SWOG head clinical research associates found that drug interaction screening was not being systematically conducted (Hertz et al., 2018).

"There is a large need for medication review and substitution to ensure safe and timely enrollment on trial, and this is something that many sites should strive to incorporate into their practice," said Ms. Lewis.

According to Ms. Lewis, pharmacists can also play a critical role in proactively screening patients and suggesting clinical trial possibilities, and a partnership with an AP can further enhance those discussions and decision-making.

"At Emory, our section director who is a PharmD by training and I have had an incredible collaboration and have helped grow the program because of our separate areas of expertise," said Ms. Lewis. "I think that a partnership between a nurse practitioner/physician assistant and a pharmacist could benefit other sites, too."

Disclosure

Ms. Lewis has served on the speakers bureau for Genentech.

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