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

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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-
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

Figure 1. Planning and conducting a clinical trial: Role of the advanced practitioner. Reprinted from Welch et al. (2017).
patients,” she said. “Handling reconsents is a criti-
cal 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 inter-
views of adult cancer patients, an online survey
of physicians and research staff (physician assis-
tants, nurse practitioners, staff and research nurs-
es, 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 rea-
sons influenced patient decisions, none of the pa-
tients interviewed agreed.

“The disconnect between clinical-team and pa-

tient-cited reasons for declining a trial may contrib-
ute to fewer patients being approached about trial
options,” said Ms. Lewis, who noted that reconcil-
ing 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 assump-
tions about their interest in trials or their readi-
ness to have some of these conversations,” she
continued. “We certainly want to meet people
where they are and with their preferred commu-
nication style, but it’s important that we include
information about clinical trial enrollment at ev-

ey 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 dis-
cuss trials. According to Ms. Lewis, telemedicine
may be especially impactful in this area by pro-
moting 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 estab-
lished 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. Accord-
ing 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 adher-
ance, 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 enroll-
ment on trial, and this is something that many
sites should strive to incorporate into their prac-
tice,” said Ms. Lewis.

According to Ms. Lewis, pharmacists can also
play a critical role in proactively screening pa-
tients 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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