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Blazing Trails With Research: Paving the Way for Advanced Practice Providers

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Authors' disclosures of conflicts of interest are found at the end of this article.

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Abstract

Introduction: In September 2021, the National Cancer Institute (NCI) expanded the ability for advanced practice providers (APP) to practice more autonomously by being able to write orders for research-related anti-cancer therapy. **Objectives:** The goal was to align with NCI guidance to permit APPs to independently write non-Cycle 1 Day 1 study agent orders. **Methods:** An academic institution created a process to comply with the NCI's memorandum. Health-system policy was updated to reflect this new capability. A tracking system was established to monitor NCI's Registration and Credentialing Roster (RCR) expiration dates. An audit process was created to verify alignment between signed electronic research-related anti-cancer therapy orders and Delegation of Tasks Logs. **Results:** To date, no adverse comments about APPs' abilities to sign anti-cancer trial orders have been received from organizations that accredit or support clinical trials. In addition, no APPs have lost the ability to sign anti-cancer therapy orders because they failed to renew their RCR within the expiration period. To facilitate this capability in a timely manner, a research-specific onboarding experience was created. **Conclusion:** APPs may safely write anti-cancer treatment orders for patients enrolled in clinical trials. Additionally, such privilege may contribute to the enhanced participation of APPs through research.

At the University of Colorado Anschutz Medical Campus, the ability to independently sign study agent orders had been a longstanding concern impacting job satisfaction among nurse practitioners and physician associates within Medical Oncology. Although credentialed to sign orders for standard-of-care anticancer treatments, advanced practice providers (APPs) faced workflow challenges due to a separate and restrictive process for patients enrolled

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in clinical trials. Specifically, APPs were able to independently conduct pretreatment visits. However, they were not permitted to independently sign research-related treatment orders. This restriction resulted in workflow inefficiencies and contributed to provider frustration.

In 2018, the Advanced Practitioner Society for Hematology and Oncology (APSHO) joined several professional organizations to better understand the role of APPs within oncology settings (Bruinooge et al., 2018). This survey concluded that as many as 7,000 oncology APPs provide direct patient care, including counseling, prescribing, treatment management, and follow-up visits. A subsequent survey of 400 oncology advanced practitioners conducted in early 2020 discovered that more than 90% of respondents worked in settings that offered clinical trials, 90% of respondents felt that oncology practitioners should be involved in clinical research, and that 73% of oncology practitioners wanted to become more involved in clinical research (Braun-Inglis et al., 2022).

To better understand the roles of APPs in clinical trials, the Cancer Therapy Evaluation Program (CTEP) within the Division of Cancer Treatment and Diagnosis of the National Cancer Institute (NCI) conducted a survey. According to the findings shared on the CTEP website from this March 2021 survey, 80 clinical trial sites responded. The sites reported that: (A) There are APPs at more than 90% of sites that participated in phase II and III trials; (B) APPs at 68% of sites participated in phase I trials; and (C) 30% of sites permitted APPs to have anti-cancer trial orders cosigned by physician colleagues. Notably, 60% of sites supported APPs independently writing anti-cancer trial orders with the hope of increasing study enrollment and participant retention (National Cancer Institute, n.d.).

In September 2021, the National Cancer Institute issued a memorandum entitled, "Guidance and Update on Advanced Practice Providers Writing Study Agent Orders on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP)." This memorandum specifies that APPs may independently write orders for study agents when: (A) Qualified per institutional policy; (B) registered within the NCI's Registration and Credentialing Roster (RCR) as Non-Physician Investigators (NPIVRs); and (C) added to Delegation of Tasks Log (DTL) with "investigational new drug (IND) prescribing" status (National Cancer Institute; n.d.).

This memorandum acknowledged the important roles of APPs in clinical trials and sought to reduce barriers associated with clinical trial participation. Ultimately, it provided guidance and support from the nation's leading cancer research organization for APPs to practice at the top of their scope. Shortly after this memorandum was issued, the Division of Medical Oncology of the University of Colorado Hospital sought to align with the NCI's guidance to permit APPs to write non-Cycle 1 Day 1 study agent orders independently.

METHODS

Updating Policy and Procedure

The preparation process to implement the NCI's memorandum was divided into three phases to match the specified criteria: (A) Update health-system policy to reflect this new capability; (B) expand the current tracking system to monitor individual NCI's Registration and Credentialing Roster (RCR) expiration dates for eligible APPs; and (C) create an audit process to verify alignment between signed electronic research-related anti-cancer therapy orders and DTL.

To modify organizational policy, guidance from an expert clinical nurse specialist was sought. The clinical nurse specialist spearheaded the change process across our expanding healthcare system located in three diverse regions. In January 2022, the system-wide "Management of Anti-Cancer Agents" policy was officially revised to include this specific sentence: "Research anti-cancer agents are ordered by a provider listed as an investigator on the IRB-approved project." The system policy continues to specify that physicians write original orders for anti-cancer agents (i.e., Cycle 1 Day 1 orders).

Over 12 months, a small team collaborated to create an internal policy regarding RCRs. An Organizational Procedure was drafted and approved by the Cancer Clinical Trials Office Senior Clinical Manager, the Health System Research Administrator, and the Director of Oncology Pharmacy

Services. This Organizational Procedure is signed by each APP who would like to sign anti-cancer clinical trial orders and a witness. This Procedure specifies that an APP must maintain an active status within the NCI RCR as an NPIVR. Internally, a list of RCR expiration dates is maintained and reviewed at least monthly. If an RCR is not maintained, the individual's APP ability to sign both standard-of-care and clinical trial orders is rescinded. Such revocation streamlines pharmacy processes and tracking.

Notably, this Organizational Procedure specifies that the DTL Administrator for each protocol must add the task "IND prescribing" for each qualified NPIVR. Advanced practice providers may conduct visits for patients enrolled on clinical trials only after they have completed prerequisite work (including reading and understanding specific protocols). In the event questions or concerns arise, the Organizational Procedure states that an APP should not sign treatment orders. Also, if an APP is not listed on a specific DTL, then the APP may not write or sign orders for that trial. Individual APPs and the Cancer Clinical Trials Office assume responsibility for ensuring accuracy of DTLs. The Organizational Procedure acknowledges that Delegation of Authority (DOA) logs may be used, and that APPs should comply with NCI guidance. For trials opened prior to October 2022, a Master Note to File applies. According to the Cancer Center's Associate Director of Clinical Research, this capability applies to industry-sponsored trials and single patient investigational drugs when an APP has previous knowledge and experience of a specific drug per the Organizational Procedure agreement.

ENSURING COMPLIANCE

In June 2022, a pilot project with two disease-specific APP teams was conducted. This pilot helped to formalize processes and ensure compliance. The Director of Oncology Pharmacy Services ran reports of signed anti-cancer trial orders signed by APPs. The Cancer Clinical Trials Office subsequently reviewed DTLs for compliance. In December 2022, the Organizational Procedure was finalized. The pilot project became the current process. Approved lists of APPs who may sign clinical trial orders are also periodically provided to the Manager of Pharmacy Hospital Operations to disseminate to pharmacy colleagues authorizing therapy preparation.

The Director of Oncology Pharmacy Services, the Cancer Clinical Trials Office Senior Manager, and the Lead Medical Oncology APP continue to audit DTLs and DOAs at least every 6 months. These audits have highlighted important concepts to address including single patient investigational drugs. Advanced practice providers with previous knowledge and experience of a specific drug may continue to sign research treatments orders for such drugs in compliance with the Organizational Procedure. Accordingly, appropriate documentation of training may be requested for audit purposes. If concerns arise, an APP should not sign anti-cancer treatment orders.

To date, feedback about this ability to sign clinical trials orders has been overwhelmingly positive. In total, 27 of 28 Medical Oncology APPs have been credentialed by the Medical Staff Board to sign standard-of-care anti-cancer therapy orders. The one non-credentialed APP works in the hereditary cancer clinic and maintains her RCR status for prevention studies. Notably, two gynecologic oncology APPs requested to adopt the Medical Oncology APP process. Furthermore, no adverse comments about APPs' abilities to sign anti-cancer trial orders have been received from organizations that accredit or support clinical trials. Also, none of the 30 APPs have lost the ability to sign anti-cancer therapy orders because they failed to renew their RCRs within the expiration period.

DESIGNING AN EFFECTIVE ONBOARDING EXPERIENCE

To support the timely implementation of this capability, a research-specific onboarding program was then developed. The onboarding program was designed to ensure that APPs were adequately prepared to assume such research-related responsibilities as soon as they chose to do so. Previously, newly hired APPs were not given protective time to complete required training. Thus, they needed to simultaneously learn a new role and find time to complete required clinical training and research training. This led to frustration

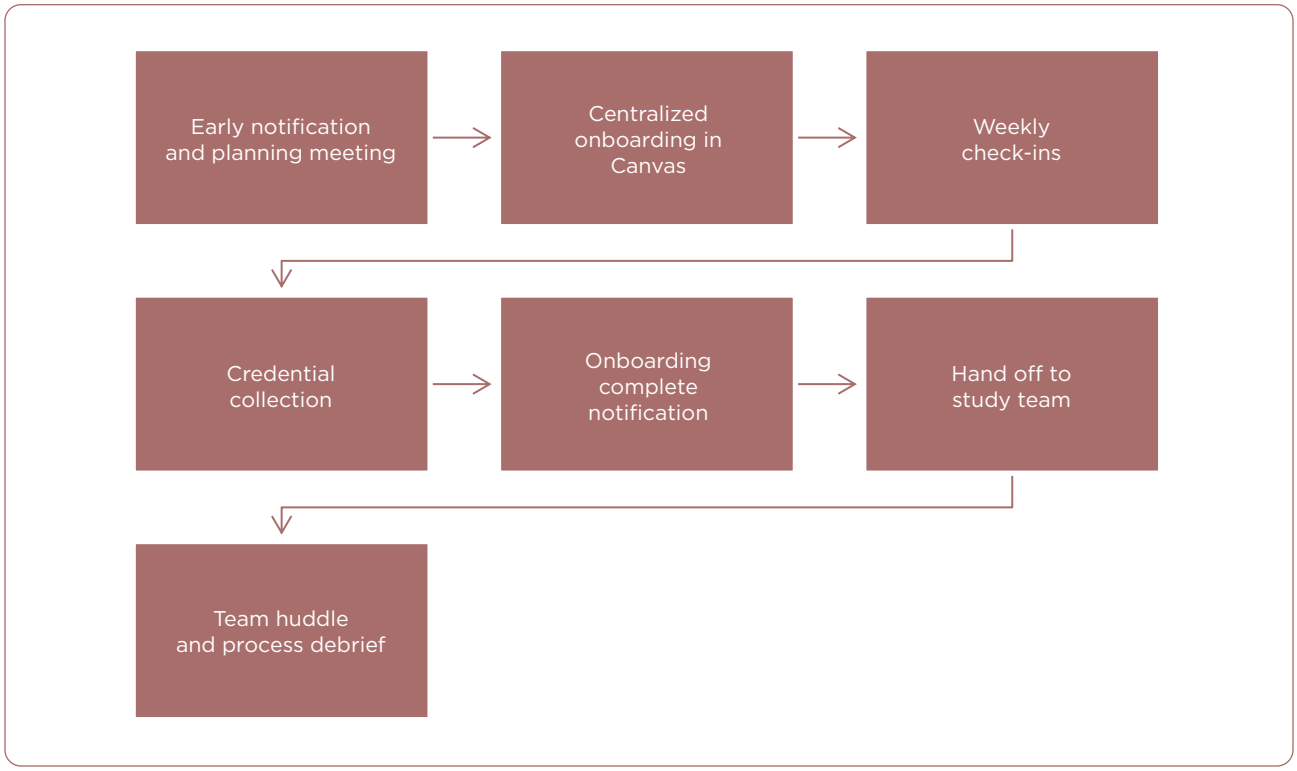

Figure 1. Administrative process for onboarding Medical Oncology APPs at the University of Colorado Cancer Center.

among newly hired APPs and delays in completing necessary training.

The University of Colorado Hospital has selected the Advanced Practitioner Society for Hematology and Oncology (APSHO) Cancer Therapy Prescribing Course as a credentialing prerequisite for APPs to sign standard-of-care anti-cancer treatment orders (APSHO, 2025). A certificate of completion for this course is also required for electronic health record functionality. Because of its content, this comprehensive course is paid for by the Division of Medical Oncology prior to an APP's date of hire. The University of Colorado Cancer Center requires additional research training including the Collaborative Institutional Training Initiative (CITI) program (Collaborative Institutional Training Initiative, n.d.).

After brainstorming with the Cancer Center's Learning and Development Team, a process was developed (Figure 1). The Medical Oncology APP onboarding process now begins with an early notification to an APP who is joining the Medical Oncology Team. This notification is communicated as early as possible to allow representatives from the School of Medicine (Division of Medical Oncology Team and the University of Colorado Cancer Center [UCCC]) Operations Learning and Development Team to discuss necessary details. The APP is allotted approximately 2 to 3 weeks to complete clinical and research onboarding. Research onboarding items and documentation are centralized in Canvas, the University of Colorado's learning management system. The Operations Learning and Development Team conducts weekly check-ins with Medical Oncology APPs and communicates progress to Medical Oncology representatives. Once onboarding is complete, a notification is sent to relevant parties in the Division of Medical Oncology and UCCC's Cancer Clinical Trials Offices (CCTO). The APP is then introduced to the study team. After each onboarding iteration, a debrief is held to discuss the process and identify areas for improvement. During these debriefs, open positions are reviewed to proactively plan for future APPs who will require onboarding.

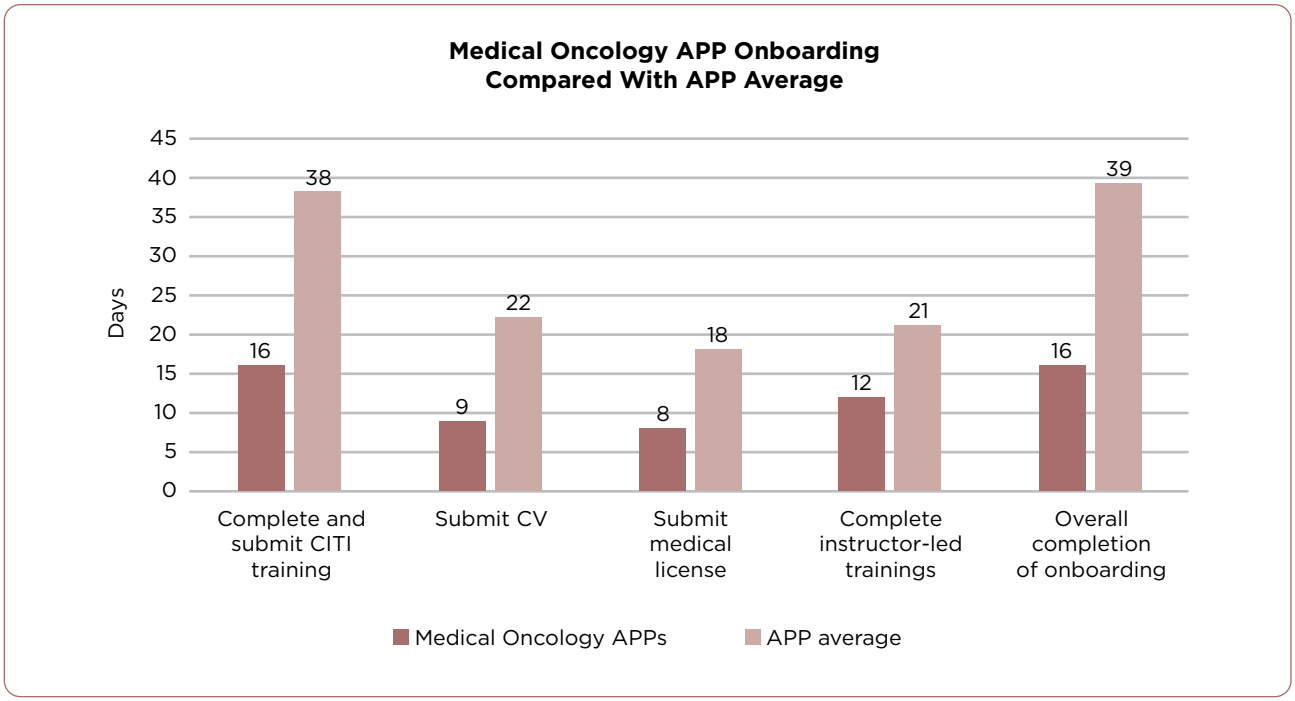

Figure 2. Graph showing average onboarding time (in days) to complete several onboarding tasks for Medical Oncology APPs compared with the average for APPs onboarded at UCCC between August 2023 and December 2024. Percentage difference from average: CITI training (58%), submit CV (59%), submit medical license (56%), complete instructor-led trainings (43%), and complete onboarding (59%).

OUTCOMES

Medical Oncology APPs are now told at the time of hire about hospital credentialing, billing credentialing, and research credentialing. Medical Oncology APPs are given a checklist documenting their onboarding needs for these requirements. They are also given protective time at the beginning of their employment to complete the APSHO Cancer Therapy Prescribing Course and their required research training. This process has decreased the amount of time necessary to complete research onboarding and increased the completion rate of required tasks (Figure 2). The data indicate that Medical Oncology APPs complete all onboarding items faster than the average of APPs onboarded at UCCC. Figure 2 shows that Medical Oncology APPs complete onboarding items in 40% to 60% of the time that it takes the average of all APPs onboarded at UCCC. The results highlight the effectiveness of structured onboarding and having time scheduled to complete it before taking on clinical responsibilities. Medical Oncology APPs also appreciate the dedicated time.

DISCUSSION

Medical Oncology APPs within the University of Colorado academic institution find satisfaction by participating in clinical trials and research. The CTEP memorandum has increased opportunities for Medical Oncology APPs to fully participate in clinical trials. Medical Oncology APPs also feel empowered to serve in clinical research leadership roles. One Medical Oncology APP currently serves on an institutional review board, while another Medical Oncology APP is a clinical member of the Cancer Center conducting research studies. Within the coming months, another Medical Oncology APP plans to serve as a principal investigator on a supportive oncology trial. This University of Colorado Medical Oncology example supports the concept that APPs are key members of both clinical teams and research teams, as explained by Braun-Inglis et al. (2023). Organizations may choose to adapt or modify this process to effectively and efficiently expand APP participation in clinical research with favorable results.

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Disclosure

The authors have no conflicts of interest to disclose.

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