The AP Role in Clinical Research: 2022 ASCO Annual Meeting Highlights for the Advanced Practitioner


Elizabeth Koselke, PharmD, BCOP, of The US Oncology Network, describes a clinical pharmacist intervention to screen patients and improve clinical trial enrollment. **Christa Braun-Inglis, DNP, APRN, FNP-BC, AOCNP®,** of the University of Hawai'i Cancer Center, details a team approach to both increase clinical trial accrual and improve clinical trial conduct.

Abstract 1503

Oncology Clinical Pharmacist Intervention Leads to Increased Clinical Trial Enrollment in The US Oncology Network's MYLUNG® Consortium

By JADPRO Staff

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The addition of a remote clinical pharmacist to screen potentially eligible patients significantly increased clinical trial enrollment in Protocol 2 of the Molecularly Informed Lung Cancer Treatment in a Community Cancer Network: A Pragmatic Consortium (MYLUNG) research study. The results were presented by Elizabeth Koselke, PharmD, BCOP, of The US Oncology Network (The Network), and colleagues at the 2022 ASCO Annual Meeting. These findings highlight how clinical pharmacists are uniquely positioned within the multidisciplinary team to address barriers to clinical trial accrual.

The MYLUNG Consortium is a collaborative effort by The Network, US Oncology Research, and Ontada to observe up to 12,000 community-based, metastatic non–small cell lung cancer (mNSCLC) patients over a 5-year period to deepen understanding of molecular testing barriers. The research study is divided into three protocols. Protocol 1 was presented at last year's ASCO Annual Meeting and was a retrospective study of approximately 3,500 patients with mNSCLC that found that less than 50% of patients were tested for *ALK*, *BRAF*, *EGFR*, *ROS1*, and *PD-L1* mutations.

This year, Koselke and colleagues presented on a screening intervention from Protocol 2, which enrolled approximately 1,000 patients from about 10 practices to monitor the real-world patient journey from presentation through their first line of cancer therapy, focusing on how diagnostic biomarker information is obtained, utilized, and operationalized in decision-making.

Study Design

The Network implemented a clinical pharmacist (ClinReview) to remotely review chemotherapy regimen orders and a weekly custom recruitment report within six community practices in The

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Network (n = 149 physicians). The ClinReview pharmacist identified, screened, and assisted with recruitment of eligible patients for enrollment in the MYLUNG Consortium study. Enrollments and intervention data were tracked to monitor the impact of the pharmacist intervention.

Study Results

Over a 6-month period, the ClinReview pharmacist screened 367 potentially eligible patients. 325 patients were recommended for enrollment, and 103 patients (32%) were consented and enrolled. Enrollment due to this ClinReview intervention increased monthly and ranged from 5 enrollments in the first month to 33 enrollments in month 6. Average monthly enrollment was significantly greater after ClinReview intervention (3.4 patients/month vs. 6.8 patients/month; p = 0.008). Of the 154 patients recommended for enrollment who were not enrolled, 104 (68%) exceeded their eligibility window allowed by the trial, 15 (10%) were deceased or enrolled into hospice care, 10 (6%) declined trial participation, and 25 (16%) transferred care or were treated at outside facilities.

Conclusions

The results demonstrate that incorporation of an oncology clinical pharmacist in clinical research teams significantly enhanced clinical trial enrollment. The remote pharmacist easily adapted into clinic workflows in community oncology practices.

Looking Forward

Protocol 3 of the MYLUNG Consortium will serve as a platform upon which prospectively assessed interventional strategies in patient-engagement algorithms will be conducted. Up to 7,500 patients from approximately 20 participating practices will be recruited over a 5-year period. The individual clinical trials will integrate findings from the previous protocols and explore new processes and associated outcomes to help providers make the best treatment recommendations based on the data available and improve access to testing and appropriate therapies for mNSCLC patients.

The Advanced Practitioner Perspective

Elizabeth Koselke, PharmD, BCOP
The US Oncology Network

In the past decade, the role of the clinical oncology pharmacist has significantly expanded, and pharmacists are now viewed as an integral part of the multidisciplinary team within both the academic and community health-care setting. Pharmacists are uniquely trained to assess patient data, including chemotherapy and supportive care regimens, and review comprehensive genomic panels, making them excellent resources to the care team.

Although advances in science are quickly unlocking new oncologic treatment opportunities, timely enrollment onto clinical trials continues to be a challenge, threatening the development of novel agents. To address this challenge, we assessed if clinical oncology pharmacists, through evaluating patient parameters during chemotherapy order review and utilizing a customized weekly report, could improve patient enrollment. Working remotely through a centralized EMR, pharmacists can efficiently assess appropriate inclusion/exclusion criteria and communicate with providers and clinical trial staff. Our data support utilizing an interdisciplinary approach to trial enrollment while streamlining processes to increase speed and efficiency in real-world clinical research.

Moving forward, oncology clinical pharmacists should be more involved in screening for patients for both observational and treatment trials. As oncology protocols grow more complex with the inclusion of targeted agents and mutation-specific basket trials, a clinical provider, such as a pharmacist, can be the perfect addition to the research team to analyze comprehensive biomarker test results and capture appropriate patients for enrollment. The role of the oncology clinical pharmacist will continue to develop into non-traditional roles as our strengths as a member of the provider team continue to be validated.

Updated 8-month data from Protocol 2 of the MYLUNG Consortium study will be expanded upon in a future report. Future studies confirming the role of a pharmacist screening intervention in larger, prospective, complex oncology protocols are warranted.

Disclosure: Dr. Koselke has no conflicts of interest to disclose.

Abstract e13524

Optimizing a Team Approach for Successful Accrual and Conduct of Clinical Trials

By JADPRO Staff

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With only about 2% to 8% of adult oncology patients participating in clinical trials, low clinical trial accrual presents a challenge for progress in drug development and care delivery. Advanced practitioners (APs) can play a crucial role on the health-care team to enhance accrual in clinical trials, as discussed by Christa Braun-Inglis, DNP, APRN, FNP-BC, AOCNP®, of the University of Hawai'i Cancer Center, in an abstract at the 2022 ASCO Annual Meeting.

Study Details

From 2019 to 2021, an oncologist and AP team at a community breast oncology-focused practice in an NCI Community Oncology Research Program in Hawai'i successfully maintained a high rate of clinical trial accrual, according to study lead Dr. Braun-Inglis. The team worked in conjunction with a clinical research coordinator (CRC) to develop a workflow to approach and offer clinical trials to patients in the practice with the goal of increasing clinical trial accrual and improving clinical trial conduct.

The practice developed a comprehensive team approach between the oncologist, AP, and CRC. This approach included four components: 1) Clinic workflow for clinical trial screening, introduction, and follow-up of potential participants; 2) Shared clinical trial visits between the oncologist and AP; 3) Protocol reviews by the oncologist who reviewed treatment protocols and AP who reviewed symptom management and cancer care delivery research (CCDR) protocols (all clinical trial reviews were discussed with the CRC for coordination input); and 4) Protocol leadership between the oncologist serving as local primary investigator (PI) on treatment trials and AP serving as local PI and/or site champion on symptom management and CCDR protocols.

Study Results

During the study period, the practice accrued over 23% of their patients to clinical trials in a community practice setting, despite the COVID-19 pandemic. Of the 149 unique accruals during this period, 59% of accruals were interventional trials and 41% were observational trials. Clinical trial accrual was racially diverse and mirrored the patient population. During this period, there were minimal protocol deviations observed based on review of shadow charts.

Conclusions

Through this team approach, the practice has been successful in having a high rate of clinical trial accrual while maintaining excellent clinical trial conduct even during the pandemic. Dr. Braun-Inglis comments that the team approach that utilizes the AP to the full scope of practice along with CRC empowerment and the engaged oncologist were the keys to success.

The Advanced Practitioner Perspective

Christa Braun-Inglis, DNP, APRN, FNP-BC, AOCNP®, University of Hawai'i Cancer Center

Currently, only 2% to 8% of the adult oncology population enrolls in a clinical trial, with more than 20% of trials failing to meet accrual goals. This abstract highlights a community oncology practice utilizing a team approach for successful accrual and conduct in their patient population from 2019 to 2021. The practice was able to accrue 23% of patients to a clinical trial during this time, far above the national average.

The team consisted of an oncologist, advanced practitioner (AP), and clinical research coordinator (CRC). The team used a multipronged approach, which included a clinic workflow that involved clinical trial screening, introduction, and follow-up of potential participants that all members of the team were involved in. Alternating visits between the oncologist and AP kept both clinicians engaged in the protocol. There was a shared responsibility of protocol reviews, with the oncologist taking the lead on treatment protocols and

the AP reviewing symptom management and cancer care delivery research (CCDR) protocols. All clinical trial reviews were discussed with the CRC for coordination input and overall feasibility. Finally, there was a shared leadership role between the oncologist and AP in terms of enrolling investigator and even site primary investigator. The oncologist primarily took leadership on the treatment trials and the AP had leadership roles on the symptom management and CCDR protocols.

This abstract highlights the key role of the AP in multiple aspects of clinical research, which include recruitment, consent and enrollment, protocol conduct, and leadership. Advanced practitioners have a unique skill set that can bring value to all aspects of clinical research. These study findings emphasize the value of the AP in clinical research and on the overall team.

Disclosure: Dr. Braun-Inglis has no conflicts of interest to disclose.