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ORIGINAL RESEARCH

Impact of an Oncology Clinical Pharmacist Intervention on Clinical Trial Enrollment in The US Oncology Network's MYLUNG Consortium

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Abstract

Introduction: The Molecularly Informed Lung Cancer Treatment in a Community Cancer Network: A Pragmatic Consortium™ (MYLUNG) clinical trial platform aims to advance the use of precision medicine in patients with non–small cell lung cancer through a series of prospective and iterative clinical trials. Timely patient accrual onto oncology clinical trials is a known practice challenge and impaired accrual rates can lead to premature trial closure or properly powered trial outcomes. The US Oncology Network recently implemented a clinical pharmacist (ClinReview) initiative to provide remote clinical services to screen patients for enrollment onto MYLUNG Protocol 2. This study aims to evaluate the effect of the remote clinical pharmacist intervention on study enrollment rates. **Methods:** An oncology-trained clinical pharmacist remotely reviewed systemic chemotherapy treatment orders during normal workflow and, in addition, a weekly custom recruitment report within six community Network practices (149 physicians). The pharmacist identified, screened, and assisted with the communication regarding eligible patients for enrollment. The onsite research team received timely and relevant patient data to facilitate expedited enrollment. Enrollment and intervention data were tracked to monitor the impact of the pharmacist intervention. Monthly enrollment was evaluated using a paired *t*-test. **Results:** Over 8 months, the pharmacist screened 506 potentially eligible patients; 34% were enrolled. Average monthly enrollment was significantly greater following the ClinReview intervention (3.4 vs. 6.6 patients/month; $p = .02$).

Among the 289 patients not enrolled, 73% exceeded their eligibility window, 9% died or enrolled into hospice, 4% declined participation, and 13% transferred care or were treated at outside facilities. **Conclusions:** Incorporating an oncology clinical pharmacist into the clinical research team was associated with improved clinical trial enrollment. Validation of the effect of multidisciplinary interventions across a broader spectrum of differentially resourced oncology practices will be conducted within future MYLUNG iterations.

The targetable genomic landscape of non–small cell lung cancer (NSCLC) is expanding, providing more therapeutic options for patients. The MYLUNG Consortium™ (Molecularly Informed Lung Cancer treatment in a Community Cancer Network: A Pragmatic Consortium) aims to identify and remove barriers to timely and appropriate comprehensive biomarker testing of patients with metastatic NSCLC (mNSCLC) treated at community oncology practices within The US Oncology Network (Robert et al., 2021). The US Oncology Network is an affiliated cohort of community practices with approximately 1,400 physicians within 40 states in the US, caring for approximately 12% of newly diagnosed cancer patients in the United States (The US Oncology Network, 2022). The MYLUNG Consortium is an ongoing program enrolling and evaluating clinical information from approximately 12,000 patients with NSCLC over a 5-year period and is structured around three separate protocols (Evangelist et al., 2021; Robert et al., 2022). Protocol 2, the current protocol, is a prospective study examining the operational feasibility of patients obtaining comprehensive biomarker testing prior to initiating therapy.

Accrual to cancer clinical trials is challenging, with only 3% to 8% of adult patients with cancer currently participating in clinical trials (American Cancer Society Cancer Action Network, 2019). One fifth of trials sponsored by the National Cancer Institute's (NCI) National Clinical Trials Network have either closed due to low accrual rates or accrued less than 50% of their targeted sample size. Poor clinical trial performance impacts trial duration, sample size, and resource needs, resulting in increased staffing needs and overall clinical trial costs (American Cancer Society Cancer Action Network, 2019; Bennette et al., 2016). Most importantly, poor clinical trial performance can affect statistical power, such that safety and efficacy of new drugs cannot be appropriately assessed.

Inadequate patient enrollment may be due to numerous concurrent factors. Providers may lack time to support intensive identification criteria and enrollment activities (American Cancer Society Cancer Action Network, 2019; Baquet et al., 2008; Hillyer et al., 2020). Appropriately trained support personnel may be lacking to identify and recruit patients and support these increasingly complex oncology trial protocols, especially at smaller community oncology practices (American Cancer Society Cancer Action Network, 2019; Hallquist Viale, 2016; Hauck et al., 2021). Providers may not have adequate time to search for and educate patients on open and enrolling clinical trials (Chen et al., 2013). Finally, patients may hesitate to participate in clinical trials because they lack understanding of the benefits of clinical research, do not trust the research process in general, or have other priorities (e.g., scheduling, travel restrictions, and financial burden). These reasons may be especially true in underserved populations (Baquet et al., 2008; Borno et al., 2021; Brooks et al., 2015).

Many strategies have been employed to attempt to enhance clinical trial enrollment. For example, automated reporting algorithms designed to screen patient records to match eligibility criteria can improve average monthly trial enrollment by up to 80% (Haddad et al., 2018). Electronic health record (EHR)-based clinical trial alert systems at the point of care have been associated with increased recruitment rates (Embi et al., 2005; Embi & Leonard, 2012). In addition, health-care providers outside of the immediate research team, such as pharmacists, can support recruitment efforts (Braun-Inglis et al., 2022; Jacobs et al., 2014). Since pharmacists have preestablished relationships with both patients and the multidisciplinary health-care team, pharmacist

recruitment is a plausible method for improving enrollment (Fletcher et al., 2020). However, limited published evidence is currently available to demonstrate the role of pharmacists within a patient-screening intervention to improve trial recruitment and enrollment.

In 2010, the American Society of Clinical Oncology (ASCO) and the NCI cosponsored a symposium to examine clinical trial accrual challenges. They found that published research was lacking in strategies for improving patient enrollment into oncology clinical trials (Denicoff et al., 2013). Researchers at the symposium suggested that large clinical trials should implement and examine accrual interventions to provide evidence-based strategies for the future. Additionally, they suggested using a multidisciplinary research team and combining multiple accrual strategies to maximize enrollment opportunities.

Set within MYLUNG Protocol 2, this study aimed to evaluate the ability of a remote clinical pharmacist to identify eligible patients through both the normal clinical review workflow and the evaluation of a weekly generated recruitment report and the resulting effect on clinical trial accrual rates.

METHODS

The MYLUNG study, following the recommendations of the ASCO/NCI symposium, created a centralized support system to enable high-volume, efficient screening of patients to reduce the workload of physicians and onsite recruitment staff. The US Oncology Network employed centralized pharmacists to review systemic treatment orders within various Network practices across the United States through the "ClinReview" program. Through their partnership with community-based oncology providers and their connection with the US Oncology Research team, the pharmacist could remotely screen and identify appropriate patients for open trials, both at their practice site and across the entire US Oncology Network in real time.

Protocol 2 of MYLUNG prospectively enrolled adult patients within The Network with untreated, early stage, locally advanced, or metastatic NSCLC who were eligible for systemic therapy. Patients were identified utilizing the EHR. For this protocol, patients were required to sign consent and enroll within 30 days of initiating primary systemic therapy. The EHR, iKnowMed, captured histories of outpatient practice encounters for patients receiving care, including results of biomarker testing, diagnosis, and treatment administration, and other patient data.

Approximately 6 months after the initiation of MYLUNG Protocol 2, a customizable recruitment report was created for all open trial sites. The report utilized protocol-specific inclusion and exclusion criteria to capture potential trial participants. The report identified patients by utilizing qualifying diagnosis codes, patient appointments scheduled within a 14-day window, and systemic treatment regimens starting within the past 30 days. Patients were excluded from the report if they had already been enrolled in the MYLUNG Protocol 2, they were starting a second line or later line of therapy for NSCLC, or were marked as deceased/inactive within the EHR. The report was autogenerated weekly and sent to clinical trial personnel at enrolling sites as well as the ClinReview pharmacist, who then remotely reviewed the reports. Systemic treatment regimen orders were also reviewed by the remote clinical pharmacist during normal workflow at the time of order entry, prior to the appearance of the patient on the automated reports, to identify eligible patients in an expedited fashion.

Figure 1 shows the steps of the pharmacist intervention, which was completed at 6 of the 11 sites with the MYLUNG Protocol 2 open. Sites had self-selected for the pharmacist intervention, and selection was initially based on practices with a perceived slow enrollment rate based on their NSCLC patient volumes. Through the combination of cycle 1, day 1 clinical order review at the time of provider order entry and the review of the weekly autogenerated report, the pharmacist correctly identified, screened, and then referred eligible patients to trial coordinators for enrollment in the MYLUNG study. After this initial screening, a curated, concise, and secure weekly email was sent to clinical research staff at each study site with relevant patient information, treatment start dates, and enrollment eligibility deadlines. Upcoming patient visit dates were entered into a comments field to identify when the patient would next be onsite and available to discuss and

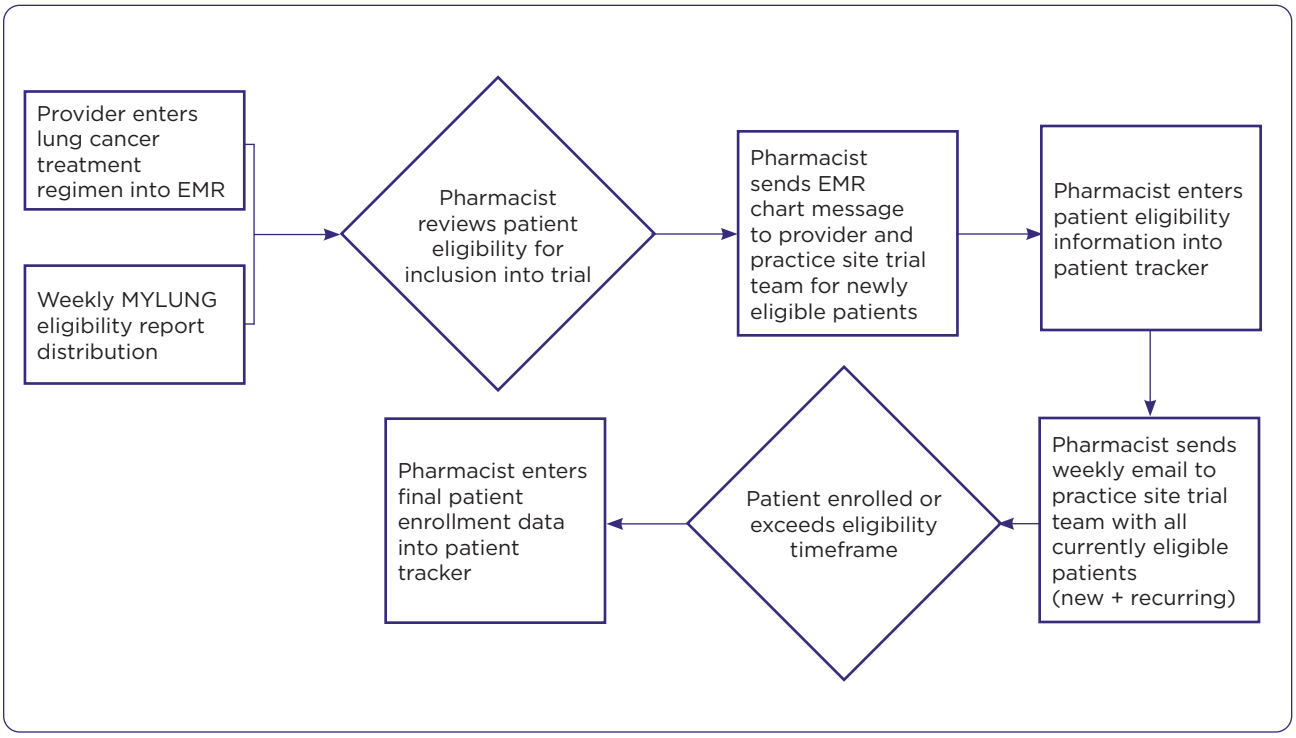

Figure 1. Description of the clinical oncology pharmacist intervention to support patient enrollment in MYLUNG Protocol 2.

consent to participation in the MYLUNG protocol. In addition to the curated weekly emails, when patients were identified during systemic treatment order review, an electronic medical record chart message was sent to notify the provider and the clinical research team of eligibility. Communication practices could be customized to suit the workflow of trial sites. Onsite clinical research coordinators and providers then used this information to approach patients about trial enrollment and consent.

Once a patient was recommended for enrollment, the pharmacist entered recommended patient information into an electronic data collection tool. Data included treatment start dates, source of eligibility information (clinical order review vs. autogenerated report), study enrollment date, status of the enrollment process, and reason for not enrolling, if applicable. Patient enrollment and intervention data were tracked to assess the effects of the pharmacist intervention. Patients enrolled onto the MYLUNG clinical trial who were not directly recommended to onsite staff by the pharmacist were not counted as attributable to the pharmacist intervention.

Investigators collected and analyzed patient enrollment data for the MYLUNG trial with clinical pharmacist intervention, utilizing a historical control of enrollment onto the MYLUNG trial for comparison (i.e., the months the trial was open at the practice preceding the pharmacist intervention). Data for the historical control, the time the clinical trial was open and enrolling at a site prior to the pharmacist intervention, as well as data from the practices without the pharmacist intervention were identified from MYLUNG investigators utilizing their clinical trial management system. Data collection included only the patients recommended for enrollment, and included reasons patients were not enrolled, if applicable. The primary study outcome, average monthly patient enrollment, was evaluated using a paired *t*-test. Enrollment trends were also evaluated with respect to the introduction of the weekly customized report and pharmacist intervention. Trends due to the pharmacist intervention and introduction of the weekly customized report could not be individually evaluated in the practices with a pharmacist intervention, as these interventions occurred nearly simultaneously.

Average monthly enrollments were normalized by average monthly NSCLC treatment initiations at each study location, which allowed an evaluation of overall trends with respect to the enrollment interventions. Practice data and NSCLC patient volumes were collected from internal US Oncology Network databases. Additional data elements and outcomes were evaluated using descriptive statistics.

RESULTS

The MYLUNG Protocol 2 was conducted across 11 community-based oncology practices in The US Oncology Network from January 18, 2021, to September 8, 2022; the oncology pharmacist intervention was implemented at six of the practice sites (n = 149 physicians; Table 1). Over an 8-month period, the oncology pharmacist screened 506 patients for potential enrollment, and 170 (34%) were enrolled. The reasons patients were not enrolled into the study included exceeding the 30-day eligibility window after treatment initiation, death or enrollment into hospice care, declining trial participation, or transferring care to a facility outside the study (Figure 2). Table 1 details the demographics of participating practices. Notably, in the participating US Oncology Network study locations, nearly 200 patients with NSCLC are started on treatment annually at each practice.

Table 1. Practice Demographics

	Median (range)
Included practices	6
Sites per practice	9 (3–15)
Hematologists/oncologists per practice	25 (12–42)
Research staff per practice	12 (3–16)
Open clinical trials per practice	43 (13–89)
Patients with NSCLC started on treatment per practice per year	189 (86–358)
Total patients with NSCLC screened for enrollment[a], *n*	506
Total patients with NSCLC enrolled into the study, *n*	170

Note. NSCLC = non–small cell lung cancer
[a]Patients were screened over a period of 8 months.

Monthly enrollment into the MYLUNG study protocol improved after the implementation of the oncology pharmacist intervention at all six practice sites. The average monthly enrollment significantly increased, from 3.4 to 6.6 patient enrollments per site, per month (p = .02) after the ClinReview pharmacist intervention (Figure 3A).

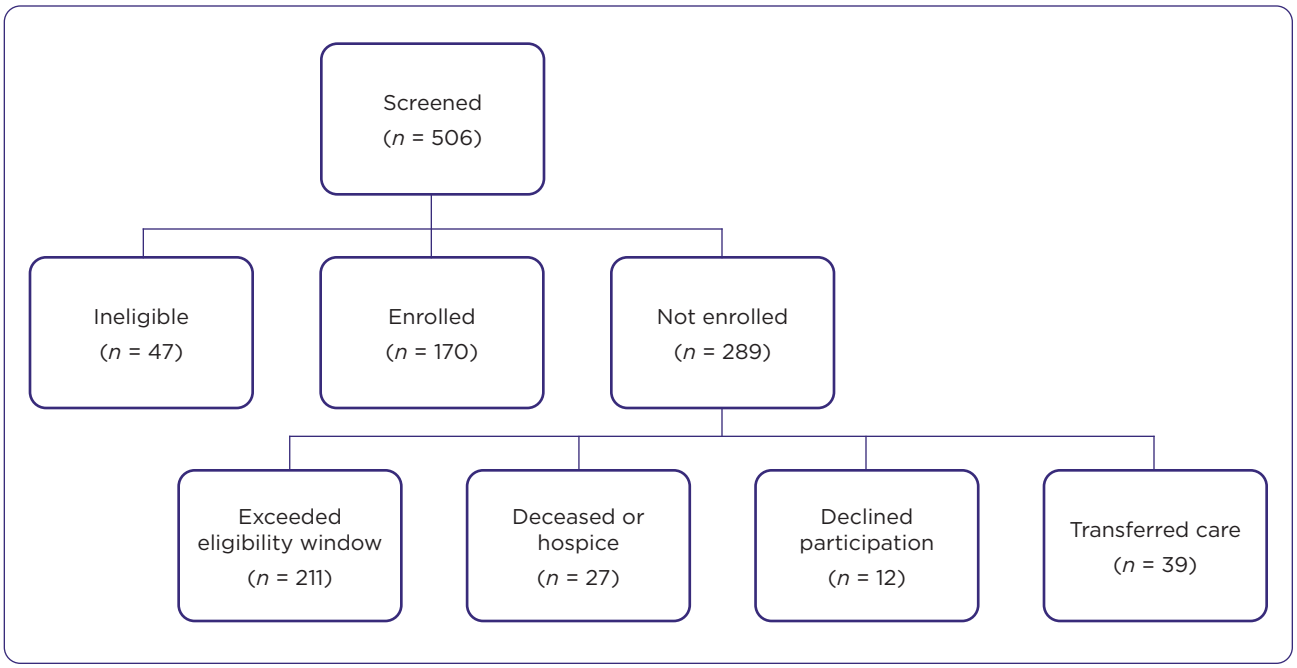

Figure 2. Study attrition.

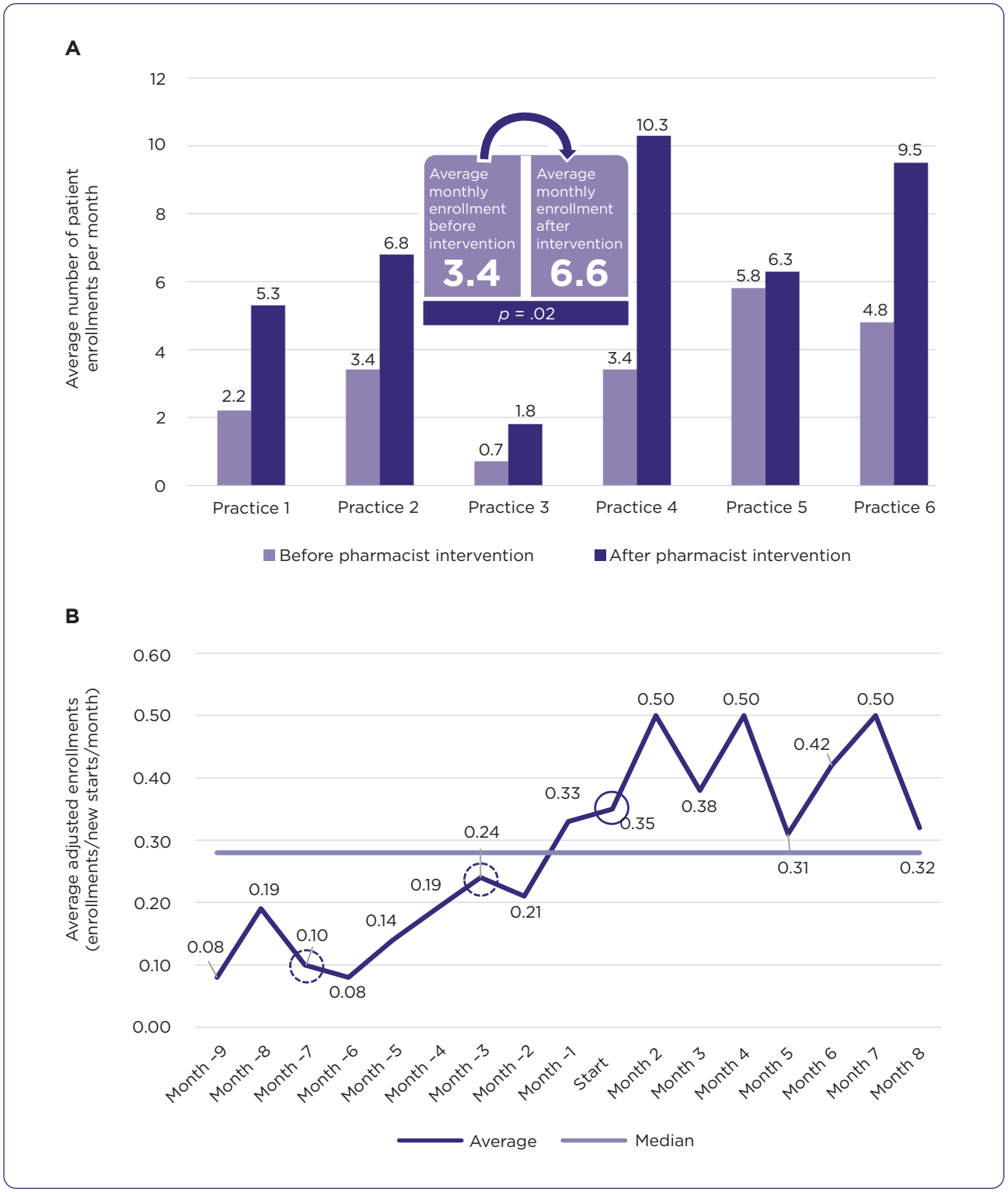

Figure 3. (A) Clinical pharmacist intervention impact on MYLUNG patient enrollment. (B) Run chart for monthly average MYLUNG enrollments per practice, adjusted for number of new treatment initiations per practice. Dashed circles mark the introduction of the weekly custom report (7 months before intervention for 3 sites and at 3 months before intervention for the remaining 3 sites). The solid circle marks the introduction of the pharmacist intervention.

Although not shown to be statistically significant, sites without the pharmacist intervention were analyzed during the same timeframe and showed a trend toward improvement in patient enrollment, from 3.2 to 4.9 patients per month (p = .24) after the release of the weekly report. The weekly customized report was introduced 7 months before intervention for three sites and at 3 months before intervention for the remaining three pharmacist intervention sites (Figure 3B, dashed circles). After adjusting for the number of new patient treatment initiations for NSCLC in sites with the pharmacist intervention, the overall enrollment showed a trend of improvement over time after the introduction of the weekly report at all sites. The trend also depicts a numerically greater increase immediately after the implementation of the intervention, which was then maintained (Figure 3B, solid circles). Additionally, following the pharmacist intervention, all adjusted monthly enrollments were greater than the average adjusted enrollments (Figure 3B, horizontal line).

DISCUSSION

Previous studies evaluating pharmacists as an engagement tool to enroll patients onto clinical trials have leveraged the pharmacist's position within a community retail pharmacy setting and emphasized patient education as the primary patient engagement technique. These approaches have demonstrated moderate success (Abdel Shaheed et al., 2014; Fletcher et al., 2020; Getz, 2013). However, there remains limited literature evaluating the role of a clinical pharmacist as a potential screening tool at the time of order review or through the aid of an autogenerated, targeted report. With the implementation of a remote oncology pharmacist intervention supporting MYLUNG recruitment and communication efforts, enrollment rates significantly improved at all participating enrollment sites and remained above the study period median enrollment, indicating sustainability. The weekly report released to all practice sites did improve enrollment at both the pharmacist intervention sites as well as the non-pharmacist intervention sites, although at a lower, non-statistically significant rate. The combination of approaches, i.e., the report and pharmacist intervention, appears to deliver the greatest impact. The use of a pharmacist as a screening tool was continued and financially supported through the conclusion of MYLUNG Protocol 2.

Other challenges have also interrupted patient enrollment, such as staffing shortages and the COVID-19 pandemic (Bakouny et al., 2022), leading to clinical trial holds and interrupting progress of clinical trial enrollment. Establishment of centralized, remote positions offers two advantages. First, such positions can address these hiring and staffing difficulties. Second, recruitment of remote staff could potentially cover wider areas of the United States, yielding a broader and more diverse application pool if eligibility extends to a large community network of providers. Remote staff could promote the capture of patients more representative of the general population, including underserved communities, and the resulting clinical trials would address a wider range of patient needs. Future directions for remote clinical trial staff could include teleconsultation or patient education in the remote setting, freeing up time for onsite recruitment staff and allowing flexibility in the allocation of duties. Centralized roles could be filled by pharmacists or other qualified health-care clinical trial staff, depending on the complexity of the specific clinical trial. These centralized roles may be especially advantageous in large community provider networks where operations are more widespread, as opposed to academic institutions, which often have more dedicated research specialists on site.

While MYLUNG is an observational nonintervention trial, pharmacists can also assist with the identification of patients for clinical trials where patients will be receiving later lines of therapy or for more complicated oncology treatment protocols during their normal workflow. As such, pharmacists are uniquely positioned within oncology clinics to identify appropriate patients for clinical trials (Hematology/Oncology Pharmacy Association, 2019). Although pharmacist evaluation of a recruitment report may not be feasible for most clinical trial scenarios, every systemic treatment regimen placed by a physician is typically evaluated by a pharmacist prior to administration. As long as pharmacists are acutely aware of open trials at their practice, local or remote pharmacists

reviewing treatment regimens can quickly and efficiently assess patients for appropriate inclusion/exclusion criteria for enrolling trials at their practice sites independent of disease state or phase of trial. If done within normal pharmacist workflow as an added clinical check, additional staffing for trial screening would not always be necessary and therefore would not increase practice costs. Additionally, if lines of communication with providers and clinical trial staff at the practice are already established, the efficiency of a pharmacist intervention is anecdotally improved. It can take time to establish these crucial relationships when work is completed in the remote setting.

As oncology protocols grow more complex with biomarker-informed targeted agents and mutation-specific basket trials opening, a clinical provider, such as a pharmacist, can further support the multidisciplinary research team after comprehensive biomarker testing has resulted to capture appropriate patients for enrollment (Cunanan et al., 2017). Although sophisticated genomic reporting tools can collate patients expressing specific biomarkers, often a deeper dive into eligibility requirements is required to ensure that patients meet all clinical requirements, a task that can efficiently be completed by an oncology pharmacist.

The scope and role of the ambulatory oncology pharmacist has shifted over the years and continues to evolve (Hematology/Oncology Pharmacy Association, 2019). The addition of patient screening for clinical trial eligibility either within an oncology pharmacist workflow or as an additional dedicated screening task is not without precedence as oncology pharmacists are highly versatile, adaptable, and educated to understand the nuance of clinical trial eligibility requirements.

Limitations

The study has several limitations that may affect the drawing of conclusions. First, in some instances investigators were unaware of other outside initiatives at individual practices to improve molecular testing of patients with NSCLC, such as bundled order sets within the EHR to ease provider burden. Such initiatives could have improved visibility of the eligible patients and encouraged participation with the MYLUNG protocol, introducing a confounding factor. Second, the study results may have been related to improved momentum that is often seen in observational trials after the initial accrual intervention. Third, this study examined a small number of oncology practices. Fourth, there was no comparison between the effect of a pharmacist vs. another dedicated, potentially less costly, qualified health professional reviewing the reports for potential enrollment based on eligibility criteria. Lastly, the time required by the pharmacist to complete the weekly report review was not specifically captured in this study. Larger studies are needed to determine if a pharmacist intervention can support patient trial screening across a larger number of more diverse practices with a wider variety of patient and staffing characteristics. Even so, these preliminary results provide real-world evidence that the multidisciplinary approach proposed at the ASCO/NCI symposium can improve patient trial enrollment.

CONCLUSION

Within Protocol 2 of the MYLUNG study, the incorporation of an oncology clinical pharmacist into the clinical research team as a screening tool was associated with improvements in clinical trial enrollment rates when combined with other enrollment strategies. The results suggest that a remote clinical pharmacist can adapt to clinic workflows in community oncology practices to achieve outcomes. Finally, the incorporation of a clinical pharmacist into the multidisciplinary research team together with a weekly report appears to support the ASCO/NCI finding that the use of a combination of accrual strategies should be considered best practice to enhance clinical trial enrollment onto oncology protocols.

Disclosure

Amgen, AstraZeneca, Eli Lilly, Genentech, Janssen, and Mirati are research partners of MYLUNG Consortium. Dr. Coleman has received grants or contracts from AstraZeneca, Clovis, Genelux, Genmab, Merck, Immunogen, and Roche/Genentech; consulting fees from Agenus, Alkermes, AstraZeneca, Clovis, Deciphera, Genelux, Genmab, GSK, Immunogen, OncoQuest, Onxerna, Regeneron, Roche/Genentech, Novocure, Merck, and AbbVie; payment or honoraria from AstraZeneca, Clovis, Roche/Genentech, and Merck; and

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