Category: Trial Recruitment and Study Conduct - Work in progress

Development of a Clinical Trials Screening Coordinator Role and Workflow to Improve Recruitment

D. Goodridge, M. Ugrenovic-Petrovic, E. Royster, S. Fazilova, A. Aminpour, F. Bustamante, G. Giammarino, H. Soliman

Moffitt Cancer Center

1. Background

The process of enrolling patients to oncology clinical trials has become increasingly challenging due to the complexity of eligibility criteria, making the trial more selective. Cancer survivors have been reported to be more likely to enroll when their physicians were perceived to have spent a great deal of effort to find a clinical trial versus those physicians who spent moderate or little effort[1]. A survey of oncologists from the Eastern Cooperative Oncology Group identified practical limitations such as excessive paperwork or additional time required as barriers that decreased physician clinical trial participation.[1] Yet, Campillo-Gimenez concluded that prescreening for clinical trial enrollment could be improved by systematic review of medical reports.[2] Many institutions utilize clinical research coordinators (CRC) to assist in patient recruitment; however, studies show that many CRCs are already working more than their scheduled 40-hour work week managing patient care and the core responsibilities of the CRC.[3] "Being overworked was reported as one of the top negative aspects about their job, and 15 percent of respondents listed burnout as a reason for leaving their job."[3]

2. Goals

The role of the Clinical Trials Screening Coordinator (CTSC) was developed at Moffitt Cancer Center (MCC) to improve the identification of potential clinical trial participants and increase physician engagement in clinical trials.

3. Solutions and Methods

The CTSC position was embedded in the clinic as a central liaison, aiding the clinic team and CRC in the rapid and timely identification of patients for clinical trial enrollment. This initiative was piloted in 2015 within a large disease program at MCC. The CTSC role requires experience in oncology clinical research and disease-specific knowledge.

The CTSC collaborates closely with the trial's principal investigator and CRC to understand trial slot availability. Daily, the CTSC pre-screens new patients' medical records against a portfolio of active trials. When one or more trial matches are identified, the CTSC shares trial options with the treating physician prior to the patient's appointments. Additionally, the CTSC is stationed in the clinic, and on the day the patient arrives, may be available to present informed consent if the CRC is otherwise engaged in other activities.

4. Outcomes

As of January 2024, six disease programs have hired and trained CTSC roles. Programs with CTSCs have benefited from the timely identification of potential trial patients and improved communication among providers and research staff in determining patient eligibility. Additional collaboration with other clinical teams, including nurse navigators who have initial contact with patients new to MCC, has also expanded. Subsequently, there has been a greater than 50 percent increase in the number of pre-screened patients in these programs. They also report a 24–48-hour turnaround time regarding eligibility.

Category: Trial Recruitment and Study Conduct - Work in progress

5. Lessons Learned and Future Directions

The CTSCs convene monthly to discuss challenges, find solutions to common issues, and promote cohesiveness among their individual workflows. As MCC opens additional ambulatory centers capable of supporting clinical trials, CTSCs have begun shifting their prescreening to these other locations. CTSCs have also begun to develop mitigation plans to research leadership for underperforming trials. Lastly, CTSCs at MCC working toward accrual strategies focused on underserved communities.

References:

[1] Chen, L., Grant, J., Cheung, W. Y., & Kennecke, H. F. (2013). Screening intervention to identify eligible patients and improve accrual to phase II-IV oncology clinical trials. *J Oncol Pract*, *9*(4), e174-181. https://doi.org/10.1200/JOP.2012.000763

[2] Campillo-Gimenez, B., Buscail, C., Zekri, O., Laguerre, B., Le Prise, E., De Crevoisier, R., & Cuggia, M. (2015). Improving the pre-screening of eligible patients in order to increase enrollment in cancer clinical trials. *Trials*, *16*, 15. https://doi.org/10.1186/s13063-014-0535-7

[3] Speicher, L. A., Fromell, G., Avery, S., Brassil, D., Carlson, L., Stevens, E., & Toms, M. (2012). The critical need for academic health centers to assess the training, support, and career development requirements of clinical research coordinators: recommendations from the Clinical and Translational Science Award Research Coordinator Taskforce. *Clin Transl Sci*, *5*(6), 470-475. https://doi.org/10.1111/j.1752-8062.2012.00423.x