



Enhancing Tumor Marker Utilization in Early Phase Clinical Trials: An APP-Led Education Initiative

Amanda Brink, DNP, APRN, FNP-BC, AOCNP

University of Texas MD Anderson Cancer Center, Department of Investigational Cancer Therapeutics

Background

When monitoring the response to treatment for oncology patients, clinicians consider radiographic, clinical, and laboratory findings. Advanced practice providers (APPs) play a vital role in treatment decision making, including evaluating the trend of a patient's tumor marker. In an early phase clinical trial clinic, the clinical and research teams collaborate to coordinate patient care. Initially, the research team drafts protocol-related orders for the APP's signature. However, the clinical team observed that these orders frequently omitted tumor markers, resulting in the team being unable to obtain crucial information about the patient's treatment response when baseline measurements were unavailable. This study assesses the effectiveness of an APP-led education initiative in improving the utilization of tumor markers.

Methods

The author surveyed clinic APPs and research teams to understand their preferences for ordering tumor markers. All clinic APPs (n=13) agreed that it was important to order tumor markers before the patient starts a new treatment. Most APPs believed that it was the responsibility of the research team to order the tumor marker. Most members of the research team agreed it was their responsibility to order tumor markers. Two main barriers to ordering tumor markers were lack of knowledge regarding which tumor markers to order and the absence of a requirement in the protocol to order tumor markers. The author developed an educational presentation on tumor markers for both research and APP teams. It covered their use in treatment decision-making and gave a list of tumor markers by disease site.

Cancer Type	Tumor Marker
Appendiceal	CEA, CA 19-9
Breast	CA 15-3, CA 27.29, CEA
Cervical	CA-125, CEA
Cholangiocarcinoma	CEA, CA 19-9
Colorectal	CEA, CA 19-9
Endometrial	CA-125, CEA
Esophageal	CEA
Gastric	CEA, CA 19-9
Germ cell tumors/testicular	Alpha-fetoprotein (AFP), Beta-hCG
Hepatocellular carcinoma	Alpha-fetoprotein (AFP), CEA
Lung	CEA, Chromogranin A for small cell lung
Medullary thyroid	Calcitonin, CEA
Paraganglioma and Pheochromocytoma	Chromogranin A, serum metanephrines
Ovarian/primary peritoneal/fallopian tube	CA-125, CA 15-3, CEA for mucinous ovarian
Pancreatic	CA 19-9, CEA
Papillary thyroid	Serum thyroglobulin and antithyroglobulin antibodies, CEA
Prostate	PSA, CEA

Table 1. Cancer type and corresponding tumor marker chart.

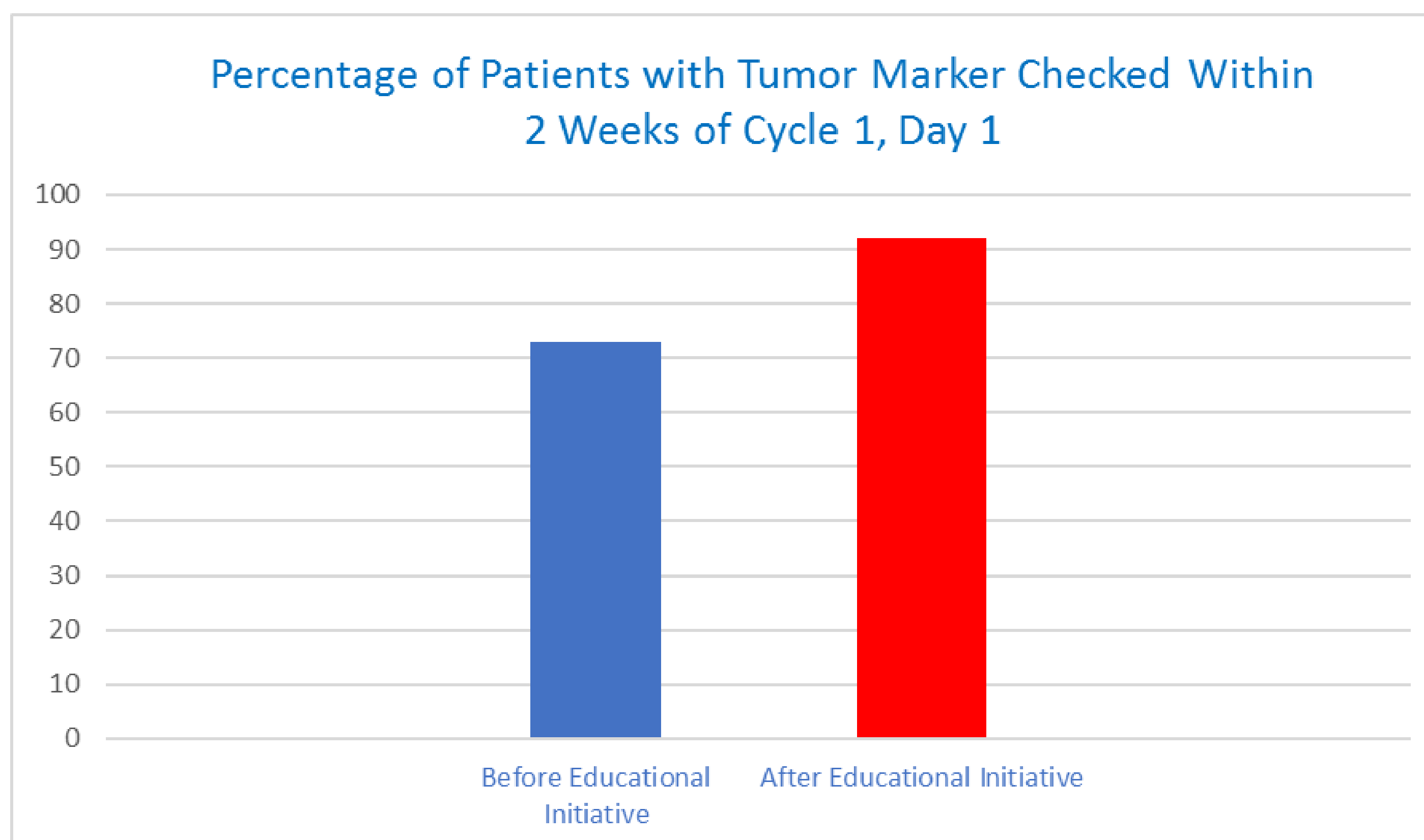


Figure 1. Percentage of patients with tumor markers checked within 2 weeks of cycle 1, day 1 before and after educational initiative.

Results/Conclusions

Patient charts were reviewed for the 3-month period preceding the education initiative. Out of 236 patients who had a tumor type with an associated tumor marker, 73% had their tumor marker drawn within 2 weeks of cycle 1 day 1. The objective of this project was to increase this percentage to 90% or higher. Following the education initiative, charts were analyzed for another 3-month period. Among 199 patients who had a tumor type with an associated tumor marker, 92% had their tumor marker drawn within 2 weeks of cycle 1 day 1.

Study Limitations

The study focused on tumor markers obtained before or on cycle 1 day 1 due to differing opinions among APPs regarding post-cycle 1 day 1 marker collection. Some APPs preferred to obtain tumor markers with each new cycle, while others preferred to do so only during re-staging cycles. To ensure comprehensive data collection, tumor markers drawn within two weeks of cycle 1 day 1 were included in the analysis as tumor markers might be checked during the study screening period, which typically lasts for two weeks. Ideally, tumor markers should be drawn as close to cycle 1 day 1 as feasible.

Future Implications

In a dynamic early phase clinical trial clinic, new protocols with distinct requirements are continually introduced, along with a frequent influx of new study team members, including unlicensed personnel. Therefore, it is crucial to ensure that the APP-led education initiative for tumor markers is not a one-time occurrence. When writing protocols, clinicians may improve comprehensive patient assessment by including tumor marker measurement in protocol laboratory requirements.