

Evaluation of a Pharmacist-Directed Personalized Cancer Medicine Clinical Service and Development of Tools along with Best Practices to Support Pharmacist Adoption

ABSTRACT

Cancer genomic mutations (i.e., somatic mutations) are predictive of sensitivity or resistance to more than 50 targeted chemotherapeutic agents, with numerous targeted drugs in development. Application of next generation sequencing (NGS) panels to identify somatic mutations that can be pharmacologically targeted is emerging as routine patient care. The U.S. Food and Drug Administration (FDA) recently approved a somatic NGS panel for solid tumors that interrogates for genetic alterations in 309 genes, with the Centers for Medicare & Medicaid Services proposing coverage of this companion diagnostic. The 2018 ASHP Foundation Pharmacy Forecast predicts that by the year 2024 at least 75% of all cancer patients will receive somatically targeted therapies. In other words, every cancer patient will have somatic NGS panels performed as part of standard clinical practice to identify targetable mutations. Because somatically targeted drugs are becoming the major treatment modality of cancer therapy, it is absolutely imperative that pharmacists have a role in personalized cancer medicine.

Pharmacists already provide invaluable oncology services encompassing the personalization of drug regimens based on therapeutic drug monitoring, drug interactions, weight, age, kidney function, and liver function. Pharmacists also have a vital role in value-based care by ensuring optimal use of expensive anti-cancer agents. Pharmacists are uniquely qualified to expand personalized medicine services to include the selection of cancer drugs based on somatic NGS results. Driving the need for somatic NGS services is that oncologists often have limited access to expert advice regarding interpretations and drug selection. Indeed, pharmacists are well positioned to be the personalized medicine experts.

This proposal addresses the evaluation of an innovative pharmacist-directed personalized cancer medicine service that interprets somatic NGS results and provides therapeutic recommendations. Moffitt Cancer Center's Personalized Medicine Clinical Service (Moffitt-PMCS), which consists of 3 pharmacy-trained Attendings, interprets over 1,000 NGS panel results per year as part of routine patient care. Moffitt-PMCS Attendings enter therapeutic recommendations into the electronic health record, meet with oncologists and patients to discuss results, and when warranted assist with acquisition of off-label therapy. **We hypothesize that Moffitt-PMCS is of value to the healthcare organization by providing expertise for interpretation of genomic results and identification of optimal therapeutic regimens thereby improving patient care.** Our hypothesis will be addressed by two aims: 1) ascertain the percentage of patients with a clinically actionable NGS result who would benefit from therapeutic recommendations provided by a personalized cancer medicine service; 2) assess if accepted Moffitt-PMCS therapeutic recommendations result in a clinical response. We anticipate aim 1 will demonstrate that the majority of patients have clinically actionable NGS results demonstrating the need for pharmacists to expand clinical models to include precision cancer medicine. We anticipate aim 2 will demonstrate that patients who received a molecularly-targeted therapy recommended by Moffitt-PMCS had clinical benefit as measured by the tumor objective response rate. These findings will demonstrate that a pharmacist-led personalized medicine service can dispense expert interpretations of somatic NGS panels and formulate personalized medicine therapeutic strategies that are effective. However, there are relatively few resources for supporting the establishment of pharmacy-based somatic NGS clinical services. Aim 3 addresses the critical deliverables of somatic NGS implementation guidelines and a somatic personalized medicine toolbox that can be disseminated to diverse clinical settings to promote adoption of pharmacist-driven personalized medicine services. The results and deliverables from this proposal will provide a model for advancing personalized medicine pharmacy services.