

An Innovative Approach to Navigating Patients Through Cancer Diagnostics

Precision Medicine Stewards: Applying Precision Principles to Biomarker Testing Processes to Improve Patient Access

Precision medicine is all about the details. It is stepping away from a one-size-fits-all approach for cancer diagnostics and when implemented correctly, ensures each patient has access to the most appropriate biomarker testing and associated treatment options. Therefore, it is only natural that with the transition to more complex testing, cancer programs can benefit from customizing their staff as well, by designating a precision medicine expert to navigate the labyrinth of biomarker testing processes and results.

With a marked increase in recommendation for somatic genomic testing for patients with metastatic or advanced cancer¹ and an increase in U.S. Food and Drug Administration (FDA) approval of biomarker-directed therapies and clinical trials in recent years,² cancer programs have been exploring new ways to meet the demands of guideline-concordant biomarker testing. Precision medicine stewards—defined as a member of the multidisciplinary team who is focused exclusively on biomarker test ordering, biopsy samples, coordination of logistics for tissue transport, and delivery/receipt of results—are gaining momentum as the ideal solution for improved care coordination workflows.

In early 2022, the Association of Community Cancer Centers (ACCC) embarked on a mission to make the case for implementation of precision medicine stewards through education and awareness-building about the unique role and value of these dedicated navigators. ACCC's *Precision Medicine Stewardship* education program, in partnership with the Academy of Oncology Nurse and Patient Navigators (AONN) and the American Society for Clinical Pathology (ASCP), and supported by AstraZeneca and Blueprint Medicines, showcases oncology programs that have successfully integrated these stewards into their respective centers and shares expert insights on this role as an important member of the multidisciplinary oncology team.

In August 2022, as interest continued to grow among providers, ACCC brought together experts from oncology programs nationwide (representative of academic and community-based programs who had successfully implemented any type of precision medicine stewards, as well as those who were considering the addition of one) to participate in a series of three focus groups to examine the mechanics, the advantages, and the feasibility of this undertaking. ACCC shares an inside look at these discussions and paves the way for integrating precision medicine stewards in programs nationwide.

Mechanics of the Role

One of the first issues the focus groups considered was what, exactly, a precision medicine steward could do that would make an immediate impact on care coordination, as well as how the role can be differentiated from existing roles, such as nurse or patient navigators.



Stewards act as the central liaison between oncologists, patients, nursing teams, pathology teams, and external reference laboratories.

Discussions revealed that while essential tasks for the role can vary across cancer programs, stewards share core responsibilities related to testing coordination—from test ordering to results reporting and all tasks in between. Stewards also act as the central liaison between oncologists, patients, nursing teams, pathology teams, and external reference laboratories. Additional responsibilities could be added depending on the specific needs of the cancer program, the clinical background of stewards (e.g., nurse navigator, laboratory professional, etc.), and order volumes.

In cancer programs that have been successful in implementing precision medicine stewards, such as Sanford Health in Sioux Falls, S.D., TriHealth Cancer and Blood Institute in Cincinnati, Ohio, and Astera Cancer Care in East Brunswick, N.J., the role has taken on different models and titles (oncology nurse navigator genomics, precision medicine test coordinator, and molecular processor, respectively) with varying qualification requirements. However, customizing the role, selecting the appropriate individual, and laying the groundwork to ensure that individual would be successful in their role was not without its challenges.

Courtney Rice, MS, LGC, manager of Precision Medicine and Genetics Services at TriHealth Cancer and Blood Institute explained. "Trying to standardize, and finding the right individual, was a challenge—we are a community-based system,

so the test coordinator [must] support all specialties and all cancer diagnoses. What is unified about this role...we actually have two [precision medicine testing coordinators] and they job share to cross cover for each other...is that they could help coordinate testing from a colon cancer and then a lung cancer and then a breast cancer, [as long as it was] a molecular order that the physician wanted to place. To help streamline the process, we had our key physician champions in all areas of our Cancer Institute meet and vet different lab vendors so that we could select a preferred lab; that decision really helped standardize the initial process for getting samples sent out and returned, and then we built upon that process with our one-offs for whenever a provider wanted to use a different laboratory. So, getting the clinical staff to agree and standardize some parts of the role and the way this individual would work with the rest of the team was important."

Nearly all successful precision medicine steward models have encompassed the following key responsibilities related to biomarker testing:

- Evaluates insurance coverage (which reference labs are in-network vs. out-of-network); completes necessary prior authorization paperwork; assists eligible patients to complete patient financial assistance applications offered by reference labs
- Enters patient information into the reference lab portal when the order is placed; streamlines and simplifies test ordering process for ordering providers (most often the oncologist)
- Contacts appropriate pathology group (if diagnostic tissue involves external institution) and coordinates logistics for tissue transport and tracking to the reference lab
- Coordinates liquid biopsy orders if ordering concurrent liquid and tissue testing, or if the sample quantity is not sufficient to complete tissue-based testing; tracks both tissue and liquid biopsy test results
- Retrieves the test results from the lab portal; informs the ordering provider of results and/or scans into the EHR.

Depending on the institution and clinical background of the precision medicine steward, other tasks may include:

- Meets with the patient to discuss the clinical importance of biomarker testing and how results can impact treatment planning; engages in shared decision-making conversations
- Works with IT to develop electronic order sets for send-out biomarker tests; creates different order sets for each reference lab
- Works with reference labs and hospital IT to integrate electronic health record (EHR) modules (e.g., the Epic Genomics Module) for test results to be viewed as discrete data fields in the EHR
- Tracks the status of financial assistance applications; contacts patients to gather missing information to minimize assistance decision delay
- Prepares patient case summaries for molecular tumor board discussions
- Identifies potential clinical trials based on test results
- Coordinates with genetic counselors to identify opportunities where both hereditary and somatic testing is needed.

Benefits to Cancer Care Programs

As the road to biomarker testing in real-time has been bumpy for some community cancer programs facing operational challenges with test ordering, insurance approvals, and lengthy turnaround times for results, the concept of a precision medicine steward and its benefits was both highly relevant and welcomed by clinical staff.

Crystal Enstad, MBA, BSN, RN, OCN, Sanford Health's oncology nurse navigator-genomics (Sanford's equivalent of a precision medicine steward) explained. "Connecting with our nurse navigators and clinic nurses, as well as listening to the oncologists themselves, they really needed one point of contact, an efficient workflow, and timely results. The patient needed to be educated on their out-of-pocket expenses, what the testing was for and why, and why we [providers] needed those results. And so, I really set out to be that one-stop-shop."

With the addition of a steward, the test ordering and results processes, which can be complex and time-consuming for oncologists and clinical staff, are streamlined. Administrative tasks, such as entering patient demographics into the reference lab portal, coordinating logistics associated with tissue transport, and tracking test results, can be centralized and managed by the steward, freeing the clinical staff to focus on clinical tasks and direct patient care.

Conversations and administrative processes that may have been previously handled by nurse navigators or genetic counselors, such as pre-authorizations, financial assistance paperwork, and patient education on the importance and role of biomarker testing, can also be moved to precision medicine stewards. Moreover, as significant disparities in NGS (next generation sequencing) testing rates have been observed among Black and White patients with lung, breast, and colorectal cancer,³ cancer programs that treat underserved populations who face unique challenges around biomarker testing⁴ can utilize stewards to help patients overcome barriers to access.

Rice described the positive reception by clinical staff at TriHealth. "Once we spoke to the primary nurses and the oncologists and explained the role, they were so thankful to hand over all the work that was falling to the primary nurses in clinic that was viewed as administrative."

Furthermore, through the power of technology and the addition of this single role, TriHealth's turnaround time from or-

der to results decreased from an average of 24 days to 12 days and the quantity not sufficient (QNS) rate of testing decreased by five percent (unpublished, internal data).

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Building Support for Stewards

While the advantages of centralizing tasks with one steward is ostensibly more efficient, focus groups expressed concerns with the potential challenges and financial implications associated with adding more full-time employees (FTEs) to programs that are already stretched thin. As staffing shortages nationwide continue, many cancer programs have become accustomed to utilizing multiple members of the cancer care team to handle various aspects of biomarker testing processes, such as oncology nurses, navigators, or pathology lab assistants. In addition, for cancer programs with lower biomarker test volumes or programs where tissue-testing is performed by in-house pathology teams, the value-added benefits may not be as easily discernable.

Therefore, cancer programs that have been successful in implementing the precision medicine steward model stressed the importance of gaining leadership support at the outset, through establishment of a precision medicine steering committee or similar group. They also emphasized the critical role metrics can play in supporting implementation and sustainability, and gave examples highlighted below.

Other focus group participants, who do not yet have this type of role in their cancer program, shared suggestions on what they believed would help to move precision medicine stewards from idea to implementation.

Pablo Gutman, MD, medical director of Holy Cross Cancer Institute and medical director of Holy Cross's clinical laboratories, brought the perspective of community-based hospitals. "Buy-in from medical oncology is fundamental in developing biomarker

testing at the community level. Hospitals are concerned with the costs associated with these types of tests, and medical oncologists are in a unique position to explain and help develop algorithms for efficient and cost-sensitive testing. The hospital pathology department cannot do this on its own.”

Participants from academic medical centers shared another perspective. With the push to increase enrollment in clinical trials, particularly from underserved populations, investigators (i.e., medical oncologists) can be instrumental in advocating for biomarker testing. As an efficient system and quick turnaround times are essential to enabling more patients to undergo biomarker testing, which is often an eligibility requirement for clinical trials, precision medicine stewards can streamline workflows and in turn, impact enrollment rates.

Metrics, Metrics, Metrics

Nearly all cancer programs with successful precision medicine stewards in place emphasized the value of developing and tracking key performance metrics for success. Being able to break down data and track biomarker testing statistics to prove efficiencies, identify quality gaps, and opportunities for improvement, is pivotal to building justification, support, and sustainability for the role.

Some of these key performance metrics include:

- Time from test ordering to result delivery
- Time from diagnosis to treatment with a targeted therapy
- Percentage of patients (for whom testing is clinically indicated) who receive complete biomarker testing
- Percentage of patients who apply for financial assistance and receive aid
- Percentage of patients who receive a surprise medical bill from a reference lab
- Percentage of patients who receive an insurance denial for testing coverage
- Patient experience scores (e.g., patient satisfaction)
- Patient retention
- Provider satisfaction scores

Enstad described the early days of implementation, before using metrics. “When I first started my role, we had no way to harness or identify who or how many genomic tests we were sending out to anyone...we would describe it as the wild, wild west. Everyone just kind of did their own thing.”

Buy-in from medical oncology is fundamental in developing biomarker testing at the community level. Hospitals are concerned with the costs associated with these types of tests, and medical oncologists are in a unique position to explain and help develop algorithms for efficient and cost-sensitive testing.

Once Sanford and other cancer programs with precision medicine stewards began tracking performance metrics that justified the role, highlighting successes, and identifying gaps, the game changed. In fact, Sanford Health has already begun exploring ways to expand this role, evaluating the feasibility of deploying oncology nurse navigator genomics at all Sanford locations or alternatively, centralizing the role and utilizing telehealth to serve multiple locations.

In addition to these metrics, successful cancer programs suggested measuring the frequency (and types) of quality improvement projects that result from biomarker testing data, such as the percentage of eligible patients from underserved populations who receive testing, thereby improving health equity. Another important success metric, measuring the number of patients identified for clinical trials based on biomarker results, would serve to increase patient enrollment in clinical trials.

Final Thoughts

Paving the way for precision medicine stewards is about more than simply adding another FTE to the cancer care program roster. The steward can play an integral role on the multidisciplinary team to streamline and improve operational processes, increase efficiency, reduce turnaround times, and make significant headway towards increasing patient participation in clinical trials and improving health equity. In the rapidly evolving precision medicine landscape with multiple players, the precision medicine steward is the key player who can help drive the game and keep the biomarker ball moving.

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