An Innovative Approach to Navigating Patients Through Cancer Diagnostics

Precision Medicine Stewards: A Case Study from Sanford Health

Researchers have made great strides in identifying genetic mutations that drive uncontrolled cellular growth and, ultimately, cancer. However, there remains a well-recognized disconnect between guideline-concordant testing and real-word clinical practice. Medically underserved populations, in particular, face significant challenges in accessing the latest advances in cancer diagnostics and appropriate biomarker testing.[1] To address this shortcoming, the Association of Community Cancer Centers (ACCC) developed the project "Precision Medicine Stewardship." Through this project, ACCC explores how some cancer programs are addressing the challenges and barriers around cancer biomarker testing.

One approach is to designate a cancer care team member as a "precision medicine steward," that is, a promoter and navigator for biopsy samples and/or biomarker testing processes and results. This individual serves as the point person to ensure biomarker testing moves forward in a timely and efficient manner. The steward also helps ensure patients are equipped with everything they need to fully participate in shared decision-making about their treatment choices.

ACCC shares how Sanford Health introduced its own "precision medicine steward" through the development of a pilot Oncology Nurse Navigator, Genomics (ONNG) role, which has improved coordination of its biomarker testing program.

Innovation to Action

Sanford Health, the largest rural health system in the United States, offers comprehensive cancer services through four major cancer centers located in Sioux Falls, South Dakota; Fargo, North Dakota; Bismarck, North Dakota; and Bemidji, Minnesota. These centers serve as regional hubs to offer cancer services to a large rural community of patients. At Sanford Health, many patients with advanced cancers receive broad genomic sequencing and are discussed at genomics tumor board (held twice each week; remote clinicians participate virtually). Recognizing the need to centralize and improve coordination around biomarker testing, Sanford piloted the role of an ONNG starting with one site (Sioux Falls) in early 2021.

Under the leadership of the Cancer Genomics Steering Committee, Sanford developed a job description and designed the role so that the ONNG works closely with medical oncology, laboratory operations, pathology, testing vendors, and genetic counseling to improve coordination around the cancer biomarker testing process.

Biomarker Testing: Multigene Panels

In February 2022, the American Society of Clinical Oncology (ASCO) released a provisional clinical opinion on somatic genomic testing for patients with metastatic or advanced cancer.[2] The authors wrote, "Patients with metastatic or advanced cancer should undergo genomic sequencing in a certified laboratory if the presence of one or more specific genomic alterations has regulatory approval as biomarkers to guide the use of, or exclusion from, certain treatments for their disease. Multigene panel–based assays should be used if more than one biomarker-linked therapy is approved for the patient's disease… Multigene testing may also assist in treatment selection by identifying additional targets when there are few or no genotype-based therapy approvals for the patient's disease."

The ONNG Role

The job description included responsibilities such as:

- Meets with patients to discuss biomarker testing and explain the clinical importance of how the results may impact treatment planning. Discusses whether the test will only be performed on tissue or if blood will also be required. Coordinates a blood draw if needed.
- Coordinates with the genetic counseling team if patients meet certain criteria for hereditary genetic testing.
- Reviews the patient's health insurance coverage to confirm that biomarker testing will be covered by the reference lab selected by the oncologist. If the lab is out-of-network, an in-network lab is used, if available.
- Assists the patient with identifying out-of-pocket cost for biomarker testing and completes any financial assistance forms available.
- Completes prior authorization paperwork, as needed. Assists with providing additional documentation or medical necessity documentation.
- Enters the biomarker test order into the electronic health record (EHR) using a templated electronic order.
- Enters the biomarker test order into the vendor portal on behalf of the ordering provider.
- Checks lab portals for test results. Notifies medical oncologist when results are available. Provides the results to pathology support to upload into the EHR
- Maintains a patient list and tracks the biomarker testing status to check for any unexpected delays or problems.

Oncology Nurse Navigator, Genomics[3]

The Oncology Nurse Navigator, Genomics is a working title for a precision medicine steward at Sanford Health and is not to be confused with other nursing titles and credentials, such as:

- Advanced Genetics Nurse (AGN-BC)
- Advanced Practice Nurse in Genetics (APGN-BC)
- Clinical Genomics Nurse (CGN)
- Advanced Clinical Genomics Nurse (ACGN)

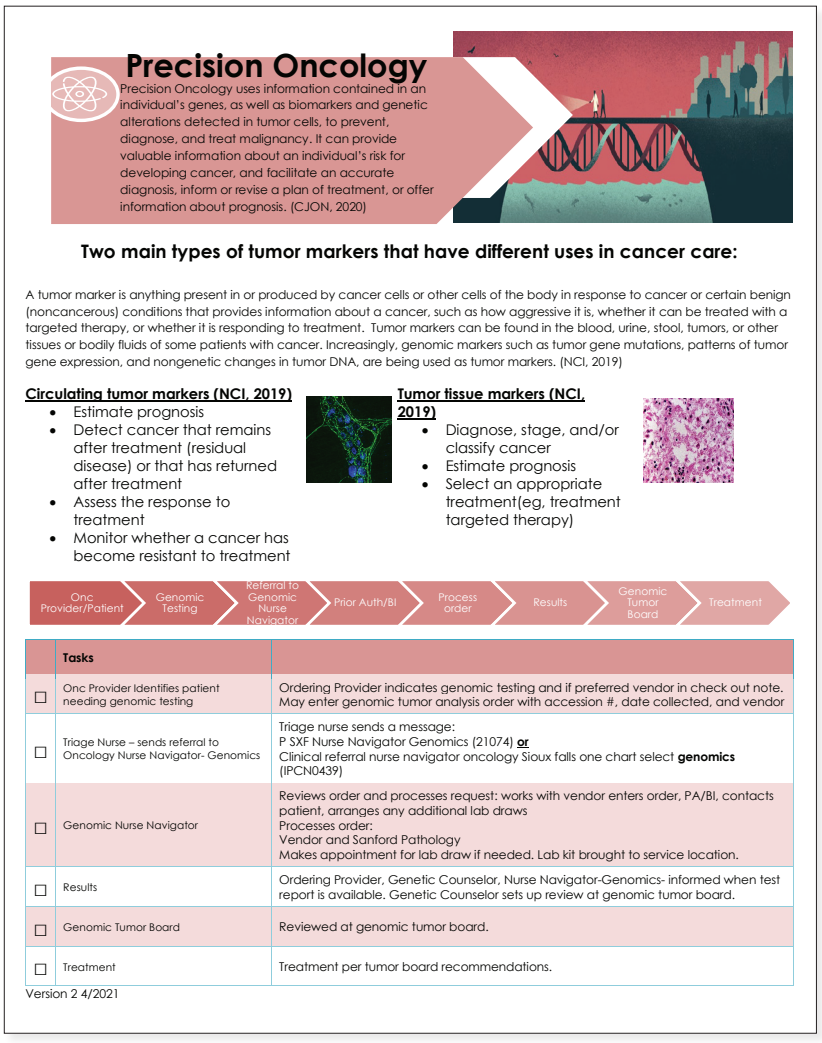
Note: This is not meant to be a comprehensive list and does not include older credentials (e.g., APNG) that have been retired or renamed.

Improving Patient Care

The Sanford team designed the role of the ONNG to address several common challenges around cancer biomarker testing including:

CHALLENGE	SOLUTION
Patients may not understand why biomarker testing is needed.	The ONNG meets with the patient to explain the clinical importance of biomarker testing.
Staying current on genomic testing options, vendor portals, and patient testing results may be unmanageable for clinic nurse staff and may result in missed tests, long wait times, delays in communication, and corrections in the ordering process.	The ONNG is one point of contact for the medical oncologist, patient, pathology, and genomic testing vendor, and stays current with genomic testing options, vendor portals, and patient test results.
Each testing vendor has their own portal, order forms, coverage, genomic panel, and variant nomenclature.	The ONNG meets with each testing vendor, develops a facility account, and serves as the main point of contact for the vendor on issues related to testing, orders, billing/insurance, and product/service updates.
Insurance companies may not cover certain biomarker tests (or specific labs may be out-of-network). As a result, the insurance company may deny testing. The patient may receive a surprise medical bill from the reference lab.	The ONNG reviews the patient's insurance coverage to determine whether the test is covered and confirms that the selected reference lab is in-network. Then, they complete financial assistance forms to assist the patient and help to identify out-of-pocket expenses prior to test ordering.
Coordinating and tracking the status of the test (e.g., sample received, testing in-process, etc.) can be difficult.	The ONNG works with IT and pathology to build templated electronic test orders for specific labs to ease coordination and tracking, along with ensuring the genomic test results get uploaded into the patient's EHR.

Figure 1. An Example of a Staff Education Handout



Precision Oncology

Precision Oncology uses information contained in an individual's genes, as well as biomarkers and genetic alterations detected in tumor cells, to prevent, diagnose, and treat malignancy. It can provide valuable information about an individual's risk for developing cancer, and facilitate an accurate diagnosis, inform or revise a plan of treatment, or offer information about prognosis. (CJON, 2020)

Two main types of tumor markers that have different uses in cancer care:

A tumor marker is anything present in or produced by cancer cells or other cells of the body in response to cancer or certain benign (noncancerous) conditions that provides information about a cancer, such as how aggressive it is, whether it can be treated with a targeted therapy, or whether it is responding to treatment. Tumor markers can be found in the blood, urine, stool, tumors, or other tissues or bodily fluids of some patients with cancer. Increasingly, genomic markers such as tumor gene mutations, patterns of tumor gene expression, and nongenetic changes in tumor DNA, are being used as tumor markers. (NCI, 2019)

Circulating tumor markers (NCI, 2019)

- Estimate prognosis
- Detect cancer that remains after treatment (residual disease) or that has returned after treatment
- Assess the response to treatment
- Monitor whether a cancer has become resistant to treatment

Tumor tissue markers (NCI, 2019)

- Diagnose, stage, and/or classify cancer
- Estimate prognosis
- Select an appropriate treatment(eg, treatment targeted therapy)

Onc Provider/Patient → Genomic Testing → Referral to Genomic Nurse Navigator → Prior Auth/BI → Process order → Results → Genomic Tumor Board → Treatment

	Tasks	
☐	Onc Provider Identifies patient needing genomic testing	Ordering Provider indicates genomic testing and if preferred vendor in check out note. May enter genomic tumor analysis order with accession #, date collected, and vendor
☐	Triage Nurse – sends referral to Oncology Nurse Navigator- Genomics	Triage nurse sends a message: P SXF Nurse Navigator Genomics (21074) **or** Clinical referral nurse navigator oncology Sioux falls one chart select **genomics** (IPCN0439)
☐	Genomic Nurse Navigator	Reviews order and processes request: works with vendor enters order, PA/BI, contacts patient, arranges any additional lab draws Processes order: Vendor and Sanford Pathology Makes appointment for lab draw if needed. Lab kit brought to service location.
☐	Results	Ordering Provider, Genetic Counselor, Nurse Navigator-Genomics- informed when test report is available. Genetic Counselor sets up review at genomic tumor board.
☐	Genomic Tumor Board	Reviewed at genomic tumor board.
☐	Treatment	Treatment per tumor board recommendations.

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Other Responsibilities

Key Performance Indicator (KPI) Reports

The ONNG participates in this KPI review process. Through team collaboration and interdisciplinary work groups, the Laboratory Business Operations Advisor developed a report that captures key performance indicators related to biomarker testing.

The report captures the answers to these questions:

- Which reference labs are used least/most?
- What are the minimum, average, and maximum turnaround times for test results from each of the reference labs?
- How often does each reference lab report that the sample quantity was not sufficient?
- What are the minimum, average, and maximum out-of-pocket costs for patients when they receive testing from different labs?

The Laboratory Business Operations Advisor collects data from each vendor and generates a report that is reviewed by the Cancer Genomics Steering Committee. The committee also uses these reports to determine which reference labs are best for biomarker testing. The ONNG uses this report to guide patient care and optimize genomic program services.

Patient Education

The ONNG develops education materials designed to help oncology clinic staff understand the role of biomarker testing. (See Figure 1, above.)

Electronic Order Templates

The ONNG works closely with IT to build new electronic order templates as reference labs are vetted and approved by the

Cancer Genomics Steering Committee. These orders incorporate the use of EHR-enabled SmartPhrases (templates or blocks of text pulled directly from the patient's health record) to expedite the process.

Future Direction

As the use of cancer biomarker testing continues to expand, cancer programs may find that a precision medicine steward can improve the clinical workflow and ensure that patients are receiving timely testing. Sanford has seen the value of the ONNG and has been exploring ways to expand this role. One option is to hire and train ONNGs at all Sanford locations. Another possibility is to centralize the ONNG role and incorporate telehealth visits when needed. These decisions may be impacted further as more biomarker testing occurs in-house and fewer samples are sent out for testing. Moreover, the use of liquid biopsy is expanding and certain patients with cancer may receive sequential biomarker testing throughout the treatment journey to identify resistance genes or new genomic alterations, making the addition of precision medicine stewards more important than ever. ■

Learn more at:
accc-cancer.org/precision-medicine-stewardship

References

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3. Kerber AS, Ledbetter NJ. Scope and standards: defining the advanced practice role in genetics. *Clin J Oncol Nurs.* 2017;21(3):309-313. doi: 10.1188/17.CJON.309-313

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