Implementation of a Centralized Model for Precision Medicine with EHR Integration

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Mercy is the seventh largest Catholic health care organization in the United States with over 40 acute care and specialty hospitals across 7 states and over 40,000 employees plus 4300 integrated providers. A driving value of Mercy is to provide innovative personalized care. Establishing a Center for Precision Medicine that focuses upon providing the right care at the right time for the right patient seemed like the natural next step to serve our predominately rural communities.

Precision medicine is a tailored approach to health care that incorporates individual variability in genes, the surrounding environment, and the lifestyle of each person. The concept of leveraging the genomic profile of a patient started to evolve after the sequencing of the human genome began in 2000.[1]

The term *precision medicine* had a breakthrough emergence between 2009 and 2010, but the concept of targeted evidence-based treatment decisions was realized back in the 1950s.[1] The Obama administration launched a US initiative for precision medicine in 2015. That initiative helped to change our methods from a traditional strategic approach for similar groups of patients to a more tailored approach involving the ability to diagnose, treat, and prevent disease based on an individual's genetic makeup. Consequently, precision medicine now focuses on patient-centered decision-making, and it is based on the *4 Ps*: predictive, preventive, personalized, and participative.[2] Although it took time, Mercy's current precision medicine offerings include multicancer early detection (MCED), germline, somatic, and pharmacogenomics testing and a precision wellness program. This is the story of that journey.

Integrations of Genomics at Mercy

To assist in managing at-risk patients, Mercy started using germline diagnostics in the early 2000s and incorporated somatic testing on known oncology patients as it became available. However, the broad incorporation of these genomic tests into practice was not standardized or uniform; it frequently involved multiple different vendors even in the same community or clinic. There was a desire to standardize the genomics offering across Mercy, since infrastructure barriers significantly limited the ability to implement a systemwide approach. One of the most important barriers that needed to be overcome was taking Mercy from 3 separate episodes of electronic health recording (EHR) from Epic (Epic Systems, Inc) to a single instance of Epic used across the entire health system. Even with a single instance of Epic, use of the usual HL7 interface into the EHR was a time consuming and expensive endeavor until upgrades in Epic's Aura platform made it substantially more efficient. The next infrastructure upgrade was a move of clinical data to a cloud-based platform that allowed for more efficient manipulation of data for metrics development and monitoring through dashboards.

> Another recognized challenge was that multicancer early detection testing was new and associated with questions that many primary care providers were not equipped, and did not have the time, to answer.

The overarching desire was to add tremendous efficiency to orders, authorization, and resulting workflow as well as to enable in-line decision support so that providers would electively migrate to an integrated system solution. Specific criteria were used for the selection of the next-generation sequencing (NGS) vendor of choice—they needed to have Aura integration capability with Epic and to offer multiple NGS (eg, somatic, liquid, germline, and pharmacogenomics testing) that would justify the EHR integration expense. The final selection was made after web-based presentations from different vendors were given and an online vote among oncologists who attended the webinars was taken. This started the process of integrating orders and results in our EHR, incorporating the orders into tumor boards, establishing molecular tumor boards to increase awareness, and using data to drive improved outcomes such as increasing NGS testing of all lung cancers.

The selection of the MCED test was different than was the selection of a broader NGS vendor in that there was only 1 test on the market

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1 in 16 have a gene variant that increases toxicity risk with 5-FU [1]

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- "DPYD gene variants associated with DPD deficiency were linked to a **25.6 times** increased risk of fluoropyrimidine-related mortality" [2]
- FDA label for fluorouracil states to "consider testing for genetic variants of DPYD prior to initiating" [3]
- DPYD-guided reduced fluoropyrimidine dosing had **no negative affect on survivability** in an exploratory analysis [4]

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1. Jhun EH, Walker JD, Elnashar G, et al. CGE24-094: Recommendation and genotyping discrepancies in DPYD for oncology patients. 2024 Apr 5;22(2.5). Doi: https://doi.org/10.6004/jnccn.2023.7179.
2. Sharma BB, Rai K, Blunt H, et al. Pathogenic DPYD variants and treatment-related mortality in patients receiving fluoropyrimidine chemotherapy: a systematic review and meta-analysis. Oncologist. 2021;26(12):1008-1016.
3. Fluorouracil injection, solution. [Product Information]. Gland Pharma Limited. Updated February 26, 2024. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ea3497db-23b9-4ace-9a6f-b54853d04a82 Accessed June 2024.
4. Knikman, Jonathan E., et al. "Survival of patients with cancer with DPYD variant alleles and dose-individualized fluoropyrimidine therapy—a matched-pair analysis." Journal of Clinical Oncology 41.35 (2023): 5411-5421.

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that received FDA breakthrough status approval. There was some concern about being an early adaptor in this space, but a market analysis revealed that patients in our catchment area were already having this test performed. Another recognized challenge was that MCED testing was new and associated with questions that many primary care providers (PCPs) were not equipped, and did not have the time, to answer. The process for offering this test with standardized counseling and expectations became the topic of discussion. There was also a desire to have similar oversight of germline testing and recognition that standardized workflow and counseling were also extremely important. In response to these concerns, Mercy's Center for Precision Medicine was established.

This program offers busy patients the ability to complete all testing in 1 morning and take the results of these tests with a plan for improved future health.

The Center for Precision Medicine

The goal of the Center for Precision Medicine is to offer complex NGS testing across the 5-state catchment area. It is staffed by a medical director, nurse practitioners, registered nurses, and a patient access representative who are licensed in these states. The first major offering was the MCED test, but the germline and pharmacogenomics tests followed shortly thereafter. The infrastructure changes that preceded the Center's formation allowed these providers to order the tests and track the data from across the system.

A major advantage of the Center for Precision Medicine is that it lessens the burden on our PCPs and other providers regarding these complicated tests. It allows for a standardized workflow and counseling that helps to ensure the appropriate ordering and interpretation of these tests to provide the best patient experience. While somatic testing is left to oncologists, the centralized approach for these other NGS tests allows patients to be *navigated* through the entire process.

Targeted outreach and marketing in Mercy's geographic areas and dedicated website development brought patients to the Center for Precision Medicine. The centralized team connects with patients to answer general and specific questions about these tests before they are ordered. A major focus is ensuring that patients understand the purpose of these tests. Frequently, patients misunderstand the purpose of the MCED test—they truly seek germline cancer testing. The centralized team also connects patients who have a positive MCED signal or deleterious mutation to their local community resources. The centralized team develops and personalizes clinical workflows for each potential positive MCED signal that includes a virtual review with 1 or more specialists when necessary (**Figure 1**). When cancer is confirmed, the centralized team connects the patient to a local oncology nurse navigator to create a smooth transition as they move forward in their treatment.

While our medical oncologists order somatic testing, the precision medicine team assists in monitoring these tests via dashboard tools. An example of this would be the importance of NGS testing for stage IV lung cancers. Monitoring of this data through the genomics tab and dashboards showed that 1 of the community cancer centers was ordering genomic profiling on only 64% of our eligible patients with lung cancer. Development of a standardized workflow using the local lung cancer nurse navigator resulted in an increase in genomic profiling of eligible stage IV lung cancers from 64% to 96% (**Figure 2**). This improvement in NGS testing optimized the ability of these patients to receive targeted precision therapy.

Several available screening tools to determine patient eligibility for germline testing are based on standardized national guidelines. Despite the availability of these screening tools, many health systems lack a formalized integration of these surveys into routine patient care. The Center for Precision Medicine team enlisted website development to offer germline screening via Mercy.net intake; the intake then was linked to the centralized team so that a patient could be referred for virtual visits with a genetic counselor and for orders for germline cancer testing. Once the website was developed, rack cards and posters with QR codes that linked back to the Mercy.net and the National Comprehensive Cancer Network (NCCN) eligibility questionnaire were deployed in primary care, women's health, and oncology clinics. These passive outreaches relied on patients to seek out the survey while looking for information about MCED testing on the website or while waiting in their providers' offices.

Mercy has begun rolling out several pilot programs to PCP and obstetrics-gynecology (ob-gyn) clinics that will actively recruit patients to the germline survey tool; short message service texting then will direct them to the Mercy.net site. Referral orders for germline testing were also developed that allow PCP and ob-gyn clinics to direct patients to the team at the Center for Precision Medicine for management. A significant advantage to using the integrated vendor for germline testing is that the discrete genomics data reside in Epic's genomic module. The discrete data in the genomics module allow for clinical decision support to be developed that assists providers with subsequent imaging or screening as recommended by national guidelines. The Center for Precision Medicine has incorporated other essential components (eg, cascade testing, a connection with local high-risk clinics for various diseases) into their standardized workflow.

The Center for Precision Medicine also orders a pharmacogenomics test that shows how genes affect a person's response to medications. The most common current use for this at Mercy is in the field of psychiatry; however, this will expand into oncology and cardiology in the future. These results are also stored in the genomics module so that they will always be available for that patent.

Mercy has made several precision medicine offerings through a unique proactive approach to health as part of the precision wellness program. In this program, patients can receive MCED, germline, pharmacogenomics, and food sensitivity testing along with imaging such as AAA ultrasound and cardiac calcium scoring. These tests are coupled with a functional nutrition consult and personalized fitness assessment to help patients tailor a proactive health program to best address their personal health needs. This program offers busy patients

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Figure 1. Example of a Clinical Pathway

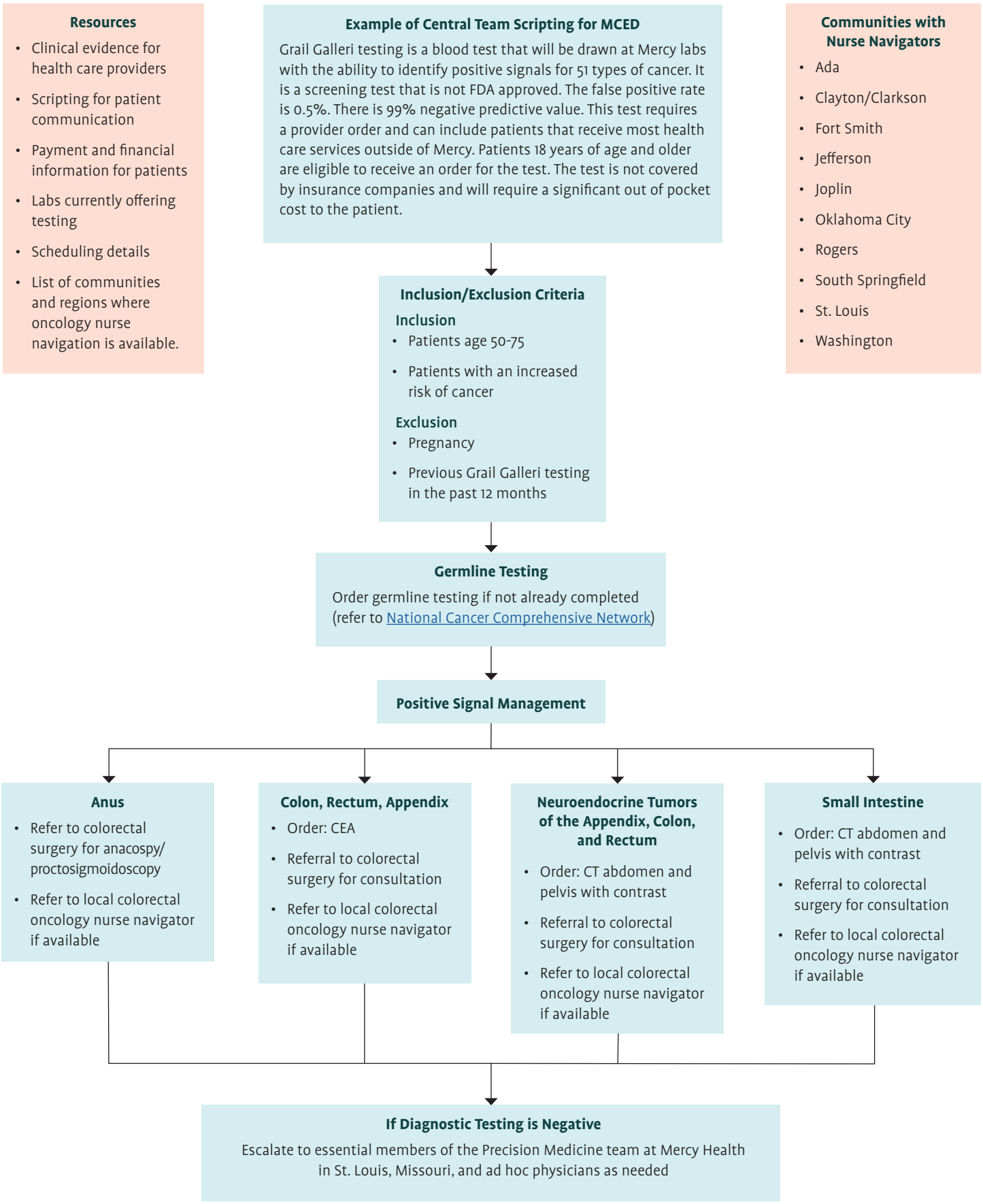
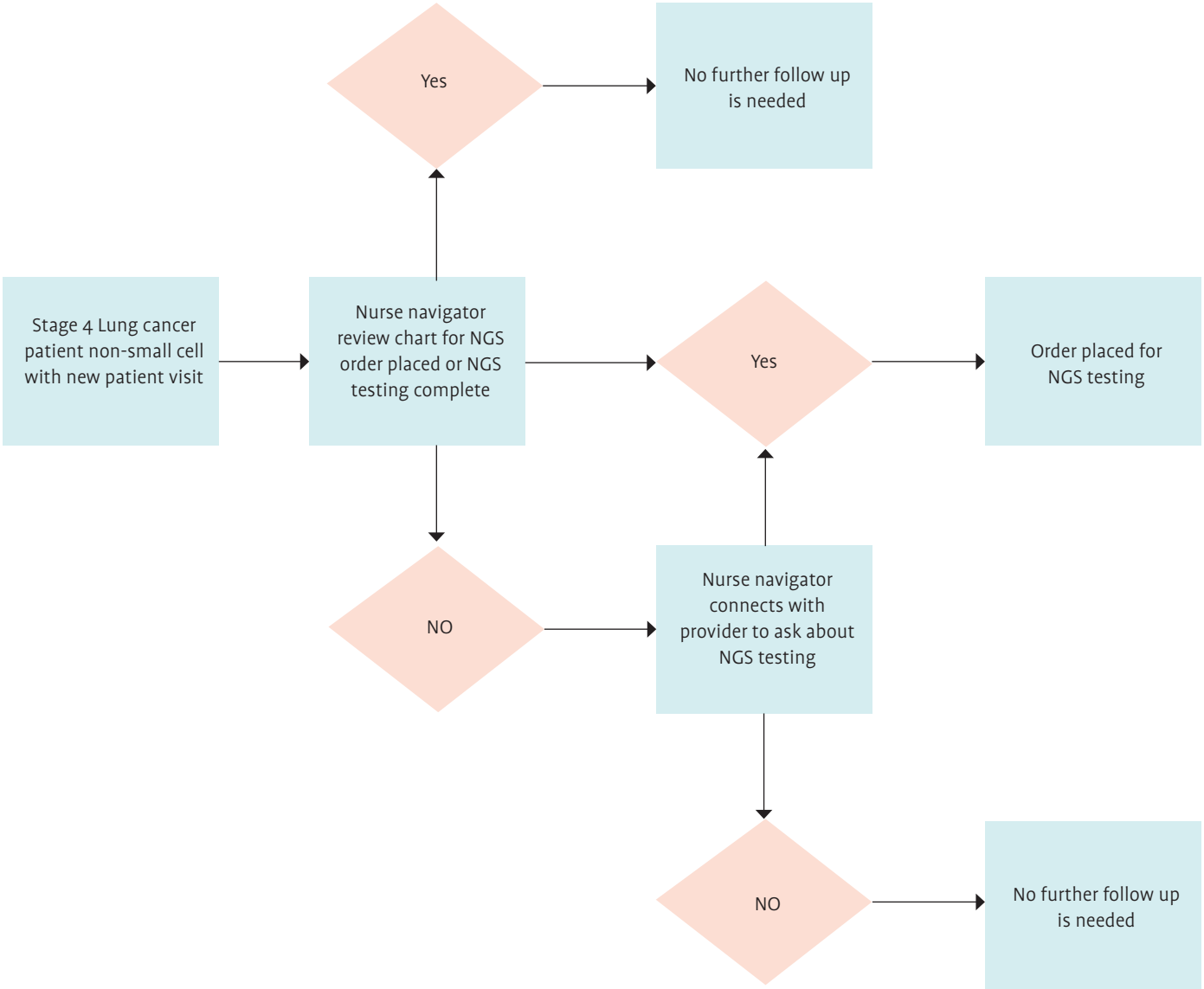


Figure 2. Lung Cancer NGS Testing Flow Map



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the ability to complete all testing in 1 morning and take the results of these tests with a plan for improved future health. Currently, this is a fee-for-service program that serves as a test environment for any future precision medicine offerings that are new to the market without support from insurance providers.

Mercy has leveraged several NGS offerings through a centralized precision medicine team. This team facilitated the integration of a major NGS vendor with the EHR as well as NGS-specific website development. The team has developed both clinical and implementation expertise in this field. Staff members use standardized workflows, counseling, and documentation to improve the patient experience with MCED, somatic, germline, and pharmacogenomics testing as well as with a unique executive wellness program. OI

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References

1. Strianese O, Rizzo F, Ciccarelli M, et al. Precision and personalized medicine: How genomic approach improves the management of cardiovascular and neurodegenerative disease. Genes (Basel). 2020;11(7):747. doi:10.3390/genes11070747

2. Boffetta P, Collatuzzo G. Application of P4 (predictive, preventive, personalized, participatory) approach to occupational medicine. Med Lav. 2022;113(1):e2022009. doi:10.23749/mdl.v113i1.12622