Adventist Health, CancerIQ Collaboration Identifying More Patients for Guidelines-Supported Genetic Testing

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CHICAGO – Adventist Health in Roseville, California, has expanded a program where they are more comprehensively evaluating patients in the primary care setting and within breast imaging centers for their inherited predisposition for cancer. Although using this strategy only a subset of patients will meet the criteria for genetic testing, the program is enabling the organization to better identify those who should be tested according to current guidelines.

Adventist said that the strategy has more tightly integrated genomics into primary care, increased revenue, and potentially will save money and lives in the long term.

Eventually, the health system would like to see current guidelines evolve to account for the insufficiency of relying heavily on family history to decide which patients should receive genetic testing.

The Adventist Health Early All-Around Detection (AHEAD) program, a multidisciplinary initiative to improve assessment of hereditary cancer risk, has grown from two pilot clinics last May to about 30 sites within the Adventist Health network. That is up from 22 since December.

Two Adventist physician leaders were to present an update about the AHEAD program in March at the 2020 Healthcare Information and Management Systems Society (HIMSS) conference that was canceled due to the COVID-19 pandemic. Instead, Candace Westgate, creator and medical director of AHEAD, and Feyi Olopade Ayodele, CEO of technology partner CancerIQ, shared their data with GenomeWeb.

Chicago-based CancerIQ makes a suite of technology for streamlining genetic testing management and integrating clinical decision support. Its platform scans family history, performs predictive risk modeling over time, and automates compliance with National Comprehensive Cancer Network (NCCN) guidelines.

The vendor is in the process of integrating its technology into Adventist's electronic medical records system, which is made by Cerner, through a custom app built following the Fast Healthcare Interoperability Resources (FHIR) standard.

"When you have corporate involvement and enterprise-level initiatives of this scale, it can really help with rapid adoption of these technologies," Ayodele said. She also credited Adventist's participation in the Cerner Open Developer Experience (CODE) program to encourage third parties to build interoperability apps.

Cerner validated the CancerIQ connector app last month, according to Ayodele. "Making CancerIQ part of routine workflow and integrating it into the EMR and showing that that's the path [to precision medicine] is ultimately how we went from two to 30 [sites] in a very short period of time," she said.

This will allow Adventist to add users to the CancerIQ platform without having to take them out of their Cerner workflows.

"Through that program we're going to make it a lot easier for future programs to enroll in AHEAD, knowing that there won't be that additional barrier or eyeballs on a different application outside of Cerner," Ayodele said of CODE.

Adventist Health started the pilot with one primary care clinic and one breast imaging center. From the time CancerIQ went live in the primary care clinic in May 2019 through the end of last year, the organization screened nearly five times more patients in primary care than in the same period of 2018, according to data Westgate was to present at HIMSS, mostly due to more comprehensive collection of family medical history and risk assessment.

The breast imaging center was able to offer genetic testing and counseling to approximately 11 times more patients, all of whom met NCCN and the US Preventive Services Task Force guidelines, during a six-month trial in 2018 than in the preceding six months. Numbers fell off sharply after the center temporarily returned to paper processes from February through April 2019.

According to Ayodele, before Adventist started using CancerIQ, the health system was unable to know right away if patients met guidelines, and even if they did qualify, there was no suitable pathway for those individuals to access genetic tests.

With CancerIQ, Adventist posted a $627,000 increase in revenue due to the collaboration for preventive cancer screening services last year, including from breast MRIs, clinical breast exams, and therapies including tamoxifen and prophylactic mastectomies and salpingo-oophorectomies, according to the presentation Westgate prepared with Dana Zanone, vice president and health informatics officer at Adventist.

The health system projected offering genetic risk screening to 100,000 patients this year, about 60 percent of whom might have been classified as average risk due to incomplete information on family medical histories, though the forecast predates the COVID-19 pandemic that has changed hospitals' priorities. At that level, Adventist Health would bring in an additional $38.9 million in revenues from preventive services and potentially achieve $79.8 million in long-term cost savings from early detection of breast, ovarian, and colorectal cancers.

Westgate said that AHEAD has led to a 20 percent increase in patient compliance with breast cancer test recommendations from their physicians.

"We're starting to see a significant improvement in our quality metrics just because we are having a discussion with our patients about their family history," said Westgate, an Ob/Gyn at Adventist Health St. Helena in Napa County, California.

Ayodele said that this program changes the way that health systems think about genetics by getting more than just genetic specialists interested and involved. "We've found a way of making it simple and easy to apply and easy for even the primary care physician to latch onto because we're helping them deliver more tailored, personalized, and informed preventative care that they're already doing today," she said.

That has helped Adventist Health identify cancers earlier in patients at elevated risk, in part through better adherence to cancer prevention plans. "But, the other thing that we're starting to see is there's also improved adherence for even those average-risk patients," Ayodele said.

Adventist's program comes as expert bodies are encouraging thoroughly assessing cancer patients for their inherited risks but cautioning against offering everyone genetic testing. In

December, the American College of Medical Genetics and Genomics released a statement saying that it doesn't advocate providing genetic testing to all breast cancer patients. However, ACMG encouraged all breast cancer patients to be evaluated for their inherited cancer risks, since healthcare systems are doing such a poor job of identifying those who meet current guidelines for genetic testing.

Some experts, meanwhile, are open to broader genetic testing approaches. The American Society of Breast Surgeons recommends testing all breast cancer patients for mutations in BRCA1, BRCA2, and PALB2. And a panel at the National Society of Genetic Counselors' (NCGC) annual meeting in November was split on whether all newly diagnosed breast cancer patients should undergo multi-gene panel genetic testing, as well as the scope of testing.

The AHEAD program is not restricted to just patients who have been diagnosed with breast cancer, however. The moderator of the NCGC panel, Lisa Madlensky, director of the family cancer genetics program at the Moores Cancer Center at the University of California, San Diego, expressed skepticism about the findings at Adventist Health.

With CancerIQ, Adventist uses the both the Tyrer-Cuzick model and NCCN guidelines to assess breast cancer risk based on patients' family and medical history. Madlensky said that the Tyler-Cuzick model "is known to overestimate breast cancer risk under many circumstances and is the favored model for clinics who have a goal of identifying more women at increased risk and doing more screening with MRI."

"While there is certainly a role for automated processes to help identify patients who are appropriate for testing and have fallen through the cracks, the overall message here seems to be one of increasing revenue by generating more MRIs using an automated process," Madlensky said.

"If your goal is to generate a lot of screening interventions, then this is great news. If your goal is to reduce burden on patients, lower, potential risks and harms, then this is actually kind of concerning," she said.

Madlensky does not see one assessment model being superior to others. "This is one of the challenges with large-scale algorithmic risk assessment," she said.

The Breast Cancer Surveillance Consortium model might be "preferred" when clinicians have accurate information on breast density and prior biopsy results for women without an extensive family history of breast cancer, Madlensky said.

"In other cases, it may be that we don't want to use a model at all, because there are clear guidelines that can be used," Madlensky added. For example, a woman with bilateral breast biopsies showing atypia should be advised to take risk-reducing medication like tamoxifen, regardless of all the other factors in a risk model, she said.

Madlensky also mentioned the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA), an emerging approach from the UK that emphasizes extensive family history. However, BOADICEA remains in beta.

According to Madlensky, there is just not enough data to support widespread cancer screening outside of high-risk populations. It may lead to overtesting and divert resources from other areas with greater need.

Madlensky is a coinvestigator on the University of California system's Women Informed to Screen Depending on Measures of Risk (WISDOM) program, a longitudinal study meant to incorporate genetic risk factors into personalized recommendations for breast cancer screening. By combining testing for nine breast cancer genes, a polygenic risk score — the

subject of recent controversy — and other modeling, the researchers hope to see if a personalized approach leads to better outcomes than the typical approach of annual mammograms for women aged 40 and older.

Madlensky said that the WISDOM study exists because there is not much evidence that large-scale breast cancer screening programs actually do improve patient outcomes.

"Claiming that the end goal is to have more people doing more screening is not really meaningful if we don't know that that actually saves lives and does not cause harm," she said. Within WISDOM, the researchers hope to gather evidence to answer some of these questions.

Early-detection programs in general might pick up more slow-growing ductal carcinoma *in situ* but could cause harm in women who are recommended for MRIs or biopsies that might not be indicated under more traditional screening techniques. "The tradeoff does not necessarily fall on the side of benefit," Madlensky said.

Meanwhile, Adventist is hoping that data from programs like AHEAD will help improve current cancer risk assessment guidelines that largely rely on family history to determine who should receive genetic testing. Westgate said that the "jury is still out" on whether it is wise to use genetics to discern risk from a more general population, but he also noted that current family history-based guidelines are inadequate, because many patients do not know their full family histories or the histories they provide may be inaccurate.

"The problem is the accuracy of the information and the data that we get. How many patients know whether their grandma had triple-negative breast cancer?" Westgate said. She underscored, however, that AHEAD is not conducting population genetic screening. While Adventist encourages patients in primary care and breast imaging centers to undergo a risk assessment, the goal is to better identify those who have a significant family history of cancer and determine if they meet NCCN or USPSTF guidelines for genetic testing.

"We know that what we have right now [in terms of guidelines] is flawed, but we know that it's so much better than what we had even five years ago because the criteria [for testing] were extremely strict back then," and it was very difficult for a patient to meet criteria, Westgate said.

To get to true population-based genetic screening at Adventist, though, the cost of testing needs to come down further and insurance companies need to eliminate repercussions for patients who might test for an elevated risk of a disease.

"We're definitely seeing a lot more patients and their providers being comfortable with making this a part of routine care in regard to identifying those at higher risk and offering them something more than just increased surveillance because of their family history," Westgate said.

The Genetic Information Nondisclosure Act has eased the concern about insurance discrimination a bit, particularly among millennial women, Westgate added.

Ayodele said that the controversy is more around genetic screening by itself than the family history-based screening that CancerIQ enables.

"I think the way we bridge the gap between people who are on either side is truly with more data," Ayodele said. A digital platform like CancerIQ's can produce the data and add to the research knowledge that might lead to changes in guidelines or identify new patterns in early cancer diagnosis.

"We see CancerIQ as a really great interim solution for truly evidence-based medicine," she said, helping clinicians follow current rules while also providing researchers with new data.

Longer term, the picture is less clear, Ayodele said. She was encouraged by the most recent USPSTF update on BRCA-related cancer risk assessment, genetic counseling, and testing, though it has maintained the focus on family history.

"They still are more comfortable for only a certain patient population to get access to genetic testing, versus everyone getting tested at once," Ayodele said. "It's not about testing. It's about early detection and prevention."