

Germline Genetic Testing, Counseling Move Remote as Pandemic Limits In-Person Care Capacity

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NEW YORK – Many healthcare systems in recent weeks have had to shift available resources and in-person care plans to increase capacity for a potential influx of SARS-CoV-2 infected patients.

While some may consider germline genetic testing for assessing hereditary cancer risk a non-essential service during this time, genetic counselors and diagnostics companies maintain that these tests still yield important information that can be provided to patients with at-home sampling and telehealth services that reduce the burden on providers and health systems. If the digital health model can demonstrate its utility in triaging genetic testing to urgent and non-urgent patients during the pandemic, industry observers predict that more services will move toward a telehealth model.

"In a crisis like this, there's going to be an increase in pressure to reduce unnecessary in-person interactions," said Othman Laraki, CEO of consumer-centered genomics company Color, one of the first companies to provide clinical-grade hereditary cancer testing on a digital platform back in 2015. "Because of the pressure that's unfortunately getting put on the system for acute care, everything that's non-acute that can be virtualized, will be."

During the pandemic, health systems are focusing on triaging urgent and non-urgent cases, and in making those calculations, cancer patients who are progressing and need to immediately go on therapies will be at the front of the line in terms of molecular testing. Patients without cancer who have a family history and are interested in learning their genetic risk would be considered less urgent and may be rescheduled for a later time.

In general, during a national public health emergency, there may be a perception that germline testing or genetic counseling to address patients' hereditary cancer risks are not top priorities. But genetic testing to assess cancer risk is still important for cancer patients, even in the short term, said Meagan Farmer, a genetic counselor at the University of Alabama at Birmingham and a business manager at digital health company My Gene Counsel.

She provided examples where such information can have a significant impact on patient management. For example, if a hereditary cancer risk assessment shows that a breast cancer patient is at increased risk for a second breast cancer, she may decide to have a double mastectomy instead of just a lumpectomy or a single mastectomy. Hereditary cancer risk information can also inform chemotherapy selection and timing.

For unaffected individuals, if testing shows them to have an increased inherited cancer risk, that may guide their screening frequency and whether to perform MRI in addition to mammograms. "And sometimes the risk is high enough that even in the absence of cancer, we recommend consideration of preventive measures like preventive mastectomy or hysterectomy," Farmer said.

Laura Panos Smith, VP of operations at Ambry Genetics, has noted a move away from prevention-oriented procedures during the pandemic, including germline testing for cancer. She has noted that some health systems are currently not doing OB-GYN wellness exams and not scheduling mammograms. "Those patients [whose cancers] we would have caught on a preventative measure, we're not reaching right now," Panos Smith said. "The hospital focus has shifted to offer genetic testing to those with a [cancer] diagnosis and those that need these results to help manage their treatment today."

According to Panos Smith, across their entire customer base, Ambry saw a decrease in overall germline risk testing orders starting last week, but an increase in overall proportion of saliva kit orders. Panos Smith added that a large number of Ambry's clients are genetic counselors, and the company has still seen a reasonable uptake of germline genetic testing from that group.

A spokesperson for Myriad Genetics, one of the leading commercial labs for hereditary cancer testing, said it was too early to tell if the pandemic has had an impact on germline genetic test orders. Color and GeneDx said they've not yet seen an impact on orders.

Additionally, Color, Ambry, Myriad, and GeneDx are not expecting any service disruptions in their laboratories. All have moved their non-lab personnel off-site, are staggering essential lab workers' schedules, and are spacing out workspaces in order to minimize contact in line with public health guidance. None of the companies have noticed a marked delay in the turnaround time for test results.

During the public health crisis, these companies are also trying to facilitate germline testing when needed, by encouraging greater use of at-home saliva sample collection kits and by providing other supportive resources.

"Our initial response to this pandemic was to make sure physicians have the tools they needed to be able to conduct genetic counseling and order testing virtually," said Panos Smith. These include highlighting [online applications](#) and virtual guides for counseling and interpreting tests available on Ambry's website.

Ambry is now transitioning to shipping saliva kits directly to patients' homes when doctors order testing and walking other clients like patients or caregivers through how to order at-home saliva kits through their website and how the sample collection and testing process would work.

Prior to the pandemic, GeneDx said that close to 50 percent of the sample types they collected were through buccal swabs, or cheek swabs. This was due to the ease of collection and patient comfort with such sampling, according to Rachel Klein, chief officer for genetic services at GeneDx. Klein is expecting doctors to increasingly use this method of sampling through at-home collection kits.

"GeneDX can ship the patient the kits, the patient or the parents or a caregiver can collect that sample and ship it back to the laboratory for testing," she said, adding that GeneDx has developed instructional videos to ensure people are collecting samples correctly so there is sufficient DNA for analysis

Klein said that GeneDx can also work with providers, genetic counselors, and patients to streamline the testing process, whether it's walking patients through what results or recommendations they should bring to the attention of their physician, or having physicians mark which tests should be fast-tracked by GeneDx.

Color has been set up from its inception for at-home sample collection. The company also was among the first companies to include a free telephone genetic counseling session for the price of testing.

When Color was started a few years ago, it was initially only focused on cancer risk genetic testing for genes like BRCA 1 and BRCA 2. Testing then had been very expensive for hereditary cancer. Laraki said he realized that one of the biggest barriers to access aside from the financial cost to patients was convenience and the overhead costs for labs associated with the traditional clinical testing.

"We took the access model that involved a lot of in-person interactions to one that was heavily digital and virtualized, which made that ... clinical-grade genetics much more accessible to broader populations," he said.

Now, the pandemic is highlighting the value of the digital model that Color embraced years ago, starting with hereditary cancer testing. "Showing up in person multiple times in order to receive a test is extremely costly, even if you exclude the direct financial costs," Laraki said. "The accessibility impact of these models is going to be brought forward in a window of time like this." Further, the pandemic will help doctors, payors, and health systems better understand which patients need in-person evaluations, which can be directed to telemedicine, and which patients' care can be delayed without consequences, he added.

Laraki, along with other experts in the genetics space, believe the public health crisis will push more healthcare virtual, a shift that's been a longtime coming.

While different health systems will embrace different strategies, Laraki is of the view that every health service that can be virtualized, will be, as a side effect of the pandemic, and that these changes could be integrated into the new normal even as the crisis resides.

"The field of genetics evolves rapidly already," said Farmer, noting that in this space, health technology companies like My Gene Counsel and others are already developing creative solutions to expand access to genetic testing and counseling. "A silver lining in this crisis is that it has catalyzed the development and implementation of some of these [virtual] solutions and approaches and encouraged collaboration."

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