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Exact Sciences Looks Ahead As Cologuard Marks 10th Anniversary

by [Elizabeth Orr](#)

Exact Sciences' Cologuard at-home colorectal cancer screening test was the first of its kind when it was introduced to the US market in 2014. What's ahead for the company as its flagship product moves into its second decade? Medical director Paul Limburg spoke to *Medtech Insight* about the potential of home cancer screening.

Medtech Insight speaks with industry experts about trends and innovations with potential to transform cancer care.

In 2014, Cologuard entered the US market as the first at-home diagnostic for colorectal cancer. Since then, 16 million Americans have been screened with the test. The company estimates that because cancers can be detected at an earlier stage using Cologuard, use of the test has saved the health care system \$22bn.

But Exact Sciences medical director Paul Limburg told *Medtech Insight* that the test still has not reached its full potential.

as been called the most
prevented type of cancer," he
flow of opportunity where we can
even those early-stage, more
cancers, through effective
's all sorts of data to demonstrate
out unfortunately, there's still



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Source: Exact Sciences

about 60 million Americans that are unscreened or under-screened, meaning that they aren't up to date with the recommended guidelines.”

About 150,000 Americans are diagnosed with colorectal cancer each year, making it the fourth most common type of cancer in the country. (The first is breast cancer, with 313,000 cases per year.) And for reasons researchers have not yet identified, colorectal cancer is becoming more common in younger people. People aged 54 or younger now account for 20% of all cases, while incidence has dropped in people aged 65 and younger. Government guidelines recommend regular screenings beginning at age 45.

Advanced Test Expected This Year

Next up for Cologuard is an updated version of the test, Cologuard Plus. The US Food and Drug Administration is currently reviewing data from a 20,000-person study, which showed better results than existing tests. The company hopes to get FDA authorization for Cologuard Plus before the end of the year. (Also see "[Exact Sciences Nails Colorectal Cancer Test Trial Ahead Of Planned Submission](#)" - Medtech Insight, 22 Jun, 2023.)

Meanwhile, the company is working to identify a wider range of cellular-level markers associated with different cancers that can be used to build molecular diagnostics across high-priority areas. Exact Sciences has developed tests for breast and prostate cancers in addition to colorectal and is working on a blood-based test that will screen for multiple cancers that do not currently have a recommended screening option.

“We've got risk stratification tests, we've got single cancer screening tests, we're developing multi-cancer screening tests, and then we've got our treatment decision tests,” Limburg said. “Once cancer has been diagnosed, we've got, for example, our oncology products that can help clinicians and patients understand, do I need chemotherapy? If yes, what type of chemotherapy? Has my chemotherapy been effective? And we do that with tissue tests and blood tests.”

“I don't think it's ever going to be a one-size-fits-all, but having a non-invasive, home-based option like Cologuard is growing in terms of adoption and interest at the provider and patient level.” – Paul Limburg

The company is working on a blood-based screening test for colorectal cancer in addition to the

current stool-based version. However, Limburg said the stool-based version may remain the most sensitive option.

“In order to find these cancer-associated markers in the blood, they have to get into the blood,” he explained. “And that may or may not happen right now. With pre-cancers in particular, the markers may never get into the blood in sufficient quantity for us to have high enough detection rate.”

He anticipates that the blood-based test could be most valuable as a “second line” option for patients who are not willing or able to access the stool-based test or a colonoscopy. He also noted that colonoscopies may remain the preferred screening method for some patients because they only need to be repeated every 10 years if the test is negative, while Cologuard and similar tests must be repeated every three years.

“I don't think it's ever going to be a one-size-fits-all,” Limburg said. “But having a non-invasive, home-based option like Cologuard is growing in terms of adoption and interest at the provider and patient level.”

‘Always Start With Patients’

Exact Sciences has been a trailblazer for the at-home cancer screening market. What advice would Limburg give other test developers who may want to emulate its success?

“Always start with patients,” he said. “What is the clinical need, and how best could a team address that unmet need?”

In the case of Cologuard, he said, there was a space in the market for an at-home screening test. Exact Sciences worked with Mayo Clinic researchers to identify biomarkers that were highly accurate to colorectal cancer and develop an effective test process that could be scaled up while providing a high level of patient support.

“It's no small feat that Exact Sciences can now meet that growth when demand has exceeded 16 million tests,” he said. “So start with a clinical problem that is patient-centered. Bring the best talent together to try to figure out what is the right solution. Make sure that you've got scalability in mind as you begin to deliver that solution, and always continue to improve.”