Harnessing Biomedical Innovation: Modernizing VA Healthcare for the Future
Written Testimony Submitted to
U.S. House Committee on Veterans' Affairs
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Thank you for the opportunity to provide written testimony in response to the Committee's hearing on modernizing healthcare at the Department of Veterans Affairs (VA). As discussed at the hearing, it is imperative that veterans have more options for healthcare and greater access to healthcare technologies and innovations. As Chairman Bost succinctly put it, "[v]eterans can't afford to wait." We would like to discuss speeding the delivery of cutting-edge technologies and innovative diagnostics for colorectal cancer screening further below.

Colorectal Cancer is the Second Deadliest Cancer in the U.S.

Colorectal cancer causes more than 50,000 deaths annually. Of particular concern is the significant increase in the incidence of colorectal cancer among younger Americans. Since 1994, cases of early-onset colorectal cancer (i.e., colorectal cancer diagnosed before the age of 50) have increased by 51%, and since 2004, there has been a rapid shift in mortality patterns, with colorectal cancer moving from being the fourth leading cause of cancer-related deaths among young men and women to now being the leading cause in men and the second leading cause in women.[1]

Colorectal Cancer Can Be Prevented Through Regular Screening

Colorectal cancer is the most preventable cancer if people get screened for it regularly. Colorectal cancer almost always develops from precancerous polyps (abnormal growths, also called adenomas) in the colon or rectum. If you can find and remove the precancerous polyps through screening, you can head off cancer before it develops. Fortunately, routine colorectal cancer screenings for Americans aged 45 years and older are a very effective intervention to detect precancerous polyps so that they can be removed before they develop into cancer, thereby preventing colorectal cancer.[2] A New England Journal of Medicine study concluded that the more adenomas found during screening, the less cancer is subsequently diagnosed.[3]

Screening can also identify early-stage cancer. When colorectal cancer is found at an early stage, before it has spread, it is more treatable, and the five-year relative survival rate is about 90%. The percentage of individuals diagnosed with advanced-stage colorectal cancer has increased from 52% in the mid-2000s to 60% in 2019.[4] Survival rates are lower when cancer has

[1] https://www.nbcnews.com/health/health-news/colon-cancer-deaths-younger-men-women-report-rcna134084
[2] https://www.cdc.gov/chronicdisease/programs-impact/pop/colorectal-cancer.htm
[3] https://www.nejm.org/doi/full/10.1056/NEJMoa1309086
[4] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772

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spread outside the colon or rectum.[5] Unfortunately, many patients avoid screening, and so their cancer is diagnosed at later stages. Approximately 40% of patients fail to get screened in part because they do not want to have a colonoscopy, which is the gold standard for colorectal cancer screening in the U.S. Colonoscopies are frequently met with patient aversion due to the required bowel preparation, sedation, and potential time away from work.[6]

Despite this highly effective approach to disease prevention, one in four adults aged 45 to 75 are not getting screened as recommended. In 2021, only 19.7%, or fewer than four million out of 19 million eligible adults aged 45-49 were up to date with their colorectal cancer screening.[7] As such, it is essential that more colorectal cancer screening options be available to people aged 45 and older and that such tests be accessible and affordable for all who are eligible for screening.

New FDA-Approved, Non-Invasive Colorectal Cancer Screening Tests

An alternative to colonoscopy for average-risk patients is non-invasive screening tests, like Geneoscopy's ColoSense, which can be used at home. ColoSense can play a critical role in addressing access to care challenges by reducing barriers to early detection, particularly among hard-to-reach populations where access to care is limited, such as rural communities. Traditional screening methods, like colonoscopies, can be inaccessible due to cost, geographic location, or the need for specialized facilities – challenges that disproportionately affect low-income, rural, and minority communities. A non-invasive test such as ColoSense offers a more affordable, convenient, and less intimidating option, increasing the likelihood that patients will seek regular screenings, and as a result detect precancerous polyps and colorectal cancer at earlier stages when it is most treatable.

Everyone is at some risk for developing colorectal cancer, though some groups are at elevated risk. As noted earlier, of serious concern, is that colorectal cancer incidence and mortality rates among people ages 45-54 have increased in recent years. The percentage of all individuals diagnosed with colorectal cancer who are under the age of 55 doubled from 11% in 1995 to 20% in 2019.[8] In 2021, the U.S. Preventive Services Task Force (USPSTF) lowered the recommended age for people to begin colorectal cancer screening from 50 to 45.[9] With that change, 17 million more people entered the recommended screening cohort. Clearly, there is an urgent need to increase screening efforts.

[5] https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/detection.html
[6] https://www.sciencedirect.com/science/article/pii/S2211335519300750
[7] https://www.cdc.gov/pcd/issues/2023/23_0071.htm
[8] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772
[9] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations

Expanding Access to Colorectal Cancer Screening in the VA & Building Public-Private Partnerships

Expanding access to colorectal cancer screening is one of the VA's stated goals, with the VA diagnosing an estimated 4,000 new colorectal cancer cases each year.[10] The VA recognizes the role new technologies can play in colorectal cancer detection, having introduced artificial intelligence (AI) tools through its National Colorectal Cancer Screening Program (NCSP) to aid in the detection of pre-cancerous polyps.[11]

Geneoscopy believes the VA can build on these important efforts by speeding the adoption of newly approved technologies and devices. As technological innovations in the field of colorectal preventive screening and diagnostics advance, more effective screening modalities become available. Top-line data from the CRC-PREVENT clinical study for Geneoscopy's test demonstrated 93% sensitivity for colorectal cancer and 45% sensitivity for AA in average-risk individuals.[12] In addition, ColoSense's ability to detect AA does not materially erode for the youngest screening bracket of 45-49-year-olds as occurs in other screening methods.[13] This finding may lead physicians to choose different screening modalities for different patient demographics. When it comes to screening, more choice is better, and the best colorectal cancer screening test for a given patient is the one that physicians will use. Geneoscopy's clinical trial showed that the new technology worked successfully for people across demographic groups all over the country and has the real promise to advance the vital goal of increasing access to healthcare innovation for historically underserved populations. In Geneoscopy's trial, 30% of participants had an income below $50,000 annually, 9% were on Medicaid, and 5% were from rural areas.[14]

There are a few key hurdles to bringing life-saving cancer screening tests to patients. First, getting approval by the Food and Drug Administration (FDA); second, qualifying for coverage and payment by the Centers for Medicare and Medicaid Services (CMS) and being adopted by other federal agencies, like the VA; and third, inclusion in the USPSTF screening recommendations given that commercial insurers generally will not cover a test until it is included in USPSTF guidelines. Start-up companies like Geneoscopy take risks when developing new technologies and face the "valley of death" when coverage and guidelines inclusion do not come quickly after FDA approval.

We are glad the committee recognizes these challenges companies like Geneoscopy face. We were encouraged by Rep. McGarvey's mention of expanding public-private partnerships and pilot programs by granting the VA the ability to make advance market commitments and use Other Transaction Authority (OTA). This kind of predictability and flexibility would help

[10] https://news.va.gov/129165/expanding-colorectal-cancer-screening-treatment/
[11] https://news.va.gov/122055/va-colonoscopies-ai-increase-polyp-detection/
[12] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001
[13] https://doi.org/10.1158/1940-6207.CAPR-20-0294
[14] https://pubmed.ncbi.nlm.nih.gov/37870871/

innovators like Geneoscopy get across the "valley of death" while speeding care delivery to veterans. ColoSense received FDA approval through the Breakthrough Devices Program in May 2024 and still faces a significant delay for CMS coverage nearly a year later. Further, there has been no movement by the USPSTF or the National Committee for Quality Assurance (NCQA) to update their colorectal cancer screening guidelines, which is thwarting commercial insurance coverage. The VA can bridge this gap to the benefit of veterans and in the process incentivize medical innovation. We too want to see "partnership[s] where the VA and industry develop solutions collaboratively that ultimately save money, generate revenue and provide better healthcare for our veterans."[15]

About Geneoscopy

Geneoscopy was founded in 2015 with a vision to improve how gastrointestinal diseases are prevented, detected, and treated. My sister, Dr. Erica Barnell, and I co-founded Geneoscopy after Erica developed a groundbreaking technology to isolate and interrogate stool-derived eukaryotic RNA while she was pursuing her MD/PhD at Washington University School of Medicine in St. Louis, Missouri. Geneoscopy's initial product is ColoSense, a noninvasive colorectal cancer screening test that detects colorectal cancer and high-risk precancerous polyps—advanced adenomas.[16] Designated a Breakthrough Device by FDA, ColoSense received FDA approval on May 3, 2024.[17]

[15] Rep. Morgan McGarvey, "Harnessing Biomedical Innovation: Modernizing VA Healthcare for the Future," *Bloomberg Government,* p. 35, https://www.bgov.com/next/news/SU3B9X0799MP.
[16] https://pubmed.ncbi.nlm.nih.gov/11916153/
[17] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230001