Galleri, a Blood Test to Detect Over 50 Cancers, Misses the Mark in Clinical Trial

The multi-cancer blood test failed to reduce late-stage diagnoses; trial results don't support the test's rollout, says an expert.

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Galleri, a blood test that aims to detect over 50 cancers, illustrates the promise and popularity of an emerging technology to screen for cancer. Although the blood test is not approved by the Food and Drug Administration, more than 185,000 tests were sold to consumers in 2025 at a list price of $949 each. But do the scientific data back the hype? The much anticipated results of a clinical trial evaluating Galleri failed to show that the test reduced Stage III and IV cancer diagnoses over three years, marking a setback for Grail, the test's British manufacturer.

The results indicate that Galleri is "not a very good test," cancer geneticist Richard Houlston, MD, PhD, told the New York Times. "This doesn't support rollout within the American health care system."

But a deeper dive suggests the results are not so cut-and-dried. Many questions remain unanswered. For example, if the trial had followed more people over a longer period, the resulting data might have been different (three years is a relatively short amount of time considering most people develop cancer later in life).

What's more, examining a test's ability to detect cancer earlier may not be the best way to measure a potential benefit to the patient, Richard M. Hoffman, MD, MPH, told Medscape. It's possible that screening tests could find slow-growing cancers that pose no harm to patients, thereby leading to overdiagnosis and unnecessary anxiety and cost. Hoffman is the lead author of a recent American Cancer Society consensus statement about these cancer-detecting blood tests. Reducing cancer mortality "is the ultimate goal of screening," Hoffman said, and the verdict on that data is not settled.

“I would hope that these results do not dampen enthusiasm for what is potentially a paradigm-shifting approach to cancer screening,” Hoffman told Medscape. “These tests are continually evolving to improve their diagnostic accuracy and may find a better niche by limiting the number of tested cancers, targeting high-risk populations and being used for cancer surveillance.”

What did the recent clinical trial measure? For three years, England’s National Health Service (NHS) followed 142,000 people ages 50 to 77 to evaluate annual multi-cancer screening with Galleri. The goal was to show that the test reduced late-stage cancers (Stages III and IV), which would indicate it is an effective early detection method.

Unfortunately, the study did not show a significant reduction in detection of late-stage cancers in people screened with Galleri compared with those who weren’t.

However, the trial led to other key findings, according to a Galleri press release, including:

- A reduction in Stage III and IV cancers was not found, but a downward trend was observed after the prevalent screening round.
- Stage IV diagnoses of 12 deadly cancers decreased with each year of screening.
- Standard-of-care screening and annual screening with Galleri together led to a fourfold improvement in breast, colorectal, cervical and high-risk lung cancer detection rates.
- Increase in the number of Stage I and II cancers in 12 deadly cancer types typically found in later stages.
- Galleri test screening led to a reduction in cancer detection through emergency presentation, which is associated with high mortality and health care costs.

“As an oncologist, I see how profound the difference is between Stage III and Stage IV disease,” said Charles Swanton, MD, PhD, one of the NHS-Galleri trial’s chief investigators, in a press release. “When cancer is detected before distant metastatic spread, we can often treat with curative intent, combining surgery, radiotherapy and systemic therapy in an effort to eradicate all disease. Once distant metastases are established, treatment typically shifts toward long-term disease control and symptom management; durable cures become uncommon in most solid tumors. Reducing the proportion of patients diagnosed with metastatic disease is therefore not merely a statistical aim, it dramatically increases the number of patients for whom eradication of disease and cure is possible.”

While this new form of cancer screening is promising, the trial shows that the blood tests are not quite ready for market. Other multi-cancer detection tests are being evaluated through pilot studies and trials, such as the Vanguard Study.

In the United States, such tests are available to consumers. But since the FDA hasn't approved any of them, most health insurers do not cover the costs. The Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act was recently signed into law to authorize Medicare to cover FDA-approved cancer-detecting blood tests beginning in 2028.

To read more about cancer screening via blood tests, click #blood test or see "How Well Can Blood Tests Detect Multiple Cancers Early."

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