Q&A: Weighing the potential risks and benefits of multi-cancer early detection tests

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As Americans, we've become accustomed to the nearly unique experience of seeing commercials for medicines like prescription drugs on television—only the U.S. and New Zealand allow this kind of direct-

to-consumer (DTC) advertising.

The proliferation of such commercials in recent years has prompted concern among public health experts and consumer advocacy groups alike. Because they emphasize the potential benefits of a product, in this case a drug, some feel that the ads may not provide accurate and balanced information to patients and may also contribute to rising healthcare costs.

In the following Q & A, Glyn Elwyn, MD, Ph.D., MSc, a professor of The Dartmouth Institute for Health Policy and Clinical Practice, discusses similar concerns about a new and emerging medical product: multi-cancer early detection tests (MCEDs), which may soon be widely available to consumers.

Elwyn and colleagues Kevin Selby, MD, MAS, from the Center for Primary Care and Public Health at the University of Lausanne, Switzerland, and Robert Volk, Ph.D., from the University of Texas MD Andersen Cancer Center, talk about the potential benefits and harms of the tests in a recent paper published in the *Annals of Internal Medicine*.

What was your main goal in publishing this paper?

To alert clinicians to the fact that these tests are coming and they're coming pretty quickly, we think. When they start advertising MCEDs widely to the public, there's likely going to be a surge of interest and high expectations from consumers. But with that interest comes the potential to cause a lot of challenges.

For example, when a new test appears accompanied by direct-to-consumer advertisements, physicians often feel a bit blindsided—especially in primary care where we're supposed to know a little about many different things. The options feel like, "either I dig in

and just say 'no,' or I accept it and write the prescription." The second feels easier because, up front, it's just a "simple" blood test. It's the downstream consequences that are complex.

By helping primary care physicians articulate what an informed patient should know before doing the test, we hope to lessen the shock and make for better conversations.

Can you describe what MCED tests are and how they work?

MCEDs are blood tests that are designed to search for a range of cancers—these tests have been developed to look for about fifty different tumor types at the same time.

MCEDs work by identifying tiny quantities of DNA from cancer cells that float free in the bloodstream and also specific protein biomarkers that have been released into your blood by early-stage cancer cells before any symptoms or signs of disease take place. They use a proprietary computer program that says, "If this protein and this DNA from a cancer cell is present, you might have a cancer of the kidney, for example, or of the thyroid—now you need to look more carefully at those areas." So, it's a signal to look more closely, and not a definitive diagnostic test.

Why are MCEDs so controversial?

While none of these tests are currently approved by the FDA, some are already available commercially through the Clinical Laboratory Improvement Act. You can order them from a doctor that works in a clinical organization for a cost of around $1,000. There is a worry that they may become widely available before most clinicians are aware of them, and before they become fully tested and are found to be helpful.

We know that regular screenings for some kinds of cancers—such as colorectal, breast, and cervical—as recommended by the U.S. Preventive Services Task Force, is warranted because early detection has shown reductions in both incidence and mortality from cancer. These screening methods have been studied in many scientific trials and have been found to be helpful.

One real appeal of MCEDs is that they have the potential to detect cancers that aren't commonly screened for. But we don't know whether early diagnosis of some of these cancers is going to be helpful in the long run. Potential harms might include overdiagnosis, cascades of additional testing, many false positives, increased anxiety, and more expensive care.

Scientists worry about something called "lead-time bias," where tests like this make you aware of the diagnosis but do not change the outcome in the long run. And while these tests are being marketed at a cost of around $1,000, it's not yet clear if insurers will provide any coverage for them.

What do you hope to see happen as a result of your paper?

More discussion about the potential downsides of these tests, and caution on the part of consumers and health professionals. We would suggest that a taskforce needs to look at these and make a policy recommendation about their use.

In addition, I think the development of a shared decision making tool that primary care doctors can use with patients would be very helpful in guiding their conversations about MCEDs. This would help them weigh all of the pros and cons and make an informed decision about whether or

not getting one of these tests makes sense for them.

More information: Kevin Selby et al, Multi-cancer Early Detection Tests, Primary Care, and Shared Decision Making, *Annals of Internal Medicine* (2023). DOI: 10.7326/M23-0067

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