A roadblock to personalized cancer care?

August 1 2013

This is Daniel F. Hayes, M.D. Credit: University of Michigan Comprehensive Cancer Center

There's a major roadblock to creating personalized cancer care. Doctors need a way to target treatments to patients most likely to benefit and avoid treating those who will not. Tumor biomarker tests can help do this.

The problem, according to a new commentary paper, is that, unlike drugs or other therapies, cancer biomarker tests are undervalued by doctors and patients. The authors say that inconsistent regulatory rules, inadequate payment and underfunded tumor biomarker research has left us in a vicious cycle that prevents development and testing of reliable biomarker tests that could be used to personalize clinical care of patients with cancer.

"Right now biomarkers are not valued nearly to the extent that we see with therapeutics. But if a tumor biomarker test is being used to decide whether a patient should receive a certain treatment, then it is as critical for patient care as a therapeutic agent. A bad test is as dangerous as a bad drug," says Daniel F. Hayes, M.D., clinical director of the breast oncology program at the University of Michigan Comprehensive Cancer Center.

Hayes led a blue-ribbon panel of experts from universities, corporations, insurance and advocacy organizations to outline the issues in a commentary published today in *Science Translational Medicine*.

Tumor biomarker tests look at the genetic or molecular make-up of a tumor to determine whether the cancer is likely to progress, and if so, if it is likely to respond to treatment. If the test is good, it can help doctors decide when a patient can safely skip further therapy, or it can be used to direct which drug might be most likely to help. The result: "personalized medicine," which means patients get treatments that benefit them specifically and they avoid treatments – including their costs and side effects – that are not likely to make a difference for them.

The regulatory process, the research funding, the reimbursement, even the standards for journal publications for tumor biomarker tests are all meager compared to the robust support for drug development, the authors say.

This creates a vicious cycle in which researchers and drug companies don't invest in tumor biomarker research, tests are not fully evaluated in clinical trials, and tests with uncertain value in terms of predicting the success of treatment are published. This in turn means that few of these tests are included in evidence-based care guidelines, leaving health care professionals unsure of whether or how to use the test, and third-party payers unsure of how much to pay for them.

The authors outline five recommendations and suggest that all five must be addressed to break the vicious cycle:

1. Reform regulatory review of tumor biomarker tests
2. Increase reimbursement for tumor biomarker tests that are proven to help determine which therapies will or are working
3. Increase investment for tumor biomarker research so it's comparable to new drug research
4. Increase the rigor for peer review of tumor biomarker publications
5. Include only proven biomarker tests in evidence-based care guidelines

"These recommendations are not about creating more regulation; they are about creating an even playing field that allows tumor biomarker tests to be developed and proven clinically relevant. We want to stimulate innovation yet hold investigators and clinicians to the highest scientific standards – as we now do for therapeutics," Hayes says. "We need to change the way we value tumor biomarkers in this country."

More information: Reference: *Science Translational Medicine*, Vol. 5, No. 196, July 31, 2013.