'Viewpoint' addresses IOM report on genome-based therapeutics and companion diagnostics

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The promise of personalized medicine, says University of Vermont (UVM) molecular pathologist Debra Leonard, M.D., Ph.D., is the ability to tailor therapy based on markers in the patient's genome and, in the case of cancer, in the cancer's genome. Making this determination depends on not one, but several genetic tests, but the system guiding the development of those tests is complex, and plagued with challenges.

In a February 12, 2014 Online First *Journal of the American Medical Association* "Viewpoint" article, Leonard and colleagues address this issue in conjunction with the concurrent release of an Institute of Medicine (IOM) Workshop Summary Report on "Co-Development of Genome-Based Therapeutics and Companion Diagnostic Tests." A professor and chair of pathology at UVM and Fletcher Allen Health Care, Leonard serves as a representative of the American College of Pathology on the IOM's committee on Translating Genomic-Based Research for Health, which organized the workshop and authored the report.

"Whenever a drug is developed that will target a pathway underlying disease, you need a test that says the patient will benefit," explains Leonard. "The development of companion diagnostic tests to determine if a patient will respond to a specific drug is very complex and needs to be changed, but will require changes from many stakeholders, including test developers, pharmaceutical companies, the Food and Drug

Administration, the Centers for Medicare and Medicaid Services, and other payers."

The concept of what is called the FDA's "Companion Diagnostic Pathway," explains Leonard, allows for assessment of the test to predict a drug's benefit, within the same clinical drug trial to assess the new drug's effectiveness as a treatment. Cancer specialists are the primary users of these types of drugs and tests.

In their "Viewpoint" article, Leonard and colleagues Robert McCormack, Ph.D., and Joanne Armstrong, M.D., M.P.H., who represent the testing and medical insurance industry respectively, argue for stakeholders' support of "a strategy to co-develop and co-submit to the FDA a diagnostic test (companion diagnostic [CoDx]) that specifically targets a drug to patients predicted to respond." The authors share that "regulatory and business challenges . . . hamper the broader field of diagnostic testing" and not just the companion diagnostic pathway.

Currently, there are two pathways for test co-development – the FDA's in vitro diagnostic (IVD) tests and laboratory-developed tests (LDTs). Each has its own set of regulations and safety measures, as well as costs and insurance reimbursement eligibility. "The coexistence of two test development pathways is problematic, especially for co-developed CoDx tests, and requires clarification," writes Leonard and colleagues.

As an example of the current co-development CoDx environment, Leonard provides a potential scenario of a lung cancer patient for whom an oncologist may be considering several different drugs for treatment. "The pathologist has to do multiple separate CoDx tests, unless the institution does its own LDT that combines all the individual tests into a single test," Leonard explains, which is done in some pathology laboratories, predominantly using next-generation genetic sequencing.

This combined test reduces the number of tests required, can conserve tissue and produce more medically-relevant results. However, insurance payers will not always cover the breadth of the tests.

"A university-based lab can run a single test to assess 28 genes, but an insurance company might only cover three of the gene tests," she admits.

The "Viewpoint" article addresses reimbursement and other economic obstacles, such as the investment environment for CoDx co-development and the costs associated with performing laboratory tests. The IOM Roundtable workshop explored these challenges, as well as discussed solutions to the companion diagnostic test co-development process.

"The goal was agreement on a unified plan, with every player doing their part," says Leonard, adding that "This issue needs thinking outside the box, with the patients at the center of the discussion."

More information: *JAMA* Online First "Viewpoint" link: jama.jamanetwork.com/article.a … px?articleID=1831289

Provided by University of Vermont

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