Researchers argue for a 'new paradigm' in the world of healthcare

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(Medical Xpress)—Two innovative programs designed to improve the availability of emerging medical technologies that can help patients receive more effective, efficient and personalized health care are advanced in a commentary written by a team of scientists and policy experts, including seven from Arizona State University, and published today in *Science Translational Medicine*.

The March 13 article, "Regulatory and Reimbursement Innovation," explores the benefits of coverage with evidence development (CED) and parallel review for the regulation and reimbursement of molecular diagnostics. Molecular diagnostics include tests that aid in better prediction, diagnosis, prognosis and treatment of disease through the use of DNA, RNA and proteins.

The U.S. Food and Drug Administration (FDA) requires certain diagnostic tests to provide reasonable assurances of safety and effectiveness before they can be marketed. The Centers for Medicare and Medicaid Services (CMS) determines whether such products are "reasonable and necessary" before they can be covered by Medicare. The FDA and CMS currently are reviewing CED and parallel review for more widespread use, according to the article.

One of the co-authors, ASU Regents' Professor Gary Marchant, faculty director of the Center for Law, Science & Innovation (LSI) at ASU's Sandra Day O'Connor College of Law, said these tests are expected to improve health outcomes by giving providers optimal treatment choices

for their patients.

"It's a new paradigm of health care," said Marchant, who founded LSI's Program on Personalized Medicine, Law & Policy, the nation's first law-school program that fosters the discipline's study through collaborative, multidisciplinary evaluation of critical issues. "And it's a critical time for both of these innovative programs, because agencies of the federal government are actively considering expanding them.

"These tests produce complex algorithms that can help your physician direct your health care, where you should go for treatment and what medications can – and cannot – help you," he said. "People are dying unnecessarily, and we need to get these diagnostics out more quickly and with better data."

Regulatory and reimbursement roadblocks hinder the tests' development and slow their integration into routine care decisions, according to lead author Rachel Lindor, LSI research director. A graduate of the law school's J.D. program who is now completing her M.D. at Mayo Medical School, Lindor began researching these issues during an externship in 2011 at the U.S. Department of Health and Human Services.

An LSI-hosted workshop in April 2012, "Potential Solutions to Regulatory and Reimbursement Barrier for Molecular Diagnostics: Parallel Review and Coverage with Evidence Development," followed. It drew notable experts from government, industry and academia to brainstorm solutions to these barriers; their input led to the now-published article.

"Overall, the group seemed to agree that both of these policies were good in theory, but there were pieces of each that made people skeptical they would actually work," Lindor said. "We came up with a few changes at the workshop that we thought would make them more

attractive for developers who may have products coming up through the pipeline."

Parallel review enables developers to meet with both CMS and FDA early in a product's review process, in order to clarify the agencies' evidentiary expectations and reduce inefficiencies. CED allows CMS to temporarily cover new products not yet supported by sufficient evidence to meet its "reasonable and necessary" coverage threshold while additional data are evaluated.

"Our recommendations on CED focused on trying to streamline the process so developers wouldn't see it as a hurdle to getting paid for their products – things like smoothing out the way that FDA and CMS work together when they review the same product and shortening the time it takes for CMS to actually start a CED," Lindor explained. "The group was also concerned about CMS' hints that CED may be used by local Medicare contractors, so one of our recommendations was that CMS provide some more logistics on how exactly that would work."

Lindor said tweaks to the parallel review program could make it more amenable to diagnostic test developers and speed the tests' access to insurers, care providers and patients.

"Our group recommended that CMS give developers some assurance that there will be some benefits to participating, which could be done by shortening the time it takes to go through the process, or by providing more flexibility about what type of payment decisions would come from the review," Lindor said. "We also recommended that the policy be made available to a broader range of products than it's open to now."

"The primary goals of these two programmatic recommendations are to more quickly and accurately determine the appropriate role for new medical technologies in medical practice and patient care," said Denis

Cortese, director of ASU's Health Care Delivery and Policy Program, and a co-author of the article.

Another co-author, George Poste, chief scientist of ASU's Complex Adaptive Systems Initiative, said molecular diagnostics have enormous potential to increase diagnostic accuracy and increase the efficacy and safety of drugs in multiple diseases.

"Current ambiguities in regulation and reimbursement policies for these new tests are a major barrier to corporate investment and R&D innovation," Poste said.

Provided by Arizona State University