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Inaccurate Testing Costing Time and Money

A new report from the FDA reveals that unreliable, inaccurate medical testing continues to be a major obstacle to patient safety and is also a factor behind unnecessary increase in medical and drug expenses and unnecessary medical procedures.

The report evaluated 20 case studies that involved various tests used for cancer, autism, Lyme disease and heart disease. The findings show that there exist wide-ranging, systemic problems and there was a prevalence of unnecessary tests despite any evidence that there was a need for them. These tests increase the risk of false positives and subsequently surgery - which may not be the right treatment strategy to begin with.

Inaccurate test results have also led to women opting for an abortion because the tests indicate fetal abnormalities. The report highlights that over 150,000 people who were given tests for a genetic variant that possibly increases heart disease risk were likely over- or undertreated with cholesterol-lowering drugs.

See also: Improving Patient Safety by Cutting Misdiagnosis

A major challenge in monitoring inaccurate medical test results lies in the fact that health agencies do not usually collect or report any information on adverse events that may have been a result of lab-developed tests.

Unreliable, inaccurate testing may prove to a major stumbling block for President Obama's Precision Medicare Initiative as it relies primarily on personalising healthcare based on the results of diagnostic tests. FDA generally reviews commercial tests before they are sold to labs but tests that are manufactured within a single laboratory rarely go through the same scrutiny.

The report recommends that there is a need to increase regulatory power over manufacturers and that new standards should be implemented to bring about a change in the regulatory framework for laboratories.

"The problems are more prevalent than people want to recognize," Jeffrey E. Shuren, MD., the director of the Center for Devices and Radiological Health at the FDA, told the *New York Times*. "Doctors and patients rely on these tests to make well-informed healthcare decisions. If they get inaccurate results, they can make the wrong decisions, and people get hurt as a result."

Source: FDA

Image Credit: Flickr

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