

Are IVDs Being Overused or Underused?

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PLOS One published an article, "[The Landscape of Inappropriate Laboratory Testing: A 15-Year Meta-Analysis](#) [1]," that examined 15 years' worth of published research on this topic and revealed some surprising findings about IVDs in the clinical lab. Led by investigators at Beth Israel Deaconess Medical Center, the large-scale analysis of 1.6 million test results from 46 of the 50 most commonly ordered IVDs found that 30 percent of all tests are probably unnecessary and overused. But even more surprising, the study also suggested that equally as many necessary IVD tests may be going unordered and underused.

"Lab tests are used in all medical specialties, affecting virtually all patients," said Ramy Arnaout, MD, DPhil, Associate Director of the Clinical Microbiology Laboratories in the Department of Pathology at Beth Israel Deaconess Medical Center and Assistant Professor of Pathology at Harvard Medical School, who was the article's senior author. "While working with my clinical colleagues around the hospital, I often found myself wondering about the appropriateness or inappropriateness of all of these tests. In developing this study, my coauthors and I wanted to learn more about overall lab test utilization so that we could better understand how and where errors were occurring in this extremely high-volume activity."

While the study found both overuse and underuse to be prevalent problems throughout laboratory testing, the overall findings pointed to bigger issues. "It's not ordering more tests or fewer tests that we should be aiming for. It's ordering the right tests, however few or many that is," said Arnaout. "Remember, lab tests are inexpensive. Ordering one more test or one less test isn't going to bend the curve, even if we do it across the board. It's everything that happens next, the downstream visits, the surgeries, and the hospital stays, that matters to patients and to the economy and should matter to us."

"This paper explored many of the nuances surrounding exactly how, when, and why lab tests are ordered and misordered," said Jeffrey Saffitz, MD, Ph.D., Chairman of Pathology at Beth Israel Deaconess Medical Center. "Many times, the reasons for ordering tests seems to be based on dogma, the way it's always been done. This comprehensive and meticulous analysis showed that there are patterns in laboratory test utilization that can reveal when we do a good job at ordering tests and where we need to do better."

For the study, the authors undertook a thorough review of the medical literature. Going back to 1997 (the year that the last previous review of lab tests had been conducted), Arnaout and his coauthors searched a host of databases by matching terms such as "laboratory," "blood test," "utilization," "overuse," and "underuse." After coming up with approximately 34,000 papers, the authors further refined their search and examined 42 papers on laboratory utilization.

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From this examination, the authors estimated the overall prevalence of inappropriate testing, including overuse (tests that are ordered but not indicated) and underuse (tests that are indicated but not ordered). They also distinguished between inappropriate initial testing, which occurs during a clinician's first evaluation of a patient or in response to new signs or symptoms, and inappropriate repeat testing, which occurs when the same tests are repeated (often multiple times) during a patient's hospitalization.

I asked IVD manufacturers and industry groups to take a look at this study and share their thoughts on its claims that IVDs are overused and unnecessary. As expected, the responses I received challenged the study's findings.

"Understanding whether or the extent to which tests are over- or underutilized is complicated, and requires examination of many different variables," said Andy Fish, Executive Director of AdvaMedDx. "A number of studies on this topic seem to indicate that both over- and underutilization exist in various clinical settings. This analysis in particular cites underutilization as being widespread, and possibly as prevalent as overutilization of testing. This is especially concerning, as necessary tests that are not ordered could potentially lead to patient harm and greater long-term costs to the healthcare system."

"It is important to note that this study does not evaluate the clinical performance characteristics or quality of individual laboratory-based tests or laboratory testing in general," said Przemek Jedrysik, Associate Director of Public Relations at Qiagen. "Rather, it does ask if existing laboratory tests are used in the most effective way possible. There is no doubt that modern diagnostics can significantly improve patient outcomes and help save healthcare dollars. Examples include FDA-approved companion diagnostics that are designed to detect specific mutations in order to direct patients to specific treatments and helps to reduce initial overutilization of tests by giving healthcare providers precise results. Given this, we firmly believe that the significance of diagnostic information in the healthcare system will and has to dramatically increase going forward."

At the same time, IVD manufacturers realize that given the questions and doubts being raised about the clinical effectiveness and necessity of IVDs, they need to work with their laboratory customers and physicians to educate them about IVDs.

"We support the position that every lab test should support clinical care and clinical decision making," said Todd A. Siesky, Senior Director of Communications at Roche Diagnostics. "To the extent that some tests are overutilized and some tests are underutilized, this is why we are currently working with several customers to explore innovative ways to better ensure that each test ordered is the right test for the right patient at the right time."

"Given the importance of diagnostic testing in guiding treatment decisions, we believe it is important that better clinical decision support systems are developed and put in place to help the medical community identify appropriate tests to guide patient care and ensure the full value of diagnostic testing is being realized," said

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Fish of AdvaMedDx. "We would be interested in engaging further with medical professional societies to better understand the challenges involved in ensuring appropriate testing. The development of additional quality measures regarding the appropriate use of diagnostics could help reduce inappropriate testing, especially with regard to underutilization, which poses the risk of significant harm to patients."

"Healthcare professionals need a solid understanding of how to effectively use modern diagnostic tools to improve decision-making and patient care in clinical settings," said Jedrysik of Qiagen. "The outcomes of the study suggest that improvement in this area is needed, and also that underutilization of laboratory tests is significantly more prevalent than overutilization of diagnostic procedures. In order to address potential shortcomings in the handling of diagnostics, we believe that a concentrated effort by all parties is necessary. This includes both educational initiatives and an even clearer inclusion of laboratory tests into clinical decision-making models."

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