Generating Evidence for Genomic Diagnostic Test Development: Workshop Summary

Roundtable on Translating Genomic-Based Research for Health, Board on Health Sciences Policy, Institute of Medicine

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Ten years after the sequencing of the human genome, scientists have developed genetic tests that can predict a person's response to certain drugs, estimate the risk of developing Alzheimer's disease, and make other predictions based on known links between genes and diseases. However, genetic tests have yet to become a routine part of medical care, in part because there is not enough evidence to show they help improve patients' health.

The Institute of Medicine (IOM) held a workshop to explore how researchers can gather better evidence more efficiently on the clinical utility of genetic tests. *Generating Evidence for Genomic Diagnostic Test Development* compares the evidence that is required for decisions regarding clearance, use, and reimbursement, to the evidence that is currently generated. The report also addresses innovative and efficient ways to generate high-quality evidence, as well as barriers to generating this evidence.

Generating Evidence for Genomic Diagnostic Test Development contains information that will be of great value to regulators and policymakers, payers, health-care providers, researchers, funders, and evidence-based review groups.

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