

Addressing Challenges in Genetic Test Evaluation: Evaluation Frameworks and Assessment of Analytic Validity



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(Dylan Schaden)

ADDRESSING CHALLENGES IN GENETIC TEST EVALUATION: EVALUATION FRAMEWORKS AND ASSESSMENT OF ANALYTIC VALIDITY

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Createspace. Paperback. Book Condition: New. This item is printed on demand. Paperback. 110 pages. Dimensions: 11.0in. x 8.5in. x 0.2in. Genetic testing is a rapidly expanding area with many clinical applications. While the introduction of new genetic tests creates tremendous potential for improving patient care, it is essential to evaluate these tests thoroughly to ensure that they are accurate and lead to improved patient outcomes when used in clinical practice settings. While the general principles for evaluating genetic tests are similar to those for evaluating other clinical tests, there are differences in how the principles are applied and the degree to which certain issues are relevant. The context for genetic testing is often more complex than that of other clinical tests. Evaluating the clinical impact of genetic tests under a broad range of clinical scenarios, particularly when the evaluation involves heritable conditions, requires use of appropriate frameworks. To date, systematic reviewers have not been consistent in their approaches to evaluating genetic tests. Clarifying a set of analytic frameworks customized for different testing scenarios but sharing the same principles could be beneficial to the practice of genetic testing evaluation. Another challenge in evaluating genetic tests is the assessment of analytic validity. Analytic validity refers to the ability of a laboratory test to accurately and reliably measure the properties or characteristics it is intended to measure (e. g. , the presence of a gene mutation). Evaluation of a genetic tests analytic validity is often required as part of the effort to establish the aforementioned chain of evidence. The paucity of published data and a lack of an optimized search strategy for identifying data on analytic validity from gray literature remain a major barrier to evaluating analytic validity of genetic tests. Meanwhile, there is a lack of established quality assessment guidance for assessing analytic...



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