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Citation

Authors' objectives
To outline study design principles used to evaluate the accuracy of diagnostic tests and introduce measurements of diagnostic test accuracy; and to provide an analytic evidence-based framework used by the MDRC when conducting systematic reviews of diagnostic test literature.

Authors' conclusions
Studies to determine the safety and efficacy of diagnostic tests are difficult to conduct and are open to sources of potential bias. They require careful attention to principles of design and potential sources of bias if they are to provide valid and useful information to clinicians, patients, and policy makers.

This report describes the analytic framework used by the MDRC Technology Assessment Program to guide the assignment of quality and diagnostic efficacy levels to studies of diagnostic tests. The framework outlines a defined sequence of steps designed to assure that each review meets the criteria for evidence-based medicine. These fundamental questions are addressed:

- Where does an individual study fall in the hierarchy of diagnostic efficacy? - What is the quality of the individual studies that were intended to measure the technology's characteristics as a diagnostic test? - How strong is the evidence supporting a causal link between the use of the technology and improved outcomes of care?

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