Evaluation of diagnostic tests when there is no gold standard. A review of methods
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Record Status
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Citation

Authors' objectives
"We systematically searched the literature for methods that have been proposed and/or applied in situations without a 'gold' standard, that is, a reference standard that is without error. Our project had the following aims: To generate an overview and classification of methods that have been proposed To evaluate medical tests when there is no gold standard. To describe the main methods discussing rationale, assumptions, strengths and weaknesses. To describe and explain examples from the literature that applied one or more of the methods in our overview. To provide general guidance to researchers facing research situations where there is no gold standard." (from executive summary)

Authors' conclusions
Conclusions The majority of methods try to impute, adjust or construct a reference standard in an effort to obtain the familiar diagnostic accuracy statistics such as pairs of sensitivity and specificity or likelihood ratios. In situations that deviate only marginally from the classical diagnostic accuracy paradigm, for example where there are few missing values on an otherwise acceptable reference standard or where the magnitude and type of imperfection in a reference standard is well documented, these are valuable methods. However, in situations where an acceptable reference standard does not exist, holding on to the accuracy paradigm is less fruitful. In these situations, applying the concept of clinical test validation can provide a significant methodological advance. Validating a test means that scientists and practitioners examine, using a number of different methods, whether the results of an index test are meaningful in practice. Validation will always be a gradual process. It will involve the scientific and clinical community defining a threshold, a point in the validation process, whereby the information gathered would be considered sufficient to allow clinical use of the test with confidence.

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