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Types of Bias in Studies of Diagnostic Test Accuracy

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Introduction

The quality of diagnostic accuracy studies assessment is determined by its design, the methods by which the study sample is recruited, the testing involved, blinding in the process of interpreting tests and the study report integrity. Table 1 highlights the main types of bias that can occur in diagnostic accuracy studies [1-8].

	Type of bias	When does it occur?	Impact on accuracy	Preventative measures
Patients/Subjects	Selection bias	When eligible patients are not enrolled consecutively or randomly	Usually leads to overestimation of accuracy	Consider all eligible patients and enrol either consecutively or randomly
	Spectrum bias	When included patients do not represent the intended spectrum of severity for the target condition or alternative conditions	Depends on which end of the disease spectrum the included patients represent	Ensure that the included patients represent a broad sample of those that the test is intended for use with in clinical practice
Index test	Information bias	When the index results are interpreted with knowledge of the reference test results, or with more (or less) information than in practice	Usually leads to overestimation of accuracy, unless less clinical information is provided than in practice, which may result in an under estimation of accuracy	Index test results should be interpreted without knowledge of the reference test results, or with more (or less) information than in practice
Reference test	Misclassification bias	When the reference test does not correctly classify patients with the target condition	Depends on whether both the reference and index test make the same mistakes	Ensure that the reference correctly classifies patients within the target condition
	Partial verification bias	When a non-random set of patients does not undergo the reference test	Usually leads to overestimation of sensitivity, effect on specificity varies	Ensure that all patients undergo both the reference and index tests
	Disease/ Condition progression bias Perform the reference and index with minimal delay.	When the patients' condition changes between administering the index and reference test	Under- or Overestimation of accuracy, depending on the change in the patients' condition	Ideally at the same time where practical
	Differential verification bias	When a non-random set of patients is verified with a second or third reference test, especially when this selection depends on the index test result	Usually leads to overestimation of accuracy	Ensure that all patients undergo both the reference and index tests
	Information bias	When the reference test data is interpreted with the knowledge of the index test results	Usually leads to overestimation of accuracy	Usually leads to overestimation of accuracy
	Incorporation bias	When the index test is incorporated in a (composite) reference test	Usually leads to overestimation of accuracy	Ensure that the reference and test are performed separately
Data analysis	Excluded data	When uninterruptable or intermediate test results and withdrawals are not included in the analysis	Usually leads to overestimation of accuracy	Ensure that all patients who entered the study are accounted for and that all uninterruptable or intermediate test results are explained

Patient selection
Was a consecutive or random sample of patients enrolled?
Was a case-control design avoided?
Did the study avoid inappropriate exclusions?
Index tests
Were the index test results interpreted without knowledge of the results of the reference standard?
If a threshold was used, was it pre-specified?
Reference standard/test
Is the reference standard likely to correctly classify the target condition?
Were the reference standard results interpreted without knowledge of the results of the index test?
Flow and timing
Was there an appropriate interval between the index test and reference standard?
Did all patients receive the same reference standard?
Were all patients included in the analysis?

Table 1: Understanding this bias can improve the design and evaluation of diagnostic accuracy studies.

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