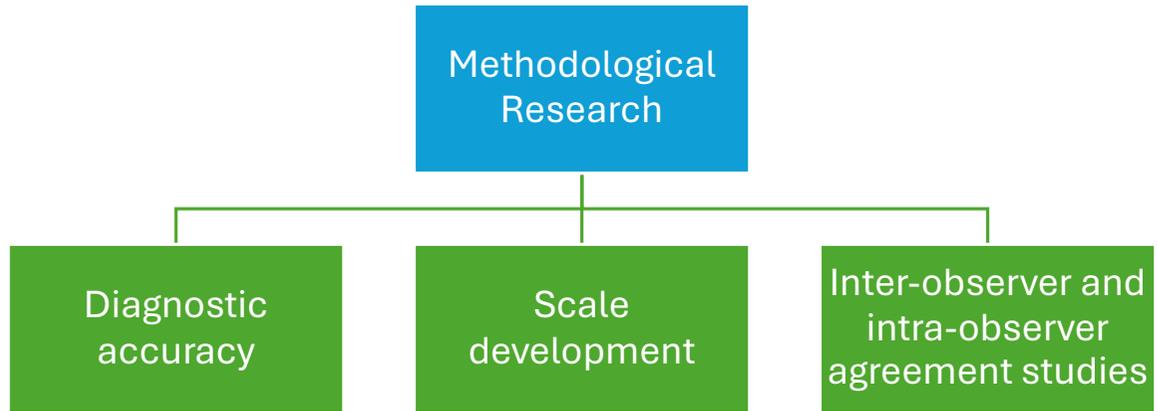# Methodological Designs

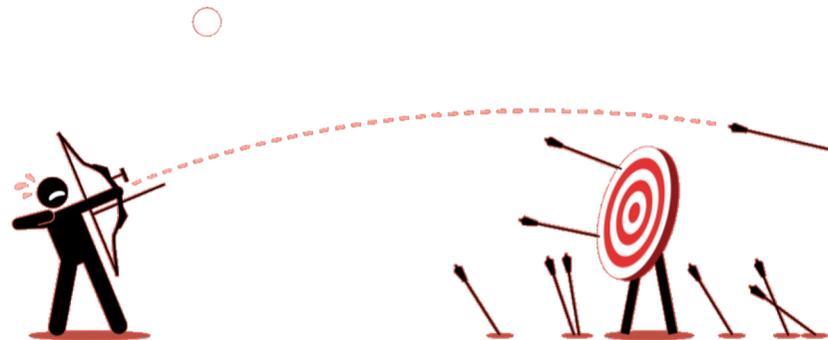Assoc. Prof. Dr. Doğukan ÖZEN

Methodological Designs

- Various physical examination and laboratory methods are used in the diagnosis of diseases and in screening programs to distinguish patients from healthy people/animals.

- These are the studies carried out to determine how valid these methods are in diagnosing the person/animal correctly and to determine the extent of the observation-measurement errors caused by the people who use these methods.

Methodological Designs

Observation/
Measurement
quality

- Validity
- Reliability

Methodological
Research

- Diagnostic accuracy
- Scale development
- Inter-observer and intra-observer agreement studies

1.Diagnostic accuracy studies

o   Also called clinical validity studies.

o   Evaluate the test's accuracy in discriminating between patients with or without the target condition (disease)

✓   The characteristics of the test (e.g. sensitivity and specificity) may inform what role the index test (the new test under evaluation) plays in the diagnostic pathway; is it a triage, add-on or replacement test?

1.Diagnostic accuracy studies

Measures of diagnostic accuracy

How well this test discriminates between certain two conditions of interest (health and disease)?

- Sensitivity

- Specificity

Performance measures of binary diagnostic tests

- The area under the ROC curve

Performance measure of continuous outcome diagnostic tests

- Predictive values

- Likelihood ratios

1.Diagnostic accuracy studies

Measures of diagnostic accuracy
Sensitivity and spesificity

Sensitivity : the proportion of participants correctly identified by the index test as having the target condition e.g. those with the disease

"Sensitivity=(a/a+c)*100"

Specificity : the proportion of participants correctly identified by the index as not having the target condition

"Specificity=(b/b+d)*100"

2x2 decision matrix in cases where the disease state and test result have two results as positive/negative:

New Diagnostic test	Disease Status Reference Test (Gold Standard) Results	
	Disease +	*Disease -*
Disease +	**a** True positive	**b** False positive
Disease -	**c** False negative	**d** True negative

Sensitivity or Specificity? Which measure is more beneficial?

Sensitivity measures how often a test correctly generates a positive result for people who have the condition that's being tested for (also known as the "true positive" rate). A test that's highly sensitive will flag almost everyone who has the disease and not generate many false-negative results.

      (Example: a test with 90% sensitivity will correctly return a positive result for 90% of people who have the disease, but will return a negative result — a false-negative — for 10% of the people who have the disease and should have tested positive.)

Specificity measures a test's ability to correctly generate a *negative* result for people who *don't* have the condition that's being tested for (also known as the "true negative" rate). A high-specificity test will correctly rule out almost everyone who *doesn't* have the disease and won't generate many false-positive results.

      (Example: a test with 90% specificity will correctly return a negative result for 90% of people who don't have the disease, but will return a positive result — a false-positive — for 10% of the people who don't have the disease and should have tested negative.)