

Healthcare Information & Decision Equation: **Information → Decision → Action → Outcome**
Is the diagnostic test accurate → Is it useful → Is it usable?

Quick Assessment:

The goal of diagnostic test is to identify individuals who could potentially benefit from other interventions (Cochrane Handbook). Important considerations in diagnostic testing include the following:

Net Benefit

- Does the new test provide improved accuracy and predictive value over existing tests?
- Will adoption lead to improved clinically meaningful outcomes?
- Do benefits outweigh harms?

Measures of Test Function (aka Estimates of Test Performance)

What are the accuracy and predictive capabilities of the test (from 2 x 2 table)?

Test Result	Disease	
	Present	Absent
+	a True Positives	b False Positives
-	c False Negatives	d True Negatives

Sensitivity (proportion of true positives) = $a/a+c$

Specificity (proportion of true negatives) = $d/b+d$

Practical usefulness is limited because these measures are dependent upon people known to have or not have the disease.

+Predictive Value (chance of having disease if test is positive) = $a/a+b$

- Predictive Value (chance of not having disease if test is negative) = $d/c+d$

More practical for use in patients in whom disease is unknown.

Likelihood Ratios (change from pretest to post test odds): The likelihood ratio combines information from sensitivity and specificity and indicates **how much the odds of disease change based on a positive or a negative result**. It is used together with the pre-test odds, which can be derived from prevalence information of the disease found in the study or by clinical judgment. By multiplying the pre-test odds by the likelihood ratio the post-test odds can be calculated:

+Likelihood Ratio (+LR) (positive test) = $\text{sens}/1-\text{spec}$

-Likelihood Ratio (-LR) (negative test) = $1-\text{sens}/\text{spec}$

Heavily dependent upon judgment and risky to apply unless pre-test odds are uncertain (~50 percent or less).

General Considerations

- Diagnostic testing is based on use of intermediate outcomes which raises possibility that test may not truly result in clinical significance.
- Although observational studies are acceptable for accuracy, RCTs are needed to demonstrate benefits for people exposed to testing.
- Typically there are trade-offs between the paired test function values. For example, increased specificity often comes at the cost of decreased sensitivity.
- Values of statistics from 2 x 2 table are likely to vary with different populations. Disease prevalence, for example, affects predictive value.
- Frequently there is no single, accurate test for diagnosis. For example the diagnosis of rheumatoid arthritis involves history, physical exam plus laboratory testing.
- Frequently there is a clinical need to choose a less accurate method due to cost or risk (e.g., chest x-ray vs lung bx).

Critical Appraisal Considerations

1. Was the index test compared to a reasonable gold standard (reference) test?
2. Were the tests compared together sufficiently close in time to prevent a change in condition to affect test results?
3. Did the study include an appropriate population?
4. Was the reference test applied to all patients, or a random sample of patients, with and without the disease?
5. Were assessors blinded to the results of the comparison test?
6. Does the new test find the same spectrum of disease as the reference test?
7. Were the number of withdrawals and indeterminate tests acceptable?
8. Was assessment blind?