DIAGNOSIS WORKSHEET

Adapted from Evidence-Based Medicine: How to practice and teach EBM: Third edition

Citation:

Are the results of this diagnostic study valid?

1. Was there an independent, blind comparison with a reference ("gold") standard of diagnosis? • Is reference standard used acceptable? • Is the test part of the reference standard test? • Is there a blind comparison with the reference standard test?	
2. Did the patient sample include an appropriate spectrum of patients to whom the diagnostic test will be applied in clinical practice? • How is the distribution of disease severity? • How is the distribution of competing diseases?	
3. Was the reference standard applied regardless of the diagnostic test result? • Were both reference standard and test applied to all patients?	
4. Was the test (or cluster of tests) validated in a second, independent group of patients? • Be considered for clusters of tests of clinical prediction rules	
5. Overall, are the results of the study valid?	

WHAT WERE THE RESULTS?

Are the valid results of this diagnostic study important?

SAMPLE CALCULATIONS

		Target disorder (iron deficiency anemia)		Totals
		Present	**Absent**	
Diagnostic test result (serum ferritin)	**Positive (< 65 mmol/L)**	**731 a**	**270 b**	**1001 a+b**
	Negative (≥ 65 mmol/L)	**78 c**	**1500 d**	**1578 c+d**
Totals		**809 a+c**	**1770 b+d**	**2579 a+b+c+d**

Sensitivity = a/(a+c) = 731/809 = 90%
Specificity = d/(b+d) = 1500/1770 = 85%

Likelihood ratio for a positive test result = LR+ = sens/(1-spec) = 90%/15% = 6
Likelihood ratio for a negative test result = LR - = (1-sens)/spec = 10%/85% = 0.12
Positive Predictive Value = a/(a+b) = 731/1001 = 73%
Negative Predictive Value = d/(c+d) = 1500/1578 = 95%

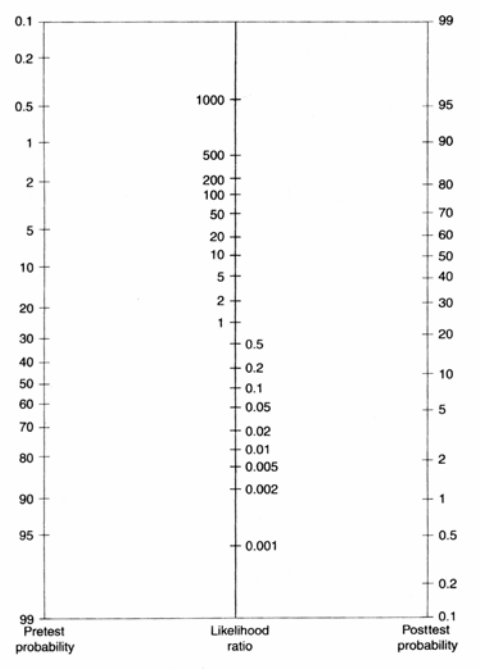
Pre-test probability (prevalence) = (a+c)/(a+b+c+d) = 809/2579 = 32%
Pre-test odds = prevalence/(1-prevalence) = 31%/69% = 0.45
Post-test odds = pre-test odds × LR+ = 0.45*6 = 2.7
Post-test probability = post-test odds/(post-test odds +1) = 2.7/3.7 = 0.73 = 73%

Positive Predictive Value = Post-test probability (for positive test result)
Negative Predictive Value = 1 - Post-test probability (for negative test result)

YOUR CALCULATIONS

		Target disorder		Totals
		Present	**Absent**	
Diagnostic test result	**Positive**	**a**	**b**	**a+b**
	Negative	**c**	**d**	**c+d**
Totals		**a+c**	**b+d**	**a+b+c+d**

Normogram



Sensitivity = a/(a+c) =
Specificity = d/(b+d) =
Likelihood ratio for a positive test result = LR+ = sens/(1-spec) =
Likelihood ratio for a negative test result = LR – = (1-sens)/spec =

Positive Predictive Value = a/(a+b) =
Negative Predictive Value = d/(c+d) =

Pre-test probability (prevalence) = (a+c)/(a+b+c+d) =
Pre-test odds = prevalence/(1-prevalence) =
Post-test odds = pre-test odds × LR+ =
Post-test probability = post-test odds/(post-test odds +1) =

Can you apply this valid, important evidence about a diagnostic test in caring for your patient?

1. Is the diagnostic test available, affordable, accurate, and precise in your setting?
 	
• Were the methods for performing the test described in sufficient detail to permit replication?
  o Preparation of patient?
  o Performance of test?
  o Analysis and interpretation of results?
• Will the reproducibility of the test result and its interpretation be satisfactory in my setting?
  • Reader skill and experience
  • Quality of equipment.	

2. Are the results applicable to my patients?
 	
• Are the study patients similar to your own?
  o Do your patient's characteristics approximate the inclusion/exclusion criteria for the study?
  o Similar distribution of disease severity?
  o Similar distribution of competing diseases?
  o Compelling reasons why the results should not be applied?	

3. Can you generate a clinically sensible estimate of your patient's pre-test probability? • From personal experience, prevalence statistics, practice databases, or primary studies. • Is it unlikely that the disease possibilities or probabilities have changed since the evidence was gathered?	

4. Will the resulting post-test probabilities affect your management and help your patient?
• Could it move you across a test–treatment threshold?
  • Treatment threshold:
  o What is the probability of disease above which you would recommend treatment? (There is no right or wrong answer to this question since it is a value judgment).
  • Test threshold:
  o What is the probability of disease below which you would end diagnostic testing? (Another value judgments)
• Would the consequences of the test help your patient?
  o Information from test will lead to change of management beneficial to patient?
  o Is target disorder dangerous if left undiagnosed?
  o Is test risk acceptable?
  o Does effective treatment exist?	

Additional notes: