CRITICAL APPRAISAL OF DIAGNOSTIC STUDY

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Are the results valid?

R – Was the diagnostic test evaluated in a Representative spectrum of patients (like those in whom it would be used in practice)?	
What is best?	Where do I find the information?
It is ideal if the diagnostic test is applied to the full spectrum of patients - those with mild, severe, early and late cases of the target disorder. It is also best if the patients are randomly selected or consecutive admissions so that selection bias is minimized.	The ***Methods*** section should tell you how patients were enrolled and whether they were randomly selected or consecutive admissions. It should also tell you where patients came from and whether they are likely to be representative of the patients in whom the test is to be used.

A – Was the reference standard ascertained regardless of the index test result?	
What is best?	Where do I find the information?
Ideally both the index test and the reference standard should be carried out on all patients in the study. In some situations where the reference standard is invasive or expensive there may be reservations about subjecting patients with a negative index test result (and thus a low probability of disease) to the reference standard. An alternative reference standard is to follow-up people for an appropriate period of time (dependent on disease in question) to see if they are truly negative.	The ***Methods*** section should indicate whether or not the reference standard was applied to all patients or if an alternative reference standard (e.g., follow-up) was applied to those who tested negative on the index test.

Mbo – Was there an independent, blind comparison between the index test and an appropriate reference ('gold') standard of diagnosis?

What is best?	Where do I find the information?
First the reference standard should be appropriate - as close to the 'truth' as possible. Sometimes there may not be a single reference test that is suitable and a combination of tests may be used to indicate the presence of disease. Second, the reference standard and the index test being assessed should be applied to each patient independently and blindly. Those who interpreted the results of one test should not be aware of the results of the other test.	The ***Methods*** section should have a description of the reference standard used and if you are unsure of whether or not this is an appropriate reference standard you may need to do some background searching in the area. The ***Methods*** section should also describe who conducted the two tests and whether each was conducted independently and blinded to the results of the other.

Are the results important?

Are test characteristics presented?

There are two types of results commonly reported in diagnostic test studies. One concerns the accuracy of the test and is reflected in the sensitivity and specificity. The other concerns how the test performs in the population being tested and is reflected in predictive values (also called post-test probabilities).

The first step is to draw a ***2 x 2 table*** as shown below. Try to fill all blanks by information the article telling you and simple calculation.

		Presence of disease Reference standard		Totals
		+ve	–ve	
Index test	+ve	a	b	a+b
	–ve	c	d	c+d
Totals		a+c	b+d	a+b+c+d

- **Sensitivity, Sn= a/(a+c)**
- **Specificity, Sp= d/(b+d)**
- **Likelihood ratio for +ve test, LR^+ = Sn/(1–Sp)= (a/b) × (b+d)/(a+c)**
- **Likelihood ratio for –ve test, LR^- = (1–Sn)/Sp= (c/d) × (b+d)/(a+c)**

➢ Usually independent of population *but with exceptions*

		Presence of disease Reference standard		Totals
		+ve	–ve	
Index test	+ve	a	b	a+b
	–ve	c	d	c+d
Totals		a+c	b+d	a+b+c+d

- **Pre-test probability (prevalence, *p)* = (a'+c')/(a'+b'+c'+d')** = (a+c)/(a+b+c+d)
- **Pre-test odds = *p*/(1–*p*)** = (a+c)/(b+d)

➢ Varied with population

		Presence of disease Reference standard		Totals
		+ve	–ve	
Index test	+ve	a	b	a+b
	–ve	c	d	c+d
Totals		a+c	b+d	a+b+c+d

- **Positive predictive value, PPV = $p \times Sn/\{p \times Sn + (1-p) \times (1-Sp)\}$** = a/(a+b)
- **Negative predictive value, NPV = $(1-p) \times Sp/\{p \times (1-Sn)+(1-p) \times Sp\}$** = d/(c+d)

➢ Depend on population and test

		Presence of disease Reference standard		Totals
		+ve	-ve	
Index test	+ve	a	b	a+b
	–ve	c	d	c+d
Totals		a+c	b+d	a+b+c+d

- Index test +ve
  - **Post-test odds = pre-test odds** $\times$ **LR$^+$ = {*p*/(1-*p*)}** $\times$ **{Sn/(1-Sp)}** = a/b
  - **Post-test probability = post-test odds/(post-test odds+1)** = ***p*** $\times$ **Sn / {*p*** $\times$ **Sn + (1-*p*)** $\times$ **(1-Sp)} = PPV** = a/(a+b)
- Index test –ve
  - **Post-test odds = pre-test odds** $\times$ **LR$^-$ = {*p*/(1-*p*)}** $\times$ **{(1-Sn)/Sp}** = c/d
  - **Post-test probability= post-test odds/(post-test odds+1)** = ***p*** $\times$ **(1-Sn) / {*p*** $\times$ **(1-Sn) + (1-*p*)** $\times$ **Sp} = 1 - NPV** = c/(c+d)

➢ Depended on population and test

Before Application

Were the methods for performing the test described in sufficient detail to permit replication?	
What is best?	Where do I find the information?
The article should have sufficient description of the test to allow its replication and also interpretation of the results.	The ***Methods*** section should describe the test in detail.

APPLICATION OF DIAGNOSTIC STUDY

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Can you apply this valid, important evidence in caring for your patient?

Is the diagnostic test available, affordable, accurate, and precise in your setting?
The index test should be available and affordable to make it practical in your setting; accurate and precise enough in your setting to achieve the impact size of reviewed literature.

Can you generate a clinically sensible estimate of your patient's pre-test probability?	
Are the study patients similar to your own? Only **bold type** portion of the aforementioned formula was applicable.	Ideally they should be similar to carry our the results. Prevalence of your patient should be obtained from personal experience, epidemiologic statistics, practice databases, or primary studies to calculate the 'true' post-test probability. You can usually adopt the LR from evidence reviewed *but with some exceptions* (e.g., those of mammography from Western countries).
Is it unlikely that the disease possibilities or probabilities have changed since the evidence was gathered?	Be careful when you gather evidence. Some information will lost during this process. Review each individual evidence before make a clinical bottom line.

Will the resulting post-test probabilities affect your management and help your patient?	
Could it move you across a test-treatment threshold?	If the validity and impact size of the evidence were acceptable and compatible with your clinical judgment, to change medical behavior was possible.
Would your patient be a willing partner in carrying it out?	Patients' preferences should be considered before carrying out medical decisions.

Would the consequences of the test help your patient?

The evidence was expected to answer your PICO questions specifically. The evidence supported our confidence in choosing best decision in our practice.

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THANK YOU VERY MUCH

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