

Jeffrey S. Barkin, MD

1. Use of a 2 x 2 grid

- a) **sensitivity/specificity**
- b) **True/False Positives and True/False Negatives**
- c) **Errors Type 1 and 2**
- d) **Alpha, beta**
- e) **P values**

2. Risk

- a) **Relative Risk**
- b) **Absolute Risk**
- c) **Treatment Effects – NNT/NNH**

3. Likelihood of Being Helped or Harmed

4. Effect Size

Comparing the conclusions drawn from a clinical trial with the true state of affairs

Sensitivity = TP = $\frac{W}{W+Y}$

Specificity = TN = $\frac{Z}{X+Z}$

		The true state of affairs			
		Drug A is better than drug B		Drug A is no better than drug B	
Conclusion drawn from a clinical trial	Drug A is better than drug B	TP Correct	$\begin{matrix} w & x \\ y & z \end{matrix}$	Error	FP
	Drug A is no better than drug B	Error	$\begin{matrix} w & x \\ y & z \end{matrix}$	Correct	TN

TP = true-positive; FP = false-positive; FN = false-negative; TN = true-negative.

i. Naming the erroneous conclusions from a clinical trial

		The true state of affairs			
		Drug A is better than drug B		Drug A is no better than drug B	
Conclusion drawn from a clinical trial	Drug A is better than drug B	TP Correct ($1 - \beta = \text{power}$)	$\begin{matrix} w & x \\ y & z \end{matrix}$	Type I error (risk of making this error = $\alpha = \text{the P value!}$)	FP
	Drug A is no better than drug B	Type II error (risk of making this error = β)	$\begin{matrix} w & x \\ y & z \end{matrix}$	Correct	TN

Patient status at entry	Adverse event rates		Relative risk reduction RRR
	Placebo P	Active A	$\frac{P - A}{P} = \text{RRR}$

Patient status at entry	Adverse events			Absolute risk reduction ARR
	Placebo P	Active A	RRR	$P - A = \text{ARR}$
Prior target organ damage	.22	.08	64%	$.22 - .08 = .14$
No prior organ damage	.10	.04	60%	$.10 - .04 = .06$

Adverse events				Number needed to treat NNT
Placebo P	Active A	RRR	ARR	$\frac{1}{\text{ARR}} = \text{NNT}$

Likelihood of Being Helped or Harmed

$$\text{LHH} = \text{NNH}/\text{NNT}$$

A high LHH and low NNT is desirable in making a treatment choice. It has been suggested that an LHH of > 1 may help determine use of a treatment.

Effect Size

Effect size is a direct measure of how strong (or weak) the effect of a given treatment is on outcome. It numerically compares the two groups under study.

Effect size of 0 – 0.3 shows little to no effect;

Effect size of 0.3 to 0.5 shows small effect;

Effect size of 0.5 – 0.8 shows moderate effect;

Effect size $= > 0.8$ shows strong effect.

Bibliography

Evidence Based Medicine How to Practice and Teach EBM 3rd edition
Straus SE, Richardson W S, Glasziou P, Haynes RB Elsevier press 2005

Clinical Epidemiology A Basic Science for Clinical Medicine 2nd edition
Sackett DL, Haynes RB, Guyatt GH, Tugwell P Little, Brown and
Company 1991

Clinical Epidemiology The Essentials 4th edition Fletcher RW, Fletcher
SW Lippincott Williams & Wilkins 2005

Interpreting the Medical Literature 5th edition Geyhlbach SH McGraw
Hill 2006