

Appraisal Worksheet Etiology (Harm)

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Citation:

Are the results of the study valid?

1.	Were there clearly defined groups of patients, similar in all important ways other than exposure to the treatment or other cause?	
2.	Were treatments/exposures and clinical outcomes measured in the same ways in both groups (was the assessment of outcomes either objective or blinded to exposure)?	
3.	Was the follow-up of study patients sufficiently long and complete?	
4.	Do the results satisfy some "diagnostic tests for causation"?	
5.	Is it clear that the exposure preceded the onset of the outcome?	
6.	Is there a dose–response gradient?	
7.	Is there positive evidence from a "dechallenge- rechallenge" study?	
8.	Is the association consistent from study to study?	
9.	Does the association make biological sense?	

Are the results of this study important?

1.	What is the magnitude of the association between the exposure and outcome?	
2.	What is the precision of the estimate of the association between exposure and outcome?	

Adapted from: Straus, SE, et al. 2005. *Evidence-Based Medicine: How to Practice and Teach EBM*, 3rd edition. Edinburgh: Elsevier.

		Adverse outcome		Totals
		Present (case)	Absent (control)	
Exposed to the	Yes (cohort)	A	В	A+B
treatment	No (cohort)	С	D	C+D
Totals		A+C	B+D	A+B+C+D

In a randomized trial or cohort study: relative risk (RR) \rightarrow [A/(A+B)]/[C/(C+D)] In a case–control study: odds ratio/relative odds (OR) \rightarrow AD/BC

Can this study be applied to your patient?

1.	Do the results apply to our patient?	
2.	Is our patient so different from those in the study that its results don't apply?	
3.	What are our patient's risks of the adverse event?	
	To calculate the NNH (number needed to treat to harm one) for any odds ratio (OR) and our patient's expected event rate for this adverse event if they were not exposed to this treatment (PEER):	
	$NNH = \frac{PEER(OR-1)+1}{PEER(OR-1)\times(1-PEER)}$	
4.	What are our patient's preferences, concerns and expectations from this treatment?	
5.	What alternative treatments are available?	