

HARM/AETIOLOGY WORKSHEET

Citation:

Are the results of this harm study valid?	
Were there clearly defined groups of patients, similar in all important ways other than exposure to the treatment or other cause?	
Were treatment exposures and clinical outcomes measured the same ways in both groups (e.g., was the assessment of outcomes either objective (e.g., death) or blinded to exposure)?	
Was the follow-up of study patients complete and long enough?	
Do the results satisfy some "diagnostic tests for causation"? <ul style="list-style-type: none"> • Is it clear that the exposure preceded the onset of the outcome? • Is there a dose-response gradient? • Is there positive evidence from a "dechallenge-rechallenge" study? • Is the association consistent from study to study? • Does the association make biological sense? 	

Are the valid results from this harm study important?

How is the magnitude and precision of the association between the exposure and outcome?	See below.
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		Adverse Outcome		Totals
		Present (Case)	Absent (Control)	
Exposed to the Treatment	Yes (Cohort)	a	b	a+b
	No (Cohort)	c	d	c+d
	Totals	a+c	b+d	a+b+c+d

In a randomized trial or cohort study: Relative Risk = $RR = [a/(a+b)]/[c/(c+d)]$

In a case-control study: Odds Ratio (or Relative Odds) = $OR = ad/bc$

For a cohort study the NNH (number needed to harm) =

$$1 / |(CER - EER)|$$

where CER = control group event rate and EER = exposed group event rate

In this study:

		Absolute 'Risk Reduction' ARR	Number Needed to Harm NNH
CER	EER	$ (CER - EER) $	$1/ARR$

Should these valid, potentially important results of change the treatment of your patient?	
Is our patient so different from those in the study that its results cannot apply?	
What are our patient's risks of the adverse outcome? What is our patient's potential benefit from the therapy?	
What are our patient's preferences, concerns and expectations from this treatment?	
What alternative treatments are available?	

Additional Notes: