

HARM 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 treatments/exposures and clinical outcomes measured in the same ways in both groups (was the assessment of outcomes either objective or blinded to exposure)?	
Was the follow-up of study patients complete and long enough?	
Do the results satisfy some “diagnostic tests for causation”?	
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?

		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 randomised trial or cohort study: relative risk = $RR = \{a/(a+b)\} / \{c/(c+d)\}$

In a case-control study: odds ratio (or relative odds) = $OR = ad/bc$