

CRITICAL REVIEW FORM: HARM II**Citation:**

Pasternak et al: Ondansetron in Pregnancy and Risk of Adverse Fetal Outcomes. *N Engl J Med* 2013; 368: 814-23. DOI: 10.1056/NEJMoa1211035

Guide		Comments
I	Are the results valid?	
A	Did experimental and control groups begin the study with a similar prognosis?	
1	Did the investigators demonstrate similarity with respect to all known determinants of outcome; did they adjust for differences in the analysis?	
2	For case-control studies: Were exposed patients equally likely to be identified in the two groups?	
B	Did experimental and control groups retain a similar prognosis after the study started?	
3	Were the outcomes and exposures measured in the same way in the groups being compared?	
4	Was the follow-up sufficiently complete?	
II	What are the results?*	
1	How strong is the association between exposure outcomes?	
2	How precise is the estimate of risk?	

III	How can I apply the results to my patient care?	
1	Were the study patients similar to my patient?	
2	Was the duration of follow-up adequate?	
3	Should I consider my patient to be at risk for adverse outcomes?	