Harm/Etiology

1. Is this evidence about harm valid?
    a. Were there clearly defined groups of patients, similar in all important ways other than exposure to the treatment or other cause?
    b. 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?)
    c. Was the follow-up of the study patients sufficiently long (for the outcome to occur) and complete?
    d. Do the results of the harm study fulfill some of the diagnostic tests for causation?
        i. Is it clear that the exposure preceded the onset of the outcome?
        ii. Is there a dose-response gradient?
        iii. Is there any positive evidence from a "dechallenge-rechallenge" study?
        iv. Is the association consistent from study to study?
        v. Does the association make biological sense?
2. Is this valid evidence about harm important?

	Adverse Outcome		Totals
	Present (Case)	Absent (Controls)	
Exposed to Treatment (RCT or cohort)	a	b	a+b
Not Exposed to Treatment (RCT or cohort)	c	d	c+d
Totals	a+c	b+d	a+b+c+d

   a. In a randomized trial or cohort study:
      i. RR = [a/(a+b)]/[c/(c+d)]
   b. Is a case-control study:
      i. Relative odds = ad/bc
   c. What is the magnitude of the association between the exposure and outcome?
   d. What is the precision of the estimate of the association between the exposure and the outcome?
3. To convert odds ratio (or relative odds) to a NNH:
   a. NNH = 1 + [PEER*(OR-1)]/(1-PEER)*(PEER)*(OR-1)
4. Can we apply the valid, important results of this harm study to our patient?
   a. Is our patient so different from those included in the study that its results cannot apply?
   b. What is our patient's risk of benefit and harm from the agent?
   c. What are our patient's preferences, concerns, and expectations from this treatment?
   d. What alternative treatments are available?