Learning Objectives:
1. Consider the different types of methodology that are used to look at questions of Harm.
2. Understand the strengths (if there are any) and weaknesses of a case-control study.
3. Discuss what you do when there is no controlled trial evidence for a clinical question. How do you apply this information to patient care?

Case Scenario:
The patient is a 15-year-old young man with severe acne. He presents after trying and failing over the counter and other prescribed therapies requesting Accutane. He states that his best friend tried this and it made his acne completely go away. He is very stressed over social issues at school. This school year has been very difficult for him and he feels that his acne has played a role in some of his social isolation. He is doing more poorly in school and his parents report that he is increasingly emotionally labile and irritable. When you ask his mother if she suspects that he is depressed, she answers, “no more than any other 15 year old boy on the planet.”

You write a prescription for Accutane and the teenager happily leaves your clinic. Your medical student asks you whether there is an association between the use of Accutane and depression and suicide. You say that you are aware that there is a warning pertaining to this. You send your medical student to try to find an answer.

The PICO clinical question is defined as:

In Patients with Acne, is there a relationship between the Intervention Accutane (isotretinoin) and Outcome of depression or suicide?

Being rather a competitive individual, you decide to ‘race’ your medical student. You are going to look this up on UpToDate to see what it says about this relationship and she is going to do a quick medline search. Much to your chagrin, you return at the exact same moment with the same citation. She, however has pulled the full text pdf article off the web, whereas you only have the abstract from UpToDate.

Each of you found the following article:

Wysowski, DK, Pitts, M, Beitz, J


At first glance, you can see that this is not a controlled trial, but in your assessment it is the best data available on this question. Please review the

Duke Program on Teaching Evidence-Based Practice
HARM Sample Packet #3: Case Series/Report
A great case of lousy evidence. A look at a case series from the FDA.

paper and decide whether the evidence presented should make you change your thinking about the patient you saw this morning.