

## HARM II

### **Objectives:**

To learn how to apply to clinical practice the results of papers that assesses issues of harm. This includes:

1. Determining whether the results of the study are valid.
2. Understanding the magnitude and precision of the effect
3. Deciding on how to apply the results to your clinical practice

### **Assignment:**

1. Read the attached scenario.
2. Read the attached guidelines for reading articles concerning harm.
3. Critically appraise the attached article using the accompanying worksheet.
4. Describe how you would address the question raised in the scenario taking into account your review of the article.

### **Clinical Scenario:**

One of your longtime patients presents for a clinic visit. She is a healthy 30-year old female who is pregnant for a second time. Her initial pregnancy was uncomplicated. She is at 12 weeks gestation based on her last menstrual period, and presents for symptoms of nausea and vomiting. You diagnose her with nausea and vomiting of pregnancy (NVP) and discuss the condition, interventions and expected course with her. Even after this patient-centered discussion, your patient seems anxious. She mentions that she had been taking ondansetron that was previously prescribed to her for a gastroenteritis illness. This dramatically improved the nausea and vomiting episodes she had been experiencing. However, she has seen advertisements by malpractice attorneys questioning the fetal safety of ondansetron in pregnancy.

You dig into the far reaches of your mind to remember clinical pharmacology and physiology. You recall ondansetron is a selective 5-HT<sub>3</sub> receptor antagonist, and that the FDA lists it as pregnancy category B (animal studies have failed to show risk, no adequate human trials).

You pursue the topic further by referencing the clinical literature. A PubMed Clinical Queries search is performed with the search terms: ONDANSETRON, PREGNANCY, SAFETY, using a Therapy/Broad filter. 16 citations are identified. You identify a recent New England Journal of Medicine study to answer the question.

### **Attachments:**

- 1) Pasternak B, et al. "Ondansetron in pregnancy and risk of adverse fetal outcomes". *The New England Journal of Medicine*. 2013. 368(9):814-823
- 2) Guyatt G, Meade MO, Cook DJ, Rennie D, Editors, *The Users' Guides to the Medical Literature, A Manual for Evidence-Based Clinical Practice*. 3rd Edition. McGraw-Hill 2015, Chapter 14, pp 301-314
- 3) Critical appraisal worksheet