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**Case Study #1 – Cardiovascular: Vioxx**

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1. **What is Vioxx and why was it withdrawn?**

Vioxx is the commercial name of nonsteroidal anti-inflammatory drug rofecoxib, which was approved by the Food and Drug Administration (FDA) in 1999 and widely promoted as a pain reliever [ref]. However, since then, studies and analyses confirmed that Vioxx raised the risk of developing a confirmed adjudicated thrombotic cardiovascular event, including myocardial infarction, unstable angina, cardiac thrombus, etc., compared placebo [ref]. Thus, Vioxx was withdrawn from the market in 2004.

1. **What types health care data would Vioxx researchers need to determine its effect on the risk of myocardial infarction?  Why? How did you get to this conclusion? How could this data be used to determine its effect on the risk of myocardial infarction?**

to determine its effect on the risk of myocardial infarction, Our search yielded 2 major randomized trials, the Vioxx Gastrointestinal Outcomes Research Study (VIGOR; 8076 patients) and the Celecoxib Long-term Arthritis Safety Study (CLASS; 8059 patients), as well as 2 smaller trials with approximately 1000 patients each. The results from VIGOR showed that the relative risk of developing a confirmed adjudicated thrombotic cardiovascular event (myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks) with rofecoxib treatment compared with naproxen was 2.38 (95% confidence interval, 1.39-4.00; P = .002). There was no significant difference in cardiovascular event (myocardial infarction, stroke, and death) rates between celecoxib and nonsteroidal anti-inflammatory agents in CLASS. The annualized myocardial infarction rates for COX-2 inhibitors in both VIGOR and CLASS were significantly higher than that in the placebo group of a recent meta-analysis of 23 407 patients in primary prevention trials (0.52%): 0.74% with rofecoxib (P = .04 compared with the placebo group of the meta-analysis) and 0.80% with celecoxib (P = .02 compared with the placebo group of the meta-analysis).

1. **How could Vioxx researchers go about getting these data for a patient like JM? What are the barriers to getting this type of data (privacy, lack of data standards, etc)?**
2. **What types of technology or applications could be used to help inform providers about the emerging risks of medications they prescribe?**
3. **Do some research on either two privacy or medication solutions that are currently available and share them, with a brief description and a link with more details.**