Case Study 1 – Cardiovascular: Vioxx

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 *What is Vioxx and why was it withdrawn?*

Vioxx, manufactured by Merck & Co, is a COX-2 selective non-steroidal and anti-inflammatory drug (NSAID) similar to ibuprofen. Vioxx can only be obtained through a prescription in order to relieve pain due to arthritis, acute pain or painful menstrual cycles [1]. Vioxx was considered a good alternative for patients requiring high doses of NSAIDs since Vioxx reduces the risk of bleeding in the stomach, common for other NSAIDs.

Vioxx was withdrawn voluntarily by Merck Corporation in 2004 after an independent study stopped short after 18-month when the participants showed high occurrence of heart attacks and strokes. While the FDA did begin an investigation, Merck pulled the drug from the market before an FDA ruling was determined, thus Vioxx was not mandated to be removed by FDA. Furthermore, it appears Vioxx may be making a market comeback for some special edge-case patients which may have no alternatives and where the benefits may outweigh the drawbacks [2].

2. *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?*

In order to determine Vioxx effect on Myocardial Infarctions, the researchers would need information regarding both the drug (Vioxx) and the observed effects (Myocardial Infarctions).

The drug information required by the researchers would require at least the dosage, the duration, the prescription and all other prescribed and non-prescribed pharmaceuticals being taken by the patient. There is always a possibility of adverse effects for patients taking multiple drugs, as drug interaction can be unpredictable and harder to determine than single drug effects on their own. Thus, it is important for the researchers to gather the data about other drugs, both prescribed and over-the-counter, from the patient in order to determine, or rule out, any links between Vioxx and other drugs as having negative side effects.

From any patient who received a myocardial infarction, while taking Vioxx, the researchers would require: prior medical history to show any history of heart problems, EKG report to show heart muscle activity, Chest X-Ray to show cause of infarction, blood test for report of released chemicals by breaking heart muscles, Blood-Oxygen Saturation, Blood Pressure and Pulse rate. This information would be required in order

to determine the exact cause and method of heart failure. If a patient has a history of heart failure, or if all heart failure cases had different causes the conclusion may point to an undermined result. However, if a significant number of heart failure occurrences have a similar cause, it may point to a link to the drug.

3. 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)?

In order to run a medical study of Vioxx effects on Myocardial Infarction occurrences, the researches would have to attain proper documentation from both, the institutional Review Board (IRB) and the patients undergoing the study.

An IRB is a consort of medical professionals which review the proposed study in order to minimize risk to participants wellbeing during the study. The proposal would have to address patient safety, privacy and informational security as well as listing all known risks to patient health. Additionally, if the study is receiving any government sponsorship, the FDA will have to be notified and an approval for the study would have to be attained from the FDA as well [3].

The patient would have to be provided a consent form in order to enroll in the study, and the ability to stop participation at any moment. Additionally, the patient would be provided a self-reported questionnaire to gather data about other drugs and life-style in order to rule out other causes for heart-failure. Furthermore, the researchers may need consent for release of medical information, in order to gather the hospital data of any patients which do undergo myocardial infarction occurrences [3]. The researchers, throughout the study and afterwards, must protect patient information at all costs to ensure privacy and anonymity for any results which may become public.

4. What types of technology or applications could be used to help inform providers about the emerging risks of medications they prescribe?

An application can be developed which provide a subscription-based model for doctors and physicians where those medical professionals can subscribe to alerts on information about specific drugs, drug types, or drug families. The user can also set an alert level where they are alerted on relevant FDA information if the drug is recalled, investigated, or simply if any new research trials have been approved.

This kind of application would allow the FDA to notify U.S. physicians, doctors, pharmacists, or other medical professionals to receive alerts based on their preferences and most prescribed drug choices. Doctors can track new studies which applied for approval from the FDA, or only be alerted to the latest FDA findings on existing drugs. The subscriber approach would allow for maximum flexibility for the doctors, without overburdening with irrelevant information.

5. 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.

One Vioxx alternative undergoing research is that of blocking an enzyme called microsomal prostaglandin E synthase. Waht the researchers discovered, in genetically modified mice, is that blocking this enzyme produced the same pain managing and digestive benefits as Vioxx without the myocardical side effects associated with it. By using s selective inhibitor for this enzyme, an alternative the Vioxx may be synthesized which provides all the benefits, without the risks of Vioxx [5].

Another Vioxx alternative is a combination of well known drugs which appear to alleviate pain while reducing heart and intestinal risk. Through a combination of non-COX-2 pain reliever drug and a gastro-protective medicine, the effect of Vioxx on pain relief can be maintained while the GI tract is safe from the pain-relief drug. This combination minimizes the effects on the heart as well. An added benefit of this approach is the fact that the two drugs have long histories of use and provide a much better risk/reward ratio than any new drug which may enter the market with limited research and unknown side-effects [6].

References

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