**Assessment of the Consistency of Pregnancy Labeling Across Therapeutic Classes**

**Introduction**

The publication was seen as a miracle drug in terms of its ability to treat morning sickness and nausea in pregnant women and became infamous as a result of the teratogenic effects such as phocomelia. As a result of the problem with thalidomide during the 1950s and 1960s, the implications of taking certain medications during pregnancy were brought to light.

In 2003, it was reported that approximately 4.1 million births occurred in the United States alone. It has also been reported that approximately 50% of the pregnancies that occur in the United States are planned. Pregnant women often have to take medication during the term of their pregnancy for chronic conditions such as diabetes, asthma, hypertension, and depression or for pregnancy induced conditions such as nausea. The lack of treatment can be dangerous to not only the mother but to her fetus as well. In one study, the most commonly prescribed drugs not including vitamins were analgesics, blood-glucose regulators, and drugs prescribed for anxiety. It is estimated that women take an average of 3-6 drugs while they are pregnant.

Due to an increasing trend in women having children later on in their lifetime the potential use of medication during pregnancy will most likely increase.

The perception of what drugs are considered safe is not only for pregnant women but also prescribers in variable and is further complicated by the limited number of clinical studies in pregnant women. Some women hold misperceptions about the serious risks when taking certain medications while pregnant and may and end up terminating pregnancies as a result of these perceptions. These misconceptions may also be further exacerbated since many clinicians do not receive specialized training in prescribing medications for pregnant women. In order to make better recommendations and understand potential risks for prescribing medications during pregnancy, physicians often depend on the information provided in a drug label. In 1979, the A, B, C, D, and X category classification that is based on adverse events and potential benefits of a particular drug was implemented in the United States in order to standardize pregnancy labeling (as shown in the table below). The current category system has been criticized for being too simplistic because of an imprecise classification hierarchy of risk.

Pregnant women often depend on the pregnancy labeling to provide them with necessary information to properly use and prescribe medications during pregnancy.

**Human Studies were defined as postmarketing or epidemiological studies reported in the label. Human Adverse Event reports were not limited to studies but also included reports that were mentioned in the label. None of the drugs were classified as pregnancy category A.**

Seven of the eight drugs in the Angiotensin II Receptor Antagonist therapeutic class fell into more than one pregnancy category (C/D) depending on the trimester.

**Conclusion & Future Works**

The study focused on drugs marketed in the US and their FDA-approved labels. It will be useful for future research to examine the pregnancy labeling of drugs marketed outside the United States.

**References**


**Tables**

- **FDA Pregnancy Risk Categories**
- **Top 20 therapeutic classes**
- **Consistency of Pregnancy Information within Pregnancy Categories**

**Diagrams**

- **Presentation of Adverse Events Drugs in the Top 20 Therapeutic Categories**
- **Nursing Recommendations for the Top 20 Therapeutic Categories**