

Pregnancy Medications

Jessica C. Leek; Hasan Arif.

Author Information and Affiliations

Authors

Jessica C. Leek¹; Hasan Arif².

Affiliations

¹ Midwestern University - AZCOM

² Thomas Jefferson University Hospital

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Continuing Education Activity

The treatment of common medical conditions during pregnancy frequently becomes complicated due to the potential effects that medications can have on fetal growth and development. While the use of many medications during pregnancy has drastically declined in recent years as new information about their risks surfaces, the use of others has increased as recent research has reassured their safety. While the utilization of drugs continues to evolve as more knowledge is gained regarding their safety and efficacy, information regarding the risks of medication use during pregnancy and lactation remains relatively limited due to barriers to clinical research. This activity reviews the evaluation medications used during pregnancy and highlights the role of the interprofessional team in making appropriate medication selection.

Objectives:

- Identify the issues of concern in regards to the ethical and legal implications of medication use in pregnancy.
- Describe the issues of concern in regards to medication use in unplanned pregnancies.
- Outline the clinical significance of use of drugs with risk categories of A, B, C, D, and X.
- Summarize the evaluation of medications used during pregnancy and outline the role of the interprofessional team in making appropriate medication selection.

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Introduction

The treatment of common medical conditions during pregnancy frequently becomes complicated due to the potential effects that medications can have on fetal growth and development. While the use of many medications during pregnancy has drastically declined in recent years as new information about their risks surfaces, the use of others has increased as recent research has reassured their safety. While the utilization of drugs continues to evolve as more knowledge is gained regarding their safety and efficacy, information regarding the risks of medication use during pregnancy and lactation remains relatively limited due to barriers to clinical research.[1]

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Issues of Concern

Studies aimed at understanding the effects of medication use during pregnancy bring various ethical and legal considerations to light. Pregnancy itself is a therapeutic dilemma, as the health risks and benefits to both the mother and the developing fetus must be considered. The core ethical principles can be argued in support of both parties. On the one hand, autonomy and beneficence imply that pregnant women should have the capacity to decide whether or not they would like to participate in clinical trials which could have potential therapeutic benefits, given they understand the risks and possible consequences. However, the principle of nonmaleficence can also be argued with the goal of protecting the developing fetus from potential harm. In instances where the purpose of the clinical research is something other than meeting the health needs of the mother, it is generally accepted that the risk to the fetus must be small. It becomes difficult to establish clear definitions as to what constitutes a therapeutic need and what is considered minimal risk. As a result of the vagueness surrounding this issue, pregnant women are often excluded from participation in drug trials, dampening clinicians' knowledge regarding the safety and efficacy of medication use during pregnancy. It thus perpetuates a cycle where patients and physicians strive to know more about the impact of medication use but are unable to obtain adequate information in order to make definitive, evidence-based clinical decisions.[5][6][7]

Another important clinical consideration is the fact that approximately half of all pregnancies in the United States are unplanned. As a result, many women take medications before they are even aware that they are pregnant, making it difficult to pinpoint when any adverse effects occurred and whether or not a specific medication may have contributed to maldevelopment or fetal loss.

Clinical Significance

The clinical significance of medication use during pregnancy is related to the therapeutic benefit for the expectant mother and the potential adverse effects on fetal growth and development. While the detrimental effects of various classes of medications on fetal development have been well documented, a significant proportion of available drugs have not been studied extensively enough to know whether or not there are definitive links to fetal harm. This leads to ambiguity in what can and cannot be safely taken during pregnancy, leading patients to avoid medications that have not been definitively demonstrated to be safe.[8][9][10]

Although the long-standing FDA pregnancy risk categories A, B, C, D, and X provide a guideline for the relative safety of medications, more detailed information is necessary in order to fully understand the efficacy and safety of medication use during pregnancy and lactation. In 2009, the FDA conducted a study to understand better how healthcare providers make treatment decisions regarding their pregnant patients. Researchers found that physicians relied more heavily on the FDA pregnancy categories than they did on any other available resource, leading the FDA to replace the overly simplistic pregnancy risk categories with a new system entitled the Pregnancy and Lactation Labeling Rule (PLLR). The intent was to devise a system that would minimize misinformation and would better assist physicians and their patients in making evidence-based clinical decisions. However, despite the FDA's recent overhaul of the existing classification system, many physicians continue to use the traditionally accepted pregnancy categories.

Previous Pregnancy-Risk Categories

These have been in use since 1979 and are defined as follows:

- *Category A:* No risk in human studies (studies in pregnant women have not demonstrated a risk to the fetus during the first trimester).
- *Category B:* No risk in animal studies (there are no adequate studies in humans, but animal studies did not demonstrate a risk to the fetus).
- *Category C:* Risk cannot be ruled out. There are no satisfactory studies in pregnant women, but animal studies demonstrated a risk to the fetus; potential benefits of the drug may outweigh the risks.
- *Category D:* Evidence of risk (studies in pregnant women have demonstrated a risk to the fetus; potential benefits of the drug may outweigh the risks).
- *Category X:* Contraindicated (studies in pregnant women have demonstrated a risk to the fetus, and/or human or animal studies have shown fetal abnormalities; risks of the drug outweigh the potential benefits).

The PLLR, which officially took effect in 2015, aims to provide patients and healthcare providers with relevant information that allows for informed clinical interpretation and medical management. In addition, the new rule seeks to avoid misinformation by mandating that prescription drug labels be updated as information regarding medications becomes outdated.

New Pregnancy-Risk Categories

These include subset categories.

- *Pregnancy (including labor and delivery)*
 1. Pregnancy exposure registry
 2. Risk summary
 3. Clinical considerations
 4. Data
- *Lactation*
 1. Risk summary
 2. Clinical considerations
 3. Data
- *Females and Males of Reproductive Potential*
 1. Pregnancy testing
 2. Contraception
 3. Infertility

The pregnancy subsection contains a registry that collects data on pregnant women and notes any potential risks of medication use to the mother and the developing fetus. The lactation subsection contains information regarding the timing of breastfeeding, excretion of drugs in breastmilk, and risks to the infant. Finally, the females and males of reproductive potential subsection include

relevant clinical information and recommendations about fertility, miscarriage, contraception, and pregnancy testing. Although the FDA's PLLR labeling system is a vast improvement from the previous categories, there are still rarely "yes" or "no" answers in regards to the safety of medications. Therapeutic drug use during pregnancy continues to require extensive risk-benefit analysis, and clinical decisions often vary on a case-by-case basis given the health needs of the expectant mother.

Other Issues

There are times when a medication may be needed for a pregnant or nursing mother. Before starting any medication, it is wise to consult with a pharmacist and an obstetrician. During the later stages of pregnancy one may have many options but during the early stage of pregnancy, the potential to cause harm with medications is enormous. So if possible, avoid medications in pregnant women.

Enhancing Healthcare Team Outcomes

By far the majority of medications are not recommended during pregnancy. All healthcare workers who prescribe medications have a responsibility in educating the pregnant patient not to take any medication, prescription or over the counter, without first speaking to the provider. While the thalidomide tragedy took place nearly four decades ago, it was one of the first to reveal the tragic side effects that drugs can have on the fetus. Nurses and pharmacists should always speak to pregnant patients about medications and their potential harm to the fetus. For pregnant patients who are ill, the first consideration should always be one that does not involve a drug. Of course, there are many situations where there is no choice but to use a medication, but the onus is on the healthcare provider to weigh the benefits and the risks; consulting a pharmacist is prudent in such instances if there is any doubt. When medications are used, the nursing staff should be extra vigilant regarding the potential for adverse effects to the fetus and the mother and report all concerns to the prescriber. This is one situation where an interprofessional team approach is critical for improved patient outcomes. [Level 5]

Review Questions

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