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SAFETY INFORMATION COMMUNICATION

MEDICATIONS DURING PREGNANCY

1. Introduction

Various medications are used during pregnancy despite a lack of data in this unique setting. Treatment and dosing strategies are based on standard adult doses, even though dosing, safety, and efficacy were determined in healthy, mostly male, individuals. In some instances, treatment may be withheld from pregnant women due to concerns about maternal or fetal safety. Additionally, over two-thirds of women take prescription drugs during pregnancy, with treatment and dosing strategies based on data from healthy male volunteers and nonpregnant women, with little consideration for the complex physiology of pregnancy and its unique disease states.

Pregnancy is a unique period in a woman's life. Many changes occur in her body that can affect how medications work. During pregnancy, a woman's gastric pH increases, and gastric motility decreases, which can influence the rate and extent of medication absorption. Maternal plasma volume also increases, leading to changes in the volume of distribution. Additionally, higher levels of progesterone and estradiol may impact the hepatic metabolism of certain medications. The glomerular filtration rate rises due to increased renal blood flow, which can affect the clearance of medications that are excreted by the kidneys. Despite these changes, the pharmacology of most medications remains largely unaffected, and dose adjustments are generally not necessary.

Similarly, variations in physiology can alter the pharmacokinetics or pharmacodynamics that determine drug dosing and effects. Therefore, detailed pharmacologic information is essential for adjusting treatment strategies during pregnancy. Understanding both pregnancy physiology and the gestation-specific pharmacology of different agents is crucial to providing effective treatment and minimizing maternal and fetal risks. Unfortunately, most drug studies have excluded pregnant women due to often mistaken concerns about fatal risks.

It is against this background that the Rwanda FDA communicates these important risks to healthcare professionals and pregnant women for the adoption of adequate risk minimization measures. And to educate healthcare professionals, pregnant women, and the general public on the risks of using certain medications during pregnancy and to promote safer alternatives.

2. *Description*

The placenta is an organ of exchange that allows the mother to transfer nutrients and medications to the fetus; therefore, medications given to pregnant women can potentially impact the developing fetus. The fetus is generally at the highest risk of developing teratogenic effects from medications during the first trimester, but this varies depending on the drug. The use of medications during pregnancy should be carefully evaluated to weigh the benefits and risks for both the mother and the fetus. After assessment, some medications may be used cautiously during certain trimesters and avoided in others. All efforts should be made to maximize the benefit-to-risk balance.

Drugs with low molecular weight, low maternal protein binding, low ionization, and high lipophilicity are more likely to cross the placenta and cause pharmacologic eeffects. The developing foetus's body systems are not mature; therefore, the fetus may lack the ability to metabolize medications, causing teratogenic effects.

3. *Information to Healthcare Professionals*

The potential teratogenic risk of medications is categorized by an A, B, C, D, X system.

- **Category A:** Controlled studies in women have failed to demonstrate a risk to the fetus in the first trimester, and there is no evidence of risk in later trimesters. The possibility of fetal harm appears remote. Medications in this class are considered safe to use in pregnancy. Examples of medications in this class are ***vitamins and levothyroxine.***
- **Category B:** Either animal-reproduction studies have not demonstrated a fetal risk, but there are no controlled studies in pregnant women, or animal studies have demonstrated risk to the fetus that was not confirmed in controlled studies in pregnant women in the first trimester, and there is no evidence of a risk in later trimesters. Medications in this class are generally considered safe. Examples of medications in this class are ***acetaminophen and amoxicillin.***
- **Category C:** Studies in animals have revealed adverse effects on the fetus, and there are no controlled studies in women, or studies in women and animals are not available. Drugs from this class can be given to pregnant women if the benefit to the mother outweighs the risk to the fetus. Examples of medications in this class are ***diltiazem and spironolactone.***
- **Category D:** Evidence of human fetal risk has been documented, but the benefits to the mother may be acceptable despite the risk to the fetus. Drugs in this class may be used in pregnancy if the benefits to the mother outweigh the risk to the fetus (i.e., a life-threatening situation or a serious disease for which safer medication cannot be used or is not efficacious). Examples of medications in this class are ***phenytoin and valproic acid.***
- **Category X:** Studies in animals or humans have demonstrated teratogenic effects. The risk to the fetus outweighs any potential benefit to the mother. Drugs in this category are contraindicated in pregnancy. Examples of medications in this class are ***thalidomide and warfarin.***

4. *Information for pregnant women*

- Do not self-medicate during pregnancy, even with over the counter (OTC) drugs, herbal products, or supplements.
- Always check with a healthcare professional before starting, continuing, or stopping any medication.
- Some medications may be essential for managing chronic conditions (e.g., hypertension, diabetes, asthma) and should not be stopped without medical advice.
- Some medications may cause birth defects (teratogenic effects) that may lead to miscarriage or preterm birth, affect fetal development or growth, or cause neonatal withdrawal or other complications after birth
- The first trimester (weeks 1–13) is the most sensitive period for fetal organ development, and medication exposure during this time can be particularly risky.
- Use medications known to be safe in pregnancy when alternatives are available.
- Keep an up-to-date list of all medications (including traditional or herbal products) and share it with your healthcare provider.
- Attend all prenatal visits to monitor the health of both mother and baby, especially when medications are being used.

- Immediately report any adverse effects or unusual symptoms to a healthcare provider.

5. ***List of medicinal products that are most likely to cause harm during pregnancy***
   - Antibiotics
   - Antiepileptic drugs (AEDs)
   - Cough and cold
   - Diabetes Mellitus
   - Analgesic
   - Immunization etc.

6. ***Reporting channel***

Patients and healthcare professionals are urged to report any suspected adverse drug event or reaction associated with pharmaceutical products, especially during pregnancy, to Rwanda FDA by using the online reporting tool (VigiMobile for medicines). This tool is available on the Rwanda FDA website at *https://vigiflow-eforms.who-umc.org/rw/adr,* or through the online reporting system (PViMS) accessible at *https://pvims.rwandafda.gov.rw/security/landing.*

Sincerely,

02-OCTOBER-2025

Prof. Emile BIENVENU
Director General

7. *References*

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