# Drug Prescribing and Global Comparison of Drug Categorization in Pregnancy

Satish Kumar Bassattikoppalu Puttegowda, Saniya Shaikh\*, Amarmani Shivapur, Sowjanya Annajappa

Department of Pharmacy, Practice, Sri Adichunchanagiri College of Pharmacy, B.G. Nagara, Mandya, Karnataka, INDIA.

#### **ABSTRACT**

Background: Prescribing drugs during pregnancy requires careful evaluation to ensure maternal health and fetal safety. Drug pharmacokinetics are altered during pregnancy, and certain medications pose teratogenic risks. Despite the critical importance of safe drug use in this population, inconsistencies exist in prescribing patterns and drug categorization frameworks globally. Objectives: This review evaluates drug prescribing patterns during pregnancy, comparing global drug categorization systems, and establishing the need for harmonization for better maternal and fetal outcomes. Materials and Methods: Literature from main regulatory quidelines, research articles, and global reports was reviewed systematically. Global practices' variations and gaps were analyzed comparatively by conducting a comparative analysis of categorization frameworks set forth by the U.S. FDA, EMA, and Australian TGA. Results: The review demonstrates that drug classification systems vary significantly by region, while risk estimates and classifications are inconsistent. Although off-label use is still prevalent since there is a dearth of pregnancy-specific data, prescribing patterns show a preference for critical drugs. The results highlight the necessity of unified regulatory strategies and stronger pharmacovigilance. Conclusion: Developing standardized drug categories requires international cooperation to improve evidence-based prescribing during pregnancy. Pregnant women can be treated effectively while minimizing potential risks with the help of improved regulatory guidance and comprehensive research into pharmacokinetics during pregnancy.

**Keywords:** Drug Prescribing Pattern, Pregnancy Risk Categories, Pregnancy Drug Categorization, Maternal-Fetal Safety.

#### **Correspondence:**

#### Mrs. Saniya Shaikh

2<sup>nd</sup> Year, M. Pharm, Department of Pharmacy Practice, Sri Adichunchanagiri College of Pharmacy, B.G. Nagara, Mandya-571448, Karnataka, INDIA. Email: saniyashaikhjaveed@gmail.com

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# **INTRODUCTION**

The most valuable time a woman experiences in her life is during pregnancy. It represents unique physiological changes that make it extremely difficult for doctors to manage the disease and choose the best course of treatment with drugs. Pregnancy-related drug therapy is always a specific concern because all drugs have the potential to harm the fetus. A prescription audit is a technique created specifically to document objectively to physicians how well their treatment complies with their own criteria. Therefore, prescription auditing is both a technique and a tool, and its use is both an art and a science.

According to the World Health Organization (WHO), "rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, at the lowest cost to them and their community." This definition really captures



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the basis of rational drug use: using the right drug, in the right dosage, at the right cost.<sup>3</sup> Due to the rising prevalence of chronic conditions in mothers, drug exposure during pregnancy is a phenomenon that is becoming more and more common. Drug transfer becomes more intense in the third trimester due to raised maternal and placental blood flow, reduced placental thickness, and increased surface area. Prescribers must consider the lives of both the mother and the fetus during pregnancy because the placental barrier is insufficient, allowing lipid-soluble and lipid-insoluble drugs to cross it.<sup>4</sup>

The usage of medicines during pregnancy has risen dramatically worldwide. According to some research studies, over 50% of expectant mothers use social drugs and prescription or over-the-counter medications at some point throughout their pregnancy. Drugs used to treat a condition or symptom are responsible for about 2-3% of all birth abnormalities. The use of medication during pregnancy has been a concern since the identification of birth abnormalities linked to the use of thalidomide in the early stages of pregnancy in 1960s.<sup>5</sup> Although birth defects affect 5% of infants who are checked at birth, their prevalence can reach 8%. Drugs are known to be responsible for around 1% of the possible external causal factor for teratogenic consequences.<sup>5,6</sup>

Prescription medication use during pregnancy should be handled with extreme caution because the fetus's physical and mental development is at risk. According to multiple studies carried out in developed countries where drug prescription is most commonly practiced, interventional treatments are necessary to ensure rational prescription throughout the early stages of pregnancy. Effective and sensible drug use must be guaranteed, and the medications must be safe in order to have the intended impact.<sup>1</sup> Facilitating rational drug use is the key objective of a study on drug prescribing patterns.7 Prescriptions must be prepared with the appropriate dosage for the appropriate diagnosis, correct information, and a reasonable price in order to be used logically. This is known as the RIGHT rule (right medicine, right patient, right dosage, and right cost).1 Without understanding how medications are prescribed and used, it might be difficult to start a conversation about rational use of drugs and suggest steps to enhance prescribing procedures.<sup>7</sup>

# DRUG PRESCRIBING PATTERN DURING PREGNANCY

Prescribing during pregnancy is guided by the principle of balancing maternal benefit against fetal risk. Commonly used drug classes include:

# **Vitamins and Supplements**

Prenatal vitamins, particularly folic acid and iron supplements are routinely prescribed during pregnancy to prevent maternal anemia and neural tube defects in the fetus. Folic acid supplementation during first trimester is critical for fetal neural development, iron supports increased maternal blood volume. Calcium and vitamin D are also recommended to support maternal and fetal bone health.<sup>8</sup>

### **Analgesics**

Paracetamol remains the preferred choice and first line treatment for fever and pain relief during pregnancy. However, several studies indicates that prolonged or high-dose use has been associated with potential neuro-developmental outcomes in children. More severe pain can be treated by adding codeine or other opioid medication. It is not recommended to use NSAIDs throughout the third trimester; instead, other analgesics should be explored during the first trimester.<sup>9,10</sup>

# **Antibiotics**

Infections during pregnancy, such as urinary tract infections and respiratory infections, are treated with antibiotics that have a proven safety profile. Penicillins, cephalosporins, and macrolides are the antibiotics of choice due to their minimal teratogenic risk. However, tetracyclines and fluoroquinolones are avoided due to risks of skeletal abnormalities and cartilage damage, respectively.<sup>11,12</sup>

## **Antihypertensives**

Gestational hypertension and preeclampsia are significant concerns during pregnancy. Methyldopa, labetalol, and nifedipine are considered safe options. ACE inhibitors and angiotensin receptor blockers are contraindicated due to risks of fetal renal dysgenesis and other complications.<sup>13</sup>

#### **Antiemetics**

Nausea and vomiting, particularly in the first trimester, are managed using antiemetics such as pyridoxine-doxylamine combinations are widely prescribed and are supported by evidence for safety and efficacy. <sup>14</sup> Ondansetron is used in severe cases, while some studies have raised concerns about the use of ondansetron and prescribed cautiously due to concerns about potential teratogenic effects. <sup>15</sup>

### **Antidiabetics**

Insulin remains the drug of choice for gestational diabetes as it does not cross the placenta. Oral hypoglycemics, including metformin, have been used more frequently, but they are typically given under strict medical supervision.<sup>16</sup>

A recent observational study in India reported that over 75% of pregnant women received multiple drug prescriptions, with 85% including iron and folic acid, and 32% receiving antibiotics. However, inappropriate prescribing was noted in 12% of cases, highlighting the importance of audit-based interventions.<sup>1</sup>

# DRUG CATEGORIZATION SYSTEMS: A GLOBAL PERSPECTIVE

Drug categorization systems provide a structured framework for assessing and communicating the safety of medications during pregnancy. These methods help medical professionals make evidence-based prescribing decisions by classifying medications according to their potential risks to the health of the mother and growing fetus. This section explores major categorization frameworks used globally, highlights their differences, and examines the challenges associated with harmonization.

# FDA PREGNANCY RISK CATEGORIES: (UNITED STATES)

In 1979, the United States Food and Drug Administration (FDA) established a procedure for determining a pharmaceutical drug's risk of pregnancy. After 1983, all drugs were categorized using the five pregnancy risk classifications (A, B, C, D, and X). Based on available information from both humans and animals, it indicates the degree of caution that should be used to each prescription and illustrates how the drug affects the fetus. However, the risk factors that have been assigned might sometimes be difficult to grasp because they may not necessarily reflect the most recent studies.<sup>17</sup>

Since 1979, these have been in use, and are defined as follows:

**Category A:** Human studies have shown no risk (pregnant women's studies have not shown a harm to the fetus during their first trimester) (e.g., folic acid and levothyroxine).

**Category B:** Animal studies showed no risk (no sufficient human research exists, but animal research did not show fetal harm) (e.g., amoxicillin).

**Category C:** Risk cannot be ruled out. Animal studies showed a risk to the fetus, but there are no adequate studies in pregnant women. The drug's possible advantages might exceed the risks (e.g., fluconazole).

Category D: Evidence of risk (studies in pregnant women have shown a risk to the fetus; potential benefits of the drug may outweigh the risks) (e.g., lithium).

**Category X:** Contraindicated (drugs have more risks than benefits; studies in pregnant women have showed fetal abnormalities<sup>18</sup> (e.g., isotretinoin).

In the past, the FDA has authorized the labelling of medications with pregnancy categories A, B, C, D, and X, even though these labels did not ultimately prove effective. As a result, it created three further subsections that must be listed on medication labels and give information about the drug in a uniform manner in compliance with FDA regulations (known as the Pregnancy and Lactation Labelling (Drugs) Final Rule [PLLR]).<sup>19,20</sup>

# **Pregnancy**

It comprises information about the medication's safety during pregnancy, including whether or not the recommended medication is safe for the health of the mother and fetus. Additionally, it contains information about a particular registry that keeps track of data demonstrating the beneficial or detrimental impact of various medications on the health of expectant mothers.

# Lactation

In includes the information about drug use during the lactation or breastfeeding period, it also discusses whether and how much of a drug is present in breast milk, as well as how the drug may impact the health of the child.

# The reproductive potential of males and females

It covers topics such as infertility, pregnancy testing, and contraception in relation to the medications.

More importantly, the third rule will not apply to over-the-counter or non-prescription medications, and the pregnancy and breastfeeding will be covered under the additional three subheadings (Risk Summary, Data, and Clinical considerations). 18,20

# TGA PREGNANCY CATEGORIES: (AUSTRALIA)

The Australian Therapeutic Goods Administration (TGA) employs a letter-based categorization system similar to the FDA but with the significant differences. This pregnancy risk classification system for medicines is based on the safety information of the drug. The categories are: A, B1-B3, C, D, X.

**Category A:** pharmaceutical substances that have been given to a significant proportion of pregnant women and women of reproductive age without showing any increase in the prevalence of congenital defects or other negative effects on the growing fetus (e.g., paracetamol).

**Category B:** Based on animal studies, it is categorized into B1, B2, and B3.

**B1:** No evidence of a higher incidence of fetal harm has been found in animal studies (e.g., COVID-19 vaccine).

**B2:** The existing data does not indicate a higher incidence of fetal harm; however, animal studies are either insufficient or nonexistent (e.g., amphotericin B).

**B3:** Studies on animals has revealed a higher incidence of fetal injury, the relevance of which is uncertain in humans (e.g., clobetasone butyrate).

**Category C:** Drugs that have had or may be suspected of having negative effects on a human fetus or neonate without generating abnormalities because of their pharmacological activities (e.g., corticosteroids).

**Category D:** Drugs that have caused, are suspected of causing, or may be predicted to cause irreparable damage or a higher incidence of fetal abnormalities in humans. Adverse pharmacological effects are another possibility for these medications (e.g., warfarin).

**Category X:** Drugs that should not be taken during pregnancy or when pregnancy is possible due to the significant risk of lasting harm to the fetus<sup>21</sup> (e.g., isotretinoin).

# **EMA GUIDANCE: (EUROPIAN UNION)**

The European Medicines Agency (EMA) does not follow a fixed categorization system like the Old FDA or Australian TGA classifications. Instead, drug safety during pregnancy is evaluated and detailed in the Summary of Product Characteristics (SmPC) for each medication. Based on evidence from preclinical research, post-marketing surveillance, and clinical trials, the SmPC offers thorough information about a drug's usage during pregnancy and lactation.

These include:

**Animal and Human Data:** Results from teratogenicity studies in animals and observational studies in humans.

**Fetal Risk Information:** Information on adverse outcomes and recommendations for use during pregnancy.

**Risk Management Strategies:** Recommendations for clinicians on how to reduce the risk.

The EMA's approach is drug-specific and takes into account the different risks and benefits of drugs. However, reliance on narrative descriptions may result in variability in interpretation among healthcare providers.<sup>22</sup>

# WHO ESSENTIAL MEDICINES FOR PREGNANCY: (GLOBAL)

The World Health Organization (WHO) has a dedicated list of core medicines for pregnancy to be used as a guideline for resource-limited settings. This list emphasizes:

**Safety and Efficacy:** Only medicines with established safety profiles are included.

**Accessibility:** Aimed at ensuring access to necessary drugs for common conditions during pregnancy.

**Risk Mitigation:** Provides guidelines for appropriate use to minimize risks (WHO, 2021).

While the WHO list is invaluable for low-resource settings, it lacks the comprehensive risk stratification seen in other systems<sup>23</sup> (See Table 1 for comparison of categorization systems). Each system reflects regional healthcare priorities, and their divergence presents challenges for global harmonization. While the FDA

and EMA emphasize individualized data, the TGA offers rapid categorization, and the WHO list prioritizes accessibility.<sup>22,23</sup>

# **CHALLENGES IN GLOBAL HARMONIZATION**

Several challenges impede the global harmonization of drug categorization systems during pregnancy:

- **1. Unreliable Risk Terminology:** Terms such as "fetal risk" and "teratogenicity" may be defined and interpreted differently across systems, leads to ambiguity.
- **2. Lack of Universal Standards:** Global harmonization is challenging since each system reflects its regional interests.
- **3. Data Gaps:** Accurate classification across all systems is hampered by a lack of pregnancy-specific data. Inconsistent regional classification results from a lack of study on medication pharmacokinetics during pregnancy.
- **4. Off-label drug use** is still prevalent because there aren't enough clinical trials specifically for pregnant women.<sup>12</sup>
- **5. Clinicians' interpretation:** Inconsistent prescribing practices may result from differences in providers' comprehension and implementation of categorization standards.
- **6. Differing Regulatory Priorities:** Depending on the healthcare system and demographic demands in their area, agencies give varying priority to different facets of medication safety and accessibility. For example, the FDA and EMA concentrate on comprehensive risk data for developed healthcare systems,

Table 1: Comparison of drug categorization systems, regulatory frameworks, and risk assessment approaches.

Aspect	FDA (US)	TGA (Australia)	EMA (EU)	WHO (GLOBAL)
Framework type and Approach	Letter Categories (A, B, C, D and X), now PLLR (narrative descriptions) include risk summaries, clinical considerations, and available data to inform prescribers. 17,18	Letter categories (A, B (B <sub>1</sub> B <sub>2</sub> B <sub>3</sub> ), C, D and X) Includes B subcategories for more nuanced classifications. <sup>21</sup>	Narrative descriptions (SmPC) include results from animal and human studies, adverse effect details, and recommendations for use during pregnancy. <sup>22</sup>	Essential medicines list for pregnancy, prioritizing in resource settings. <sup>23</sup>
Human vs. Animal data	Old system: Separate PLLR: Complex. 19,20	Emphasis on animal data. <sup>21</sup>	Relies on both human and animal data. <sup>22</sup>	Assessed for safety using both. <sup>23</sup>
Granularity	Moderate	High	High	Low
Focus	Risk benefit assessment	Risk Stratification	Individual drug data	Safety in resource setting
Ease of Use	Old: Moderate	High	Moderate	High
	Narrative: Complex	(letter categories)	(requires interpretation)	(focused list)
Regional Relevance	Developed markets	Adapted for Australia	Developed markets	Low-resource settings
Granularity of Risk Data	High	Moderate	High	Low
Integration of Real-World Data	Moderate	Low	Moderate	Low

Table 2: Strengths, weaknesses and limitations of the drug categorization systems.

Aspect	FDA (US)	TGA (Australia)	EMA (EU)	WHO (GLOBAL)
Strengths	Provides detailed risk assessments for both pregnancy and lactation.	Clear, concise categorization aids in rapid decision-making.	Offers drug-specific, detailed guidance.	Highly relevant for resource settings.
	Encourages personalized prescribing decisions by presenting comprehensive data.	Subcategories within "B" offer better differentiation of risk levels.	Emphasizes clinical decision-making based on individualized risk-benefit analyses.	Focuses on safety and efficacy.
Weaknesses	Narrative format can be challenging for quick reference, especially in busy clinical settings.	Like the FDA's letter system, it may oversimplify complex risk assessments.	Lack of a unified risk categorization system can lead to variability in interpretation among providers.	Does not provide detailed risk stratification or comprehensive data on newer drugs.
	Limited real-world data integration due to reliance on clinical trials and post-marketing studies.	Limited emphasis on detailed narrative descriptions.		
Limitations	Category system: Overs implification (previously) and Lacks context or specific information about the type of risk PPLR: Complex and may require more time to interpret. <sup>19,20</sup>	Limited data for some drugs Relies heavily on animal studies, which may not always predict human outcomes. <sup>21</sup>	Lack of unified risk categorization system Variability in interpretation among providers. <sup>22</sup>	It is invaluable for low-resource settings, it lacks the comprehensive risk stratification Broad and general. <sup>23</sup>

whereas the WHO EML prioritizes availability and affordability (WHO, 2021).  $^{23}$ 

**7. Ethical and Cultural Aspects:** Different cultural perspectives on risk have an impact on how medications are prescribed and how policies are developed (Table 2 summarizes the strengths and limitations of each system).

# FUTURE DIRECTIONS AND RECOMMENDATIONS

- **1. Global Standardization of Categories:** Development of a global categorization system that incorporates the advantages of current models (e.g., simple risk categories with extensive narratives).
- **2. Enhanced Pharmacovigilance:** Using observational studies and registries to better gather information on medication safety during pregnancy.
- **3. Enhanced Data Sharing and Research:** Global initiatives to communicate pharmacovigilance data among regulatory bodies and expand clinical research on pregnant populations.
- **4. Education for Providers:** Training programs that instruct health care providers in how to accurately analyze and use global drug safety information. Arming healthcare professionals with the skills needed to effectively comprehend and implement recommendations.

**5. Global Cooperation**: urging regulatory agencies to cooperate in sharing knowledge and to harmonize practices.<sup>24</sup>

#### CONCLUSION

Medication prescribing in pregnancy is a fine balance between maternal health needs and fetal safety. This review underscores the need for robust drug categorization systems that can help healthcare providers make the right decisions. Drug categorization systems vary considerably around the world, with different approaches having different strengths and limitations. The FDA's PLLR and EMA's narrative approach prioritize comprehensive data but require a lot of interpretation by clinicians. The TGA's letter-based system and WHO's essential medicines list are practical solutions but can oversimplify risk assessments. Healthcare providers need to be knowledgeable about the subtleties of regional drug classification systems and prepared to synthesize available data to make patient-centered decisions. Continued education and access to up-to-date guidelines are critical for minimizing risks associated with drug use during pregnancy. Suggestions for Policy and Research: Harmonization of Policies, Extension of Research, and Pharmacovigilance systems. These enable international medication classification systems to decrease disparities and increase safety outcomes. The shortages in data need encouraging ethical protection of the participation of pregnant women in clinical research and improvement in the identification of adverse drug reactions and the provision

of information for regulatory updates as two advantages in strengthening international networks of pharmacovigilance.

As medical science progresses, the door will open for more dependable and consistent drug prescription standards through the inclusion of scientific evidence, innovative research techniques, and international cooperation. A fundamental component of maternal and fetal healthcare will continue to be ensuring the safe use of medications during pregnancy, requiring constant commitment by healthcare professionals, researchers, and policymakers.

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#### **CONFLICT OF INTEREST**

The authors declare that there is no conflict of interest.

### **ABBREVIATIONS**

WHO: World Health Organization; FDA: Food and Drug Administration; PPLR: Pregnancy and Lactation Labelling Rule; TGA: Therapeutic Goods Administration; EMA: European Medicines Agency; SmPC: Summary of Product Characteristics.

#### **SUMMARY**

This review evaluates global variations in drug categorization systems during pregnancy, focusing on the FDA, TGA, EMA, and WHO frameworks. It highlights the importance of harmonizing risk classification to ensure safer maternal and fetal outcomes. The prevalence of off-label prescribing and insufficient pregnancy-specific data are critical concerns. Comparative analysis reveals strengths and limitations in each regulatory system, emphasizing the need for a unified, evidence-based approach. Enhanced pharmacovigilance, research collaboration, and clinician education are recommended for improving drug safety during pregnancy.

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