WISELEAF SCIENTIFIC VENTURES

COMPREHENSIVE PREGNANCY CARE: AN EVIDENCE-BASED MULTIDISCIPLINARY APPROACH

Chapter 5: Safe Medication Use during Pregnancy: Pharmaceutical Care and Drug Safety

Dr. Richa Srivastava[1], Ojaswi Goswami[2]

1. Professor, Department of Pharmaceutics, Ambekeshwar Group Of Institutions, Kathwara, Maa Chandrika Devi Road, Bakshi Talab, Lucknow, UP, India.
2. Student, Department of Faculty of Pharmacy, Veer Madho Singh Bhandari Uttarakhand Technical University, Sudhowala, Dehradun, Uttarakhand, India.

Mail id - lilllyricha@gmail.com

Abstract

Pregnancy is a special physiological process during which important maternal changes can influence the pharmacokinetics of drugs, their therapeutic effects, and safety. Proper use of medications is necessary to treat illnesses in the mother and pregnancy-related problems while avoiding possible adverse effects on the developing fetus. The present chapter deals with the principles of safe drug use during pregnancy and describes the physiological features affecting the absorption, distribution, metabolism, and elimination of drugs, the transfer of drugs from the mother to the fetus, teratogenicity, the periods of critical fetal development, and risk-benefit analysis. It explains the methods of appropriate prescription and nonprescription drug use, self-medication, drug-drug and drug-food interactions, and the use of nutritional supplements. Furthermore, the chapter underscores the significance of pharmacovigilance, pregnancy exposure surveillance, and adverse drug reaction documentation in enhancing the validity of the evidences for medication safety. Specific roles played by pharmacists in the process of medication review, reconciliation, patient counseling, adherence support, assessment of interactions, and collaboration with other specialists are analyzed. Moreover, some new approaches are mentioned that may contribute to ensuring personalized pharmacotherapy such as precision medicine, pharmacogenomics, artificial intelligence, digital healthcare, and real-world evidence. To summarize, pharmacotherapy based on using evidence, taking into account patients' needs and involving various specialists is of great importance for improving the process of treating women and solving the issues referring to the protection of fetuses and infants.

Keywords

Pregnancy; Medication Safety; Pharmaceutical Care; Pharmacovigilance; Teratogenicity

5.1 Introduction

Pregnancy is an extraordinary physical condition characterized by numerous physiological, anatomical and metabolic changes affecting maternal health and fetal development. During pregnancy, women may need some medications to cope with both acute and chronic illnesses, pregnancy-related health problems, as well as some ailments, infections, and deficiencies. However, the choice of medications should be taken seriously since all drugs taken by a pregnant woman may enter their bloodstream and reach the fetus.[1] Therefore, it is necessary to find equilibrium between benefits for the mother and harm to the fetus. Multiple factors influence the safety of drug utilization in pregnant women, such as a kind of drug, dose used, duration of treatment course, drug administration route, gestational age, and maternal characteristics, as well as the degree of the drug transfer through placenta. It should be noted that physiological changes occurring during pregnancy may change drug absorption, distribution, metabolism, and excretion, which in turn might affect drug activity and therapeutic effect. Furthermore, the developing fetus may present higher risk of certain side effects of the drug during specific developmental periods. Therefore, it is impossible to categorize goods as simply “safe” or “unsafe”; each case should be considered for its particular clinical situation and gathered evidence. [2]

Apart from prescription drugs, pregnant women can also take OTC products, vitamins and nutritional supplements, herbal remedies, and traditional medicines without notifying their doctors. [3] Although medicines might prove to be beneficial, their undesired consequences arise due to self-medication, false assumption that “natural” remedies are safe, and risks of excessive dosing, contamination, low-quality products, and herb-drug interaction. Consequently, pharmaceutical care plays a vital role in the advancement of rational and secure use of medications by pregnant women. Pharmacists can make significant contributions by conducting medication history reviews, identifying possible drug-related issues, assessing potential drug interactions, giving patient education, observing adverse drug reactions, and encouraging drug compliance. Collaborative efforts of pharmacists, doctors, nurses, and other health care practitioners may lead to individualized treatment and reduced risks of drug-related complications.[4]

It can be said that it is crucial to use pharmacovigilance in pregnancy because the data about the safety of many medicines are limited as it is difficult to conduct clinical experiments on pregnant women. Continuous monitoring and reporting of adverse drug reactions and pregnancy exposure can help in finding safety signals and improving the information on maternal pharmacotherapy. Thus, drug use during pregnancy should be based on evidence and objectives of patient-centered care. The current chapter will describe the principles of drug therapy in pregnancy, aspects of drug safety, prescription and over-the-counter medicines, drug

interactions, dietary supplements, herbal and Ayurveda medicines, pharmacovigilance, and the role of pharmacists.

5.2 Principles of Drug Therapy during Pregnancy

Pregnancy brings about challenges to the possibility of correct treatment to the mother, because of the effort to lessen all types of risks to the fetus from drugs that could potentially cause problems to the development of the fetus and the newborn. The fact is that pregnancy involves various physiological and biochemical changes, which might have an influence on the pharmacokinetics and pharmacodynamics of drugs. This situation is even more complicated by the fact that some drugs can pass the placental barrier and have the influence on the fetus. Therefore, in this situation, the treatment has to be provided following some medical indications, the period of gestation, the available safety information and the evaluation of the risks and benefits. The choice of the drug is not based only on the possible risks of fetal exposure. It is possible that if a mother is unsuccessful in receiving proper treatment for her disease she can experience serious risks both for her and baby. Some conditions like hypertension, diabetes, epilepsy, asthma, infections and mental disorders may need to be treated with medicines during pregnancy.

5.2.1 Physiological and Pharmacokinetic Changes

As shown in (Fig 1) the effects of pregnancy on the cardiovascular, gastrointestinal, renal, hepatic, and endocrine systems can influence the pharmacokinetics of the drugs in the body. Both the blood volume and the body water content increase resulting in the larger distribution volume for the drugs.[5] The composition of the tissues is also likely to change and thus the distribution of the drugs may be altered. With the decrease in albumin concentration in the plasma during pregnancy the amount of drugs bound to the plasma proteins is increased. An increase is also observed in the cardiac output, renal blood flow, and the glomerular filtration which usually leads to the higher drug clearance by the kidneys. At the same time, the changes in the liver can either increase or decrease drug metabolism. Changes in the gastrointestinal tract during pregnancy will also affect drug absorption. [6]

5.2.2 Maternal–Fetal Drug Transfer

The placenta is the connecting link between the circulation system of the mother and the fetus, making available the possibility of transfer of substances. Various different factors can influence the transfer of substances through the placenta. Due to that various substances can be transferred through the placenta, but the concentration of such substances can be different. The factors influencing the process of drugs getting through the placenta can be divided into several categories, such as the size of a molecule, lipid solubility, capacity to ionize, protein binding level, the amount of substance in the plasma and transport mechanisms in the placenta. Moreover, those factors influence not only the transfer of drugs through the placenta but also

the level of exposure to the drug throughout the period of therapy. It is worth noting that the transfer of the drug doesn't mean it is dangerous for the fetus. The danger of exposure of the fetus to certain medicine depends on the properties of the drug taken. [7]

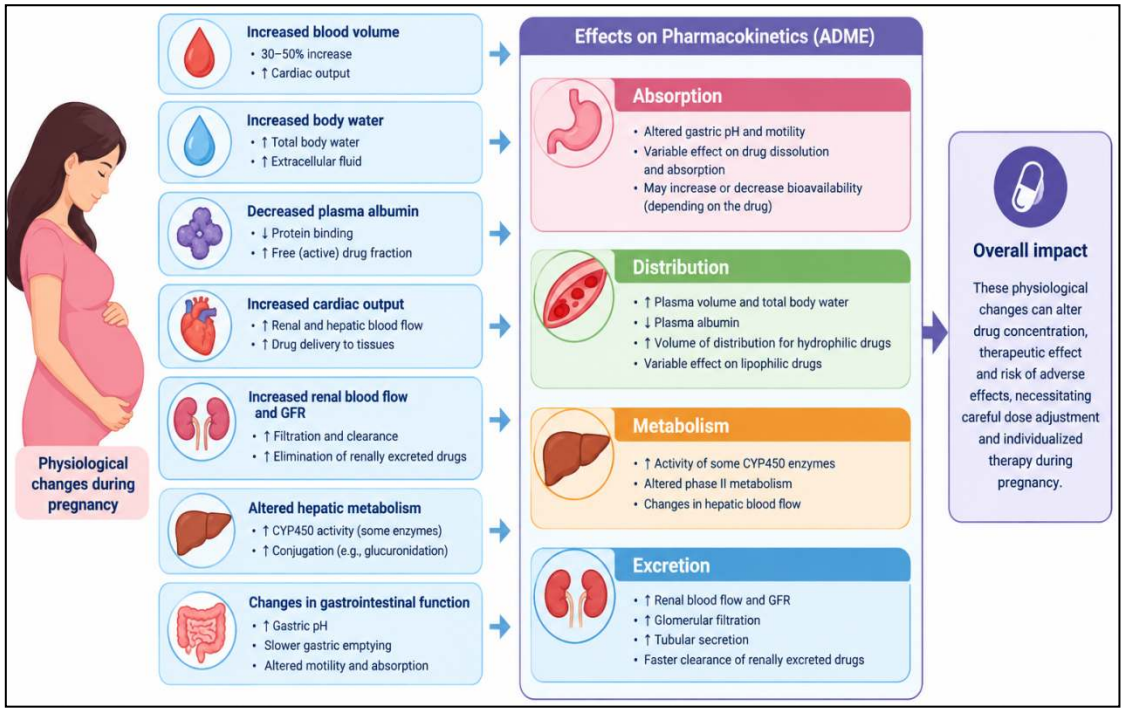


Fig 1: Physiological changes in pregnancy and their effects on pharmacokinetics

5.2.3 Risk–Benefit Assessment

As shown in (Fig 2) Risk/benefit evaluation is an essential merit of pharmacotherapy for pregnant women. It is essential for healthcare professionals to understand the possible positive outcome for mothers and the risk for fetuses and newborns. Moreover, the possible consequences of not using treatment or using it badly should also be expressed in the result of this assessment. The factors to be taken into account during the assessment are the severity of the disease, gestational stage, dosing and duration of therapy, data on fetal impact, adverse effects in mothers, alternative treatment, and the level of evidence on safety. Choice of treatment should be based on the most effective medication but taking into account the one with reliable documentation on safety in pregnancy. In any case treatment should be individual rather than relying on the assumption that all medications are absolutely safe or unsafe in pregnancy.

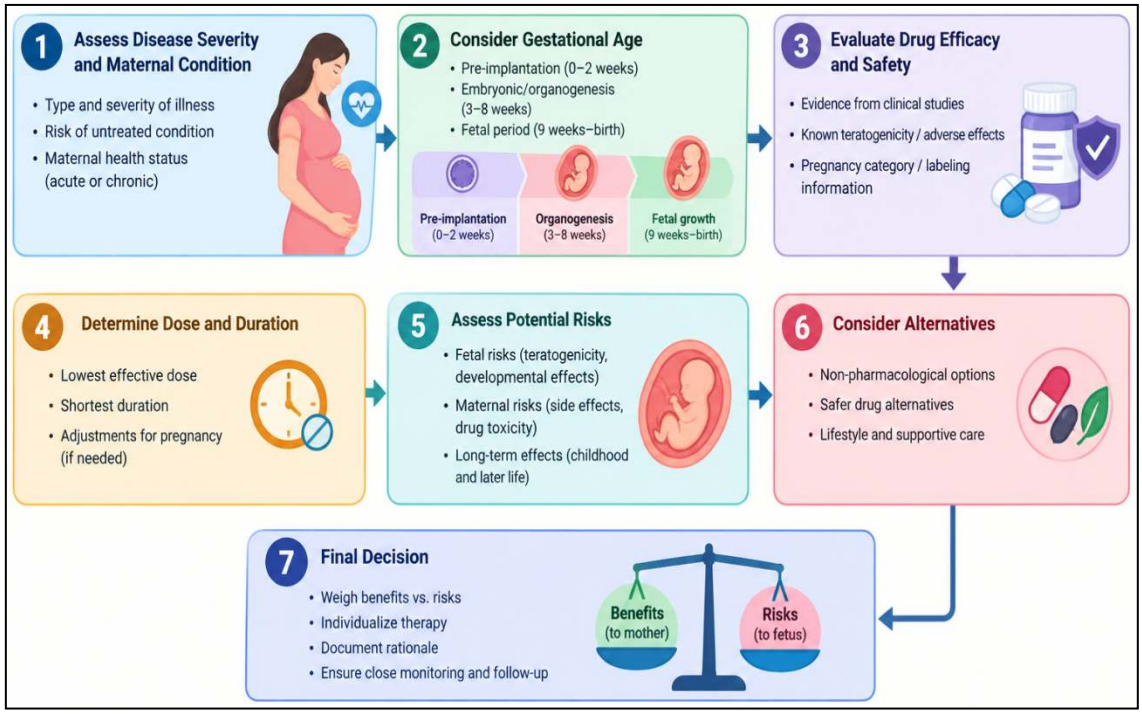


Fig 2: Risk–benefit assessment framework for medication use during pregnancy

5.2.4 Rational Drug Selection

Rational choice of drugs involves choosing a suitable drug which will provide the necessary therapeutic benefit in the way of, at the same time, taking the lowest reasonable risk for the mother and the child. In order to understand whether pharmacotherapy is needed, this should be assessed, and in case of there being any opportunities for using non-pharmacotherapy this should also be considered. [8] The choice of drug should take into account how far along the pregnancy has progressed chronologically, existing diseases of the mother and any other relevant health issues, renal and liver function, previous medications the woman was exposed to, possible drug interactions and fetal factors. Generally, one should try to use the lowest dose of medication possible for a necessary period of time to ensure efficiency in elimination of the disease. Complete medication review includes prescription medications, over-the-counter medicines, nutrition supplements, vitamins, herbal preparations, alternative medicines as well. This is due to the fact that medications include products which can cause side-effect or interaction with other drugs. Pregnant women should be advised not to begin, stop or change the dose of any medication without consulting a health professional first. [9]

5.3 Drug Safety Considerations

The safety of pharmaceuticals during pregnancy plays an important role in maternal and fetal health since drug exposure leads to the effects that depend on the drug in question, its dosage,

duration, and the stage of gestation. Certain drugs can present a greater risk of harm to the embryo and fetus, especially during the periods of rapid organogenesis. However, the risk associated with the use of pharmaceuticals should be weighed against the benefits of treatment for the mother's disease. Proper drug selection, dose adjustment, monitoring, and judicious patient counseling should help to minimize the occurrence of unnecessary adverse effects.

5.3.1 Teratogenicity and Fetal Risks

Teratogenicity is defined as the capacity of an exposure to result in abnormal structure and function in an embryo or fetus. Numerous types of medications may interfere with normal processes of cell replication, cell differentiation, functional organ maturation, and other processes in the body, and thus lead to an increased chance of congenital defects. The consequences arising from a teratogenic exposure depend on multiple variables, such as a medication properties, dose utilized, duration of exposure, and maternal metabolism. Risks that a fetus encounters after the exposure to a teratogen include, but not limited to, structural defects, impaired growth, aspects of neurodevelopmental dysfunction, functional impairment of the fetus, fetal toxicity, and negative outcomes in a newborn. Moreover, some medications may increase the likelihood of miscarriage and complications during pregnancy. It should be noted that a teratogenic study should take into consideration all available evidence both from human studies as well as experiments with animals. Additionally, appropriate consultation has to be done to minimize levels of becomimg anxious about accidental exposure. [10]

5.3.2 Critical Periods of Pregnancy

The impact of drugs on humans depends greatly on the moment when exposure occurs. The pre-implantation stage, usually considered to last until about two weeks after conception, is the period of time when exposure is expected to cause damage to embryos and embryonic death, although surviving embryos do not always exhibit structural defects. It may be referred to as the "all-or-none" period. The embryonic period, from about the third to the eighth week post-conception, is the stage of creation of organs and organ systems. [11] The influence of some harmful substances can affect these processes and lead to the appearance of severely malformed embryos. The fetal stage, starting from the ninth week after conception, is characterized by growth and maturation of both the organism and its organs. The influence of medicines can affect either growth parameters of a fetus or its functional capacities. Therefore, the timing of exposure to drugs ought to be taken into account when determining potential risks of medication for the fetus.

5.3.3 Trimester-Specific Safety

The approach to medication safety in pregnancy is different in each trimester. In the first trimester, especially during organogenesis, the embryo is at high risk for certain teratogenic effects. Thus, unnecessary exposure to medication should be minimized, and proper drug

selection should be employed. [12] The formation of major organs is completed during the second trimester, but fetal growth and development keeps occurring. Nonetheless, some drugs have an effect on organ maturation, growth, and other processes of the pregnancy. Therefore, conducting a monitoring on the safety of the treatment is considered necessary. The impact of exposure to a drug on fetal growth, organ functioning, and adaptation is evaluated during the third trimester. Despite the fact that certain medicines can be administered directly before delivery, they can cause respiratory depression of the newborn and other negative side effects. Thus, the treatment with an appropriate drug should be revised. Thus, drug safety assessment should be based on the whole pregnancy period, not only at the time of drug prescription. [13]

5.3.4 Contraindicated and High-Risk Medicines

Some medications may be contraindicated in pregnancy due to the likelihood that the risks to the fetus are greater than the benefits in treatment, or because there are alternatives that are safer to use. Others may be considered high-risk medicines, which can only be used when there is a clear rationale or when possible gains outweigh potential dangers. There are many medications that require special precautions when taken during pregnancy, including some antineoplastic agents, teratogenic drugs, certain anticonvulsants, retinoid-based drugs, and certain other medications. Identifying contraindicated or high-risk medications still cannot be solely based on older classifications. Current data, product information, guidelines, and the opinions of professionals should be used instead. In case it is absolutely necessary to use a high-risk medication for the mother's health, treatment should be tailored and monitored accordingly. If an alternative treatment is available, it can be prescribed as well. [14]

5.4 Prescription and OTC Medication Use

During pregnancy, people often use prescription and OTC medicines to treat acute ailments, chronic medical conditions, pregnancy-related symptoms and issues, various pains, and nutritional deficiencies. While numerous medications can be safely used if chosen correctly, one must carefully think about their use in pregnancy. This is primarily due to the fact that the mother’s exposure to drugs can affect both her and the developing fetus. Therefore, the choice of a treatment must take into account what the medication is used for, how far along is the pregnancy, what dosage is taken, how long is the treatment, possible adverse effects from using the medication, and if there are safer alternatives.

5.4.1 Common Prescription Medicines

A variety of prescription drugs is required for different conditions like infections, nausea, vomiting, hypertension, diabetes, asthma, disorders of the thyroid gland, anemia, and other maternal health issues. Different types of medications that pregnant women might use include certain antibiotic medicines, anti-nausea drugs, anti-hypertensive drugs, insulin or other drug therapy for lowering blood sugar, as well as nutritional supplements. However, the safety

profile of particular medications is not the same, and treatment is based on evidence and expert recommendations. When choosing a medicine, clinicians need to find the one with optimal properties, use it in the minimal effective dosage and for as little time as possible. The physician should also take into account a number of factors like the gestational age of the patient, medical history, allergies, other medications that the patient is taking, as well as the functions of their kidneys and liver. A regular review is particularly important when the treatment is conducted for a long time or a combination of drugs is used. [15]

5.4.2 Medicines for Chronic Conditions

Pregnant women with already existing chronic disease conditions may require ongoing drug treatment to ensure maternal well-being, thereby preventing complications associated with pregnancy. Some of the chronic health conditions that require ongoing pharmacological treatment throughout pregnancy include hypertension, diabetes, epilepsy, asthma, thyroid and mental health conditions. [16] Medication choice must take into account the need to control the disease and the risks posed to the fetus and newborn. Continued treatment with certain medications is critical in the management of hypertension or diabetes but may lead to severe complications if abruptly stopped. If feasible, medication therapy should be optimized prior to conception and treatments reviewed throughout the course of pregnancy. Chronic drug treatment will also need reviewing for adherence, doses, interactions, and therapeutic monitoring. Collaboration between the prescribing physician/pharmacist and other health care providers is crucial in ensuring patient-specific drug therapy and improving drug safety. [17]

5.4.3 Common OTC Medicines

OTC medicines are drugs that are available without the need for a prescription and are used for treating minor ailments like headaches, fevers, heartburns, constipation, allergic conditions, coughs, colds, and influenza syndromes. Such products include some analgesics, antacids, antihistamines, laxatives, cough remedies, etc. [18] While these medicines are easy to access, it does not mean that their OTC nature makes them suitable for use by pregnant women. Pregnant women are advised to visit their physicians before using OTC medicines, especially during the first trimester and when being treated on a frequent basis. Caution should be exercised while using combination products as they may contain several components that might lead to unnecessary or unintended exposure of the pregnant woman to the active ingredients. The type and concentration of active compounds, duration, and possible interactions with prescribed medications must be reviewed before any OTC medication is used. [19]

5.4.4 Self-Medication and Associated Risks

Self-medication is the use of medications without proper advice or monitoring by a qualified person. It may include the use of over-the-counter (OTC) medications, medicines prescribed in the past, dietary supplements, and traditional and herbal remedies. The practice of self-

medication in pregnancy carries particular risks, including incorrect medication choice, inappropriate dosage, drug interactions, side effects, or exposure to harmful substances by the fetus. Another type of self-medication is referred to as the use of the medicines that one has in their medicine cabinet or maybe ones suggested by family or friend, or even non-expert sources. Pregnant women may use OTC medications or consider "natural" remedy safe, thinking there is no danger of misusing them. Waiting to see a doctor can make a problem worse. Healthcare specialists are to educate pregnant women on the potential risks of non-supervised self-medication and motivate them to tell about any medications, including supplements or herbal medicines, they are taking. [20]

5.5 Drug Interactions during Pregnancy

When a woman is expecting, she may be on multiple drugs, be they prescriptions, over-the-counter drugs, dietary supplements, or herbal products. This is for the reason that there could be a drug-drug interaction during which one drug might cause an alteration in absorption, distribution, metabolism, and elimination of some other drug, which might lead to either a fall in the clinical efficacy of a drug or its increased toxicity. Furthermore, physiological changes that come with pregnancy can also change the way drugs behave in the body and produce a significant impact on drug-drug interactions that are otherwise insignificant. As mentioned in (Table 1) It is hence important that for the treatment of a pregnant woman, all descriptions of drugs including prescription drugs, over-the-counter drugs, vitamins, supplements, and herbal medicines should be included in her medical profile.

5.5.1 Drug–Drug Interactions

Drug interactions are defined as situations in which one drug affects the way another acts. Drug interactions either increase or decrease drug levels or lead to change in the response effect. Drug interactions involving pathways of drug absorption, binding to protein, and hepatic metabolism belong to pharmacokinetics. Drug interactions resulting in similar, complementary, or antagonistic effects are classified as pharmacodynamics interactions. The presence of many diseases, for example, hypertension, diabetes, epilepsy, infections, and other chronic diseases increases the chance of the occurrence of the clinically important interactions. In some cases drug interactions can lead to losses in effectiveness, in other cases increase the risk of side effects in the mother or the fetus. [21]

5.5.2 Drug–Food and Drug–Supplement Interactions

Medication absorption and metabolism can be influenced by food and beverage intake, hence affecting the medication's efficacy. [22] Medications have varying abilities of absorption when taken with food, and food and drinks may change the metabolism of medications. Thus, when applicable, patients need to be given sufficient advice on when to take their medications in relation to eating. The interaction between supplements and drugs should also be monitored

during pregnancy as many women use vitamins, minerals, dietary supplements, and herbal medications. For instance, certain minerals (like iron and calcium) may affect the ability of certain medications to be absorbed if they are taken together. Herbal medications may also change drug metabolism or lead to additional drug effects. As many women may not consider supplements and herbal medications as medications themselves, healthcare professionals have to be aware of those and inquire about their use when performing medication reviews. [23]

5.5.3 Prevention and Management

To prevent drug interactions, a health care professional must first acquire an accurate transaction of prior drug usage. All prescription and non-prescription medications, dietary supplements, natural or herbal medications should be evaluated before treatment options are made. According to the sources of reliable drug information and updated guidelines, any possible medicine interactions should be evaluated. Whenever some drug interactions are established it is important to manage them accordingly either preventing the combinations, choosing a different medication in order to avoid drug interaction, changing the dosage, changing the time of taking medications or increasing the frequency of carrying out control procedures. In some cases laboratory tests should be performed to determine the drug efficacy. It is also essential to provide patients with counseling in order to avoid dangerous interactions. Pregnant women should be instructed to communicate to their doctors about all medicines they consume and they should not start taking anything without consulting with the professional. It would also be helpful for pharmacists to discover the possible drugs interactions. [24]

Table 1: Types of Drug Interactions Relevant to Pregnancy

Type of interaction	Description / mechanism	Potential effect	Key management consideration
Drug–drug interaction	One drug alters the absorption, distribution, metabolism, elimination, or pharmacological effect of another drug.	Reduced therapeutic efficacy or increased adverse effects/toxicity in the mother or fetus.	Review all prescribed and non-prescribed medicines before initiating or modifying therapy.
Pharmacokinetic interaction	Interaction involving drug absorption, protein binding, metabolism, or elimination.	May increase or decrease drug concentrations and alter therapeutic response.	Assess concomitant medicines and consider dose or treatment adjustments when required.

Pharmacodynamic interaction	Two or more drugs produce similar, complementary, or antagonistic effects.	Increased effects, reduced efficacy, or increased risk of adverse reactions.	Avoid clinically significant combinations when possible and monitor the patient appropriately.
Drug–food interaction	Food or beverages may alter drug absorption or metabolism.	Changes in drug exposure and potentially reduced or increased therapeutic effect.	Provide advice regarding administration in relation to meals when applicable.
Drug–supplement interaction	Vitamins, minerals, or dietary supplements may interfere with drug absorption or effects.	Reduced drug absorption, altered therapeutic response, or increased adverse effects.	Include all supplements in the medication history and review their timing and use.
Herb–drug interaction	Herbal or traditional medicines may affect drug absorption, metabolism, transport, elimination, or pharmacological effects.	Reduced efficacy or increased adverse effects or toxicity.	Ask specifically about herbal/Ayurvedic medicine use and assess possible interactions.

5.6 Use of Supplements during Pregnancy

As mentioned in (Table 2) Nutritional requirements increase during pregnancy in order to ensure the health of pregnant women and fetuses, and proper functioning of the placenta. It is essential to follow a balanced diet since it is the main source of the nutrients needed for the healthy development of a mother and her baby. However, sometimes the intake of food is insufficient and additional supplementation is required. It includes folic acid, iron, calcium, and vitamin D. It is important to choose type, dosage, and duration of supplementation depending on maternal nutrition and health.

5.6.1 Folic Acid, Iron and Calcium

Folic acid is very important in pregnancy so as to maintain DNA in addition to neural tube formation. It is known that proper intake of folate before conception and early in pregnancy may reduce risk of neural tube malformations. [25] For many women who are already pregnant

or planning to conceive some supplements are recommended in the early stages of pregnancy. In addition, women at higher risk should receive additional amounts of the vitamin in consultation with health care specialists. Iron need in pregnant women rises significantly due to increase in blood volume, amount of red blood cells, needs of fetus and placenta. Therefore, taking proper amount of iron is essential for prevention of iron deficiency and oxygen supply to mother and child. Iron supplementation may be necessary if the amount of the metal consumed is insufficient. It is also important to take into consideration the negative effects of iron like nausea and gastrointestinal problems. Calcium is important for developing bones in fetuses, affecting the cardiovascular and neuromuscular performance of expectant mothers. Adequate calcium intake may lower the risk of high blood pressure complications in pregnancy for women with low dietary calcium intake. Calcium supplementation must be done at the right time as calcium interferes with absorption of certain medications and minerals like iron.

5.6.2 Vitamin D and Other Supplements

Vitamin D plays an essential role in the metabolism of calcium and phosphorus, bone formation, and bone health of females. Some expectant women may need to take vitamin D supplements depending on their clinical judgment and recommended guidelines. Proper intake of vitamin D is necessary in order to maintain both normal physiological state in pregnant women and their fetuses, however, high D vitamins doses should be avoided. Apart from vitamin D, other nutrients like vitamin B12, iodine, zinc, and omega-3 fatty acids may also be essential in pregnancy. The need to take vitamin D supplements depends on dietary consumption, nutrient intake, and physiological processes, as well as some risk factors. In case a woman was on a restrictive diet, attention should be paid to the nutrients that are hardly provided by her usual food. A woman should choose the multivitamin and multimineral preparations carefully due to different compositions and nutrient content. [26]

5.6.3 Risks of Excessive Supplementation

Even though dietary supplements can help avoid deficiencies, using them incorrectly or taking too much may lead to negative effects. Some vitamin and mineral compounds may build up in the body to an unhealthy level. Additionally, some forms of fat-soluble vitamins can be toxic if taken in high doses, especially vitamins A and D in pregnant women. Getting excessive amounts of certain minerals may lead to various stomach problems and hinder absorption of other nutrients or likely interfere with medications. Another problematic issue is that some individuals may take more than one product with the same nutrients, which can cause overdose. Self-prescribing dietary supplements according to recommendations made by unqualified persons can potentially increase the risk. Therefore, it is essential for pregnant women to inform their healthcare providers about vitamins, minerals, multivitamins, herbal supplements, or any other products they may take. [27]

Table 2: Common Nutritional Supplements During Pregnancy: Benefits and Safety Considerations

Supplement	Key benefit	Safety consideration
Folic acid	Supports fetal neural tube development	Avoid excessive or unnecessary use
Iron	Supports maternal blood formation and fetal growth	Excess intake may cause gastrointestinal effects
Calcium	Supports fetal bone development and maternal health	May interfere with iron and drug absorption
Vitamin D	Supports calcium metabolism and bone health	Avoid high-dose supplementation
Vitamin B12	Supports nutritional requirements	Consider supplementation when dietary intake is inadequate
Iodine	Supports maternal and fetal nutritional needs	Use an appropriate dose
Zinc	Supports nutritional requirements	Avoid excessive intake
Omega-3 fatty acids	Provides nutritional support during pregnancy	Use appropriate doses and suitable products
Multivitamins	Help meet nutritional requirements	Avoid duplication and excessive intake

5.7 Herbal Medicines and Ayurveda-Based Approaches

The herbal medicine and Ayurveda approach during the pregnancy is considered as a supplementary method of treatment which helps in the management of minor pregnancy complications. The herbal preparations may include teas, powders, decoctions, tablets, capsules, oils, and polyherbal preparations. Although some herbal products may have traditional benefits, the safety of these products during pregnancy is to be thoroughly considered due to limited data regarding exposure to foetus, correct dosages, toxicity, and drug interferences.

5.7.1 Common Herbal and Ayurvedic Preparations

The most commonly used herbal medications may contain such ingredients as ginger, mint, chamomile, fennel, turmeric, and garlic. [28] Ginger, for instance, has been used to fight nausea and vomiting both in tradition and in clinical practices. The Ayurveda method includes the preparation of medicated herbal tablets, powders, oils etc. [29]

5.7.2 Potential Benefits and Risks

A few herbal products might offer useful effects for particular symptoms in the correct manner and use with assistance from experts. Nonetheless, there is still little amount of proof while having yields of herbal treatment while being pregnant. As mentioned in (Table 3) the potential risks include allergic reactions, specific gastrointestinal effects, maternal toxicity, a change in blood pressure or blood glucose, bleeding, and risks of possible fetal impacts. Another factor to take into consideration is the quality of the product since it can be somehow affected due to contamination, and botanic misidentifications or some difference in the active ingredients. [30]

5.7.3 Herb–Drug Interactions

Medicinal plants can interact with prescription and over-the-counter medications in a variety of ways such as by affecting the absorption, metabolism, transport, or elimination of drugs through the body. In addition, herbal products may enhance the effects of medications that impact blood clotting, blood pressure, blood glucose levels, or the central nervous system. The interactions that occur between the herbal products and prescription medications may either lessen the therapeutic effect of the medications or result in increased side effects. It is therefore advisable for health care providers to inquire of pregnant patients whether or not they have been taking herbal or Ayurvedic medications, as these patients may not think of herbal or Ayurvedic products as medicines. [31]

5.7.4 Evidence-Based Use

The evidence-based approach to the use of herbal and Ayurveda remedies during pregnancy must keep in view aspects related to quality, safety, effectiveness, dosage, the length of treatment, and available clinical evidence. Reliance solely on the traditional use of these remedies cannot guarantee their safety. Products with questionable composition or unsatisfactory safety cannot be used unless a safer option is available Pregnant women should be encouraged to inform their physician of any herbal and traditional medicine. Pharmacists and other representatives of the healthcare system should be involved in assessing the ingredients, possible drug interactions, and providing consulting services on herbs that can be used safely under strict supervision.

Table 3: Potential Benefits and Risks of Herbal and Ayurvedic Medicines during Pregnancy

Aspect	Potential benefits	Potential risks / concerns
Symptom management	May help relieve symptoms such as nausea and vomiting	Limited evidence on effectiveness and pregnancy safety

Traditional preparations	May provide supportive use when appropriately selected	Variable composition and uncertain dosage
Herbal products	Some herbs may provide therapeutic or nutritional benefits	Allergic reactions, gastrointestinal effects, or maternal toxicity
Physiological effects	Certain products may influence blood pressure or blood glucose	Unwanted changes in blood pressure, glucose, or bleeding risk
Herb–drug combinations	—	May alter drug absorption, metabolism, transport, or elimination
Product quality	Standardized products may offer more consistent composition	Contamination, adulteration, misidentification, and batch variation
Evidence-based use	Expert assessment may help identify appropriate products	Traditional use alone does not establish safety during pregnancy

5.8 Safety Evaluation of Herbal Products

When evaluating the safety of herbal medications in pregnant women, it is important to keep in mind the fact that many preparations contain several active components and may not have enough data proving their safety in clinical practice. Unlike conventional medicines, herbal products manufacturers have different composition and concentration of the products. As a result, it is essential to evaluate quality, authenticity, purity, potential toxicity, compatibility, and compliance with the regulations of the herbal products. [32]

5.8.1 Quality and Standardization

For the assurance of identity, purity, potency, and uniformity of herbal products, quality and standardization are very important. Proper plant species identification and choosing the right plant part is extremely important to ensure the presence of the proper therapeutic constituents required. Standardization can include controlling of the concentration of certain active or marker compounds and ensuring the identity of product from batch to batch. Good practices in manufacturing, processing, storing, packaging, and stability testing may also contribute to the quality of the final product. In pregnancy, preference should be given to the products produced by manufacturers that are known for their reliable practices and informative labeling.

5.8.2 Contamination and Adulteration

Evaluation of the toxicology of herbal substances can determine both acute and chronic toxicity, reproductive toxicity, genotoxicity, and the potential for developmental consequences. It is important to exercise caution if there isn't any pregnancy-related safety data available. In assessing safety, it is also necessary to take the dose, duration, method of administration, and

possible interactions with conventional medicines into account. Regulatory processes make sure that herbal products apply with proper quality, safety, manufacturing, and labelling standards. Nevertheless, regulations concerning herbal products may vary considerably from one state to another as well as between traditional medicines, food supplements and herbal medicinal products. Hence, pregnant women should be encouraged to use products with known ingredients and appropriate quality control systems and process professional consultants.

5.8.3 Toxicological and Regulatory Considerations

Evaluation of the toxicology of herbal substances can determine both acute and chronic toxicity, reproductive toxicity, genotoxicity, and the potential for developmental consequences. It is important to exercise caution if there isn't any pregnancy-related safety data available. In assessing safety, it is also necessary to take the dose, duration, method of administration, and possible interactions with conventional medicines into account. Regulatory processes make sure that herbal products apply with proper quality, safety, manufacturing, and labelling standards. Nevertheless, regulations concerning herbal products may vary considerably from one state to another as well as between traditional medicines, food supplements and herbal medicinal products. Hence, pregnant women should be encouraged to use products with known ingredients and appropriate quality control systems and process professional consultants.

5.9 Pharmacovigilance in Pregnancy

As shown in (Fig 3) Pharmacovigilance is essential to maintaining maternal and fetal health by enabling the identification, assessment, and prevention of the hazards related to drugs prescribed during the period of pregnancy. [33] Pregnant women are frequently not included in various clinical studies, which makes it impossible to assess the safety profile of the medicines before putting them into practice. Nonetheless, there is always a need to monitor the use of those drugs to discover any potential objections. Among the things involved in pharmacovigilance are ADR surveillance, reporting of suspected adverse reactions, signal detection, risk assessment, and follow-up of pregnancy exposures. Hence, the information obtained can ensure safer prescribing.

5.9.1 Adverse Drug Reaction Monitoring

Monitoring of adverse drug reactions provides for the detection and assessment of unwanted or harmful effects associated with any drugs administered in pregnancy. The reaction can occur in the mother as well as in the fetus or newborn and can vary due to many factors such as the type of drug, the dose of the drug, the duration of therapy, and the stage of pregnancy at which the drug is taken. While monitoring for adverse drug reactions, healthcare professionals should be aware not only of the well-known adverse effects but also the unexpected outcomes such as congenital malformations, fetal growth retardation, pregnancy termination, neonatal complications and maternal toxicity. Healthcare professionals must keep the complete records

of medication history and always monitor their patients on long-term treatment or with high-risk medications. Awareness of drugs having little or no information about pregnancy safety is of utmost importance. Information about the suspected drug, dose, duration, period of exposure, maternal condition and outcome of pregnancy should be included in the documentation of adverse drug reaction.

5.9.2 Reporting and Risk Assessment

Reporting and identifying ADRs is an important component of pharmacovigilance. Medical doctors, assistants, pharmacists, nurses, as well as other professionals working in medicine have to report all the severe or problematic ADRs in accordance with the regional or national regulations on pharmacovigilance. The report needs to include the information related to the patient, the drug that caused an undesirable reaction, the moment of exposure, the effects of ADR, and other medicines that the patient was taking. Each of the reported cases is going to contribute to the signals detection and assessment of risks related to the drugs in question. It is assumed that during the assessment special attention is going to be paid to the strength of correlation, biological possibilities, and timing of exposure.

5.9.3 Pregnancy Exposure Monitoring

Pregnancy exposure monitoring refers to the systematic collection and tracking of information regarding exposure to medicines before and during, and in some cases, after pregnancy. It can be important for gaining knowledge about the outcomes of pregnancies when no data from controlled clinical trials are available.

Information can include the name of the medicine, dose, time and duration of exposure and is to cover maternal characteristics, concomitant medications, gestational age, pregnancy outcomes, the outcome of the birth, and neonatal health condition. History of pregnancy that was exposed to medicines is important to find out certain patterns of congenital abnormalities, fetal growth restriction, complications during pregnancy and symptoms observed influenced by medications in the newborn. Pregnancy registries, observational studies, spontaneous reports, and other types of real-life data can help to assess safety of medicines, especially newly introduced medicines and medicines for diseases that have a serious prognosis and provide little information specific to pregnancy.

5.10 Role of Pharmacists in Maternal Healthcare

The importance of pharmacists in making sure safe and effective medicine use during pregnancy cannot be understated. The profession of pharmacy goes beyond dispensing drugs to include reviewing medications, recognizing drug-related issues, giving counselling to patients, ensuring adherence to prescribed medications, and making sure that any problems related to adverse drug reactions are dealt with. Due to the fact that pregnant women take both

prescription medications as well as OTC medications and supplements, pharmacists have a unique opportunity to identify possible drug safety problems. [34]

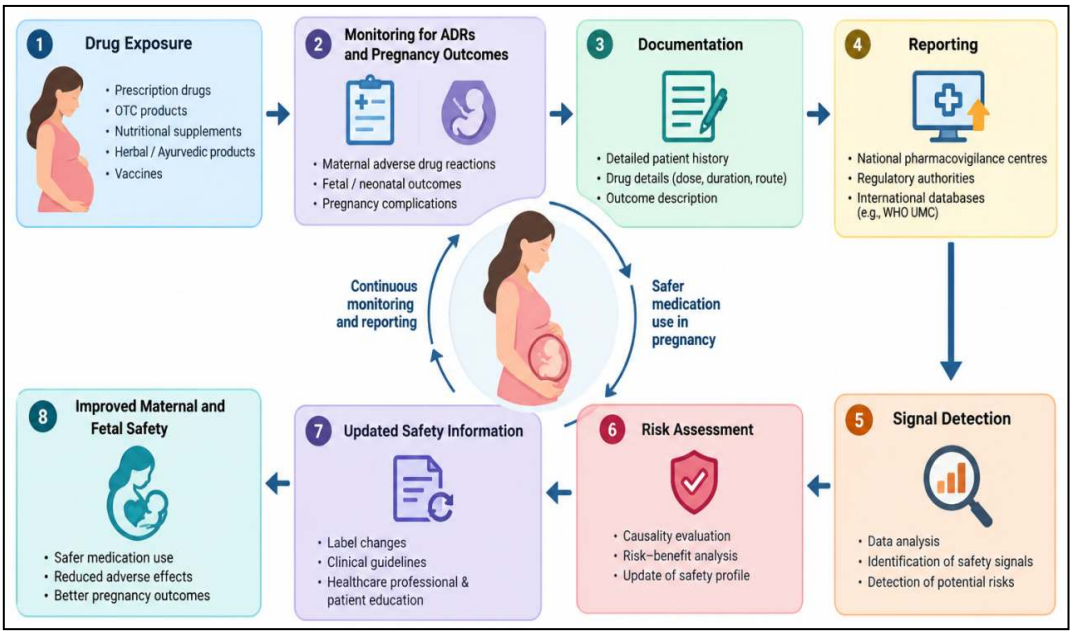


Fig 3: Pharmacovigilance pathway for Pregnancy

5.10.1 Medication Review and Reconciliation

Medication review means assessing every single drug that was taken by a woman who is in the condition of pregnancy so as to reveal the aim, efficacy, safety and dosage of the drug as well as possible interactions during the process of treatment. It is pharmacists who are good at noticing unnecessary drugs, duplicate therapy, inappropriate dosages and incorrect medications. Medication reconciliation is of great importance during the transition of care being provided, be it hospitalization, discharge or referral to another provider. It is essential for pharmacists to acquire all kinds of information concerning medications taken. All discrepancies found out should be reported to the team that prescribed it.

5.10.2 Patient Education and Counselling

Counselling of the patients is one of the fundamental pharmaceutical practices that involve care for pregnant women. The pharmacists provide the information about the intended use of the medicines and the right dosage of it, the administration rules, as well as the potential benefits and drawbacks, and proper storage. They should convey to the patients the necessity of using the prescribed therapy. The counselling process should provide information about the use of the non-prescription drugs, dietary supplements or herbal medicines and clarify that the above-mentioned products pose possible threats to the health. Expectant women need to be

encouraged to ask for medical advice before taking any medicines or starting new supplements and to inform the medical staff in case of serious side effects.

5.10.3 Medication Safety and Adherence

Pharmacists significantly aid medication safety through avoiding medicinal mistakes, discovering potential interactions, and preventing misuse of self-medication and polypharmacy. Pharmacists also improve adherence rates by addressing obstacles to adherence like unwanted side effects, complicated dosing schedules, misunderstanding instructions, and worries about fetal safety. Increasing adherence rates is necessary for chronic diseases like hypertension, diabetes, seizures, etc., because poor adherence could negatively influence the results of pregnancy and health of the fetus. Finally, pharmacists could implement various strategies to solve the adherence problem, and also recommend different ways of adhering to the medicine.

5.10.4 Interprofessional Collaboration

Ensuring safe management of medications for pregnant women calls for teamwork between pharmacists, doctors, nurses, nutritionists, and other professionals in medicine. Pharmacists lend their experience on drug use in treatment plans and recognize drug interactions or safety risks. They also suggest substitutes when needed. Pharmacists take part in monitoring drug therapy safety by keeping records of suspected adverse reactions. Communication between medical professionals ensures that all their decisions about medications take into account the needs of mothers and the safety of their unborn babies.

5.11 Emerging Trends and Future Perspectives

The field of drug safety during pregnancy is undergoing significant transformation due to advancements that have taken place in pharmacology, pharmacogenomics, digital health, artificial intelligence and in the area of real world evidence. As shown in (Fig 4) Future methodologies will increasingly aim at developing individualized solutions in medicine that take into account properties of mother, gestational age, the disease severity, genetic characteristics and the safety of the child. [35]

5.11.1 Precision Medicine and Advanced Technologies

The future of using medications in the context of pregnancy seems to go in the direction of personalized and evidence-based treatments. The purpose of precision medicine is to initiate drug selection and dosing based on particular features of a pregnant woman, including gestational age, health issues, genetic profile, drug metabolism, and report of responses to treatments. Pharmacogenomics can allow the detection of genetic variations that play the roles of drug metabolism and treatment efficiency. Artificial intelligence coupled with machine learning also show promise in ensuring medication safety during pregnancy. AI can analyze

large amounts of data obtained from electronic health records, pregnancy registries, clinical trials, and pharmacovigilance databases. Nonetheless, these advanced technologies should be used only after going through appropriate validation and training.

5.11.2 Real-World Evidence and Digital Health

Because pregnant women are often not included in clinical trials, real-world evidence is increasingly being used to help understand drug safety in pregnancy. Evidence from pregnancy exposure registers, electronic health records, observational studies, and pharmacovigilance databases will provide insight into the amount of drug taken and the effects on mothers, babies, and fetuses. Following the outcomes in these exposed pregnancies over a longer term may also help identify additional outcomes that might not be apparent immediately after birth. Digital health possesses the capability to improve drug use safety. Obtained data from apps used for drug prescriptions, telepharmacy, digital reminders, and tele-counseling can lead to increased adherence of patients to prescriptions, know about how to safely use the medication, and send information about an adverse drug reaction.

5.11.3 Herbal Medicines and Improved Safety Evaluation

The utilization of herbal and Ayurvedic remedies in pregnancy should be investigated thoroughly as there is a lack of information about their pharmacokinetics, fetal exposure, reproductive toxicity, and interactions with conventional drugs. Future studies should concentrate on standardization and authentication of raw materials, identification of active components, research on contamination and adulteration, and investigation of herb-drug interactions. Better regulation and pregnancy-related pharmacovigilance should help provide credible safety profiles of popular herbal and traditional products. More studies need to be carried out with evidence-based evaluation methods and not merely rely on the traditional use of herbal products or the belief that natural products are safe. The creation of standardized products with clearly defined components and appropriate quality control methods will contribute to their safe usage in medicine according to clinical justification.

5.11.4 Future Directions in Maternal Medication Safety

Future research must investigate effective sources of pregnancy-specific safety data and gain better insight into the long-term impacts of drug exposure on fetal as well as neonatal development. Increased use of pregnancy registries, real-world data, drug safety systems, and ethical clinical trials can help overcome evidence gaps. Research should also investigate the impact of drug exposure at various gestation times and in women suffering from chronic disorders requiring long-term treatment. A multi-disciplinary and patient-centered approach will be key for assuring safe drug use. Healthcare professionals such as pharmacists, physicians, nurses, obstetricians, scientists and statisticians, must cooperate in this effort to improve drug choice, monitoring and counseling, as well as adverse event reporting. The use

of approaches such as precision medicine, artificial intelligence and digital health can facilitate individualized treatment and reduce preventable perinatal risks.

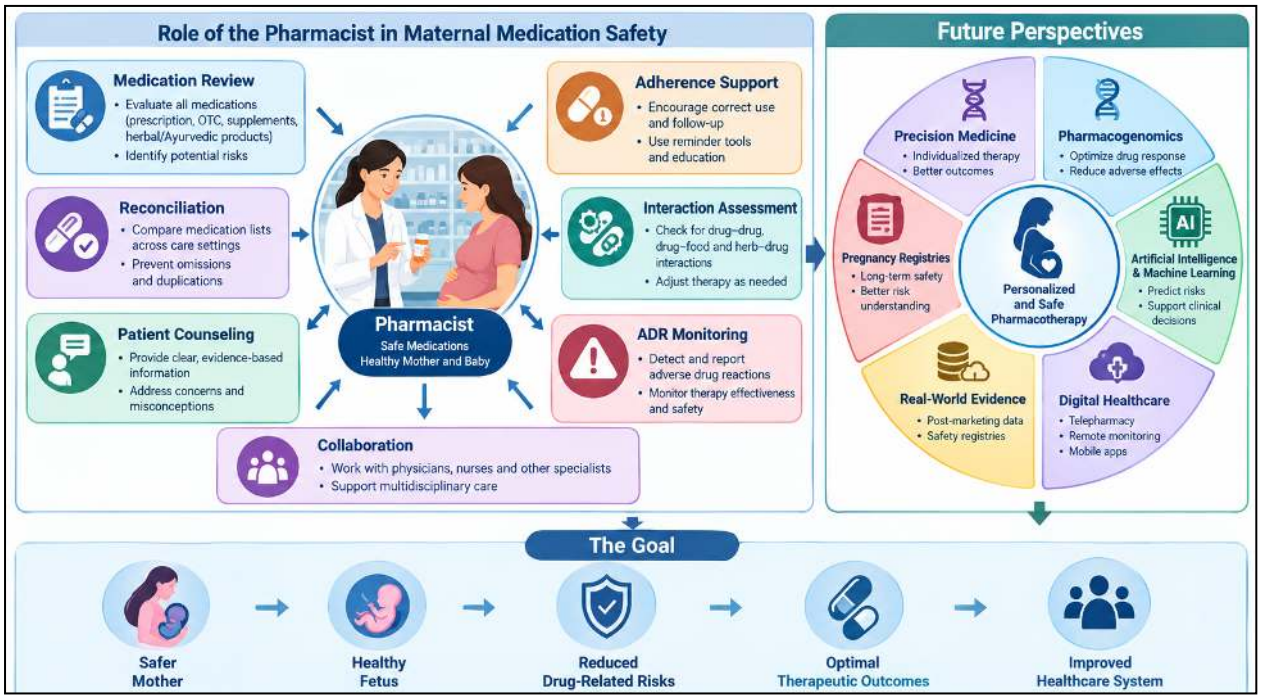


Fig 4: Future perspectives in maternal medication safety

5.12 Conclusion

Safe medication use is important during pregnancy to protect the health of both mothers and babies. The physiological and pharmacokinetic changes of pregnancy mean that the choice of medication and its dosage must take gestational age, maternal health state, and possible risks to the unborn child into account; thus, risk versus benefit assessment must be done properly in order to avoid wrong medication usage and treat important health conditions of mothers.

Various medications including prescription medicines and over-the-counter medications, nutritional supplements and maintenance remedies should be applied carefully and preferably, under the guidance of a medical practitioner. Attention must be drawn to issues of drug interactions, self-treatment, over-supplementation, product quality, and lack of evidence of safety of certain medicines and traditional medicines. The role of pharmacists comprises the drug review, interaction rate, disarray evaluation, and working with other doctors in the healthcare sector. Innovations include advanced medicine, pharmacogenomics, usage of artificial intelligence platforms, digital health solutions, and real-world evidence in medication management in pregnancy. Therefore, a patient-oriented, science-based, and interdisciplinary approach is a key to making drug use rational as well as getting optimal results.

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