Guidelines for Prescribing Medication During Pregnancy and Lactation

Because of past experiences with birth defects from medications, a more conservative approach is now being taken toward prescribing them as well as over-the-counter drugs and natural food products, especially during the first trimester and postpartum lactation. Since there is a lack of information about the risk to benefit for many medications, the goal is to avoid harm to the mother and fetus by finding the balance between the underutilization of medications required by the mother and the termination of a pregnancy due to unknown teratogenic effects.

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● Since the thalidomide disaster more than 30 years ago, healthcare providers and patients have adopted a conservative approach to medication use during pregnancy, especially in the first trimester and during postpartum lactation. The risk vs. benefit of each medication used during pregnancy must be considered for both the mother and the fetus. Unfortunately, because the risks and benefits of many medications when used during pregnancy are often not available, there may be either an underutilization of medications required by a pregnant woman or a voluntary termination of the pregnancy when a medication's teratogenic potential is unknown.

Medication Use

Medication use during pregnancy has changed over time because of various factors: new products have been marketed, concerns have arisen regarding safety and efficacy, public education has increased, and some prescription medications have been granted nonprescription status by the Food and Drug Administration (FDA). To assess the use of prescription medications, over-the-counter drugs, natural food products, and illicit drugs during pregnancy, women must be relied on to give an accurate description of drugs they used. Medications most commonly taken during pregnancy include vitamins, analgesics, calcium and iron preparations, and antibiotics. According to our experience, the mean number of medications consumed during the second and third trimesters (3.3 and 4.1) are significantly higher than the mean number taken before pregnancy (2.6).[1] Over-the-counter medications account for half of the total products taken during pregnancy. Percentages of women using caffeine, tobacco, alcohol, and illicit drugs tend to decrease as pregnancy progresses.

Potential Adverse Effects

Drugs are easily absorbed during pregnancy, and the serum concentration of albumin for drug binding is lower than when nonpregnant. Most unbound drugs or active metabolites do not have large spatial configurations or high molecular weights and, therefore, should cross the placenta easily.[2] Umbilical cord concentrations become more comparable to the mother's serum with continued exposure. The risks of new drugs to the fetus are usually not fully explored. Drugs prescribed as

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maintenance therapy during pregnancy are, therefore, usually older and have a larger body of information or experience. These older medications may not be the preferred treatment when the patient is not pregnant.

Given the abundance of available medications, it is unclear why there is a paucity of scientific information about their potential adverse effects on pregnancy.[2] Fetal exposure may be divided into three periods: (1) ovum, from fertilization to implantation; (2) embryo, from the second through the eighth week; and (3) fetus, from the eighth completed week until term. The embryo period encompasses the most critical time with respect to physical malformations because it involves organogenesis. Certain drugs may infrequently have detrimental effects when taken beyond organogenesis. There is virtually no information about long-term effects, such as growth impairment and learning or behavior problems (functional teratogenesis), that may result from chronic prenatal medication use.

Table 1 lists the known adverse effects on the fetus from exposure to specific drugs during the first trimester and beyond. Information compiled in this table is a review of the recent literature. Briggs and coworkers' *Drugs in Pregnancy and Lactation*, computerized databases, and consultation with knowledgeable colleagues have also been helpful in compiling what we consider to be reasonable advice.[3,4]

Also listed in Table 1 are the effects on the infant while exposed to various drugs during breast-feeding. The amount of drug present in the milk and consumed by the infant depends on the chemical properties of the drug and on the dose, frequency, and duration of exposure.[5] Few drugs should cause any concern, and contraindications or cautions listed in the table are more theoretical or founded on case reports rather than being evidence based. Less risk may be gained by the mother taking the medication after infant feedings or just before the infant's longest sleep period. Although nearly all drugs are excreted in breast milk, they are usually excreted in amounts (often less than 5% of the weight-adjusted maternal daily dose). The World Health Organization's recommendations for each drug are very similar to the Academy of Pediatrics' recommendations and favor breast-feeding. However, the World Health Organization is more conservative by not recommending breast-feeding if there is no information or by expressing caution about the need to monitor.

Many dilemmas exist when studying any drug, prescription or over-the-counter, and its effect on the developing fetus. Agents that have been commonly used for at least 20 years may have been studied by the Collaborative Perinatal Project or the Boston Collaborative Drug Surveillance Program.[6] Although valuable, these findings are not always conclusive and do not help in evaluating either newer drugs or drugs less commonly prescribed during pregnancy. Most human data involve small studies or case reports, which may be biased or which may merely reflect the patient's background risk for birth defects, regardless of exposure. Case reports of malformed infants after prenatal exposure to a certain drug may feature exposures to other agents and a lack of uniformity of abnormalities, making their association with a single causative agent unlikely. A lack of comparability of the dose and the route of administration can limit interpretation. For example, the short-term administration of a drug given intravenously makes it difficult to relate risk when the same medication is taken orally in a lower dose for a longer period.

Altering Drug Regimens

Drug regimens for chronic illnesses are best altered, when possible, in the preconception period

Reported Drug Effects on the Human Fetus and the Nursing Infant

Drugs	1st Trimester Effects	2nd & 3rd Trimester Effects	Breast-feeding
Analgesics			
Acetaminophen	None known*	Hepatotoxicity/nephrotoxicity w/higher doses	Safe
Narcotics	None known*	Depression, withdrawal	Not recommended
Salicylates	Frequent reports, none proven (see text)	Prolonged pregnancy and labor; hemorrhage, altered hemostasis; intracranial hemorrhage	Use w/caution, potential adverse effects on newborn
Anesthetics			
General	Anomalies (?)*, abortion (?)*	Depression	
Local	None known*	Bradycardia, seizures	
Anorexics			
Phenylpropanolamine	Eye (?)*, ear (?)*, hypospadias (?)*	None known	No information available
Meclizine	Oral cleft (?)*, eye (?)*, ear (?)*	None known	May produce jitteriness, poor feeding, decreased milk production
Antiasthmatics			
Theophylline	None known*	Jitteriness, tachycardia	May produce jitteriness, poor feeding, vomiting, cardiac arrhythmias
Terbutaline	None known*	Tachycardia, hypothermia, hypocalcemia, hypoglycemia, and hyperglycemia	Compatible
Metaproterenol	None known*	None known	No information available
Anticoagulants			
Warfarin	Nasal hypoplasia, ophthalmic abnormalities, epiphyseal stippling	Hemorrhage, stillbirth	Hemorrhagic complications
Heparin	None known	Hemorrhage (?)*, stillbirth (?)*	Safe
Anticonvulsants			
Barbiturates	Malformations (?)*	Bleeding, withdrawal	Not recommended
Carbamazepine	Craniofacial, neural tube abnormalities (?)*	Bleeding, withdrawal, growth restriction	"Probably safe"
Clonazepam	None known*	Withdrawal, depression	Not recommended (potential for apnea/cyanosis/hypotonia) serum levels should be monitored
Ethosuximide	None known*	None known*	Compatible
Phenytoin*	Craniofacial abnormalities, mental retardation, hypoplasia of phalanges	Hemorrhage, depletion of vitamin K-dependent clotting factors	Safe
Primidone	Orofacial clefts	Hemorrhage, depletion of vitamin K-dependent clotting factors, IUGR‡	May produce significant adverse effects in infants. Use with caution
Trimethadione*	Mental retardation, facial dysmorphogenesis, cardiovascular	Hemorrhage, depletion of vitamin K-dependent clotting factors, IUGR‡	No information available

Table 1

Reported Drug Effects on the Human Fetus and the Nursing Infant *(Continued)*

Drugs	1st Trimester Effects	2nd & 3rd Trimester Effects	Breast-feeding
Valproic acid*	Spina bifida, facial dysmorphogenesis	Perinatal distress, behavioral abnormalities	Safe
Anti-Infection Agents			
Aminoglycosides	None known†	Nephrotoxic (?)†	Depends on level of exposure and renal function of infant
Cephalosporins	None known†	None known†	Probably compatible
Chloramphenicol	None known†	Vascular collapse	Not recommended
Clindamycin	Unknown†	Unknown†	Compatible (potential modification of bowel flora, interference with culture interpretation after fever workup in infants)
Erythromycin	None known†	None known†	Compatible
Isoniazid	Malformations (?)†	Behavioral abnormality	Compatible
Metronidazole	None known†	None known†	Use with caution because of mutagenic and carcinogenic effect in some species
Nitrofurantoin	None known†	Hemolysis (?)†	Compatible
Penicillins	None known†	None known†	
Rifampin	Malformations not greater than general risk	None known†	Compatible
Sulfonamides	None known†	None known†	Generally compatible (should be avoided in infants with hyperbilirubinemia, prematı infants, and infants with G6. deficiency)
Trimethoprim	Cleft palate, micrognathia, limb shortening	Unknown†	Compatible
Tetracyclines	None known†	Stained deciduous teeth (enamel hypoplasia)	Compatible
Cancer Chemotherapy			
Alkylating agents	Abortion, anomalies	Hypoplastic gonads, growth restriction and delay	Breast-feeding to be avoided
Busulfan, Cisplatin	Abortion, anomalies	Hypoplastic gonads, growth restriction and delay	Breast-feeding to be avoided
Antimetabolites			
Methotrexate	Abortion, IUGR†, cranial anomalies	Hypoplastic gonads, growth restriction and delay	Contraindicated in breast-feeding
Fluorouracil/5-Fu Thioguanine Mercaptopurine	Abortion, IUGR†, cranial anomalies	Hypoplastic gonads, growth restriction and delay	No information available
Antibiotics			
Actinomycin D Bleomycin		Transient leukopenia and neutropenia in newborns	No information available
Mitotic Inhibitors			
Vinblastine	Hydrocephalus (?)†, facial clefting (?)†		No information available

Table 1 (Continued)

Reported Drug Effects on the Human Fetus and the Nursing Infant *(Continued)*

Drugs	1st Trimester Effects	2nd & 3rd Trimester Effects	Breast-feeding
Vincristine	Renal abnormalities (?)[1]	None reported	No information available
Cardiovascular Drugs			
Antihypertensives			
Methyldopa	None known	Hemolytic anemia, tremor, hypotension	Compatible
Hydralazine	Skeletal defects (?)[1]	Tachycardia, thrombocytopenia, fetal distress	Compatible
Propranolol	Unknown[1]	Bradycardia, growth retardation	Compatible
Reserpine	None known[1]	Lethargy, respiratory distress	
β-Sympathomimetics	None known[1]	Tachycardia, hypothermia, hypocalcemia, hypoglycemia, and hyperglycemia	Compatible
Digitalis	None known[1]	Bradycardia	Compatible
Cold and Cough Preparations			
Antihistamines	None known[1]	None known[1]	Contraindicated
Cough suppressants	None known[1]	None known[1]	Compatible
Decongestants	None known[1]	None known[1]	Compatible
Expectorants	Fetal goiter (?)[1]	None known[1]	Compatible
Dextromethorphan	None known[1]	None known[1]	No information available
Diuretics			
Furosemide	Unknown[1]	Death from sudden hypoperfusion, electrolyte imbalance	Found to suppress lactation
Thiazides	None known[1]	Thrombocytopenia, hypokalemia, hyperbilirubinemia, hyponatremia	Compatible
Fertility Drugs			
Clomiphene	Meiotic nondysjunction (?)[1], neural tube defects (?)[1]	Unknown[1]	No data available
Hormones			
Androgens	Masculinization of female fetus	Adrenal suppression (?)[1]	No adverse effects reported
Corticosteroids	Orofacial cleft in animals, not in humans	No adverse effects in humans	No data available
Estrogens	Cardiovascular anomalies (?)[1]	None known[1]	No reported adverse effects
Progestins	Limb and CV[2] anomalies (?)[1], "VACTERL"[3] syndrome, masculinization of female fetus (?)[1]	None known[1]	No reported adverse effects
Danazol	Virilization of female fetus (?)[1]	None known[1]	No information available
Hypoglycemics			
Insulin	None known[1]	None known[1]	Safe
Sulfonylureas	Anomalies	Suppressed insulin secretion	No reports of adverse effects
Laxatives			
Bisacodyl	Unknown[1]	Unknown[1]	
Docusate	None known[1]	None known[1]	

Table 1 (Continued)

Reported Drug Effects on the Human Fetus and the Nursing Infant *(Continued)*

Drugs	1st Trimester Effects	2nd & 3rd Trimester Effects	Breast-feeding
Mineral oil	Decreased maternal vitamin absorption	Decreased maternal vitamin absorption	
Milk of Magnesia	None known*	None known*	
Psychoactive Drugs			
Antidepressants Tricyclics	None known*	None known*	Not known*/caution
Benzodiazepines	Facial dysmorphism (?)* withdrawal	Depression, floppy infant, hypothermia,	Not known/some concern
Hydroxyzine	None known*	None known	Not recommended
Meprobamate	Cardiac anomalies (?)*, major malformations (?)*	None known	None known*
Phenothiazines	None known*	Muscle rigidity, hypothermia, tremor	Not known
Sedatives	None known*	Depression, slow learning	Not recommended
Lithium	Facial clefts; cardiovascular abnormalities	Lithium toxicity (neurologic and hepatic dysfunction)	Contraindicated
Thalidomide*	Phocomelia in 20% of cases	None known	No information available
Radiolabeled Diagnostic Drugs			
Albumin	None known*	None known*	No information available
Technetium	None known*	None known*	Not recommended during exposure—may continue 24-exposure
I^{131}(diagnostic)	None known*	None known*	Not recommended during exposure—may continue 24-hr exposure
Thyroid Drugs			
Antithyroid	Goiter, abortion, anomalies mental retardation	Goiter, airway obstruction, hyperthyroid,	Contraindicated
I^{131}(therapeutic)			
Propylthiouracil	Goiter	Same as above	Safe—monitor baby's thyroid status
Methimazole	Aplasia cutis (?)*, goiter	Same as above, aplasia cutis (?)*	Compatible—monitor fetal thyroid function
Thyroid USP	None known*	None known*	
Thyroxine	None known*	None known*	No specific information available
Tocolytics			
Alcohol*	Fetal alcohol	Intoxication, hypotonia; IUGR[1]	Contraindicated
Magnesium sulfate	None known*	Hypermagnesemia, respiratory depression	No information available
ß-Sympathomimetics	None known*	Tachycardia, hypothermia, hypocalcemia, hypo- and hyperglycemia	No information available
Vaginal Preparations			
Antifungal agents	None known*	None known*	No data available
Podophyllin	Mutagenesis (?)*	CNS[2] effects (?)*	Contraindication

Table 1 (Continued)

Reported Drug Effects on the Human Fetus and the Nursing Infant *(Continued)*

Drugs	1st Trimester Effects	2nd & 3rd Trimester Effects	Breast-feeding
Vitamins (high dose)			
A	Urogenital and craniofacial anomalies (?)†	None known†	No data available
C	None known	Scurvy after delivery	Not contraindicated
D	Supravalvular aortic stenosis (?)†	None known†	Not contraindicated
E	Unknown†	None known†	Not contraindicated
K	Unknown†	Hemorrhage, if deficiency	Not contraindicated
"Street" Drugs			
LSD	None known†	Withdrawal, behavioral effects	Contraindicated
Marijuana	"Fetal alcohol syndrome"	Behavioral effects, growth restriction	Contraindicated
Methaqualone	None known†	Withdrawal	Contraindicated
Heroin	None known†	Depression, withdrawal, growth restriction	Contraindicated
Methadone	None known†	Withdrawal, growth restriction	Contraindicated
Pentazocine	None known†	Withdrawal, growth restriction	Contraindicated
Phencyclidine	None known†	Withdrawal, neurobehavioral, growth restriction	Contraindicated
Cocaine	Placental abruption, vascular disruption, urinary tract anomalies	Withdrawal, placental abruption, vascular disruption, growth restriction	Contraindicated
Other			
Cimetidine	Unknown†	Liver impairment (?)†	Contraindicated
Caffeine	Anomalies (?)† in high doses, abortion (?)†	Jitteriness	Not recommended
Azathioprine	Abortion	Anemia, thrombocytopenia, lymphopenia, growth retardation	Not recommended
Bromocriptine	None known†	None known†	
Ibuprofen	None known†	None known†	Compatible
Spermicides	None known†	None known†	No information available
Lead	Abortion, CNS‡ disorders	Stillbirth, mental retardation	Contraindicated
Isotretinoin*	CNS‡, cardiac, facial anomalies	Stillbirth, mental retardation (?)†	Contraindicated

**Proven teratogen.*

†None known = no malformations reported in human studies or no consistent malformations in animal studies (when no human studies reported); unknown = no studies to investigate fetal effects; (?) = conflicting information to question any increased risk of a previously reported anomaly.

‡CNS = central nervous system; CV = cardiovascular; G6PD = glucose-6-phosphate dehydrogenase; IUGR = intrauterine growth retardation; VACTERL = vertebral, anal, cardiac, tracheal, esophageal, renal, and limb anomalies.

Table 1 (Continued)

to include those medications that have been most thoroughly assessed in human pregnancy and determined to pose the lowest risk. Limitations exist, however, when considering which medication is safe to continue when pregnancy either is anticipated or is already discovered. Comparative trials of drugs during pregnancy are uncommon. Because a control population is often not possible, it is also difficult to separate any hazard from the medication from that of an underlying disease. Care of the gravid patient with significant medical problems should include an assessment of the potential risk not only to the fetus but also to herself. Occasionally, alternative therapies exist that

are safer to a developing fetus. Although the minimum dose should be used, a dose that is effective should be prescribed rather than exposing the fetus to potential risk without achieving an adequate benefit from the drug. The dose may be higher than the published maximum for a nonpregnant adult.

The principles of maintenance drug therapy are the same as in the nonpregnant state. Knowledge about one or two medications for each disorder is recommended. Each drug may need to be prescribed in a higher dose or more frequently if therapeutic concentrations are to be maintained in the expanded intravascular volume during pregnancy. Symptoms of pregnancy, such as nausea, fatigue, and gastrointestinal disturbance, may mimic side effects of or toxic reactions to drugs.

Assessing Risks

Although information about prescription drug use is often scant or difficult to interpret, assessing risks associated with over-the-counter medications is even more difficult. A review of the *Physicians' Desk Reference for Nonprescription Drugs* reveals little or no information about reproductive toxicity for most of these medications.[7] Many agents contain multiple ingredients, both active and inactive, making it difficult to determine what the combined effect of these ingredients might be. Doses may not be included in the labeling of the drug, although the lowest effective dose is generally included. Some over-the-counter drugs do not require FDA approval and, thus, may not meet the standards for therapeutic effectiveness or safety.

Conclusion

A large body of information about any drug taken during pregnancy or during lactation is available to the clinician and to the patient through books, magazines, and the Internet. Much of the evidence is either anecdotal or presented with sufficient warnings to discourage its use. A discussion of these issues with the patient may set the risks and benefits into a more proper perspective, thereby alleviating certain other fears and improving on compliance. Questions about over-the-counter and natural food products should also be put into this perspective—the usual being very limited information during pregnancy and virtually no controlled trials demonstrating harm and perhaps efficacy. ●

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FERTILITY
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December 20, 1999

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Category A	Adequate studies in pregnant women have not demonstrated a risk to the fetus in the first trimester, and there is no evidence of a risk in later trimesters. The possibility of fetal harm appears remote. Example: Vitamin C when used in recommended daily allowance dosage.
Category B	Animal studies have not demonstrated fetal risk but there are no adequate studies in pregnant women, or animal studies have shown an adverse effect (other than a decrease in fertility), but adequate studies in pregnant women have not demonstrated a risk to the fetus during the first trimester and there is no evidence of risk in later trimesters). Example: Ampicillin.
Category C	Animal studies have shown an adverse effect on the fetus (teratogenic, embryocidal, or other) but there are no adequate studies in humans. The benefits from the use of the drug in pregnant women may be acceptable despite its potential risks, or there are no animal reproduction studies and no adequate studies in humans. Example: Zidovudine (AZT).
Category D	Positive evidence of human fetal risk exists, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential

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	risks (eg, for a life-threatening condition or a serious disease for which safer drugs cannot be used or are ineffective). Example: Phenytoin (anticonvulsive).
Category X	Studies in animals or humans demonstrate fetal abnormalities or adverse reaction reports indicate evidence of fetal risk. The risk of use in a pregnant woman clearly outweighs any possible benefit. Example: Isotretinoin (acne treatment)

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