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ACPE # 012-999-06-210-H01

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Drug therapy during pregnancy: Practical tips for patient counseling

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Drug therapy during pregnancy: Practical tips for patient counseling

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As you read the following article, please consider the case scenarios below:

Patient case 1: M.J. is a 29-year-old female who is two months' pregnant with her first child. She explains that she has a history of hypertension for which she has been taking hydrochlorothiazide. With her current drug regimen, M.J. has remained at goal blood pressures of 110-120/80 for the past six months. However, she is concerned that her current medication may have an adverse effect on the fetus. M.J. asks you, the pharmacist, if she should stop taking her medication while she is pregnant.

Patient case 2: L.M. is a 35-year-old patient who is six months' pregnant with her second



child. She has been having trouble sleeping for several nights, and this is causing her to be ineffective at work and drowsy during the day. She asks you whether she can take zolpidem (Ambien) to help her sleep tonight since she has some in her medicine cabinet.

The profound effects that drugs and other chemicals can have on the fetus were brought to light by the thalidomide disaster of the 1950s and '60s. This sedative/hypnotic drug was administered to women in their first trimester to alleviate stress of early pregnancy. Consequently, many babies were born with severe deformities of the arms and legs, a teratogenic effect known as *phocomelia*.

In response to the thalidomide episode, clinicians realized that other pharmaceuticals might

GOAL

To aid the pharmacist in becoming more proficient in counseling pregnant patients about the safety of drug therapy during pregnancy

CREDIT

This lesson provides two hours of CE credit and requires a passing grade of 70%.*

OBJECTIVES

Upon completion of this article, the pharmacist should be able to:

- ✓ Counsel the expectant mother on the risks or benefits, if known, of taking certain drugs during pregnancy
- ✓ List several drugs known to be harmful when taken during pregnancy
- ✓ Describe the mechanisms by which drugs can interrupt the normal outcome of pregnancy
- ✓ List the risk factors of drug-induced birth defects
- ✓ Recognize the sources of scientific information, both animal and human, used to assess the risk to the fetus in a patient who takes drugs during pregnancy, including the limitations of such data

*To receive credit you must score 70% or higher on the quiz and complete the evaluation. Upon successful completion, the University of Florida College of Pharmacy will mail Statements of Credit for written quizzes within 10 working days. Participants completing the program on-line may print a Statement of Credit after successfully completing the program.

have similar effects on the fetus. News reports became quite sensational, with bulletins and articles implicating drug after drug. Often these stories lacked objective information. Ultimately, pregnant women became increasingly concerned about the safety of any and all medication use during pregnancy.

This legacy persists today. Many obstetricians will instruct their patients not to take any drug therapies during pregnancy on the slight chance it could be harmful. There is some risk, however, in overreacting, when one considers that drug therapy plays a relatively small role in the etiology of congenital malformations (approximately 3%). Cases have been reported in which pregnancies were terminated unnecessarily after the patient was exposed to a substance later determined to be harmless. Often, the risks associated with untreated diseases such as maternal hypertension, for example, are greater to the mother and fetus than the risk of adverse effects from the drug therapy itself.

In their search for answers to questions about medication use during pregnancy, patients may approach other caregivers. Some may solicit advice from friends and family members who may be misinformed. Pharmacists can help their pregnant patients reach rational decisions by presenting the benefits and risks of medications when known and urging further consultation with the obstetrician.

Counseling pregnant women about medication use requires good communication skills and a solid knowledge base. How you present information is as important as what you say. This continuing education program will highlight special situations that call for highly refined patient-counseling skills. The purpose of this article is to first review the scientific issues pertinent to the use of drugs during pregnancy and then to discuss important considerations in communicating this information to patients who may have questions about prenatal use of drugs.

Placental transport of drugs

Both health professionals and laypersons will inquire as to whether a

particular drug crosses the placenta or not. They presume that a drug that does cross the placenta is harmful while one that does not can be safely given. This is a gross oversimplification, since most drugs do cross the placenta to some extent or another. Therefore, attention should be focused on the consequences after the drug has entered the fetus' circulation.

On the one hand, it is not always undesirable for a drug to get into the fetal environment. For example, penicillin administered to a pregnant woman with syphilis readily crosses the placenta and is found in high concentration in fetal blood. This is considered beneficial, since the baby is receiving treatment concurrently with the mother. Likewise, a condition known as *idiopathic fetal tachycardia* is a problem that may be treated by administering digoxin to the mother, since digoxin readily passes the placenta and produces equal maternal and fetal concentrations. The efficacy of zidovudine given to the mother to prevent vertical transmission of HIV from mother to child is brought about by passage of the antiretroviral to the fetal circulation.

On the other hand, some maternal medications can enter the fetal circulation and persist in the infant's body even after delivery, with adverse sequelae. Diazepam, for example, is eliminated slowly from the infant's body and may cause drowsiness and lethargy for several days after delivery. The bottom line is that most drugs cross the placenta, but few produce adverse consequences.

Mechanisms of drug effects on the fetus

Even though the number of drugs or drug categories proven to be harmful is low, the consequences can be monumental. There are several basic mechanisms by which drugs used during pregnancy, labor, and

delivery can cause adverse effects. Depending on the stage of pregnancy and the particular drug, one or more of these mechanisms may put the mother or child at risk for problems.

Table 1
Drugs with known adverse fetal effects

Antimetabolites
Finasteride/dutasteride (Avodart)
Isotretinoin and retinoic acid
Warfarin
Misoprostol
Live vaccine (e.g., rubella)
Iodides
Androgens (and other hormones)
Thalidomide
Alcohol
Penicillamine (Cuprimine)
Lithium
Tobacco (nicotine)
Antiepileptic agents

Physical malformations: Major structural malformations are most often associated with embryological exposure to chemical insults during the first trimester of pregnancy. This is the period when embryological differentiation of the organ systems is occurring, and insult by certain chemicals and drugs can interrupt this process, causing physical malformation in the fetus. There is a wide variation in the reported frequency of drug-induced physical malformation. The usual estimate is that 1% to 3% of the newborn population has some deviation from normal morphology from all causes, and that drugs and environmental chemicals account for an estimated 2% to 3% of these. Drugs and drug classes known to be teratogenic are listed in Table 1.

Pharmacologic effects: Drugs given to the mother during labor can be expected to be in the fetal circulation at the time the baby is born. The fetus, therefore, is likely to respond to the medication in the same fashion as the mother. For example, narcotics such as morphine or its derivatives are known to depress the depth as well as the rate of respiration in adults who are given relatively large doses. There is no reason to expect these effects to be less pronounced in the neonate. In fact, there is some evidence that certain drugs actually accumulate in the baby's blood, resulting in an exaggerated or prolonged response.

After birth, neonates may experience neonatal abstinence syndrome as the serum levels of certain drugs (e.g., anticonvulsants, benzodi-

Table 2

References for safety data for drug therapy during pregnancy and lactation

- American Academy of Pediatrics Committee on Drugs. *Neonatal Drug Withdrawal*. *Pediatrics* 1998;101:1079-88. Available at <http://aappolicy.aappublications.org/cgi/reprint/pediatrics;101/6/1079.pdf>.
- Briggs GG, Freeman RK, Yaffe SJ. *Drugs in Pregnancy and Lactation*, 7th edition. Baltimore: Williams and Wilkins, 2005
- Perinatology Resources. Available at www.perinatology.com/exposures/druglist.htm.
- REPRORISK System, In Micromedex Healthcare Series, 2006

azepines, barbiturates, tricyclic antidepressants) decrease. The timing of administration, dosage, and inherent toxicity of the drug therapy all determine how intensely the infant will react to a drug.

Alterations of maternal physiology (using cigarette smoking as an example): Some drugs may produce harm to the fetus by altering a physiological process necessary to maintain normal fetal well-being. For instance, drugs that alter placental blood flow may endanger the fetus by decreasing delivery of oxygen and nutrients to the fetus. Cigarette smoking causes small-for-gestational-age (SGA) babies by decreasing oxygen and nutrient supply to the fetus. Since more than 20% of women in the United States smoke cigarettes, there is a much greater chance of adverse fetal effects from smoking than from prescription drug therapies.

Smoking nearly doubles a woman's risk of having a low-birth-weight baby. In 2002, 12.2% of babies born to smokers in the United States were of low birth weight (less than 5.5 lb.), compared with 7.5% of babies of nonsmokers. Low birth weight can result from poor

growth before birth, preterm delivery, or a combination of both. Smoking also increases the risk of preterm birth prior to 37 weeks' gestation. Premature and low-birth-weight infants are at increased risk for health problems, chronic disabilities (e.g., cerebral palsy, mental retardation, and learning disabilities), and sudden infant death syndrome.

The more a pregnant woman smokes, the greater the risk to her baby. However, if a woman stops smoking by the end of her first trimester of pregnancy, she is no more likely to have a low-birth-weight baby than a woman who never smoked. Even if a woman has not been able to stop smoking in her first or second trimester, stopping during the third trimester can still improve her baby's growth. Pharmacists play a unique, influential role and can encourage smoking cessation in all patients, but it is especially important in pregnant patients.

Differences in fetal and drug metabolism: The capacity of the body to process and eliminate certain drugs may depend on the functional development of the liver and kidneys. Newborns, especially premature infants, have yet to develop maximal ability to metabolize certain drugs. The drug-metabolizing function of the liver has not reached full functional capacity until some time after birth, the time period depending on the specific drug and its metabolic pathway. Renal function is also below maximum at birth. Thus, drugs handled by the liver and some excreted by the kidneys can be expected to accumulate if neonatal drug elimination pathways are operating at less than full efficiency. Diazepam is metabolized by the newborn liver more slowly than the adult liver; therefore, diazepam persists in neonatal plasma for several days after birth, causing prolonged lethargy in the baby. The same is true for opioids (e.g., morphine, hydromorphone) and phenothiazines (e.g., promethazine).

Effects on the progress of labor: Almost all of the drugs used during the course of labor can affect the frequency and intensity of uterine con-

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tractions if given inappropriately. Excessively large doses of narcotics given before good labor has been established can effectively stop labor. The ideal sedative or analgesic agent would have no effect on normal dilation and effacement of the cervix. Spinal and epidural blocks have less potential for systemic adverse effects for both the mother and fetus, but they can affect the progress of labor.

Developmental effects on the neonate: There is a growing body of evidence that drug therapy can injure the newborn's central nervous system even in the absence of structural or physiological effects. The baby's CNS is not completely developed at birth; in fact, authors estimate that the period of rapid CNS growth continues for at least 18 months after birth. Certain medications may interfere with normal maturation of the CNS and can produce abnormalities in the behavioral capacities of the child. The overall implications of the behavioral effect of drugs are still being determined. Maternal use of selective serotonin reuptake inhibitors (SSRIs) and anticonvulsants during pregnancy may be associated with developmental delays in the neonate, although definitive evidence of this is lacking.

DETERMINING A DRUG'S SAFETY

Before pharmacists can answer questions from patients or physicians, they must seek out reliable information about the drug in question. Most practitioners rely to some extent on various tables or reference charts listing drugs with known or suspected teratogenic potential. Although such charts are useful, one must take into consideration the limitations of such data. Since these represent secondary and tertiary literature sources (i.e., they have been interpreted and abstracted by other persons), there is a chance that the interpretation made by the preparer is incorrect or inconsistent with the intent of the original author. Too often the information is adopted as absolute risk data when it was originally a single observation of a problem. Frequently, no comment is

made as to the clinical significance of the effect that has become suspect through published literature reports. Often they contain no information about drugs which appear safe to the fetus.

Therefore, for a drug that is *not listed*, it is impossible to determine whether it is safe or whether no studies have been reported one way or the other. In order to best use tables of this type, one should rely on those that are extensively referenced and that comment on the clinical significance of reported effects.

The absence of any published information on the use of a drug during pregnancy must not be construed as evidence of its safety. Table 2 shows some good reference sources for drug use during pregnancy.

PREGNANCY LABELING

The Food & Drug Administration has devised a system of pregnancy categories "based on the degree to which available information has ruled out risk to the fetus, balanced against the drug's potential benefits to the patient."

This system involves the establishment of five categories (A, B, C, D, and X) to indicate a drug's potential for causing birth defects. Each drug is placed into one of these categories, based on published data. Category A drugs are those for which well-controlled studies in women fail to demonstrate a risk to the fetus. According to the 2006 electronic version of *Physicians' Desk Reference (PDR)*, there are just a few drugs that are labeled pregnancy category A. These include thyroid hormones (e.g., liothyronine, levothyroxine), nystatin vaginal cream, and prenatal vitamins. These drugs are in category A because there are controlled trials in humans to demonstrate the safety and efficacy of these treatments during pregnancy. Also, hypothyroidism and vitamin deficiencies, if untreated, cause birth defects. Folic acid is contained in prenatal vitamins to prevent neural tube defects. Over-the-counter prenatal vitamins contain 400 mcg of folic acid along with other fat- and water-soluble vitamins and minerals.

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Drugs in category B are those for which either (1) animal studies have not demonstrated a fetal risk but there are no adequate studies in women, or (2) animal studies have uncovered some risk that has not been confirmed in actual controlled studies in women. Many drugs that are used safely in pregnant women are in pregnancy category B. For example, enoxaparin (Lovenox) 30 mg subcutaneously twice a day is a commonly used dose of anticoagulant for pregnant women. Since warfarin is teratogenic (pregnancy category X), enoxaparin is used in its place during pregnancy. Pharmacists can teach pregnant patients how to inject themselves, how to rotate the site of injection, and how to properly dispose of needles, while reassuring them that the medication will not harm the fetus.

Category C also has two meanings: (1) studies in animals have revealed adverse effects on the fetus, and there are no adequate controlled studies in women, or (2) studies in women and animals are not available. According to the 2006 electronic *PDR*, 60% of the drugs included with pregnancy categories are listed as category C.

Category D includes drugs that human experience shows to be associated with birth defects, but the potential benefits of which may be acceptable despite their known risks. A category D drug will generally be one indicated for use in life-threatening situations or serious diseases for which safer drugs cannot be used or are ineffective.

Category X includes drugs for which fetal abnormalities have been demonstrated in animal or human studies and for which the potential risks clearly outweigh the potential benefits. Such drugs are contraindicated for use during pregnancy. Table 1 contains a list of drugs and drug classes that are contraindicated in pregnancy. Notice that alcohol (ethanol) is included. Alcohol consumption during pregnancy increases the risk of congenital abnormalities. There is no known “safe” amount of alcohol that can be consumed during pregnancy.

Unfortunately, for the vast majority of drugs, this system gives limited guidance to the prescribing physician. There are few studies done in

humans that would qualify as controlled trials, thus data reflecting the true risk of use during pregnancy are unavailable. Since moral and legal questions prohibit the study of drug effects by conventional, prospective, double-blind methods, alternative and often less than ideal sources of information are relied upon. Most common is the anecdotal case report wherein the physician communicates his or her observations of a patient or patients who have taken a particular drug coincidental to the pregnancy. Unfortunately, patients want clear-cut Yes or No answers to their questions about a drug’s safety.

PATIENT COUNSELING

To be effective when counseling pregnant women, one needs good speaking skills as well as good listening skills. How information is presented is as important as what is said. This section will highlight special situations that call for highly refined patient counseling skills.

The questions patients ask: Basically, there are two types of questions that the pregnant patient will ask: (1) those regarding a drug she is *considering* taking and (2) those regarding a drug she *already has* taken. The approach to each of these is distinctly different, although the drug in question may be the same. The advice the pharmacist gives may be decidedly different depending on which of the two situations exists.

Consider, for example, a woman who is in her first trimester of pregnancy and experiences motion sickness when she takes the bus to work. She comes into the pharmacy and asks, “Is meclizine harmful to my baby if I take it during pregnancy? I took that cruise last summer, and I had a few pills left.” From this question alone you cannot be sure if she is asking whether it is safe to take this drug at some future time or if she already has taken it and now has doubts about what she has done. In the first instance, it is prudent to advise her to consider nondrug therapy, inasmuch as this would give her peace of mind that she hasn’t harmed the baby. For example, the pharmacist could inquire further into the

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nature of her complaints and perhaps recommend that she carry saltines in her purse, change her mode of transportation, or simply endure the nausea if it is not too bad. Avoidance of drug therapy altogether guarantees no increased risk to the fetus and means she has one less thing to worry about.

Quite opposite would be the situation in which the patient tells the pharmacist that she has been taking hydrochlorothiazide for hypertension and has just found out she is six weeks' pregnant. When the R.Ph. looks up the data on hydrochlorothiazide's effects in pregnancy, he discovers that the drug has not been implicated as a cause of birth defects in human pregnancy; however, it should be used during pregnancy only if it is clearly necessary. Untreated hypertension during pregnancy can lead to spontaneous miscarriage or preterm labor, all undesired consequences for mother and fetus. Thus, benefits outweigh risks for mother and fetus. The obstetrician can best advise the patient whether continued therapy with this drug is warranted or if a different antihypertensive agent is indicated.

The second opinion: Often, a patient will ask a question of the pharmacist just to get a second opinion. She already may have asked her doctor, the nurse, a neighbor, or another pharmacist, but she probably is looking for reassurance that what she has been told is correct. Before launching into any detailed discussion, the pharmacist should inquire about the patient's current understanding of the drug and its effects and where she may have obtained this information. Consider the following exchange:

Patient: "Is it OK to take aspirin while I'm pregnant?"

Pharmacist: "What have you been told by your doctor, Mrs. Wallace?"

Patient: "Well my doctor said not to take anything, not even an aspirin, but my girlfriend told me that her doctor said it was all right to take one or two tablets every now and then."

With this background, the pharmacist can tailor an answer to explain why this apparent contradiction exists. In actuality, both sources are right: Small doses of aspirin in early pregnancy are probably not harmful, but to make patients aware of the dangers of drug consumption, physicians sometimes use the common drug aspirin to emphasize the need for minimizing drug intake and for exercising great caution. By saying, "It's better to be safe than sorry," pharmacists can help their patients understand the seriousness of this issue.

The concept of benefit vs. risk: Knowledge of the overall health of the pregnant patient can prepare the pharmacist to discuss drug therapy in the context of benefits versus risks. For example, anticonvulsants (e.g., phenytoin, lamotrigine, valproic acid, phenobarbital) used in early pregnancy are associated with cleft lip and palate, neural tube defects, and other deformities in infants whose mothers have taken anticonvulsants prenatally. Yet, it is known that the risks of untreated seizure disorders on pregnancy are of great concern as well. If the physician determines that another anticonvulsant cannot (for some unknown reason) be substituted, the patient has little choice but to continue taking phenytoin if she desires to continue the pregnancy. Clearly, she must be apprised of the risks, and she must make the difficult decision to continue the pregnancy or not. But it is the responsibility of these professionals to help her understand the benefits and risks of therapy. Prenatal ultrasound testing can help assure the mother of the absence of gross abnormalities in the fetus in the second trimester.

Let us consider a different situation. Sally has been suffering from insomnia for several days. The lack of sleep is causing her to be anxious, ineffective, and drowsy at work. The following conversation may take place in the pharmacy:

Patient: "I just don't know what I'm going to do. I haven't been able to sleep for days. Would it be all right to take an Ambien [zolpidem] tonight? I have taken it in the past, and it has helped me sleep. I just

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need to get some sleep tonight.”

Pharmacist: “According to one of the best references for these types of questions, Yes, it sounds like Ambien would help you get some sleep. The FDA has not received any reports of adverse outcomes from pregnancy exposures to Ambien. Although I wouldn’t recommend regular use of Ambien for sleep during pregnancy, occasional use should be safe for you and your baby. You may also wish to try nondrug therapy measures to help you sleep, which include good sleep hygiene and relaxation techniques. Discuss with your obstetrician your difficulty sleeping to rule out any other problems.”

Patient: “OK, I will. Thank you.”

In this situation, it is fair to say that zolpidem is a low-risk compound that is in pregnancy category B. Limited human data, including registry data, suggest no risk of congenital malformations. It is not known whether zolpidem crosses the placenta, although based upon its molecular weight of 765 daltons, it probably does. Sally is suffering from severe sleep deprivation that is increasing her anxiety and affecting her daily life. If her problems were less intense, perhaps the benefit-to-risk scale would tilt in the direction of nondrug therapy. The patient should always discuss potential drug therapies with her physician as well.

A good test to help weigh the risks and benefits is to ask: “What would happen if this condition were not treated at all?” If the answer is, “The patient would likely get well anyhow,” then it is probably best not to treat the condition. Since most OTC drugs are intended for minor, self-limiting ailments, these drugs almost always should be avoided in favor of nondrug, nonherbal treatment, unless the patient has been instructed to use one.

Communicating the risks to patients: Patients have come to expect healthcare practitioners always to have precise answers to their medical questions. When it comes to drug effects on the fetus, there are few drugs or drug categories that can be said to be, without a doubt, terato-

genic. Besides thalidomide, there are the androgenic sex hormones, the antimetabolites, warfarin, large doses of vitamin A, and isotretinoin (see Table 1).

If a patient is pressing a pharmacist for a definitive answer, the pharmacist should be careful not to make recommendations that cannot be supported by at least some scientific data. To say, “Sure. Go right ahead and take it. That drug is perfectly safe,” certainly would be going beyond the boundaries of good practice. You might respond as in the next scenario:

Patient: “If I take this drug, will it hurt my baby?”

Pharmacist: “Mrs. Jones, I’ve reviewed the references available to me here in the pharmacy, and, from what I find, it appears that this drug does not impose any increased risk to your baby. One reference describes its use in 4,569 pregnancies, and the rate of malformation in babies was no higher than in the babies of women who did not receive the drug. I should remind you that there is no way I, nor anyone else for that matter, can guarantee you a completely normal baby. But, as your doctor has probably already told you, there is every reason to believe that you will have a fine, healthy baby.”

There are several key elements in this scenario. First, the pharmacist assured the patient that he had researched the question, within the limitations of his own immediate references. This shows his concern. He did not give the patient an answer off the top of his head. Instead, he gave a confident, educated response to the patient’s question.

Second, by giving the actual details of published reports, especially since the studies involved a large number of pregnant women, the pharmacist reassured the patient, who now has some perspective of how much experience there actually has been with the drug. Note that he never told the patient, “The group getting the drug had no malformation.” Instead, he implied that there is always the risk of malformations caused by things other than drugs.

Finally, the pharmacist ended the conversation by reminding the

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patient that, although the risk is small, every pregnancy is vulnerable to complications. He did end on an upbeat note about the chances for a normal baby, thus taking the patient's attention off something over which she has no control. Although the estimated frequency of birth defects from all causes is as high as 3% of all live-born infants, pregnant women shouldn't dwell on these figures.

PRACTICAL CONSIDERATIONS FOR COUNSELING PREGNANT PATIENTS

Counseling of *any* patient is not always practical to do at the time the patient comes into the pharmacy. This is especially true in a very busy operation, where pharmacists have all they can handle in just filling prescription orders. Perhaps the best way to resolve such a problem is to make an arrangement for the patient to return at a more convenient time. By saying this in a positive manner, the pharmacist will help the patient realize it will be better for both of them if she comes back later. This shows the patient that the pharmacist is genuinely interested in helping her.

Pharmacist: "Mrs. Smith, right now I don't feel I have the time to spend with you that this problem deserves. Your question is not an easy one, and I would prefer to sit down with you so I could devote my full attention to your concerns. Is there a time early tomorrow morning when you could stop by? That way, I'll have time to get some information together for you, and we can discuss it in a more relaxed atmosphere."

Patient: "It would be no problem to come by at 9:30 in the morning."

Pharmacist: "That sounds fine."

As in any counseling situation, a private area is more conducive to an exchange of information. To some, matters concerning pregnancy are particularly sensitive. If a private area is not available, perhaps there is a place at the end of the counter where some privacy can be afforded.

Special communications skills: There are several factors that apply to nearly all types of patient counseling. However, because of the delicate

nature of the pregnant patient's questions, the following factors take on special significance:

- the willingness of the pharmacist to answer questions
- the pharmacist's tone of voice
- the interest shown in the matter at hand
- the confidence with which questions are answered
- the terminology used by the pharmacist

The pharmacist's willingness to answer questions is easy for the patient to sense. Some pharmacists will discuss the case freely, while others will refuse to discuss it at all. When the R.Ph. asks pertinent questions to gain information, the patient is assured of a genuine interest on his part. In studies of pregnant women and their knowledge of the drugs they took, the most often cited reason for women not asking the pharmacist questions was a perception that he would be upset at being interrupted. The women had plenty of questions but thought the pharmacist was too busy. Whether this was an accurate assessment or not, we will never know, but this was the message they were receiving.

A friendly tone implies willingness to help. Nonverbal cues, such as direct eye contact and devoting full attention to the patient, support the notion that the pharmacist really cares. An abrupt or abrasive manner suggests that he is irritated about being asked such questions.

Pharmacists who talk to the patient while they continue to perform other tasks project a sense of disinterest in the matter at hand. It is inappropriate to end the conversation without volunteering to look further for information. Remember, enthusiasm in trying to help someone is easily sensed and is always appreciated.

Often, the same information presented in two different manners can mean the difference between its acceptance and rejection. Confidence in the information being relayed is necessary for the patient to be convinced that the pharmacist knows what he is talking about. A pharmacist who makes specific recommendations and backs them up with an explanation is far more effective than one who makes contradictory rec-

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ommendations. It is hard to have confidence in the advice being given if a pharmacist constantly prefaces his answers with, “I’m not sure, but...” or “I think that....” Good eye contact also inspires a degree of confidence in one’s answers.

Finally, it is necessary for the pharmacist to state the answer clearly and concisely. He should use terms that the patient is likely to understand. The good communicator will know his listener has understood him and will rarely need to restate or rephrase the answer. In some communication dynamics, it is obvious that the listener never got the message. Using medical jargon or presenting the information in a vague or roundabout way is sure to short-circuit information flow.

Emotional aspects: Because pregnancy brings about many changes in women, both physical and emotional, it is a period of both great excitement and apprehension. This is especially true for women who are pregnant for the first time. Normal events occurring during gestation can be mistaken for horrible complications. Frightening stories of still-birth always seem to surface as a topic of conversation—as if the expectant mother needs something else to worry about! Even friends

sometimes raise one another’s anxiety levels by making statements that are misleading, untrue, and certainly unsettling.

Reassurance often can be the best prescription for the anxious patient. The point to remember is that even though the patient’s concerns may seem trivial and unnecessary, they are very real and disconcerting to her. Nothing hits closer to the heart of a mother-to-be than the thought that she may have done something to hurt her unborn child.

Conclusion

Contrary to what expectant mothers may think, most drugs do not cause birth defects. Often, these patients have exaggerated fears based on misinformation or no information at all. Care and understanding will help allay these fears and result in a more enjoyable pregnancy.

For more information on the safety of drug therapy during pregnancy, go to Perinatology Resources at www.perinatology.com/exposures/druglist.htm.

References are available upon request.

TEST QUESTIONS

Mark the most appropriate answer. The answer form follows the test questions.

- Which of the following drugs caused a teratogenic effect called *phocomelia*?
 - Hydrochlorothiazide
 - Ranitidine
 - Thalidomide
 - Cyclophosphamide
- Digoxin is used to treat which of the following fetal conditions?
 - Idiopathic fetal tachycardia
 - Idiopathic fetal bradycardia
 - Tetralogy of Fallot
 - Herpes encephalopathy
- Major structural malformations of the fetus typically occur during which trimester?
 - First
 - Second
 - Third
 - Throughout pregnancy
- What is the incidence of drug-induced physical malformations in humans?
 - 2% to 3%
 - 1% to 12%
 - 20% to 30%
 - All birth defects are due to drug therapies.
- Certain drugs accumulate in the neonate, resulting in an exaggerated or prolonged response. What is this phenomenon called?
 - Developmental delays
 - Neonatal abstinence syndrome
 - Allergies or intolerances
 - Primary seizure disorders
- When used by pregnant women, which of the following causes small-for-gestational-age neonates by decreasing the delivery of oxygen and nutrients?
 - Cigarette smoking
 - Hydrochlorothiazide
 - Thalidomide
 - Ranitidine
- Which of the following is a pregnancy category A drug?
 - Diazepam
 - Hydrochlorothiazide
 - Zolpidem
 - Levothyroxine
- Which of the following vitamin deficiencies can cause neural tube defects?
 - Vitamin C
 - Vitamin D
 - Vitamin K
 - Folic acid
- Pregnancy category C drugs are assigned to what percentage of drugs included in the 2006 *Physicians' Desk Reference*?
 - 20%
 - 40%
 - 60%
 - 80%
- How much folic acid is contained in over-the-counter prenatal vitamins?
 - 400 mcg
 - 800 mcg
 - 1,200 mcg
 - 2,400 mcg
- When would pregnancy category D drugs be used in pregnancy?
 - Only in the third trimester when there are no alternatives
 - In life-threatening situations or diseases with no safer alternatives
 - Only during labor or when breast-feeding
 - Never
- Which of the following drugs can cause cleft palate of the neonate when used during pregnancy?
 - Pantoprazole (Protonix)
 - Diphenhydramine
 - Doxylamine
 - Phenytoin

TEST QUESTIONS

- 13.** How much alcohol is safe to consume during pregnancy?
- One glass per week
 - Two glasses per week
 - One glass per month
 - No alcohol consumption is safe during pregnancy.

Questions 14 through 16 are based on the following case:

Jane is a 27-year-old female taking warfarin 10 mg per day for a hereditary hypercoagulable state. She weighs 70 kg. She has been taking warfarin for three years since her condition was first diagnosed. She confides in you today when she requests a refill of her warfarin that she has just found out she is pregnant.

- 14.** Which of the following is the appropriate next step?
- Fill the prescription and dispense OTC prenatal vitamins
 - Refuse to fill the prescription
 - Refuse to fill prescription and dispense OTC prenatal vitamins
 - Counsel the patient on the teratogenicity of warfarin and contact her physician for an alternate anticoagulant
- 15.** The physician asks for your recommendation for an appropriate anticoagulant. What would you recommend?
- Enoxaparin 30 mg subcutaneously twice daily
 - Enoxaparin 70 mg subcutaneously twice daily
 - IV heparin in the hospital
 - No anticoagulant, use aspirin only
- 16.** The pharmacist can counsel Jane on which of the following?
- How to inject enoxaparin
 - Where to inject enoxaparin
 - How to dispose of needles
 - All of the above
- 17.** When communicating the risks to patients, the pharmacist should do which of the following first?
- Assure the patient that the question was researched
 - Give an off-the-cuff recommendation
 - Refer the patient directly to a physician
 - Provide the patient reading material, but do not say anything more
- 18.** Why is it inappropriate to “guarantee” that a drug therapy is totally safe for pregnant patients?
- Little evidence exists to prove that drug therapies are totally safe in human pregnancy.
 - There is a 1% to 3% risk of physical malformations in all pregnancies, regardless of drug therapies.
 - A false sense of security is not what the patient needs.
 - All of the above are good reasons to give patients information to weigh risks and benefits.
- 19.** Pharmacists should be ready and willing to do which of the following when counseling pregnant patients?
- Answer the patients’ questions in a kind and knowledgeable manner
 - Refer all pregnancy questions to the obstetrician
 - Use medical jargon to explain risks to patients
 - Counsel all patients in 30 seconds or less
- 20.** Ultimately, who has the final say as to whether the patient will take drug therapies during pregnancy?
- The obstetrician
 - The pharmacist
 - The family practice physician
 - The pregnant patient

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ANSWER FORM

**Drug therapy during pregnancy:
Practical tips for patient counseling**

DECEMBER 11, 2006 ACPE # 012-999-06-210-H01

Test questions start on preceding page

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