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IN A NUTSHELL



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Counseling

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Many health care providers feel uncomfortable talking to pregnant women about risk. We worry that what we say will be wrong, or unhelpful. But women with an exposure during pregnancy turn to us for answers, whether or not we feel comfortable and whether or not we have the answers.

Some practitioners won't counsel pregnant women about risks. Referral is a reasonable option, provided that reliable referral sources are readily available. Other practitioners counsel defensively; that is, they give a counseling message intended to reduce their liability for an adverse outcome. Defensive counseling is bad for the patient, but it can also backfire on the practitioner.

Consider these two true stories:

A patient had fractured her arm at 6 weeks gestation and had four x-rays in the emergency room. Her obstetrician had told her that x-ray is teratogenic, that the baby would be abnormal, and counseled the woman to have an abortion. Dissatisfied with this answer, she came to me for another opinion. It was easy to calculate that the embryo had received a negligible dose of radiation and the woman was told that there was no increased risk of birth defects. The woman lost faith in her obstetrician and switched practices.

Another woman had an abortion of her first pregnancy after her obstetrician told her that oral contraceptives, to which she had been exposed in early pregnancy, were teratogenic. During the abortion,

the uterus was perforated laterally, and the resulting uterine artery laceration resulted in hysterectomy. The woman sued the abortion clinic for negligent performance of the procedure, and also sued her obstetrician for giving her erroneous information.

These cases occurred because the obstetricians believed that recommending abortion of a wanted pregnancy in the face of an exposure was the most cautious course. They made two errors. First, they gave bad information, and second, they made decisions for their patients.

Giving Good Information

Providing good information involves more than providing good facts, although good facts are an important starting point. Consider a woman who comes for counseling because she has become pregnant while on valproic acid. The risks of this drug have been well-defined in human studies, and it seems straightforward to tell a woman that her use of valproic acid during pregnancy is associated with a 1 to 2% risk of lumbar meningocele in her child.

However, a common problem in information transfer is that patients are asking a different question than the counselor is answering. The question asked is, will my baby be normal? The question answered is, what is the risk of abnormality? Telling a woman there is a 1 to 2% chance of lumbar meningocele does not tell her whether her baby will be normal. People may

have trouble envisioning what a 1 or 2% risk means, and may not be prepared to make decisions with this kind of information.

If you tell a couple, based on ultrasound, that their baby has a lumbar meningocele, they need to learn what lumbar meningocele is, what it does to the affected child, and what treatments are available. This educational process can be difficult, particularly for parents who have little medical background. The educational process is more difficult and frustrating for everyone involved when the chance of the disorder is 1% instead of 100%.

And valproic acid-associated lumbar meningocele is as clear-cut as it gets; the incidence is well-documented and prenatal diagnostic tests for it are highly accurate. So, let's add some additional uncertainty. It has been proposed that valproic acid exposure is associated with limb abnormalities that occur at a much lower rate than lumbar meningocele. The added uncertainties are: 1. scientists are not sure whether there really is an increase in limb abnormalities; 2. if risk is increased, we don't know by how much; and 3. prenatal testing is less effective for identifying limb abnormalities than identifying neural tube defects. How do you express this poorly-defined risk to an exposed woman?

Besides expressing facts clearly, it's important to check that the communication has succeeded. The most common strategy is to ask the patient to repeat back the informa-

tion. For some people, probability of an outcome (that is, risk) is a new concept that may require creative teaching. Rolling dice is a common illustration, but may not be a good idea because patients may associate dice with gambling or luck. Some counselors use a jar containing 99 jelly beans of one color and 1 jelly bean of a different color, to illustrate a 1% risk.

Letting Patients Decide

One of the hardest things for a health care provider to deal with is a patient making the “wrong” decision, meaning one with which the counselor disagrees. It is difficult not to impose one’s views of risk and benefit onto a counseling session. But you will be a better counselor when you accept the fact that the decision belongs to the patient. The patient gets to decide how to use the information she is given, even if that decision seems wrong to the counselor.

For example, a 45-year-old woman comes to you for prenatal care. How do you handle her risk of having a baby with Down syndrome? Most practitioners would tell her that she has a 10% chance of carrying an aneuploid fetus, and that because the chance of miscarriage after chorionic villus sampling or amniocentesis is less than 0.5%, she should have the testing. But if the patient doesn’t want to take a 0.5% chance of pregnancy loss, and finds it far preferable to have an undiagnosed Down syndrome child – that’s her decision

Consider a patient I counseled concerning phenytoin effects on pregnancy. The patient was not yet pregnant, but wanted to have a child. It was important for her health that she continue medication and she wanted to know whether it would be reasonable for her to conceive or whether she should plan to adopt. The information available on phenytoin shows about

a 10% chance of having a child with a major malformation and a 40% chance of having a child with a minor malformation. While some other women would have responded with dismay, this woman responded with great relief because she had thought the chance of major malformation was closer to 100%. She felt that a 10% risk was quite reasonable, and she decided she would go ahead and conceive a child herself.

Is it fair to let women make this kind of decision? What about the child with a phenytoin-related malformation; don’t we have an obligation to prevent such an outcome?

In fact, we have no such obligation, legally or morally. The decision whether to bear a child and what level of risk is acceptable is ours only with respect to our own childbearing decisions, not those of our patients. A woman’s reproductive decisions belong to her alone.

Counseling Challenges

Many difficult situations arise when we talk to people about the reproductive effects of exposures. Here are some examples and suggested approaches.

1. “No risk is acceptable.”

I always begin counseling sessions with a discussion of baseline risks of adverse outcomes. Many people don’t know that just by getting pregnant, a woman undertakes a 30-50% risk of miscarriage, a 3-5% risk of birth defects in the baby and a risk of mental retardation in the child of around 1%. The correct question about an exposure during pregnancy is not, will my baby be normal, but will the exposure increase the background risk?

A pregnant woman I counseled told me that she could not accept even a one in a million chance that

the medication she took might cause a birth defect. I pointed out that a background risk of birth defects of 3% was the same as a 30,000 in a million chance. Was she telling me she could accept 30,000 in a million but not 30,001 in a million? Yes, she said, that was her position.

Of course, what this woman was really saying was that she could not accept the guilt associated with believing that her action had caused a birth defect. She could accept the spontaneous level of risk because that was not her fault, but she couldn’t accept the tiniest possibility of having caused a problem to her child.

Guilt is an important issue that should be confronted directly during counseling. Even exposures that don’t cause birth defects do cause guilt. If 3% of children in the general population are born with a recognized malformation, then 3% of children born after a harmless exposure will have a malformation. It can be helpful for parents to consider during counseling that bad things happen spontaneously, and that occurrence of a malformation is not proof that the parents did something wrong.

2. “Animal studies don’t apply to humans.”

Most exposures have little information available on human pregnancy outcome; pregnancy information often is available only from experimental animal studies. Being comfortable with experimental animal data will make you a more effective counselor (see *Reprotox In A Nutshell* September 2004).

Interpreting experimental animal data for counseling is not straightforward. Experimental animal studies use different designs, different dose levels, and are of varying quality. The relevance for human exposure scenarios may not be

obvious. Still, the following points may be helpful to discuss:

- All exposures that are known to produce adverse pregnancy outcome in humans also do so in experimental animal studies. There are no teratogenic exposures that, when tested in a rodent and non-rodent species up to an appropriate dose level, fail to produce a signal in the experimental studies. In other words, we have no examples of exposures that are harmful only in human pregnancy.
- Experimental animal studies that show evidence of abnormal outcome for the fetus, particular at maternally toxic dose levels, often do not appear to be harmful in human pregnancy at customary human exposure levels.
- The closer an experimental animal study comes to modeling the human exposure based on blood concentrations (as opposed to the dose put in the animal's stomach), the more predictive it is likely to be.

Critics of experimental animal studies point out that these studies focus only on specific endpoints, for example, the structure of the newborn animal's body, rather than other important endpoints, such as reading ability in the third grade. True enough, but human studies also focus on specific endpoints, such as malformations. The study showing that valproic acid causes an increase in the risk of lumbar meningomyelocele did not evaluate reading level in the third grade, either.

3. "I don't want to take medication that could hurt my baby."

It is common for people to believe that all exposures during pregnancy are bad. With respect to medications, this attitude presupposes that the untreated disease would be safer for the fetus than the medication. For diabetes mellitus, asthma, and hypertension, we know the untreated disease is worse for mother and baby than the treatments that are used. For seizure disorder, depression, and arrhythmia, we believe it likely that treatment is preferable to the untreated disease.

Women with chronic disease can be counseled when planning a pregnancy about the usefulness and potential adverse effects of therapy. Unplanned pregnancy is common, however. Counseling after pregnancy has occurred is more difficult than counseling before pregnancy, particularly when medications that are important to the health of the woman may have adverse effects on pregnancy outcome.

A useful strategy is to review medications during annual visits for all women of childbearing age. Women being treated for chronic illnesses can be counseled about pregnancy effects of their medications whether or not they are planning to become pregnant.

4. "Doctors don't know everything."

This response is common, particularly when a worried couple is

told that the exposure at issue does not increase the risk of adverse outcome. Take an exposure such as x-ray, which is viewed by the general population as harmful. A pregnant woman who has had a dental x-ray has no added risk of adverse pregnancy outcome, but she may be unable to believe this reassurance.

Being told you don't know everything may offend you, but don't take it personally, and remember that the statement is likely to be true. Still, when there is substantial experimental evidence behind your reassurance, as in the x-ray example, it may be difficult to avoid arguing with the patient.

One strategy is to admit that while it's true that doctors don't know everything, we do the best we can with what we do know. It may be helpful to use weather prediction as an analogy. When the weather report says there is a 90% chance of rain, most of us take our umbrellas, even though we all know that meteorologists don't know everything.

These suggestions won't solve every counseling difficulty, and you may have your own examples of problems you have seen in counseling. If you would like to share your own examples of difficult counseling issues or ideas about how to handle these kinds of problems, please send them to me at ascialli@sciences.com, and we will discuss them in a future issue of *Reprotox in a Nutshell*.

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