

Cancer Treatment During Pregnancy: There's Strength in Numbers for Researchers

Nora Beidler

Fortunately for patients, a cancer diagnosis during pregnancy is rare. For researchers, the rarity of the combination makes for difficult research, and gathering cases to examine becomes the initial challenge. Recently, the Motherisk program at the Hospital for Sick Children in Toronto, Canada, has begun an international registry of cases of cancer in pregnancy to contribute to this literature.

"We decided that since the combination of cancer and pregnancy is quite a rare combination, the only way that we could collect data was the Web and the Internet," said Motherisk's Michael Lishner, M.D., co-director of Motherisk's Consortium of Cancer in Pregnancy Evidence (CCoPE).

Lishner and his staff started a Web site last July that provides summaries of the current knowledge of treating pregnant cancer patients and invites physicians to enter cases in a registry. Lishner plans to collect data on the effects of cancer treatment on both the mother and child, both short- and long-term. "There has never been a prospective study published on cancer in pregnancy," he said.

With the Motherisk program, physicians can submit a brief summary of a case electronically. To help overcome bias that may be introduced through voluntary submission of information, a member of the Motherisk consortium will contact the physician to collect more details on the case and verify the information provided.

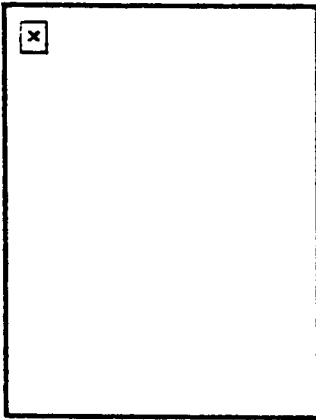
"Of course we cannot dictate the treatment protocol, because every oncologist or every hematologist is doing what he considers to be best. This is a problem with prospective collections because the groups will not be identical," said Lishner.

A Rare Occurrence

A cancer diagnosis occurs in approximately one in 1,000 pregnant women. It is a relatively rare combination, but compelling when it occurs. Treatment decisions must balance the health of the

mother with the health of the child, and also consider the emotional and ethical views of the patient and her family. Every case requires highly individual care.

"Pregnancy is very common, and cancer is very common," said Jeanne Petrek, M.D., surgical director of the Lauder Breast Center at Memorial Sloan-Kettering Cancer Center, New York. "But the intersection of the two is so uncommon, and it's really treating two patients, the mother and the baby. How to do the best by both of them is a big problem."



Dr. Jeanne Petrek

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The type of cancer, stage of the cancer at diagnosis and the gestational age of the fetus are main factors in treatment decisions. A woman, with help from her doctors and family, could begin therapy immediately, defer therapy until after birth, or terminate the pregnancy.

Edward Trimble, M.D., of the National Cancer Institute, who recently published a book on cancer treatment for pregnant patients, said, "Over the last few years, we've learned something about how we can postpone certain aspects of treatment until after the baby has been safely delivered."

In many instances treatment can proceed without compromising the mother's prognosis or harming the developing fetus.

Risks to a developing fetus are well known for some cancer therapies. Radiation therapy is avoided at any stage of pregnancy, as well as certain classes of chemotherapy drugs. Some chemotherapeutic agents are thought to be safe only when administered during the second or third trimester. Surgery is considered safest at any stage of pregnancy.

"Everything, really, that's done during pregnancy affects the developing baby—even surgery," Petrek cautioned. "The main point of chemotherapeutic agents is to kill rapidly dividing cells, which of course, *is* a fetus—rapidly dividing cells."

Teratogenesis

With many chemotherapeutic drugs, information on teratogenesis is simply unknown. "For most of our investigational agents, the new chemotherapy drugs, we don't have any evidence one way or another, so it's very hard for us to tell a person what the risks to the fetus are, whether there's going to be a risk of spontaneous abortion, malformation to the fetus, or intrauterine growth retardation," Trimble said.

A clinical trial to test new drugs only in pregnant cancer patients is not realistic. "Fortunately the incidence of pregnancy at the same time of cancer is very, very low," he continued. "It's a very specific problem, and a horrendous problem when someone is confronted with it. But the numbers are not such that we could organize a clinical trial specific for a pregnant woman who has cancer. It's not feasible to do that."

Federal guidelines say a woman cannot be excluded from a cancer clinical trial unless there is clear knowledge that the treatment poses unacceptable risks to the fetus. When the risks of a drug to a developing fetus are unknown, the woman considering the trial has the final decision.

"What our guidelines say is basically that it's up to a woman to decide. The doctor needs to discuss the trial, tell her what we know and what we don't know, and then it's up to her to make that decision," said Trimble.

Registries Available

In addition to the Motherisk registry, one has been available in the United States since 1984. It has been operated by John J. Mulvihill, M.D., the Kimberly V. Talley Chair in Genetics at the University of Oklahoma Health Sciences Center, Oklahoma City. The registry invites submissions from physicians to add to the 200 cases it gleaned from the medical literature. To add a case to Mulvihill's registry, physicians must provide information on the mother's exposure to a cancer therapy drug and follow up by providing the outcome of the pregnancy.

When a doctor or patient calls the registry for advice, Mulvihill and his staff search the database of about 300 cases. "We can compose a sort of subset of the registry listing all the cases that had exposure like she had, or is going to have, and what the outcomes of pregnancy are."

The registry primarily serves as an information service for health professionals and patients. "It's not case-controlled, analytical epidemiology, but I think this issue never will be. You can't do that experiment, and it's too rare to really get a good series in terms of controls," said Mulvihill.

He added: "We explain the flavor, or the nuances of the information and its limitations, which are many, in the hopes of getting a little bit of total perspective of our collected expertise, into a very poignant dilemma: 'me or my baby.' We just hope to make, if we can, a win-win situation out of it for as many people as possible."

Note: For information on John J. Mulvihill's registry, call 405-271-8685, or e-mail John-Mulvihill@ouhsc.edu. The Web site for the Motherisk's Consortium of Cancer in Pregnancy Evidence is <http://www.motherisk.org>.