Ethicists: Include pregnant women in national childrens' study

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An ambitious new national study that aims to follow children from conception through adulthood will miss a golden opportunity to gather data on the most underrepresented population in clinical research - pregnant women, say leading ethicists at Duke University Medical Center, Johns Hopkins and Georgetown Universities.

There's still time, however, to make small but crucial cost-effective changes that could yield valuable information for women's health from The National Children's Study.

"This is an ideal chance to study women during and following pregnancy, as well as the babies they will bear," says Anne Drapkin Lyerly, MD, an obstetrician/gynecologist and medical ethicist at Duke. She is the lead author of a paper being published online today by the American Journal of Public Health. It urges NCS organizers to make changes in the study's design before it's too late.

"The simple act of adding a few key questions on medication usage to the interviews and blood draws already scheduled can lead to a wealth of information," says
Margaret Olivia Little, director of the Kennedy Institute of Ethics, Georgetown University.

Ruth R. Faden, executive director of Johns Hopkins Berman Institute of Bioethics, added, "It makes such good sense, ethically and economically, to include a focus on pregnant women in the NCS. Just a few additional

questions could make an enormous difference to the health of women, not only during pregnancy but throughout their lives."

Although the Institute of Medicine began recommending that pregnant women be included in clinical trials 15 years ago, pregnant women remain excluded from trials for many reasons, including the ethical concerns raised when trying to strike a balance between maternal and fetal risks.

"Of course safety of medicine for a developing fetus is rightfully a concern, but it shouldn't swamp all others," notes Lyerly who adds there are social ramifications at play too. "When an untreated woman dies of cancer, there are obviously lifelong implications for a child facing life without a mother."

Nearly two-thirds of the four million women who become pregnant each year take prescription medications during their pregnancy for conditions ranging from hypertension to cancer, Lyerly says. A handful of medications are approved for use during pregnancy by the FDA, and most are for gestation or birth-related issues like anesthesia and nausea. As a result, clinicians have little evidence on which to base their recommendations.

"Pregnancy changes the body in dramatic and often unpredictable ways," says Lyerly. Previous studies show pregnancy alters liver enzymes, concentrations of sex hormones, and how quickly drugs are metabolized by and excreted from the body.
The lack of data also leaves many pregnant women under-treated for conditions where treatment could outweigh some of the potential risks. For example, poorly controlled asthma can lead to dangerous pregnancy complications and fetal growth problems while major depression is associated with poor outcomes for women and neonates.

"A large, observational study in which fetuses are not put at any additional risk is a promising and ethically uncomplicated way to gather data," says Lyerly.

That, she contends, is the design of the National Children's Study. The goal is to follow 100,000 children, with 25 percent being enrolled prior to conception and up to 90 percent during the first trimester of pregnancy. This means researchers will be in regular contact with 90,000 women throughout their pregnancy. Based on current statistics, that could potentially mean a study population including 4,000 women with diabetes, 4,000 women with pregnancy-related hypertension, 1,000 with chronic hypertension, 12,000 with depression, 4.000 to 8,000 women with asthma and 2,700 women with thyroid disease.

Many of these women will be taking one or more medications without data to back up their doctors' recommendations. And, that, she says, is exactly what the NCS researchers could be evaluating.

Lyerly and her colleagues recognize that changes to the NCS can only come at the price of additional funding. At a minimum, they say the study should be expanded by including the collection of additional data from already scheduled interviews and maternal chart reviews. "These data would document women's health outcomes related to their pregnancy."

Second, blood already being drawn from pregnant women can be used to garner information on how drugs are metabolized by the woman's body. At the very least, it would help guide the identification of drugs that require more intensive study.

"These two efforts, at very little additional cost, would result in a rich database of knowledge that could lead to critical improvements in the care of pregnant women," the trio states in their paper. "Not including

them, in our view, would be hard to justify."

Source: Duke University Medical Center (news : web)