An ethical argument: Include pregnant women in research

September 26 2008

Why aren't pregnant women included in most clinical trials? That's the question posed by leading bioethicists at Duke University Medical Center, Johns Hopkins and Georgetown Universities, who say it's time to confront the challenges that have led to the exclusion of pregnant women from important research that could positively impact maternal and fetal health.

"Only in the last two decades did people recognize that women were being excluded not just from the risks, but from the benefits of research -- primarily because of their potential to become pregnant or because of concerns that female physiology - such as menstrual cycles - might complicate study results," says Anne Drapkin Lyerly, MD, an obstetrician/gynecologist and medical ethicist at Duke.

She is the lead author of a paper appearing online and then in print in the November 2008 edition of the *International Journal of Feminist Approaches to Bioethics* detailing the justifications for responsibly including pregnant women in research. "While we've made significant progress in correcting the gender imbalance, we have a long way to go in protecting the health and safety of pregnant women and the fetuses they carry."

The Institute of Medicine has recommended that pregnant women be "presumed eligible" for participation in research since 1994. However, the authors say the "delicate condition" continues to be grounds for near-automatic exclusion from research, despite the need for more effective

treatment for women during pregnancy

More than four million women give birth in the U.S. each year, and many face medical conditions during their pregnancies that require clinical treatment. In fact, Lyerly says chronic diseases occurring during pregnancy are common: chronic hypertension and diabetes complicate nearly four percent of pregnancies each year; and an estimated 500,000 pregnant women experience psychiatric illness, cancers, autoimmune diseases and other conditions that require treatment. But in the absence of research on how medications work in pregnant women, doctors are often left guessing about how to safely and effectively treat patients through pregnancy.

"Our best predictions when it comes to dosing medications can be disastrously wrong," says Lyerly. "This conservative stance doesn't help anybody. Without adequate research on how drugs are metabolized during pregnancy, how they are absorbed, distributed in and excreted by the body, whether they cross the placenta or affect the fetus, we have little to no evidence on how to optimize the health of pregnant women or the fetuses they carry."

Lyerly and her colleagues at Johns Hopkins University's Berman Institute of Bioethics and Georgetown University clearly recognize the many challenges that need to be addressed in order to safely include pregnant women in clinical research. In fact, they are convening a meeting with officials from the FDA, NIH and leading experts in obstetrics, gynecology and maternal/fetal medicine next year to address these issues and come up with practical, public policy and moral solutions.

"It's not simply a matter of including pregnant women in studies," Lyerly explains. "We need to address what we need to do to ensure maternal and fetal safety, which diseases we should study first, and what we should do when pharmaceutical companies or institutions say no."

Source: Duke University Medical Center