**Pregnant Women Must Be Studied Too**

Imagine being pregnant with a chronic health condition such as diabetes, hypertension, depression or asthma, or being diagnosed with an illness while pregnant. Amazingly, your doctor may not know exactly what drugs or treatments, or what dose, will work best for you. This is a reality faced by millions of women every day.

The simple fact is, pregnant women get sick and sick women get pregnant. Meanwhile, rates of chronic disease are rising and women are having children at an older age. Stopping medication or avoiding new treatments is not always an option. Significant knowledge gaps exist because historically pregnant women have been excluded from medical research, mainly due to concerns about the effect on the fetus. But even a normal pregnancy has risks!

There is a common belief that medication during pregnancy is unhealthy and unwise, which creates a dilemma for women since failing to take medication, taking inappropriate doses or not being prescribed a needed treatment can be harmful or fatal for the mother or her unborn child. Today, a woman will take 3-4 medications on average during pregnancy or while breastfeeding. Health care providers, though, often have inadequate information about how a drug works during pregnancy because most medications have not been evaluated in pregnant women.

A woman who is pregnant or nursing may stop taking drugs or breastfeeding, even though that may not be the best course of action. With more information, she could stay on medications that improve her short term and long-term health and quality of life while minimizing harm to herself or her baby.

Moreover, newer medications shown to be effective in non-pregnant patients could improve outcomes in pregnancy if trials are done in pregnant women. For example, newer treatments for hepatitis C may help prevent the mother-to-child transmission of hepatitis C if studied in pregnancy.

Unfortunately, the lack of scientific information on new treatments and dosages for drugs that might be taken by women during pregnancy and lactation leads to health care providers being uncertain about prescribing a needed medication or instead substituting an older or less effective alternative. Worse, in the search for answers, many pregnant women turn to the Internet and social media, which often results in conflicting, confusing and just plain wrong advice.

Our nation must do better. Pregnant women should determine what level of risk they are willing to take. A robust, transparent informed consent process can help them make that decision. Pregnant women should not be prohibited from deciding if they want to participate in medical research, as they are now since most research protocols exclude pregnant or breastfeeding women.

Additionally, we need to improve data collection related to drugs and pregnancy, which are currently inadequate to make informed decisions. For example, the Food and Drug Administration (FDA) keeps a list of what are called Pregnancy Exposure Registries that collect health information from researchers and drug companies about women who take medicines or vaccines while pregnant.

Existing data should be standardized and easily accessible to support sound decision-making by providers and patients. Pregnancy registries should be required for new drugs, and registries must capture not just adverse events but healthy outcomes to create a baseline of both positive and negative medical information.

The Office of Management and Budget (OMB) also should finalize the long-pending FDA Pregnancy and Lactation Labeling Rule, which would provide detailed, updated information about fetal risk, clinical considerations and the quality of studies available for each drug.

Federal policymakers and the medical community must reevaluate regulations excluding pregnant women in medical research and strengthen requirements to collect as much data as possible, including follow-up with women who become pregnant and drop out of a study.

Incentives must be created for pharmaceutical companies to perform lab research and clinical trials focusing on pregnancy when seeking approval for new drugs that may be used by pregnant women. More data on drugs and treatments should be gathered and made available too.

By taking these actions, pregnant women will be better served in medical research. With 62 million women in the United States of childbearing age and 4 million births each year, getting the best possible health care is vitally important now and for generations to come.

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