Three Steps to Speedier HIV Med Approvals for Pregnant People

Right now, it typically takes six years after an HIV drug is approved to obtain data for pregnant people.

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To eliminate the disparity in HIV drug data for pregnant and breastfeeding people, regulators and drugmakers need to take four key steps, a consortium of researchers recommend in an opinion piece in the Journal of the International AIDS Society.

Right now, data on pregnant people usually don't arrive until six years after an antiretroviral is approved for other adults. This means that researchers "shift the risk of harm from occurring under trial settings in which informed consent and intensive monitoring are practiced, to occurring in routine care settings in which medications may be used despite a lack of data for evidence-based management decisions," according to the authors.

Lack of inclusion of women—pregnant or not—has been an ongoing issue in clinical trials. For example, the lack of data on cisgender women meant that the Food and Drug Administration approved Descovy (tenofovir alafenamide/emtricitabine) for HIV pre-exposure prophylaxis for everyone except those at risk of HIV through vaginal sex.

But changes won't be straightforward, wrote Risa Hoffman, MD, an infectious disease doctor at the David Geffen School of Medicine in Los Angeles, and colleagues, but they will be possible if officials and scientists follow data and recommendations laid out by the Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) and the Pregnancy and HIV/AIDS: Seeking Equitable Study (PHASES) Working Group. PRGLAC's work has been funded by the National Institute of Child Health and Human Development (NICHD) and PHASES received funding from the National Institute of Allergy and Infectious Diseases (NIAID), both part of the National Institutes of Health.

The three steps are:

- Reduce regulatory barriers. Drugmakers can design clinical trials so that they start preclinical testing for potential harms to the fetus early in the trial process—and regulators can insist that they do so. That way, by the time researchers recruit participants for their Phase IIB or Phase III

trials (the studies that show whether the drug actually works in humans), they will have the information they need to know whether it's safe to include pregnant people in those trials. Currently, risk of pregnancy complications or fetal harm is a cause for researchers to exclude many women from clinical trials, and women who become pregnant during a trial are often taken off the study drug and removed from the study. This step would also allow researchers to present that preclinical data to women who become pregnant during the study and allow them to decide if they want to continue in the trial. If women decide to go ahead, they can be regularly monitored throughout the pregnancy, and data on the infants can be kept to provide data throughout the process.

- Design smart trials with pregnancy in mind. Increasingly, trials for cancer and for COVID-19 have included mechanisms to allow people to continue in the trial, even if they have complex outcomes. Hoffman and colleagues point to the Master Adaptive Platform Trials, which fast-track drug discovery by building in plans for what to do based on interim data—for instance, having multiple cohorts within one trial, all compared against a single control group. That way, if, say, interim data on pregnant people showed abnormalities in development, researchers could adapt, rather than halt, the whole study. In short, the risk that including pregnant people could jeopardize the entire study would disappear.
- Collaborate for better outcomes for pregnant people and their children. To make all these changes, it's going to take partnerships between industry, academic researchers, nongovernmental organizations, government regulators, clinical trial sites and, of course, pregnant people themselves working together, the experts said. They suggest incentives to spur early preclinical research into potential pregnancy toxicities and regulatory rules that mandate that drugmakers test their drugs in pregnant and lactating people if preclinical data look promising.

Writing in honor of International Women's Day, the authors conclude with this thought: "Pregnant and lactating women must be protected through research, not from research. We must achieve equitable and timely inclusion of all women in clinical trials."

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