Bioethics scholars fault requirement that all women in clinical drug trials use contraception

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(Garrison, NY) Research ethics review committees often require all women of childbearing age who enroll in clinical trials to use contraceptives to protect against a developing fetus being exposed to potentially harmful drugs. A mandatory contraceptive policy is often imposed even when there is no evidence that a trial drug could harm a fetus or when women have no chance of becoming pregnancy. This requirement is excessive and can safely be relaxed in many cases, according to a report in IRB: Ethics & Human Research.

Policies on contraceptive use in research should reflect the level of potential risk the study drug poses to the fetus, write Chris Kaposy, an assistant professor of Health Care Ethics at Memorial University of Newfoundland, Canada; and Françoise Baylis, professor and Canada Research Chair in Bioethics and Philosophy at Dalhousie University in Halifax. They point to the U.S. Food and Drug Administration's categories for prescription drug labeling for drug use in pregnancy as a helpful guide. The FDA has five categories, each with different degrees of evidence of risk to fetuses.

Category A, for example, indicates that "adequate, well-controlled studies in pregnant women have not shown increased risk of fetal abnormalities." And yet the policy of the University of Nebraska Medical Center's institutional review board - which Kaposy and Baylis reviewed as a typical example of IRB contraceptive use policies -

permits researchers to petition the IRB to impose a mandatory contraception or abstinence requirement for trial participants in studies that use Category A drugs. However, the authors argue that an ideal policy for Category A drugs would not require contraception or abstinence.

The authors also say that contraception should not be mandated for women who have no chance of becoming pregnant while participating in a clinical drug trial. "Consider, for example, women who are not sexually active (e.g., nuns) or who are not sexually active in a heterosexual relationship (e.g., lesbians)," they write. Mandating contraception for these groups sends "a paternalistic message of mistrust" that undermines the normal practice of treating research participants as autonomous decision-makers.

"Our recommendations are an attempt to find an appropriate balance between the interests of potential fetuses and the autonomy and well-being of women," they write.

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