20-1329 McKay

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1

Protection by Exclusion: Another Missed Opportunity to Include Pregnant Women in Research During the Coronavirus Disease 2019 (COVID-19) Pandemic

In the timely commentary by Costantine, Landon, and Saade published in the April 2020 issue¹, the authors made a compelling argument to end the practice of "protection by exclusion," whereby pregnant women are systematically excluded from clinical trials of vaccines and therapeutics even during disease outbreaks.

The authors make one statement that requires correction. They state, "Even during the Ebola virus epidemic, pregnant women were excluded from all therapeutic and vaccine-development trials." This is not true in the still-ongoing Ebola outbreak in the Democratic Republic of Congo. While the Ebola ring-vaccination protocol (recombinant vesicular stomatitis virus—Zaire Ebola virus [rVSV-ZEBOV]; rVSV-ZEBOV-GP vaccine) started in August 2018 initially excluded pregnant women, the policy was changed 10 months into the outbreak allowing pregnant women (after the first trimester) to be included.² A second Ebola vaccine (Zabdeno [Ad26.ZEBO]) and Mvabea [MVA-BN-Filo] ebola vaccine; Ad26.ZEBOV, MVA-BN-Filo) trial that was started in November 2019 also included pregnant women.³

Furthermore, for confirmed Ebola patients, pregnant women could be enrolled in the four-arm randomized controlled trial of experimental therapeutics and 17 women with confirmed pregnancy participated.⁴

These examples provide an important precedent for the inclusion of pregnant women in trials.

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20-1329 McKay
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2
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