Letter to the editor

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An ethics call for the inclusion of pregnant women in research: Reflections of the Global Forum on Bioethics in Research

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The Global Forum on Bioethics in Research (GFBR) met on November 3 and 4 in Buenos Aires, Argentina with the purpose of discussing the ethics of research with pregnant women. The GBRF is a global platform that brings together key actors with the purpose of promoting research conducted in an ethical way, strengthening health research ethics–particularly in low- and medium-income countries–and promoting collaboration between the countries in the north and the south.[a] Some of the participants of the GFBR attending from Latin America include ethicists, researchers, ethics committee members and representatives of health authorities from Argentina, Brazil, Chile, Colombia, Ecuador, El Salvador, Guatemala, Honduras, Panama, Peru, Nicaragua and Dominican Republic.

A legitimate concern about the protection of pregnant women and their embryos or fetuses has led most of the countries in the region to restrict studies with pregnant women exclusively to those that are about pregnancy, and to require the systematic exclusion of pregnant women and women who get pregnant from the rest of studies. Certainly, throughout the history of research ethics it has been mistakenly believed that protecting a population is synonymous with excluding that population from studies. It is now known that proceeding in this way implies exposing the very population we want to protect to larger risks.

Pregnancy implies substantial physiological changes that significantly influence the way the body metabolizes medications. However, by avoiding conducting research with pregnant women, the necessary scientific evidence to inform decisions on preventive treatments and interventions with effective and safe dosage for them and their embryos or fetuses has not been produced. As an illustration, in 2001 there were barely a dozen medications approved for use during pregnancy in the United States[1], and in 2011 the Food and Drug Administration (FDA) approved, for the first time in 15 years, a medication to be used during pregnancy.[2] As a result, pregnant women's health is jeopardized every time we provide them health care. Pregnant women get sick and sick women get pregnant, and it is not known if the medications they are prescribed are efficacious or even safe for them and their embryos or fetuses.

Investigators, health professionals, health authorities, members of ethics review committees, ethicists and the scientific community in general have the moral duty to change this situation. We have the duty to actively promote research with pregnant women, which is not only allowed by international ethical guidelines, but is also a moral imperative. Refusing to conduct research with pregnant women is perpetuating the risk pregnant women are exposed to daily. It is estimated that 94% of pregnant women in the United States use at least one medication that requires a prescription, and close to 50% use four or more medications during pregnancy.[3] The responsible inclusion of pregnant women in research is a matter of equity and social justice.[4]

The authors, therefore, call attention to the importance of research with pregnant women, and call for action to promote this kind of research in the region. We must aim to change the paradigm of researchers, members of ethics review committees, sponsors and health authorities, who systematically exclude pregnant women from research. At the same time, we must strengthen our capacity to conduct a rigorous ethical analysis to determine on a case-by-case basis when is it acceptable to include pregnant women in research studies in a responsible way.

This reflection is appropriate in a context in which many Latin American countries are reviewing their regulatory frameworks for research with human subjects, since the inclusion of pregnant women in research will require a modification of many of the existing frameworks. The Zika virus outbreak has brought to the

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forefront the moral urgency to promote research with pregnant women.[5] The publication in December 2016 of the revision of *International Ethical Guidelines for Health-related Research Involving Humans* from the Council for International Organizations of Medical Sciences (CIOMS), which provides substantial orientation to include pregnant women in research in an ethical way, establishes this moment as a propitious time for a call to reflection and change in our region.[6]

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REFERENCES

1. Haire D. FDA approved obstetrics drugs: their impact on mother and baby. National Women's Health Alliance. 2001.
2. Norwitz ER, Greenberg JA. FDA approval for use of medications in pregnancy: an uphill battle. Rev Obstet Gynecol. 2011 4(2):39–41.
3. Mitchell AA, et al. Medication use during pregnancy, with particular focus on prescription drugs: 1976-2008. Am J Obstet Gynecol. 2011; 205(1):51–68.
4. Lyerly AD et al. The second wave: toward responsible inclusion of pregnant women in research. Int J Fem Approaches Bioeth. 2008; 1(2):5–22.
5. Pan American Health Organization. Zika ethics consultation: Ethics guidance on key issues raised by the outbreak (available at: http://iris.paho.org/xmlui/handle/123456789/28425). Washington D.C., 2016.
6. CIOMS. International Ethical guidelines for health-related research involving humans (available at: http://cioms.ch/ethical-guidelines-2016/WEB-CIOMS-EthicalGuidelines.pdf). Geneva, 2016.