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Using health and demographic surveillance systems for teratovigilance in Africa

Increased funding in the past decade has improved healthcare coverage of the population and access to vaccines and drugs across sub-Saharan Africa.¹ However, there is still a need to collect valid and sufficient baseline data, data on the safety of drugs and vaccines used during pregnancy, and for innovative approaches to pharmacovigilance in pregnancy to inform policy makers and to improve treatment guidelines.

Interest in establishing sustainable pharmacovigilance systems in Africa is gaining momentum thanks to plans for large-scale implementation of artemisinin-based combination therapies across Africa. However, less than 1% of individual case safety reports in WHO's database (VigiBase®) are from Africa.²

Drugs such as tetracycline, metronidazole, albendazole, mebendazole, and efavirenz are not recommended during the first trimester because of potential embryo toxicity.³ Nonetheless, these drugs are still used by women of childbearing age, and even pregnant women, by self-medication or irrational prescriptions.

A different strategy, such as continuous longitudinal follow-up, is needed to collect reliable data on pregnant women. The health and demographic surveillance system (HDSS) platform of the INDEPTH Network is one such strategy that longitudinally documents millions of person-years and vital statistics relating to individuals in specific communities.⁴ The HDSS can be used for pharmacovigilance for the general population, but specifically for pregnant women and other susceptible groups. For example, a study in Tanzania used an HDSS platform to monitor the safety of drugs during pregnancy.5

More recently, INDEPTH introduced CHESS,⁶ a new generation of population surveillance operations that integrates across population and health facility data systems and links demographic, epidemiological, mortality, morbidity, clinical, laboratory, household, environmental, health systems, and other contextual data, with a unique electronic individual identification system throughout. CHESS will make pharmacovigilance more effective.

With more than 2 million people under longitudinal evaluation in African countries, this population could generate a sufficient sample size of pregnant women for pharmacoepidemiological studies through all trimesters. Data collection staff are well trained in collecting data from sensitive vital events (eq, death, abortion, and medication, drug or vaccine adverse events). With CHESS, a form of enhanced HDSS, we could identify the main classes of medications used by pregnant women, prospectively determine the incidence and risk factors of suspected adverse events among pregnant women, identify and evaluate adverse effects that are likely to affect compliance and treatment outcomes, and, finally, demonstrate the feasibility of using the HDSS as a sustainable platform to assess the use and safety of medications to facilitate decision making in Africa.

We declare no competing interests.

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*Fati Kirakoya-Samadoulougou, Issiaka Sombié, Bernhards Ogutu, Halidou Tinto, Seni Kouanda, Alfred B Tiono, Walter Otieno, Alexander Dodoo, Mamusu Kamanda, Osman Sankoh

fati.kirakoya@ulb.ac.be

Centre de Recherche en Epidémiologie, Biostatistiques, et Recherche Clinique, Ecole de Santé Publique (FK-S), and Plate-forme Biostatistiques, Pôle Santé (FK-S), Université Libre de Bruxelles, Brussels, Belgium; Organisation Ouest Africaine de la Santé, Bobo-Dioulasco, Burkina Faso (IS); Centre for Clinical Research, Kenya Medical Research Institute, Kisumu, Kenva (BO, WO): INDEPTH Network, Accra, Ghana (BO, HT, SK, WO, MK, OS); Institut de Recherche en Sciences de la Santé, Institut Africain de Santé Publique (SK), and Unité de Recherche Clinique de Nanoro (HT), Ouagadougou, Burkina Faso; Centre National de Recherche et de Formation sur le Paludisme, Ouaqadougou, Burkina Faso (ABT); Department of Paediatrics, School of Medicine, Maseno University, Maseno, Kisumu, Kenya (WO); University of Ghana and the African Collaborating Centre for Pharmacovigilance, Accra, Ghana (AD); WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance (AD); School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa (OS); and Department of Mathematics and Statistics, Njala University, Njala, Sierra Leone (OS)

- WHO. Access to affordable essential medicines. http://www.who.int/medicines/mdg/ MDG08ChapterEMedsEn.pdf (accessed Aug 28, 2016).
- 2 Ampadu HH, Hoekman J, de Bruin ML, et al. Adverse drug reaction reporting in Africa and a comparison of individual case safety report characteristics between Africa and the rest of the world: analyses of spontaneous reports in VigiBase®. Drug Saf 2016; **39:** 335-45.
- Levine M, O'Connor AD. Obstetric toxicology: teratogens. Emerg Med Clin North Am 2012; 30: 977–90.
- 4 Sankoh O, Byass P. The INDEPTH Network: filling vital gaps in global epidemiology. Int J Epidemiol 2012; 41: 579–88.
- 5 Mosha D, Mazuguni F, Mrema S, Abdulla S, Genton B. Medication exposure during pregnancy: a pilot pharmacovigilance system using health and demographic surveillance platform. BMC Pregnancy Childbirth 2014; 14: 322.
- 6 Sankoh O. CHESS: an innovative concept for a new generation of population surveillance. *Lancet Glob Health* 2015; **3**: e742.

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