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Hepatitis C in pregnancy and the TiP-HepC registry

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Over a fifth of hepatitis C virus (HCV) infections occur in women of childbearing age.[1] At least 19 countries, including the USA, have policies or guidelines recommending universal HCV screening during pregnancy.[2] However, options for management and treatment of HCV infection during pregnancy are not well defined. Typical clinical practice is to refer and link pregnant individuals for treatment after pregnancy and the breastfeeding period; however, in practice, very few are successfully treated.[3] Despite an excellent safety profile, direct-acting antivirals (DAAs) are not recommended for use in pregnancy. To date, only one prospective clinical trial has been published assessing HCV treatment in pregnancy.[4]

Several DAAs are categorised as class B in pregnancy, a category that also includes many prenatal vitamins, acetaminophen, and other medications routinely used in pregnancy. As of February, 2022, there were 68 unique pregnancy exposure registries listed by the US Food and Drug Administration for 143 medications or vaccines. No such registry has been established to assess the safety of DAAs for the treatment of HCV in pregnancy. The Infectious Diseases Society of America and the American Association for the Study of Liver Diseases suggest treatment be considered on an individual basis after discussion between the patient and provider and understanding of the risks and benefits of treatment.[5]

With support from the US Centers for Disease Control and Prevention, the Coalition for Global Hepatitis Elimination has developed the TiP-HepC (Treatment in Pregnancy for Hepatitis C) registry and is publicly launching this registry for data collection in June,

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2022. The TiP-HepC registry collects clinical information and case reports primarily to assess pregnancy and birth outcomes after exposure to DAAs during pregnancy. Secondary outcomes include the effectiveness of treatment in pregnancy in achieving HCV cure for the mother and preventing HCV transmission from mother to infant. Retrospective data on the outcomes of mother–infant pairs exposed to DAAs during pregnancy in routine clinical practice will be solicited and collected from participating clinical providers, health-care facilities, HCV treatment programmes, and other clinical practices worldwide.

To achieve HCV cure for all, including mothers and children, providers and programmes need to understand the optimal approach to care for HCV infection in pregnancy, and establishing the safety of DAAs in pregnancy is paramount. We ask all clinicians and researchers active in the care of HCV in pregnancy to contribute data on DAA exposures in pregnancy to the TiP-HepC registry.

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