Accumulating Safety Data for Antiretroviral Therapy in Pregnancy: Increasing reporting to the Antiretroviral Pregnancy

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Background:

Exclusion of pregnant people with HIV from antiretroviral therapy (ART) clinical trials delays accumulation of pregnancy safety data. The Antiretroviral Pregnancy Registry (APR) is the largest global registry of ART exposures during pregnancy, informing global ART guidelines. Australia contributes 0.5% of reports.

This project has two aims (i) to explore awareness and barriers to clinicians in Australia reporting to the APR (ii) to support reporting by a national network of HIV providers.

Methods:

HIV providers were invited to complete a survey via the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine and the Australasian Society for Infectious Diseases subscriber lists. The survey assessed awareness of and barriers to reporting to the APR.

HIV providers interested in reporting to the APR were interviewed to assess predicted health service-specific barriers and facilitators to reporting, and provided documents to support ethics applications for approval to report.

Results:

Eighty clinicians from all States and Territories completed the survey. 38/73 (52%) were aware of the APR, but only 10% (8/80) had contributed data. The barriers to reporting were (i) lack of awareness that clinicians outside the US could report (ii) not having access to all required maternal and paediatric data (iii) perception that their contribution would be insignificant (iv) consent and ethics committee requirements.

We have established a network of HIV providers interested in reporting but have been unable to commence reporting due to uncertainty about consent, ethics requirements and the process of reporting.

Conclusion:

The major issues identified by ethics committees relate to differences in consent and data protection regulations between the US and Australia.

We are collaborating with the APR to address the identified barriers and anticipate this will facilitate more clinicians in countries outside of the US to contribute to this important registry for women with HIV.

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