



ABSTRACT

Nambisan, M., Wyszynski, D.F., Holmes, L.B. Solutions to some common problems of pregnancy registries: The experience of the AED (Antiepileptic Drug) Pregnancy Registry, *Birth Defects Research* 2003; v67:5

Pregnancy Registries provide a means of collecting data on the effect of new drugs on pregnancy outcome. The AED Pregnancy Registry, a hospital based registry, enrolls pregnant women using AEDs for any reason and determines the frequency of major malformations from postpartum interviews and records. Participants complete three telephone interviews: 1) at the time of initial call; 2) at 7 months gestational age; and 3) 4 to 8 weeks post-delivery. Medical records are obtained from neurologists and pediatricians. An independent Scientific Advisory Committee decides when findings are to be released. Three main obstacles to providing accurate data have been identified: 1) participants' loss to follow-up (LTFU); 2) incomplete medical records; and 3) selection bias. The rate of LTFU was 4.6 % for the first 3,010 enrollees. However, use of alternate contacts and a specially-designed address tracking software has helped to reduce this rate. With respect to the medical records, 37.8 % of women refused to sign written permission to allow us to access their records. Some, however, permitted telephone calls to their infants' doctors. Finally, many or most participants in the Registry are Caucasian (86%), have some college education (75%), take vitamins at conception (47.4%) and take AEDs for epilepsy or seizure disorder (85%). New advertising strategies currently underway will help target underrepresented populations.

Birth Defects Research 2003; v67:5