



Title:

Recruitment Of An Unexposed Control Group For A Pregnancy Registry. Smith CR, Holmes LB

Abstract:

Introduction: Pregnancy registries typically enroll and follow pregnant women exposed to drug(s) of interest. This design has been criticized because it lacks a control group for comparison. Some pregnancy registries use external comparison, but none has identified a control group that is well matched in methodology and demographic characteristics to the exposed population. The North American AED (antiepileptic drug) Pregnancy Registry has enrolled a group of unexposed pregnant women to be used as a control group.

Methods: Since April 2003, several concurrent strategies have been used to enroll controls. Telephone scripts describing control recruitment have been used at enrollment, 7-month, and post-partum interviews. Exposed participants were asked to refer pregnant family members or friends who were not taking AEDs to enroll as controls. A raffle with monetary prizes for both the exposed and control groups was used as incentive. Periodic direct mail and email campaigns were sent to remind participants about the controls campaign. Flyers were included in all study mailings, and notices were included in semi-annual newsletters that were sent to all participants enrolled since 1997.

Results: Between 2003 and 2007 we have enrolled 336 unexposed pregnant women. Word of mouth referrals over time yielded 49% of controls enrollment. Direct mail campaigns showed dramatic, yet short term, spikes in control enrollment. A comparison of the first 193 enrolled controls with the 124 exposed participants who referred them, showed no significant difference in demographic data such as maternal age, marital status, race, education level, and parity. The 193 controls were also compared to a larger exposed group (N=4301), again showing no difference in demographic data between the two groups.

Discussion: In our experience, a hospital-based AED pregnancy registry can recruit and enroll a demographically similar control group by using friend and family referrals, combined with an integrated marketing strategy to promote the recruitment campaign. By utilizing these methods at the start of overall enrollment, future Registries would be able to use their own control group for analysis.

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