# Significant bias in retrospective assessment of teratogenicity

Retrospective, voluntary reports of birth defects associated with medications should be interpreted cautiously because of significant reporting bias, according to Dr Benjamin Bar-Oz and colleagues from Canada, and from Janssen, Belgium. They say that *'this bias can distort the estimate of safety and risk of fetal exposure to these agents'* and may lead to *'unfounded fears among pregnant women, their families, and health professionals'*.

Dr Bar-Oz and colleagues say that a serious bias can arise in retrospective cohorts because women whose children have major birth defects, or their physicians, are more likely to report this outcome than women who have a normal pregnancy outcome. If such bias occurs, the actual rates of adverse outcomes can be distorted. They are concerned that data from such retrospective cohorts are often the first available data, and are used by clinicians to counsel patients.

The researchers found that the rate of major congenital malformations associated with first-trimester itraconazole exposure was 4-fold higher in a restrospective analysis compared with a prospective analysis [13 *vs* 3.2%; risk ratio 4.04 (95% CI 1.5–10.9)]. They studied 2 cohorts of women exposed to itraconazole during the first trimester of pregnancy that were reported to Janssen. The retrospective cohort involved 166 cases of exposure after delivery, and the prospective cohort involved 198 cases of exposure during pregnancy and before pregnancy outcome was known.

BAR-OZ B, et al. Reporting bias in retrospective ascertainment of drug-induced embryopathy. Lancet 354: 1700-1701, 13 Nov 1999 800801181