



**Disclaimer:** This newsletter, provided by ITIS, is funded by a grant from the Illinois Department of Public Health and supported by Northwestern Memorial Hospital and Northwestern University Medical School. It is for educational purposes only and is meant to summarize the information available at the time of its creation. It should be construed neither as medical advice nor opinion on any specific clinical situation. For more information on a specific clinical situation, or updated information, please consult your health care provider.

## **Updates Presented at the Organization of Teratology Services, 14th Annual Conference 2001**

The Illinois Teratogen Information Service continues to strive to provide current information regarding pregnancy exposures to patients and health care providers in the state of Illinois. This special edition of the RISK NEWSLETTER provides information on recent teratology studies regarding:

Paroxetine  
Rubella Vaccination  
Azithromycin, and  
Loratadine

### **Paroxetine:**

Birth Outcomes Among Pregnant Women Taking Paroxetine (Paxil®)  
Unfred CI et al. Teratology 63(6); June 2001

The California Teratogen Information Service performed a prospective cohort study of 101 pregnancies exposed to paroxetine and 195 controls. The data from this study did not support a significant increase in risk for a congenital malformation. Of note, within the paroxetine group, there was a greater risk for prematurity if used late in pregnancy. However, the paroxetine exposed group also had more exposure to caffeine, tobacco, alcohol and illicit drugs. No difference in the rate of minor malformation, gestational age, or low birth weight was found between the two groups

As the authors discuss, the paroxetine exposed group in this population had more risky behaviors than the control group, which may be a result of the underlying maternal condition. This may be meaningful to clinicians who counsel and manage these patients

### **Rubella Vaccination:**

Pregnancy outcome following rubella vaccination : A prospective controlled study. Levichek Z et al.  
Teratology 63(6); June 2001

There have been several cases of first trimester exposure to the rubella vaccine with no adverse effects reported. In addition, the CDC has collected over 300 reports of infants with gestational exposure to the vaccine, with no cases of birth defects reported.

The Motherisk Program conducted a prospective controlled study evaluating exposure to the rubella vaccine 3 months pre- or post-conception. There were 94 exposed pregnancies which were matched to a control group of 95 pregnancies for age, smoking, and alcohol use. There were no differences in rates of malformations, rate of prematurity, or developmental milestones between the two groups. The only difference noted between the two groups was that the exposed group had a higher incidence of therapeutic abortion (n=7) than the control group (n=0). Five of the seven women reported that the vaccine exposure influenced their decision to terminate, and two reported terminations was

recommended by their physician.

While a live attenuated vaccine virus such as the virus in the rubella vaccine has been documented to cross the placenta, this study supports previous data that rubella vaccination in pregnancy DOES NOT affect pregnancy outcome rates of malformation or developmental milestones. Based on this data and previously reported data, therapeutic abortion following exposure is NOT WARRANTED.

In addition , the recommended waiting period before becoming pregnant after a rubella vaccine has been decreased from 3 months to 28 days (MMWR 12/14/01 50(49);1117).

**Azithromycin:**

Pregnancy outcome following gestational exposure to azithromycin: A prospective controlled study. Woodland AM et al. Teratology 63(6). June 2001\par}

Azithromycin (Zithromax ®) is a macrolide antibiotic. Initial pregnancy data was limited to one study evaluating first trimester exposure.

The Motherisk Program conducted a prospective controlled study evaluating exposure to azithromycin. The study group was matched by two control groups, one diseased matched and the other non teratogenic exposed. The exposed group consisted of 47 pregnancies, 25 with first trimester use, 15 with second trimester use, and 7 with third trimester use. Two miscarriages and one major malformation was reported. This data, while limited, does not suggest an increased risk for a major malformation .

**Loratadine:**

Pregnancy outcome following gestational exposure to loratadine and other antihistamines: a prospective controlled cohort study.

Diav-Citrin OS et al. Teratology 63(6); June 2001.

Loratadine (Claritin®) is a relatively new non-sedating antihistamine.

The Israeli Teratogen Information Service conducted a prospective controlled study in which pregnancy outcome was compared between three exposure groups; loratadine , other antihistamines, and nonteratogenic exposure. There were 93 exposed pregnancies in the loratadine group (63 1st trimester), 223 in the other antihistamines groups (107 1st trimester) and 629 in the non teratogenic exposed group. There was no difference in the rate of major malformations between the three groups . This data, while limited, does not suggested an increased risk for a major malformation with loratadine use in pregnancy.

**Contributors:**

Carrie L. McMahan, MS

Coordinator , Illinois Teratogen Information Service

Eugene Pergament, MD, PhD, FACMG