

The Organization of Teratology Information Specialists (OTIS), San Diego, June, 2011
www.otispregnancy.org, by Kathie Wisner MD, Past President

This meeting is held in conjunction with the Teratology and Neurobehavioral Teratology Societies, and the focus is environmental, disease and drug exposures and their impact on pregnancy and neurodevelopmental outcome. OTIS is a dedicated group of people who provide information about exposures, including environmental, medication, substance use, and diseases. OTIS members generate “fact sheets” for education about drugs, including many psychotropics, and disease states for patient handouts (available on the website in English and Spanish). OTIS also collaborates with ENTIS (the European group). The next meeting is in Baltimore, Maryland in 2012.

The meetings are relatively small (a few hundred), which allows for questions and interactions with attendees. There were been many interesting talks at the OTIS meeting. I have identified a few below that I hope will interest our Marcè members.

Anne Drapkin Lyerly, M.D., M.A., Assistant Professor of Obstetrics & Gynecology and Associate Director of the Center for the Study of Medical Ethics and Humanities, is an ethicist who advocates for the responsible inclusion of pregnant women in medical research. She made the following points: 1) pregnant women have medical conditions that need to be treated. Lack of data means that pregnant women don't get adequate treatment, particularly at doses that are adjusted to accommodate the metabolic changes of pregnancy. 2) The majority of women take at least one prescription medication in pregnancy, and many use several. The drug-free ideal pregnancy rarely exists. 3) Reticence to treat means that pregnant women are differentially disadvantaged; for example, pregnant women were most at risk for death during the H1N1 infection. 4) The principle of justice needs to apply to pregnant women. They experience an unfair denial of the benefits of research participation or the benefits of research. Read more about the at <http://kennedyinstitute.georgetown.edu/secondwave/>

Suzan Carmichael, Ph.D., Associate Professor of Pediatrics at Stanford, spoke about The Bradford Hill criteria, which are conditions necessary to provide adequate evidence of a causal relationship between an exposure and a consequence, established by the English epidemiologist Sir Austin Bradford Hill in 1965 (Bradford-Hill A. The environment and disease: Association or causation? *Proc R Soc Med* 1965;58:295-300). http://meds.queensu.ca/medicine/obgyn/links/criteria_for_causation.htm. She applied it to thinking about pregnancy exposures and reproductive outcomes.

1. Strength of the association. How large is the effect, the relationship between the exposure and the outcome?
2. The consistency of the association. Has the same association been observed by others, in different populations, using a different method, at different times ?
3. Specificity. Does altering only the cause also alter the effect?
4. Temporal relationship. Does the cause precede the effect?
5. Biological gradient. Is there a dose response between dose of the exposure and magnitude of the outcome?
6. Plausibility. Does it make sense from a biological standpoint?
7. Coherence. Does the evidence fit with what is known about the natural history and biology of the outcome?
8. Experimental evidence. Are there any clinical studies to support the association?
9. Reasoning by analogy. Is the observed association supported by similar associations?