

Medications in Pregnancy Special Interest Group
Meeting August 19, 2008 at 24th ICPE, Copenhagen, Denmark

Minutes

1. The meeting was called to order by Lolkje de Jong van den Berg, Co-chair, at 5:33 PM; approximately 28 members were in attendance (Attached sign-in list)
2. The minutes of the meeting in Quebec City, August 21, 2007 were accepted
3. Major findings in the field were reviewed, and included:
 - a. Citations of latest findings regarding lamotrigine and clefts (publications in *Neurology* 2008;70:2152-8—Holmes et al, and *Neurology* 2008;71:714-22 Dolk H et al, and an editorial of Meador et al *Neurlogy* 2008;71:706-7.)
 - b. Discussion of proposed new FDA guidelines regarding pregnancy labeling for drugs. (Comments due to FDA by 8/31/08; PHARMA, BIO, Teratol. Soc have submitted responses) EMEA has developed similar guidelines. Diego Wyszynski offered to send citations to Lolkje for distribution to MiPSIG members.
 - c. FDA Amendments Act was cited; slides from Boston Mid-Year symposium on the topic of pregnancy are available on the ISPE website. It was noted that pregnancy registries are now a postmarketing requirement.
4. Update on organizations: Deferred in the interests of time
5. Plans for the coming year:
 - a. Providence ICPE: The first joint ISPE-Teratology Society symposium was held at the Teratology Society meeting in Monterey, July 1, 2008, with the view that future joint sessions would be held when ICPE takes place in N. America, with particular focus on the 2009 Providence meeting. It was noted that the two societies had overlapping interests--Teratology Society had a major interest in pregnancy registries, and ISPE in other approaches, including case-control studies and linked datasets. It was suggested that ENTIS might wish to participate in a similar fashion when ICPE takes place in Europe (Lolkje de Jong-van den Berg, Corinne de Vries, Helen Dolk, ENTIS-representative)

It was agreed that in addition to the poster walk, at future meetings our MiPSIG should focus on reviewing strengths/limitations of the various aspects of our research—e.g., exposures, outcomes, confounding, absolute vs. relative risk.

For the 2009 meeting, it was agreed that the focus would be on exposures; our MiPSIG would submit a proposal for a symposium on the topic, and we would also seek to reserve time following the symposium to have a workshop to further discuss the issues raised at the symposium; that latter session could take place as a regular workshop session, if the program committee agreed, or it could take place as a specific MiPSIG session (lunchtime, evening, etc). Lynn Colvin, Elizabeth Andrews, and Sonia Hernandez-Diaz agreed to coordinate this effort.

- b. Study Resources: It was agreed that a list of study resources should be developed. Elena Rivero, Judy Jones, and Susan Roberts agreed to coordinate this effort.

- c. Advanced Topics Course: It was agreed that our MiPSIG should consider offering an “Advanced Topics” course at a future ICPE, both to educate colleagues about the issues related to our research and to reinforce the unique aspects of this field. Sonia Hernandez Diaz, Elizabeth Andrews, and Lolkje de Jong van den Berg agreed to coordinate this effort.

The meeting was adjourned at 6:20 PM. A good time was had by all!

Respectfully submitted,

Allen A. Mitchell, MD, FISPE, MiPSIG Co-chair