

Medications in Pregnancy Special Interest Group (MiP SIG)  
Meeting at Providence ICPE, August 18, 2009 5:40-6:30 PM

Lolkje de Jong Van Den Berg, Co-chair, called the meeting to order at 5:40 PM

The minutes of the previous meeting (Copenhagen, August 19, 2008) were accepted without change.

No changes were suggested to the agenda.

Major findings in the field:

Harry Seifert noted that with high interest on the risks and safety of H1N1 vaccine and antivirals in pregnancy, it would be helpful to establish communication via a MiP SIG page on the ISPE website. There was enthusiasm for this suggestion, and our SIG will work to establish an appropriate format, with input from Harry.

Adrienne Einarsson reported that her group will soon be publishing experience with Tamiflu exposures in pregnancy in Japan

Regulatory obligations regarding reporting surrounding pregnancy exposures and outcomes. It was noted that efforts are underway to harmonize FDA regulations with those of other regulatory organizations. On the matter of the new (non-letter-based) pregnancy label developed by FDA, it was noted that it would not be in place this year.

Best Practice Document: The group discussed various approaches to disseminating the information our SIG was developing that was aimed at improving the quality of our work. There was positive feedback about our first-ever symposium and workshop combination, and at the present time, it was agreed that rather than attempting to develop an overarching “best practices” document, it would be preferable to put into manuscript form the symposium/workshop experiences focused this year on assessment of exposure (Lyn Colvin has volunteered to take the lead on this) and produce similar summaries for publication based on subsequent years’ programs (see below).

It was also noted that FDA is revising its pregnancy-related regulations, and that our SIG could offer to contribute to that effort.

2010 Brighton meeting: When ICPE’s take place in North America, we have collaborated with the Teratology Society in developing joint symposia (in Monterey, California, last June, and at the current ICPE). It was suggested that when ICPEs take place in Europe, we ought to similarly collaborate with ENTIS and EUROCAT, and Lolkje volunteered to coordinate that effort.

As for the proposed symposium/workshop for the Brighton meeting, there was consensus to focus on outcomes—their range, definition, and validity. Those who wish to help organize the events should contact Lolkje. Kari Furu volunteered already.

Resources: It was suggested that it would be stimulating and highly productive for students to become involved in developing the list of pharmacoepi resources (study data) that relate to our SIG, an effort initiated by Judy Jones and Susan Roberts. Irini-Alexia Terzakis volunteered to continue that effort together with Susan Roberts and Judy Jones.

Based on the growth, enthusiasm, and productivity of our SIG, the Education Committee granted our request to conduct a half-day course at the Brighton meeting. That effort will be coordinated with Sonia Hernandez-Diaz, who has taught a related course at a previous ICPE. Carol Louik volunteered to be involved. Those who wish to help and have experiences with developing courses should contact Lolkje.

Transfer of SIG chairs: The founding co-chairs, Allen Mitchell and Lolkje, reflected that though the ISPE by-laws do not provide guidance for succession, etc., both felt it was time to step down and allow others to take those roles. It was agreed that those interested in running for co-chair submit their names to Lolkje and we will have an election by email.

The meeting was adjourned at 6:30 PM.

Post meeting note: After the meeting, a member of the by-laws committee suggested that, as is the case for Councils and committees, it would be wise (though not required) to retain one co-chair for the benefit of retaining institutional memory, and that the two co-chairs serve staggered terms. We propose that we follow that guidance (Lolkje has volunteered to remain as the “senior” co-chair). Thus, the election would be for one co-chair. At a subsequent meeting, the SIG should decide how long the terms of the co-chairs should be (presumably, the newly elected cochair would become the “senior” co chair when Lolkje’s term expires, and a new “cochair would be elected). While the current co-chairs felt that this approach and process made sense, it was not raised at the meeting. Thus, if SIG members would prefer the rotation to involve both co-chairs at this time or have other suggestions, please forward them to Lolkje or Allen (don’t be shy) by the end of September. Pending feedback from members, we will contact SIG members about how many positions will be open for election and will then ask for people to volunteer to run for that/those position(s).

Respectfully submitted,

Allen A. Mitchell, FISPE, MiP SIG Co-Chair.