

BRIGHTON COLLABORATION NEWSLETTER

APRIL - JUNE 2009

Recent Meetings

The Brighton Collaboration held its **10th Annual In-Person Meeting** with the Foundation and Steering Committee on May 14-15 in Zurich, Switzerland. To accommodate and better support the growth of the Collaboration, the infrastructure of the Collaboration will change. Stay tuned for more details!

The **CIOMS/WHO Working Group** on Vaccine Pharmacovigilance met on May 11-12 in Zurich, Switzerland. This working group discussed translations of Brighton documents. Working group members planned a conference call to further refine the survey for industry regarding Brighton Collaboration case definition utilization. The group also further refined the Brighton and CIOMS Workflow process.

Results of the Online Survey for the Diarrhea Case Definition and Guidelines

The survey completed successfully with an overwhelming response, great comments and many excellent reviewers. Seventy-two reference group members took the time to review the definition and complete the online survey! Thank you to all Brighton Collaboration members who participated and/or gave additional comments to the Secretariat.

The case definition was endorsed with comments by the CIOMS/WHO WG on vaccine phamaco-vigilance during the meeting in Zurich. The working group will reconvene to continue discussion of the survey results and comments. The group hopes to complete the definition of diarrhea so that the publication process can begin.

Working Group Progress

GBS: There is immense interest in finalizing this document, particularly before the upcoming influenza season. The working group has consensus on the case definition and is finalizing the draft document to present to the Steering Committee for review and approval to post an online survey. Please look for a survey in late July.

Local Reactions - Pain at injection site: The Working group continues to look at the literature and the ethics of pain and pain assessment tools. The working group is attempting to have a broad landscape to develop the case definition based on the literature and presentations of the pain experts in the group. The next conference call will be on June 24, 2009.

Viscerotropic Disease: On March 18, the group decided to include fever, jaundice, liver dysfunction, renal dysfunction, tachycardia (not level 1), rhabdomyolysis and respiratory distress as criteria to be included in the case definition. On April 20, the group decided the term "thrombocytopenia" will not be included in the criteria to avoid confusion with the existing Brighton case definition of thrombocytopenia. Instead, Platelet count < 100,000 should be a criterion for Brighton level 1 case definition. In May, the group discussed a straw man definition created by members and the unique role of "fever". In June, the group discussed components of the levels within the case definition. The next call will be on July 15, 2009.

Viral Vector Vaccines Safety – Cross-Cutting Issues Subgroup: In March, the Subgroup discussed the 2003 WHO Recommendations on Viral Vector Vaccines. In April Dr. Christopher da Costa gave an overview of risk assessment. In May and June, the group discussed endogenous retroviruses and microbial agents in animal cell substrates. The next call will be on July 13, 2009.

Bells Palsy: The working group reconvened on March 30, 2009. Dr. Jim Sejvar volunteered to lead the group, and members agreed to his leadership. Members are now reviewing the latest draft of the document. They will discuss the preamble and guidelines during the next call, which has been postponed due to the novel H1N1 flu response.

Implementation: The working group was initially created for only 1-2 years to serve as a think tank to brainstorm and highlight the needs for vaccine safety in developing areas. Implementation Working Group work under auspices of the Brighton Collaboration will close, but it is the hope that IWG members will be able to contribute their efforts to other projects.

TB/Malaria (INIVAX): This working group for poverty related diseases is beginning the literature review. In June, the group discussed the Brighton guidelines for vaccine safety data in pre- and post-licensure clinical trials. The next call will be on July 20, 2009.