

2015 International Conference on Pharmacoepidemiology (Boston MA) Vaccine Special Interest Group (VAXSIG) Symposium

90 min session

Topic: Vaccines

Title: ISPE Vaccine Special Interest Group (VAXSIG): Challenges of Introducing New Vaccines in Resource-Limited Settings

Background: Taking advantage of the biotechnology revolution and new funding organizations (e.g., Gates Foundation), several new vaccines either are or have been developed against major killers (e.g., Ebola, Dengue, Malaria, Meningitis A). Since the main target population for these new vaccines is in low or middle income countries (LMIC), considerable challenges face key stakeholders (manufacturers, local and international authorities) in assuring adequate post-marketing surveillance (PMS) of vaccine safety and effectiveness.

Objectives: 1) To understand the difference between traditional and current environment for introduction of new vaccines in LMIC in terms of PMS capacity; 2) To describe specific adaptations needed using new vaccine examples.

Description: The symposium will be devoted to sharing experiences and plans for PMS safety and effectiveness monitoring for several new vaccines using concrete examples. Manufacturers will discuss the various adaptations they are making to meet the desired objectives in the LMIC environment (e.g., timeliness, quality, validity). Regulators and international institutions will share their perspectives on requirements for these vaccines. Lessons learned will inform introduction of new vaccines or drugs in LMICs.

Symposium format:

1. Introduction of VAXSIG and Symposium (5 min.)
2. Examples of new vaccines (15-20 min. each):
 - Ebola vaccine (Merck),
 - Malaria vaccine (GSK),
 - Dengue vaccine (Sanofi-Pasteur),
3. International institutions' perspective: experience with Meningitis A vaccine (15-20 min. WHO)
4. Discussion and Q &As (10 min.)

Moderators: Daniel Weibel, University of Rotterdam; Huifeng Yun, University of Alabama at Birmingham.

Panelists: Laurence Baril (GSK), Alena Khromova (Sanofi-Pasteur), Patricia Saddier (Merck), WHO representative (Speaker invited pending confirmation)