



Narcolepsy and Pandemic Influenza Vaccination What we know and what we need to know before the next pandemic

**March 26-27, 2018
Eurostation II, Place Victor Horta
Brussels, Belgium**

**An international workshop organized by IABS
In partnership with
Federal Agency for Medicines and Health Products (Belgium)**

This workshop will be held under Chatham House Rule

Influenza Pandemics occur when an influenza strain circulates that humans have been exposed to before. This may lead to widespread circulation and a high case fatality rate.

In 2009 pandemic, several H1N1 vaccines were developed against the new H1N1 virus and were extensively used. In Finland and Sweden an increase in narcolepsy was noted after the mass vaccination with one of these vaccines. Disparate results were seen in other countries with other vaccines. In addition, an increase of narcolepsy has been reported in countries in Asia following wild type influenza infection.

The goal of this meeting is to be prepared for the next pandemic:

- What are the latest data on the risk of narcolepsy following exposure to 2009 pandemic vaccines?
- What scientific data are available and what data are lacking to explain the phenomena that was seen in 2009-10?
- What additional work is needed to prepare for potential use of adjuvanted vaccines for a future pandemic?

Scientific Committee

Steve Black, and	Co-chair, Professor of Paediatrics at Cincinnati Children's Hospital Medical Center
Liz Miller,	Co-chair, Immunisation Hepatitis and Blood Safety Department, UK
Pieter Neels	IABS, Chair IABS Human Vaccine Committee
Daniel Brasseur	Prof. Emeritus of Paediatrics at University Libre Bruxelles
Christopher Jankosky	Associate Director for Medical Policy Office of Biostatistics and Epidemiology FDA Center for Biologics Evaluation and Research
Kari Johansen	European Centre for Disease Prevention and Control
Brigitte Keller Stanislavski	Paul-Ehrlich-Institut, Germany
Emmanuel Mignot	Stanford Center for Sleep Sciences and Medicine, Stanford, California
Hanna Nohynek	National Institute for Health and Welfare THL Helsinki Finland
Tom Shimabukuro	Immunization Safety Office Centers for Disease Control and Prevention (CDC)
Lawrence Steinman	Professor of Pediatrics, Neurology and Neurological Sciences Beckman Center for Molecular Medicine

Day 1 – Monday, 26 March, 2018

8:00 am **Registration & Welcome Coffee**

8:20 am **Introduction**
Welcome
Pieter Neels, Chair, IABS Human Vaccine Committee

8:30 am **Opening Lecture**
“Why are we here? --- what we need to understand before the next pandemic”
Steve Black, Professor of Paediatrics at Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio

Session 1 What epidemiologic studies of vaccine association have told us

Chair: Steve Black, Professor of Paediatrics at Cincinnati Children’s Hospital Medical Center

Liz Miller, Immunisation Hepatitis and Blood Safety Department, United Kingdom

8:50 am The European Experience (20 minutes lecture, 5 minutes questions)
Liz Miller, Immunisation Hepatitis and Blood Safety Department, United Kingdom

9:15 SOMNIA (20 minutes lecture, 5 minutes questions)
Miriam Sturkenboom, Julius Centre, Global Health, University Medical Center, Utrecht, The Netherlands

9:40 What do we know about the risk of narcolepsy following wild type influenza? (20 minutes lecture, 5 minutes questions)
Wan Ting Huang, Taiwan Center for Disease Control, Taipei, Taiwan

10:05 Public Health Perspectives (15 minutes each)
a) WHO – **Robert Pless**, WHO-chair GACVS, Marketed Health Products Directorate, Health Canada
b) US CDC – **Frank DeStefano**, Center for Disease Control and Prevention, Atlanta, Georgia, U.S.A.
c) ECDC – **Kari Johansen**, European Centre for Disease Prevention and Control, Solna, Sweden

10: 50 Coffee break

11:20 Regulatory Perspective: How should new adjuvanted pandemic vaccines be evaluated (15 minutes each)
a) FDA – **Christopher Jankosky**, FDA / CBER, Silver Spring, Maryland
b) EMA – **Brigitte Keller Stanislavski**, Paul-Erlich-Institute, Langen, Germany

11:50 What do we know about possible mechanisms (20 minutes each) **PART ONE**
a) *Autoreactive or viral immune-mediated pathology*
Paul-Henri Lambert: Center of Vaccinology, University of Geneva, Switzerland
b) **Robbert Van der Most**, GlaxoSmithKline Biologicals, Rixensart, Belgium
c) **Emmanuel Mignot**, Craig Reynolds Professor of Psychiatry and Behavioral Sciences; Director, Stanford Center for Sleep Sciences and Medicine, Stanford, California

14:00 Lunch

What do we know about possible mechanisms – **PART TWO -CONTINUED**

- d) **Lawrence Steinman; Sohail Ahmed**, Beckman Center for Molecular Medicine, Stanford University, Stanford, California
e) **Federica Sallusto**, Institute for Research in Biomedicine, Bellinzona, Switzerland

14:40 Discussion

Session 2 – What Needs to be Done – Work in Separate Workgroups

15:00 **Introduction to the Workgroups – Workgroups meet for two hours concurrently each (2 hours total)**
The chair will introduce the session for 10 minutes maximum and will also present a summary of the session the

following days assisted with notes taken by the co-chair(s)

- 15:15
1. WG1: What epidemiologic studies need be done? :
 - a. On the 2009 pandemic
 - b. For future pandemics

Chair: Liz Miller, Immunisation Hepatitis and Blood Safety Department, United Kingdom
Co-chair: Hanna Nohynek, National Institute for Health and Welfare (THL), Helsinki, Finl
 2. WG2: What needs to be done to better define the association of wild type influenza virus and narcolepsy?
Chair: Wan-Ting Huang, Taiwan Centers for Disease Control, Taipei, Taiwan
Co-chair: William Hausdorff, Université Libre de Bruxelles, Belgium
 3. WG3: What can be done to further study and better understand possible mechanisms?
Chair: Paul Henri Lambert, Center of Vaccinology, University of Geneva, Switzerland
Co-chair: Emmanuel Mignot, Stanford Center for Sleep Sciences and Medicine, Stanford, California
 4. WG4: What can be done to better understand the difference in observed results between Pandemrix in Europe and Arepanrix in Ontario?
Chair: Nick Andrews, Public Health England, London, United Kingdom
Co-Chairs:
Miriam Sturkenboom, University Medical Center Utrecht, The Netherlands
Robert Van der Most, GlaxoSmithKline Biologicals, Rixensart, Belgium
 5. WG5: What is a rationale public health response to a potential H7N9 pandemic threat given what we know? What data is needed for better decision making?
Chair: Robert Pless, Global Advisory Committee on Vaccine Safety, Health Canada, Canada
Co-chair: Tom Shimabukuro, Center for Disease Control and Prevention (CDC), Atlanta, Georgia

17:15 **Workgroup chairs meet to summarize their experience and prepare for Day two**

18:00 **End of Day 1
Reception**

Day 2 – Tuesday, 27 March, 2018

- 8:00 am **Registration & Coffee**
- Introduction**
- 8:20 am Announcements
Pieter Neels, Chair, IABS Human Vaccine Committee
- 8:25 am Objectives for Day 2
Steve Black, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio
Liz Miller, Immunisation Hepatitis and Blood Safety Department, United Kingdom
- 8:30 am A representative from each Workshop (chair/rapporteur) each present a 15 minute summary of their session and proposed next steps
- 9:45 A Patient perspective on what has been presented and proposed future directions.
- 10:10 Coffee break
- 10:40 Meeting Rapporteurs report – **Kathryn Edwards**, Vanderbilt University School of Medicine, Nashville, Tennessee
- 11:40 Development of consensus as to productive next steps. A concrete list of top priorities for research and future activities needed to best prepare for future use of adjuvanted influenza vaccines.
- 13:00 End of meeting

