



## Vaccine Safety Quarterly Newsletter

Issue 01/2018

Dear readers from around the globe!

The new issue of the Vaccine Safety Quarterly presents itself in a new and fresh design. We acknowledge the skills of Johanna Urban (Hochschule Hannover, University of Applied Sciences) and Viviane Seeger (Brighton Collaboration Foundation and University of Leicester) for this achievement and we hope that you will like it.

You will note that our Quarterly is shorter than it used to be. We realize that time is precious and short and precise information is preferred by most of you over lengthy articles.

I would like to thank all authors for their valuable contributions and we welcome your feedback.



Prof. Dr. Ulrich Heininger  
VSQ Editor in Chief  
University Basel Children's Hospital

Editorial

Featured  
Article

Scientific  
News &  
Updates

BCF News  
& Updates

Impressum

## Featured Article

### Knowledge, attitude, and practices of healthcare providers in Taiwan toward adverse events following seasonal influenza vaccination



Meng-Yu Chen<sup>1</sup>, Wei-I Huang<sup>2</sup>, Yi-Hsuan Chen<sup>2</sup>, Wan-Ting Huang<sup>1</sup>

<sup>1</sup> Taiwan Centers for Disease Control, Taipei, Taiwan

<sup>2</sup> Taiwan Drug Relief Foundation, Taipei, Taiwan

Monitoring adverse events following immunization (AEFI) is important to assure the safety and maintain public confidence of vaccines. In Taiwan, a seasonal influenza vaccination campaign administers approximately 3 million doses beginning October, and more than 90% of AEFI are reported by healthcare providers (HCP) to a national system collaboratively operated by Taiwan Centers for Disease Control and Taiwan Food and Drug Administration since the 2009 H1N1 pandemic. National reporting rates of AEFI with the influenza vaccines, however, decreased from 4.75 per 100,000 doses in 2010 to 2.20 in 2014.

As part of a comprehensive evaluation of the national passive vaccine safety surveillance system, a survey was developed jointly by Taiwan Centers for Disease Control and Taiwan Drug Relief Foundation in 2015. HCP who have been involved in seasonal influenza vaccination programs were asked about their knowledge, attitude, and practices regarding AEFI and reporting. During June–October 2015, local health authorities mailed the survey to 7,180 HCP (physicians, pharmacists, and nurses) participating in the vaccination network. Completed surveys were returned anonymously; data analysis excluded respondents who were non-HCP or who did not respond to the occupation question.

Of the 7180 surveys sent, 5,715 (80%) were completed. Four hundred and forty-two (8%) of the 5,715 respondents were excluded because they either were non-HCP or did not report their occupation, leaving 5,273 respondents for analyses. Most respondents were female (61%), aged 30–39 years (32%), nurses (51%), practiced in clinics (73%), reported their primary practice area as pediatrics (27%), and had been in practice for more than 10 years (69%).

HCP showed moderate knowledge (mean  $3.8 \pm 0.9$ , out of scores 0–7) and positive attitude (mean  $34.9 \pm 4.7$ , out of scores 5–50) to AEFI and reporting. Most HCP reported familiarity with AEFI reporting (70%), and always or usually informed recipients about possible AEFI (90%). Overall, 1,001 (19%) respondents had identified at least one AEFI, but only 310 (34%) of them indicated that they had ever reported to the health authorities. HCP who were aged less than 30 years (OR 2.89, 95% CI 1.09–7.69) and familiar with reporting (OR 2.69, 95% CI 1.60–4.53) were more likely to, whilst those who practiced in pediatrics were more likely not to (OR 0.58, 95% CI 0.35–0.97) report AEFI. Respondents considered “not sure if influenza vaccination causes the AEFI” (56%); “the AEFI is common and expectable” (43%); and “the patient has recovered upon the identification of the AEFI” (39%) as main reasons why they did not report AEFI.

We recommend that HCP education should include the objective of AEFI monitoring, and when and how to file an AEFI report. In-depth interviews or onsite observation of practices would help better understand barriers of AEFI reporting across different HCP.

The full text article in Chinese is available at *Epidemiology Bulletin*, Taiwan Centers for Disease Control’s biweekly official publication of public health information and recommendation.

Reference: Chen MY, Huang WI, Chen YH, Huang WT. (2017) Knowledge, attitude, and practices of healthcare providers in Taiwan toward adverse events following seasonal influenza vaccination. *Epidemiol Bull* 33(17):315–23.

Editorial

Featured Article

Scientific News & Updates

BCF News & Updates

Impressum

## Scientific News & Updates

### New Report on Immunization in Pregnancy Safety Monitoring in Low- and Middle-Income Countries (LMIC)



Maria Stepanchak, MPH  
Global Alliance to Prevent Prematurity and Stillbirth (GAPPS)

Immunization in pregnancy holds the promise of reducing morbidity and mortality among pregnant women and infants, particularly in LMIC where there is the greatest burden of vaccine-preventable disease and the most limited access to basic health services. Global efforts are underway to develop, evaluate, and implement new vaccines targeted specifically for use in pregnant women in LMIC. As these efforts go forward, it is a critical time to formulate a comprehensive approach to monitoring safety of immunizations in pregnancy in LMIC and thereby ensure program success and public confidence.

Monitoring safety of immunizations in pregnancy in LMIC presents several unique challenges. Vital registries and health reporting systems for pregnant women and infants are often inadequate, lacking the sensitivity and accuracy needed to track even severe complications of pregnancy and adverse birth outcomes such as preterm birth, fetal death, and congenital malformations. Pharmacovigilance systems that identify, evaluate, and respond to potential adverse events following immunization (AEFI) are often rudimentary in LMIC.

As global momentum is increasing to develop and implement new vaccines for use in pregnant women in LMIC, there is a need to strengthen systems that monitor vaccine safety. In response to this need, the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) has developed a report, with support from the Bill & Melinda Gates Foundation and input from a large, multidisciplinary group of experts, which summarizes the literature and existing programs in pharmacovigilance and MNCH (maternal, newborn and child health) surveillance in LMIC, identifies gaps, and outlines a roadmap for program development.

The report outlines an approach for building on existing data systems for monitoring health of pregnant women and their offspring, and adaptation of pharmacovigilance programs to address the unique events specific to immunization in pregnancy. It also includes key recommendations and an implementation plan that summarize the important role of leadership and mobilization of financial and human resources for safety monitoring in support of immunization in pregnancy program implementation in LMIC.

Lackritz EM, Stergachis A, Stepanchak M, Englund J, Tavares Da Silva F, Sevene E, Nyambayo PP, Kochhar S, Cannon M, Cultand C, Clarke E, Weibel D, Gravett C (2017) Maternal Immunization Safety Monitoring in Low- and Middle-Income Countries: A Roadmap for Program Development.

<https://www.gapps.org/PDF/MaternalImmunizationSafetyMonitoringInLMICs.pdf>

#### Literature Pointer:

Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1 pdm09 in 2010-11 and 2011-12.

James G. Donahue, Burney A. Kieke, Jennifer P. King, Frank DeStefano, Maria A. Mascola, Stephanie A. Irving, T. Craig Cheetham, Jason M. Glanz, Lisa A. Jackson, Nicola P. Klein, Allison L. Naleway, Eric Weintraub, Edward A. Belongia

URL: <http://www.sciencedirect.com/science/article/pii/S0264410X17308666>

Editorial

Featured  
Article

Scientific  
News &  
Updates

BCF News  
& Updates

Impressum

## BCF News & Updates

05.02.2018

### Virtual Institute ACADEMY

We are happy to announce that our Virtual Institute ACADEMY is now open!

With today's flood of data, the Virtual Institute ACADEMY provides structured and well-presented information and tools. Easy access, well-organised archives, traceable chats and secure links - that's what ACADEMY stands for. Our aim: One place where you can easily find the latest input and tools that suit your daily work.

The success of our Virtual Institute ACADEMY depends crucially on solidary contributions. The contribution system has been designed so that those who pay the contribution fee support those who might not have the financial means to do so. By paying your contribution you might give someone else the chance to work with the Brighton Collaboration ACADEMY.

02.01.2018

### The Vaccine Confidence Project

#### Confidence Commentary: Let Freedom Ring

Find the latest commentary by former Science Board chair Heidi Larson below.

[http://www.vaccineconfidence.org/?utm\\_source=Confidence%20Commentary%20-%20The%20VCP%20Blog&utm\\_campaign=7780b06c40-EMAIL\\_CAMPAIGN\\_2018\\_01\\_02&utm\\_medium=email&utm\\_term=0\\_7cd7558d59-7780b06c40-71039269](http://www.vaccineconfidence.org/?utm_source=Confidence%20Commentary%20-%20The%20VCP%20Blog&utm_campaign=7780b06c40-EMAIL_CAMPAIGN_2018_01_02&utm_medium=email&utm_term=0_7cd7558d59-7780b06c40-71039269)

17.11.2017

### Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA) 2nd Special Issue of Vaccine

We are happy to announce that a second special issue of the journal Vaccine has been published, comprising the second set of GAIA case definitions. Simply follow the link below to access the Vaccine journal. Thank you, everyone, for their hard work and commitment!

<http://www.sciencedirect.com/journal/vaccine/vol/35/issue/48/part/PA>

For more news and updates, follow the link below and access the recent news page of the Brighton Collaboration website:

<https://www.brightoncollaboration.org/activities/recent-news.html>

Editorial

Featured  
Article

Scientific  
News &  
Updates

BCF News  
& Updates

Impressum

# Impressum

## Volunteer Professionals

Volunteer professionals from the Brighton Collaboration, sharing invaluable expertise and committing precious time.

## Science Board

- **Dr. Barbara J. Law**, Vaccine safety consultant, Paediatric Infectious Disease subspecialist with 10 years experience as Chief of Vaccine Safety for Public Health Agency of Canada (2004-2015), CAN
- **Dr. Kathryn M. Edwards, MD**, Vanderbilt University, School of Medicine, Nashville, TN, USA
- **Daniel Salmon, BA, MPH, PhD**, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA
- **Dr. Sonali Kochhar, MD**, Global Healthcare Consulting, IND, University of Washington, Seattle, WA, US, and Erasmus University Medical Center, Rotterdam, NED
- **Dr. Clare Cutland**, Chris Hani Baragwanath Academic Hospital, Soweto, ZA
- **Dr. Wan-Ting Huang, MD**, Taiwan Centers for Disease Control, TWN, and National Taiwan University Children's Hospital, TWN
- **Dr. Helen Petousis-Harris, PhD**, University of Auckland, NZ, and Immunisation Advisory Center, NZ
- **Nicholas Wood**, Sydney Children's Hospitals Network, AUS, and University of Sydney, AUS
- **James Oleske, MD MPH**, Rutgers New Jersey Medical School, Newark, NJ, USA
- **Delese Mimi Darko**, African Vaccines Regulatory Forum AVAREF, GH

## Foundation Board

- **Dr. Jan Bonhoeffer**, President, University of Basel Children's Hospital, CH
- **Dr. Thomas Mayer**, Vice President, Attorney, Basel, CH
- **Kaspar Sutter**, Treasurer, Basel, CH
- **Dr. Caroline Cron**, Basel, CH

## Management Team

- **Simone Casagrande Valli, MBA**, Foundation Manager
- **Jorgen Bauwens, MPH**, Programme Manager
- **Viviane Seeger, BA**, Management Assistant
- **Katrin Müller, BA**, Administrative Assistant

## Publisher

Brighton Collaboration Foundation  
Spitalstrasse 33 | 4056 Basel | Switzerland  
[www.brightoncollaboration.org](http://www.brightoncollaboration.org)  
[vsq@brightoncollaboration.org](mailto:vsq@brightoncollaboration.org)

## VSQ Editorial Board

**Prof. Dr. Ulrich Heininger**, University of Basel Children's Hospital, Editor in Chief  
**Viviane Seeger, BA**, Issue Manager  
**Simone Casagrande Valli, MBA**, Associate Editor  
**Jorgen Bauwens, MPH**, Associate Editor

Editorial

Featured Article

Scientific News & Updates

BCF News & Updates

● Impressum

### Disclaimer

The findings, opinions and assertions contained in this consensus document are those of individual professional scientific VSQ contributors. They do not necessarily represent the official positions of each participant's organization (e.g. government, university or corporations).