What a Global Collaborative Network for Vaccine Safety Studies Could Contribute?

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**Meeting Objectives**

- To share practical lessons and experiences related to technical and administrative approaches in vaccine safety evaluation infrastructures

- To create links that allow more rapid communication and potential collaboration in the event that future vaccine safety concerns arise

- To delineate levels of evidence for vaccine safety from signal detection to refutation/confirmation, and to link attainable levels of evidence to infrastructure for a given adverse event

- Exploring regulatory implications of making improvements beyond the current infrastructure

- Describing and discovering synergies of a global collaborative vaccine safety network

- Identifying next steps to move forward a global collaborative vaccine safety network after the end of this meeting
WHO: Global Vaccine Safety Blueprint Project

Global capacity building and harmonized tools
- WHO and partners
- Brighton Collaboration
- CIOMS/WHO working group

Global analysis and response
- GACVS
- Other global or regional advisory bodies

National AEFI surveillance, investigation, and response
- Immunization programme
- Regulatory authority
- AEFI review committee
- Other support groups

Global signal detection and evaluation
- WHO PIDM
- Global vaccine safety data link
- Other partners

Product monitoring
- Vaccine manufacturers
- Licensing authorities in country of manufacture
- Procurement agencies
Monitoring and Investigating Vaccine Safety Globally

- Developed countries
  - UK Yellow card system / GPRD / THIN
  - US VAERS / VSD / CISA
  - Canadian CAEFISS/ IMPACT / ACCA
  - Australian ADR Advisory Committee database etc

- To foster the development of improved surveillance systems to detect any AEs of vaccine, particularly in low- and middle-income countries (LMIC)

- WHO Uppsala Monitoring Center (UMC)
  - As of 2008, ~ 90 developed and developing countries reported to UMC > 4 mln records in Vigibase
  - Reporting of ADRs is more complete than AEFI (vaccines)
  - Only a small number of countries reported AEFI
  - ~ 317,000 individual case safety reports of vaccines
**Selected Aspects of Global Advisory Committee on Vaccine Safety (GACVS)**

- Assesses any safety implications of WHO advice on global vaccine safety policies formulated by Strategic Advisory Group of Experts (SAGE)
- Review of safety data for new vaccines prior to their introduction
- Advising on development of better systems for post-marketing surveillance in LMICs
  - Some vaccines are predominantly administered in LMIC: BCG, YFV, Japanese encephalitis, endemic meningitis vaccines
  - Growing importance of vaccine production by manufacturers in LMIC (China, Mexico, Russia, India)
  - WHO pre-qualification (as of end of 2008): 83 different vaccines prequalified – 37 are manufactured in LMIC
- Discussion of methodologies designed to identify vaccine safety signals from the UMC database and further investigation of these signals
Why Collaborate on Global Vaccine Safety studies?

- Globalization and transparent communication
  - Safety alerts posted on the health agencies websites
    - Febrile seizures following CSL’s 2010-11 influenza vaccine in children in Australia (April – May 2010)
    - US CDC and FDA experts involved in investigation
    - ACIP reviewed this signal in August 2010
  - Health agencies have agreements on information exchange (US FDA, EMA, TGA, BGTD, Japanese MHLW)
  - Developing countries are learning from developed countries (US, Canada, France, Australia) on how to establish Immunization Technical Advisory Committees / Groups
  - For very rare adverse events (e.g. GBS, ADEM) data from one country is not enough
    - Assessment of GBS after H1N1 vaccination in Europe by VAESCO project
    - GBS and Meningococcal conjugate vaccine A, C, W, Y required 3 years of data using 5 largest HMOs in the US
What Happened since Global Vaccine DataNet Meeting in September 2007?

- **FDAAA2007 in the US**
  - Requires establishment of Sentinel Surveillance using linked databases
    - By end of 2010 – 25 million patients
    - By end of 2012 – 100 million patients

- **Europe: PROTECT, EU-ADR, VAESCO**

- **H1N1 influenza pandemic in March 2009 – April 2010**

- **Introduction of new vaccines in developing countries**
  - Higher benefit for rotavirus vaccine in developing countries
  - Rotavirus vaccine and intussusception: large studies in Latin America done by GSK and PAHO / CDC
  - Future vaccines (malaria, dengue) will be introduced first in developing countries
    - Intensive safety monitoring will be required
EU and US Large Linked Database Effort

 Sentinel surveillance in the US
- Vaccine Safety Datalink is a part of it
- Experience of distributed data network established by Harvard Pilgrim for Menactra and GBS study (R. Platt)
- Target of 100 million patients by the end of 2012

 EU-ADR
- Clinical data from electronic healthcare records (EHRs) of over 30 million patients from several European countries (The Netherlands, Denmark, United Kingdom, and Italy)

 PROTECT = Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
- Objective of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in Europe
- Public private partnership, multinational consortium
- EMA is coordinator, GSK is co-coordinator
- 31 partners including academics, regulators, SMEs and EFPIA companies
**Need for Vaccine Safety Data Infrastructure in Low and Middle Income Countries (LMIC)**

- Human capacity development in LMIC and at regional levels is a priority in order to address multiple vaccine safety issues
- SANEVA network in Latin America is one model of intercountry collaboration
  - Argentina, Brazil, Mexico, Panama and Venezuela
  - Joined forces to strengthen passive surveillance systems, develop active surveillance system in the region, ensure critical data analysis
- Global training capacity to develop and disseminate didactic materials, epidemiologic and laboratory reference centers to support investigation of vaccine safety alerts and communication resources to assist national programs
Expanding number of vaccines, their use in immunization programs, high attention to health protection increased the demand for comprehensive vaccine safety monitoring.

It’s critical to expand vaccine safety monitoring systems and tools for LMICs.

GACVS is recognized as a source for authoritative response to real or perceived vaccine safety issues.