

## Center for Vaccine Ethics and Policy

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### **Vaccines and Global Health: The Week in Review 26 October 2013 Center for Vaccine Ethics & Policy (CVEP)**

*This weekly summary targets news, events, announcements, articles and research in the vaccine and global health ethics and policy space and is aggregated from key governmental, NGO, international organization and industry sources, key peer-reviewed journals, and other media channels. This summary proceeds from the broad base of themes and issues monitored by the Center for Vaccine Ethics & Policy in its work: it is not intended to be exhaustive in its coverage. Vaccines: The Week in Review is also posted in pdf form and as a set of blog posts at <http://centerforvaccineethicsandpolicy.wordpress.com/>. This blog allows full-text searching of over 3,500 entries.*

*Comments and suggestions should be directed to*

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### **World Polio Day – 24 October 2013**

*"Events worldwide mark World Polio Day, as efforts to eradicate the disease intensify"*

<http://www.polioeradication.org/tabid/488/iid/327/Default.aspx>

Special World Polio Day event:

**World Polio Day: Making History**, a special [Livestream](#) (24 October, 22.30hrs GMT) event presented by Rotary and Northwestern University's Center for Global Health with speakers including Dr. Bruce Aylward, WHO Assistant Director-General for polio, emergencies and country collaboration, and Dr. Robert Murphy, Director of the Center for Global Health at Northwestern University Feinberg School of Medicine

<http://www.polioeradication.org/tabid/488/iid/327/Default.aspx#sthash.TWMBKG6S.dpuf>

### **Update: Polio this week - As of 23 October 2013**

Global Polio Eradication Initiative

Full report: <http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx>

*[Editor's extract and bolded text]*

:: In Syria, reports of suspected polio cases have emerged. A cluster of hot cases is currently being investigated, and has prompted planning for a comprehensive outbreak response across the region. See 'Syrian Arab Republic' section below for more.

:: One wild poliovirus type 1 (WPV1) case has been confirmed in Cameroon. This is the first WPV1 in the country since 2009. WPV1 was isolated from an acute flaccid paralysis (AFP) case from Ouest province, with onset of paralysis on 1 October 2013. Genetic sequencing is on-going to determine origin of the isolated virus. See 'Chad, Cameroon and Central African Republic' section for more

### ***Afghanistan***

:: One new WPV1 case was reported in the past week. The total number of WPV cases for 2013 is now eight (all WPV1), all of which were reported from Eastern Region, close to the Pakistan border. The most recent WPV1 case had onset of paralysis on 19 September, from Kunar province.

### ***Pakistan***

:: Three new WPV1 cases were reported in the past week. All were reported from Federally Administered Tribal Areas (FATA - two from FR Bannu and one from North Waziristan). The total number of WPV1 cases for Pakistan in 2013 is now 46. The most recent WPV1 case had onset of paralysis on 1 October (from FR Bannu). The majority of WPV1 cases in Pakistan this year, 34 (74%), are from FATA, of which 14 from Khyber Agency and 14 from North Waziristan.

:: The situation in North Waziristan is becoming increasingly severe, as it is the area with the largest number of children being paralysed by wild poliovirus (14 cases) and cVDPV2s (22) in all of Asia. It is in an area where immunization activities have been suspended by local leaders since June 2012. It is critical that children in these areas are vaccinated and protected from poliovirus. Immunizations in neighbouring high-risk areas are being intensified, to further boost population immunity levels in those areas and prevent further spread of this outbreak.

### ***Chad, Cameroon and Central African Republic***

:: In Cameroon, one WPV1 was reported this week from Ouest province. This is the first WPV in Cameroon since 2009 and had onset of paralysis on 1 October 2013.

:: An outbreak response is now being planned. In 2013, five large-scale supplementary immunization activities (SIAs) have already been conducted in Cameroon (in April, May, August, September and October), as the country was considered at high-risk of re-infection due to its proximity with Nigeria. The latest NIDs were conducted 11-13 October.

### ***Syrian Arab Republic***

:: See WHO GAR below

## **WHO: Global Alert and Response (GAR) – *Disease Outbreak News***

[http://www.who.int/csr/don/2013\\_03\\_12/en/index.html](http://www.who.int/csr/don/2013_03_12/en/index.html)

### **Report of suspected polio cases in the Syrian Arab Republic**

26 October 2013 - On 17 October 2013, WHO received reports of a cluster of acute flaccid paralysis (AFP) cases in the Syrian Arab Republic. This cluster of 'hot' AFP was detected in early October 2013 in Deir Al Zour province and is currently being investigated. Initial results from the national polio laboratory in Damascus indicate that two of the cases could be positive for polio – final results are awaited from the regional reference laboratory of the Eastern Mediterranean Region of WHO. Wild poliovirus was last reported in Syria in 1999.

The Ministry of Health of the Syrian Arab Republic confirms that it is treating this event as a cluster of 'hot' AFP cases, pending final laboratory confirmation, and an urgent response is currently being planned across the country. Syria is considered at high-risk for polio and other vaccine-preventable diseases due to the current situation.

A surveillance alert has been issued for the region to actively search for additional potential cases. Supplementary immunization activities in neighbouring countries are currently being planned.

WHO's International Travel and Health recommends that all travelers to and from polio-infected areas be fully vaccinated against polio.

[http://www.who.int/csr/don/2013\\_10\\_19\\_polio/en/index.html](http://www.who.int/csr/don/2013_10_19_polio/en/index.html)

## **UNICEF: Millions of children in Syria and region to be vaccinated against polio, measles, mumps and rubella**

*Major immunisation campaign under way now in Syria*

AMMAN, GENEVA, 25 October 2013 - As Syria awaits confirmation of suspected polio cases in the east of the country, UNICEF has joined the World Health Organisation and other partners in mounting a large-scale immunisation effort aimed at protecting as many children as possible both in the country and across the region against polio, as well as other vaccine-preventable diseases.

Inside Syria, a campaign led by the Ministry of Health began on October 24 targeting 2.4 million children with vaccines against polio, measles, mumps and rubella.

Around 500,000 children in Syria have not been vaccinated against polio in the past two years due to insecurity and access constraints. Prior to the conflict, immunisation coverage in Syria was about 95 per cent.

The conflict in Syria has caused immense displacement, with millions of children on the move, either inside the country or across borders into neighbouring countries and beyond. As a result, routine immunisation systems so critical to preventing childhood diseases have been disrupted or broken down, and children are now at far higher risk of diseases such as polio and measles.

UNICEF is mobilising a huge supply operation to make sure that vaccines are in place across the region, and reaching out to partners across all sectors to help raise community awareness of the importance of vaccinating children.

Multiple, supplemental immunisation campaigns against polio and other vaccine-preventable diseases will take place inside Syria and across the region through the end of the year.

[http://www.unicef.org/media/media\\_70740.html](http://www.unicef.org/media/media_70740.html)

## **WHO/Europe: Support for Turkish polio operations from a new field presence in Gaziantep**

24 October 2013

*Excerpt*

As part of the cross-regional response to a suspected poliomyelitis (polio) outbreak in the Syrian Arab Republic, Turkey is scaling up surveillance of suspected cases and vaccination of Syrian citizens under temporary protection in Turkey. A newly established WHO presence in Gaziantep, Turkey, near the border of the Syrian Arab Republic, is serving as an important centre of operations. 24 October is World Polio Day.

Of the 2 million Syrians displaced in neighbouring countries, over 500 000 have found shelter in 21 Turkish camps and private accommodation in 10 provinces. Turkish health authorities plan two rounds of supplementary immunization activities by the end of the year for all children under 5 years of age in selected provinces and for refugee children elsewhere in Turkey. Along with improved surveillance, an active search is being conducted to provide additional doses of vaccine to un- and under immunized resident children nationwide...

<http://www.euro.who.int/en/countries/turkey/news/news/2013/10/who-europe-supports-turkish-polio-operations-from-a-new-field-presence-in-gaziantep>

## **Fear of violence slows polio immunization drive in Kano, Nigeria**

IRIN – UN Office for the Coordination of Humanitarian Affairs

*Excerpt*

KANO, 22 October 2013 (IRIN) - Fear and secrecy have cloaked the roll-out of a polio campaign currently underway in northern Nigeria. Vaccinators are concealing their identities, hiding vaccinations under their veils and visiting some areas only with undercover armed

guards, following the [February murder](#) by Boko Haram of nine polio workers in the northern city of Kano.

"The [polio] campaign is done under an atmosphere of fear and secrecy, with vaccinators hiding their identity and moving around furtively for fear of being attacked," a source at the World Health Organization (WHO) office in Kano, who is involved in polio immunization campaigns, told IRIN.

The Ministry of Health temporarily suspended the immunization campaign in March 2013, as vaccinators were too frightened to continue, said Shehu Abdullahi, executive secretary of Kano State's Primary Healthcare Management Board (PHMB) in charge of polio immunizations. The campaign resumed in April...

...For the current campaign, vaccinator Jamila Ahmad told IRIN: "We conceal the polio kit under our hijab [veil] and move around as if we are going for a wedding or naming ceremony, while the supervisor trails behind us at a safe distance that will not raise any suspicion that he is with us."

Most door-to-door polio immunizations are performed by women, who can typically access homes unhindered; men would have to seek the consent of male family heads to enter homes - but male supervisors usually form part of the team...

<http://www.irinnews.org/report/98977/fear-of-violence-slows-polio-immunization-drive-in-kano>

**The Global Fund said the Tahir Foundation, based in Indonesia, will invest US\$65 million in Global Fund programs.** The contribution is being matched by the Bill & Melinda Gates Foundation for a total US\$130 million in support. The Tahir Foundation's contribution is "...by far the largest ever made to the Global Fund by a private foundation in an emerging economy, (and) will support efforts to diagnose, treat, and prevent AIDS, TB and malaria, leading causes of death and disability in Indonesia.

<http://www.theglobalfund.org/en/mediacenter/newsreleases/2013-10-21-Tahir-Contributes-USD-65-Million-to-the-Global-Fund/>

**PATH announced the appointment of Ashley Birkett, PhD as director of its Malaria Vaccine Initiative (MVI),** which "drives the development of safe and effective vaccines for the fight against malaria." Dr. Birkett is a five-year veteran of MVI, and was most recently the program's deputy director, serving simultaneously as director of research and development (R&D)—the latter a position he has held since joining PATH in 2008. Dr. David C. Kaslow, vice president of product development at PATH, said, "Since 2008, Ashley has contributed significantly to every major R&D initiative at MVI. His technical expertise, tireless passion, and indomitable leadership make him the ideal person to lead MVI in the exciting journey that lies ahead for malaria vaccine development. I am also pleased that PATH can attract and grow top talent and is able to promote such talent from within the organization."

<http://www.prnewswire.com/news-releases/path-malaria-vaccine-initiative-names-new-director-228791311.html>

The **Weekly Epidemiological Record (WER) for 25 October 2013**, vol. 88, 43 (pp. 465–476) includes:

:: Progress towards poliomyelitis eradication: Afghanistan, January 2012–August 2013  
:: Estimating meningitis hospitalization rates for sentinel hospitals conducting surveillance of invasive bacterial vaccine-preventable diseases  
<http://www.who.int/entity/wer/2013/wer8813.pdf>

**WHO: Global Alert and Response (GAR) – *Disease Outbreak News***

[http://www.who.int/csr/don/2013\\_03\\_12/en/index.html](http://www.who.int/csr/don/2013_03_12/en/index.html)

:: **Human infection with avian influenza A(H7N9) virus** – update [24 October 2013](#)  
:: **Middle East respiratory syndrome coronavirus (MERS-CoV)** - update [24 October 2013](#)  
:: **Cholera in Mexico** - [26 October 2013](#)

26 October 2013 - The Ministry of Health in Mexico has reported 171 confirmed cases, including one death, of infection with *Vibrio cholerae* O1 Ogawa toxigenic between 9 September to 18 October 2013.

In the second week of September 2013, Mexico was affected simultaneously by a hurricane and tropical storm which caused heavy rains, floods, landslides and internal displacement of populations, thus increasing the risk of diarrhoeal diseases.

Of the 171 confirmed cases, two are from the Federal District, 157 cases from the state of Hidalgo, nine from the state of Mexico, one from the state of San Luis Potosi and two from the state of Veracruz.

Eighty-six of the total confirmed cases are women and 85 are men with ages ranging from three months to 88 years old. Of these, thirty-nine cases were hospitalised...

...This is the first local transmission of cholera recorded since the 1991-2001 cholera epidemic in Mexico. The genetic profile of the bacterium obtained from patients in Mexico presents high similarity (95 percent) with the strain that is currently circulating in three Caribbean countries (Haiti, Dominican Republic and Cuba), and is different from the strain that had been circulating in Mexico during 1991-2001 epidemic.

WHO does not recommend that any travel or trade restrictions be applied to Mexico with respect to this event.

**CDC/MMWR Watch** [to 26 October 2013]

October 11, 2013 / Vol. 62 / No. 40

*No new relevant content [See CDC ACIP Meeting note below]*

**European Medicines Agency Watch** (to 26 October 2013)

*Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 21-24 October 2013*

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2013/10/news\\_detail\\_001927.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/10/news_detail_001927.jsp&mid=WC0b01ac058004d5c1)

The CHMP recommended granting extensions...for three vaccines: Synflorix, Vepacel and Pandemic Influenza Vaccine Baxter H5N1.

**WHO - Humanitarian Health Action**

<http://www.who.int/hac/en/index.html>

*No new relevant content.*

**UN Watch** to 26 October 2013

Selected meetings, press releases, and press conferences relevant to immunization, vaccines, infectious diseases, global health, etc. <http://www.un.org/en/unpress/>  
*No new relevant content.*

**World Bank/IMF Watch** to 26 October 2013

Selected press releases and other selected content relevant to immunization, vaccines, infectious diseases, global health, etc. <http://www.worldbank.org/en/news/all>  
*No new relevant content.*

**Reports/Research/Analysis/ Conferences/Meetings/Book Watch**

*Vaccines and Global Health: The Week in Review* has expanded its coverage of new reports, books, research and analysis published independent of the journal channel covered in Journal Watch below. Our interests span immunization and vaccines, as well as global public health, health governance, and associated themes. If you would like to suggest content to be included in this service, please contact David Curry at: [david.r.curry@centerforvaccineethicsandpolicy.org](mailto:david.r.curry@centerforvaccineethicsandpolicy.org)

**CDC: Meeting of the Advisory Committee on Immunization Practices (ACIP)**

22-24 October 2013

Atlanta

Agenda: <http://www.cdc.gov/vaccines/recs/acip/>. The agenda included three votes which approved considerations for use of meningococcal conjugate vaccine MenACWY-CRM in infants and young toddlers at increased risk for meningococcal disease; the 2014 Child/Adolescent Immunization Schedule; and the 2014 Adult Immunization Schedule.

<http://www.cdc.gov/media/releases/2013/a1021-acip.html>

**WHO: Strategic Advisory Group of Experts (SAGE) on Immunization**

The next SAGE meeting will take place in Geneva on 5-7 November 2013.

[Draft agenda \(as of 17 October 2013\)](#)

*Selected Agenda Topics (excerpt):*

**:: Global polio eradication initiative - Session 4**

*For decision:*

- Optimal schedule for 1 IPV dose
- Strategic framework for responding to type 2 virus detection post-OPV2 cessation
- Recommendation for a WHA resolution in 2014 on accelerated IPV introduction, based on the progress toward a global supply and financing strategy

*For discussion:*

- Strategy to ensure bOPV access to all OPV-using countries

**:: Decade of Vaccines - Global Vaccine Action Plan (GVAP) Monitoring - Session 5**

*For Decision*

SAGE will be expected to produce an independent first report on progress with the Decade of Vaccines Global Vaccine Action Plan.

Specifically, SAGE will be asked to:

- Review the DoV WG "Assessment report on DoV progress" based on:
  - the review of the "annual report on the Decade of Vaccines progress" prepared by the DOV secretariat,

- Information provided by other partners' annual reports on Decade of Vaccines progress.
- Make recommendations on any necessary changes to the formulation of the indicators, operational definitions and/or the processes for data collection.
- Identify successes, challenges and areas where additional efforts or corrective actions by countries, regions, partners, donor agencies or other parties, are needed.
- Provide recommendations and corrective actions for Members States, regions, partners, donor agencies or other parties regarding DoV GVAP implementation in a "SAGE Assessment report on the Decade of Vaccines progress" which will be the basis of the "progress report" for the WHO Board and World Health Assembly.

#### :: **Measles and rubella elimination - Session 7**

*For discussion:*

- Global status report
- Report from each Region
- How to get back on track towards global and Regional targets

*For decision:*

- Use of combined measles-rubella vaccine for both routine doses
- Criteria to guide countries on expansion of the target age range measles and measles-rubella SIAs

*For decision:*

- Vaccination of health workers

#### :: **Smallpox vaccines - Session 8**

For decision

:: The last case of Smallpox occurred in 1977. In 1980 the World Health Assembly declared this disease eradicated. A global stockpile of vaccines, held in Switzerland, was created with donations from Member States.

:: In 2004 Previous the Ad-Hoc Orthopoxvirus Committee, recommended that the stockpile should consist 200 million doses. The current physical WHO stockpile is ~ 2.4 million doses, and the virtual stockpile consists of 31 million doses.

:: In order for WHO to make an informed decision (risk-benefit) on which vaccines to stock and to be able to give advice to countries on their stockpile, WHO would like SAGE to answer the following questions:

- Which vaccine should be recommended to be used during an outbreak of smallpox? (vaccine used during the eradication, vaccine produced in tissue cell, or further attenuated vaccines).
  - Composition of stockpile
  - Size of stockpile
- What groups should be prioritized to be vaccinated while faced with limited vaccine supply?
  - Age groups, risk factors/safety aspects, vulnerable populations, ethical considerations
  - Which vaccine should be given?
- Which vaccine should be recommended for preventive use?
- Who should be targeted and with which immunization schedule? (First aid responders, army, police, health workers)

#### **WHO: Global tuberculosis report 2013**

[http://www.who.int/entity/tb/publications/global\\_report/en/index.html](http://www.who.int/entity/tb/publications/global_report/en/index.html)

- *Gains in tuberculosis control at risk due to 3 million missed patients and drug resistance*
- *Progress in TB control can be substantially accelerated by addressing these challenges*

*Excerpt from media release*

...The new data confirm that the world is on track to meet the 2015 UN Millennium Development Goals (MDGs) target of reversing TB incidence, along with the target of a 50% reduction in the mortality rate by 2015 (compared to 1990). A special "Countdown to 2015" supplement to this year's report provides full information on the progress to the international TB targets. It details if the world and countries with a high burden of TB are "on-track" or "off-track" and what can be done rapidly to accelerate impact as the 2015 deadline approaches.

*Key challenges*

The report underlines the need for a quantum leap in TB care and control which can only be achieved if two major challenges are addressed.

- Missing 3 million – around three million people (equal to one in three people falling ill with TB) are currently being 'missed' by health systems.
- Drug-resistant TB crisis – the response to test and treat all those affected by multidrug-resistant TB (MDR-TB) is inadequate.

Insufficient resources for TB are at the heart of both challenges. TB programmes do not have the capacity to find and care for people who are "hard-to-reach", often outside the formal or state health system. Weak links in the TB chain (a chain that includes detection, treatment and care) lead to such people being missed...

*...Five priority actions*

The WHO report recommends five priority actions that could make a rapid difference between now and 2015.

- Reach the 3 million TB cases missed in national notification systems by expanding access to quality testing and care services across all relevant public, private or community based providers, including hospitals and NGOs which serve large proportions of populations at risk.
- Address with urgency the MDR-TB crisis. Failure to test and treat all those ill with MDR-TB carries public health risks and grave consequences for those affected. High-level political commitment, ownership by all stakeholders, adequate financing and increased cooperation are needed to solve bottlenecks in drug supply and build capacity to deliver quality care.
- Intensify and build on TB-HIV successes to get as close as possible to full antiretroviral therapy (ART) coverage for people co-infected with TB and HIV.
- Increase domestic and international financing to close the resource gaps – now estimated at about US\$ 2 billion per year – for an effective response to TB in low- and middle-income countries. Full replenishment of the Global Fund is essential, given that most low-income countries rely heavily on international donor funding, with the Global Fund providing around 75% of financial resources in these countries.
- Accelerate rapid uptake of new tools – through technology transfer and operational research to ensure that countries and communities most at risk benefit from these innovations.

<http://www.who.int/mediacentre/news/releases/2013/tuberculosis-report-2013/en/index.html>

***Journal Watch***

*Vaccines and Global Health: The Week in Review* continues its weekly scanning of key peer-reviewed journals to identify and cite articles, commentary and editorials, books reviews and other content supporting our focus on vaccine ethics and policy. **Journal Watch is not intended to be exhaustive, but indicative of themes and issues the Center is actively tracking.** We selectively provide full text of some editorial and comment articles that are specifically relevant to our work. Successful access to some of the links provided may require subscription or other access arrangement unique to the publisher.

*If you would like to suggest other journal titles to include in this service, please contact David Curry at: [david.r.curry@centerforvaccineethicsandpolicy.org](mailto:david.r.curry@centerforvaccineethicsandpolicy.org)*

### **The American Journal of Bioethics**

[Volume 13](#), Issue 11, 2013

[http://www.tandfonline.com/toc/uajb20/current#.Uhk8Az\\_hfIY](http://www.tandfonline.com/toc/uajb20/current#.Uhk8Az_hfIY)

[No relevant content]

### **American Journal of Infection Control**

Vol 41 | No. 10 | October 2013 | Pages 853-948

<http://www.ajicjournal.org/current>

[Reviewed earlier]

### **American Journal of Public Health**

Volume 103, Issue 11 (November 2013)

<http://ajph.aphapublications.org/toc/ajph/current>

[Reviewed earlier]

### **American Journal of Tropical Medicine and Hygiene**

October 2013; 89 (4)

<http://www.ajtmh.org/content/current>

[Reviewed earlier]

### **Annals of Internal Medicine**

15 October 2013, Vol. 159. No. 8

<http://annals.org/issue.aspx>

[Reviewed earlier; No relevant content]

### **BMC Public Health**

(Accessed 26 October 2013)

<http://www.biomedcentral.com/bmcpublichealth/content>

[No new relevant content]

### **British Medical Bulletin**

Volume 107 Issue 1 September 2013  
<http://bmb.oxfordjournals.org/content/current>  
[Reviewed earlier]

## **British Medical Journal**

26 October 2013 (Vol 347, Issue 7930)  
<http://www.bmj.com/content/347/7930>

### **Editorial**

#### **Safety of the quadrivalent human papillomavirus vaccine**

BMJ 2013; 347 doi: <http://dx.doi.org/10.1136/bmj.f5631> (Published 9 October 2013)

#### *Now well established*

The prophylactic human papillomavirus (HPV) vaccines are remarkable both for their efficacy against HPV infection and related diseases,<sup>1</sup> and for their potential to prevent cervical cancer. Cervical cancer, which is caused by persistent infection with oncogenic HPV types, remains a cause of premature death in women around the world, most of whom have no access to secondary prevention through organised cervical screening programmes.<sup>2</sup> The linked study by Arnheim-Dahlström and colleagues (doi:10.1136/bmj.f5906) provides a timely and important contribution to the evidence base on the safety of the quadrivalent HPV vaccine,<sup>3</sup> which prevents HPV infection and disease due to the oncogenic types HPV-16 and HPV-18 and types HPV-6 and HPV-11, which cause genital warts.

This population based cohort analysis provides strong evidence that autoimmune conditions, neurological diseases, and thromboembolic disease are not triggered by quadrivalent HPV vaccination. Serious sudden onset conditions such as these, which are largely of undetermined cause, are sometimes falsely attributed to vaccination when population based vaccination programmes are implemented.<sup>4</sup> It is crucial that surveillance systems can rule out false associations and identify rare but real ...

<http://www.bmj.com/content/347/bmj.f5631>

### **Research**

#### **Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: cohort study**

Lisen Arnheim-Dahlström, associate professor<sup>1</sup>, Björn Pasternak, postdoctoral fellow<sup>2</sup>, Henrik Svanström, statistician<sup>2</sup>, Pär Sparén, professor<sup>1</sup>, Anders Hviid, senior investigator<sup>2</sup>  
<http://www.bmj.com/content/347/bmj.f5906>

#### *Abstract*

##### Objective

To assess the risk of serious adverse events after vaccination of adolescent girls with quadrivalent human papillomavirus (qHPV) vaccine.

##### Design

Register based cohort study.

##### Setting

Denmark and Sweden, October 2006 to December 2010.

##### Participants

997,585 girls aged 10-17, among whom 296,826 received a total of 696,420 qHPV vaccine doses.

##### Main outcome measures

Incident hospital diagnosed autoimmune, neurological, and venous thromboembolic events (53 different outcomes) up to 180 days after each qHPV vaccine dose. Only events with at least five vaccine exposed cases were considered for further assessment. Rate ratios adjusted for age, country, calendar year, and parental country of birth, education, and socioeconomic status were estimated, comparing vaccinated and unvaccinated person time. For outcomes where the rate ratio was significantly increased, we regarded three criteria as signal strengthening: analysis based on 20 or more vaccine exposed cases (reliability), rate ratio 3.0 or more (strength), and significantly increased rate ratio in country specific analyses (consistency). We additionally assessed clustering of events in time and estimated rate ratios for a risk period that started on day 181.

#### Results

Among the 53 outcomes, at least five vaccine exposed cases occurred in 29 and these were analysed further. Whereas the rate ratios for 20 of 23 autoimmune events were not significantly increased, exposure to qHPV vaccine was significantly associated with Behcet's syndrome, Raynaud's disease, and type 1 diabetes. Each of these three outcomes fulfilled only one of three predefined signal strengthening criteria. Furthermore, the pattern of distribution in time after vaccination was random for all three and the rate ratios for these outcomes in the period from day 181 after vaccination were similar to the rate ratios in the primary risk period. The rate ratios for five neurological events were not significantly increased and there were inverse associations with epilepsy (rate ratio 0.66, 95% confidence interval 0.54 to 0.80) and paralysis (0.56, 0.35 to 0.90). There was no association between exposure to qHPV vaccine and venous thromboembolism (0.86, 0.55 to 1.36).

#### Conclusions

This large cohort study found no evidence supporting associations between exposure to qHPV vaccine and autoimmune, neurological, and venous thromboembolic adverse events. Although associations for three autoimmune events were initially observed, on further assessment these were weak and not temporally related to vaccine exposure. Furthermore, the findings need to be interpreted considering the multiple outcomes assessments.

### **Bulletin of the World Health Organization**

Volume 91, Number 10, October 2013, 717-796

<http://www.who.int/bulletin/volumes/91/10/en/index.html>

[Reviewed earlier]

### **Clinical Therapeutics**

Vol 35 | No. 10 | October 2013 | Pages 1475-1652

<http://www.clinicaltherapeutics.com/current>

[No relevant content]

### **Cost Effectiveness and Resource Allocation**

(Accessed 26 October 2013)

<http://www.resource-allocation.com/>

[No new relevant content]

## **Current Opinion in Infectious Diseases.**

October 2013 - Volume 26 - Issue 5 pp: v-vi,399-492

<http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx>

[Reviewed earlier]

## **Developing World Bioethics**

August 2013 Volume 13, Issue 2 Pages ii–iii, 57–104

<http://onlinelibrary.wiley.com/doi/10.1111/dewb.2013.13.issue-2/issuetoc>

### ***Special Issue: Anti-retrovirals for treatment and prevention – new ethical challenges***

[Six articles]

#### **ARTICLE**

### **Ethical Tradeoffs in Trial Design: Case Study of an HPV Vaccine Trial in HIV-Infected Adolescent Girls in Lower Income Settings**

J.C. Lindsey, S.K. Shah, G.K. Siberry, P. Jean-Philippe, M.J. Levin

<http://onlinelibrary.wiley.com/doi/10.1111/dewb.12028/abstract>

#### *Abstract*

The Declaration of Helsinki and the Council of the International Organization of Medical Sciences provide guidance on standards of care and prevention in clinical trials. In the current and increasingly challenging research environment, the ethical status of a trial design depends not only on protection of participants, but also on social value, feasibility, and scientific validity. Using the example of a study assessing efficacy of a vaccine to prevent human papilloma virus in HIV-1 infected adolescent girls in low resource countries without access to the vaccine, we compare several trial designs which rank lower on some criteria and higher on others, giving rise to difficult trade-offs. This case demonstrates the need for developing more nuanced guidance documents to help researchers balance these often conflicting criteria.

## **Development in Practice**

Volume 23, Issue 5-06, 2013

<http://www.tandfonline.com/toc/cdip20/current>

[Reviewed earlier]

## **Emerging Infectious Diseases**

Volume 19, Number 10—October 2013

<http://www.cdc.gov/ncidod/EID/index.htm>

[Reviewed earlier]

## **The European Journal of Public Health**

Volume 23 Issue 5 October 2013

<http://eurpub.oxfordjournals.org/content/current>

[Reviewed earlier]

## **Eurosurveillance**

Volume 18, Issue 43, 24 October 2013

<http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678>

***Rapid communications***

**[Human infection with avian influenza A\(H7N9\) virus re-emerges in China in winter 2013](#)**

by E Chen, Y Chen, L Fu, Z Chen, Z Gong, H Mao, D Wang, MY Ni, P Wu, Z Yu, T He, Z Li, J Gao, S Liu, Y Shu, BJ Cowling, S Xia, H Yu

***Surveillance and outbreak reports***

**[Study of a measles outbreak in Granada with preventive measures applied by the courts, Spain, 2010 to 2011](#)**

by E Navarro, MM Mochón, MD Galicia, I Marín, J Laguna

***Abstract***

Measles had practically been eliminated in Granada since the systematic vaccination of children with two doses introduced in 1984. However, in 2009 the disease returned in the form of small outbreaks. This study describes the measles outbreak that occurred in Granada from October 2010 to August 2011 and the measures imposed to control it. Information was sourced from the records of the Andalusian epidemiological surveillance system. A total of 308 cases were recorded, representing an incidence rate of 33.6 cases per 100,000 inhabitants. The first wave of the epidemic took place in Granada city, with the majority of cases occurring among families who lived in the Albaycín neighbourhood and were opposed to vaccination for ideological and/or religious reasons. The initial cases were in unvaccinated children aged 1 to 13 years. The outbreak later spread throughout the province. To control the outbreak, the vaccination schedule for the exposed children was brought up to date. The Regional Ministry of Health decided to take legal action in order to ensure vaccination of those in the initial nucleus of the outbreak.

**Forum for Development Studies**

[Volume 40](#), Issue 3, 2013

<http://www.tandfonline.com/toc/sfds20/current>

[No relevant content]

**Global Health Governance**

Summer 2013 Archive

<http://blogs.shu.edu/ghg/category/complete-issues/summer-2013/>

***Special Series on Universal Health Coverage***

**Globalization and Health**

[Accessed 26 October 2013]

<http://www.globalizationandhealth.com/>

[No new relevant content]

**Health Affairs**

October 2013; Volume 32, Issue 10

<http://content.healthaffairs.org/content/current>

***Theme: Economic Trends & Quality Trade-Off***

[No relevant content]

### **Health and Human Rights**

Volume 15, Issue 1

<http://www.hhrjournal.org/>

***Theme: Realizing the Right to Health Through a Framework Convention on Global Health***

[Reviewed earlier]

### **Health Economics, Policy and Law**

Volume 8 / Issue 04 / October 2013

<http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue>

[Reviewed earlier; No relevant content]

### **Health Policy and Planning**

Volume 28 Issue 7 October 2013

<http://heapol.oxfordjournals.org/content/current>

[Reviewed earlier]

### **Human Vaccines & Immunotherapeutics** (formerly Human Vaccines)

October 2013 Volume 9, Issue 10

<http://www.landesbioscience.com/journals/vaccines/toc/volume/9/issue/10>

[Reviewed earlier]

### **Infectious Agents and Cancer**

<http://www.infectagentscancer.com/content>

[Accessed 26 October 2013]

[No new relevant content]

### **Infectious Diseases of Poverty**

<http://www.idpjournal.com/content>

[Accessed 26 October 2013]

[No new relevant content]

### **International Journal of Epidemiology**

Volume 42 Issue 5 October 2013

<http://ije.oxfordjournals.org/content/current>

[No relevant content]

### **International Journal of Infectious Diseases**

## **JAMA**

October 23/30, 2013, Vol 310, No. 16

<http://jama.jamanetwork.com/issue.aspx>

**Editorial** | October 23/30, 2013

### **Influenza Vaccination in 2013-2014 - Achieving 100% Participation**

Kathleen M. Neuzil, MD, MPH<sup>1</sup>

*Excerpt* <http://jama.jamanetwork.com/article.aspx?articleid=1758725>

Every year, the public and health care system experience clinical and financial consequences of influenza epidemics. Influenza infection leads to hospitalizations, deaths, excess medication usage, and days missed from work and school. Influenza is a preventable disease, and advisory bodies in the United States recommend influenza vaccine for everyone 6 months and older, with particular emphasis on the need to vaccinate young children, older adults, and persons of all ages with high-risk conditions, including cardiovascular disease.<sup>1</sup> In 2013, an unprecedented number of influenza vaccines are available in the US market, including quadrivalent vaccines, live, attenuated vaccines, high-dose vaccines, and vaccines manufactured in cell culture.<sup>1</sup> Comparative trials in certain pediatric age groups have shown the relative benefits of live, attenuated influenza vaccine and as yet unlicensed adjuvanted vaccines.<sup>2,3</sup> Likewise, studies evaluating the comparative benefits of high-dose vs standard-dose influenza vaccines in older adults are nearing completion.<sup>4</sup>...

**Original Investigation** | October 23/30, 2013

### **Association Between Influenza Vaccination and Cardiovascular Outcomes in High-Risk Patients A Meta-analysis**

Jacob A. Udell, MD, MPH, FRCPC<sup>1</sup>; Rami Zawi, MD<sup>2</sup>; Deepak L. Bhatt, MD, MPH<sup>3,4</sup>; Maryam Keshtkar-Jahromi, MD, MPH<sup>5,6</sup>; Fiona Gaughran, MD<sup>7,8</sup>; Arintaya Phrommintikul, MD<sup>9</sup>; Andrzej Ciszewski, MD<sup>10</sup>; Hossein Vakili, MD<sup>11</sup>; Elaine B. Hoffman, PhD<sup>4</sup>; Michael E. Farkouh, MD, MSc, FRCPC<sup>12</sup>; Christopher P. Cannon, MD<sup>4</sup>

*Abstract* <http://jama.jamanetwork.com/article.aspx?articleid=1758749>

Importance. Among nontraditional cardiovascular risk factors, recent influenza-like infection is associated with fatal and nonfatal atherothrombotic events.

Objectives. To determine if influenza vaccination is associated with prevention of cardiovascular events.

Data Sources and Study Selection. A systematic review and meta-analysis of MEDLINE (1946-August 2013), EMBASE (1947-August 2013), and the Cochrane Library Central Register of Controlled Trials (inception-August 2013) for randomized clinical trials (RCTs) comparing influenza vaccine vs placebo or control in patients at high risk of cardiovascular disease, reporting cardiovascular outcomes either as efficacy or safety events.

Data Extraction and Synthesis. Two investigators extracted data independently on trial design, baseline characteristics, outcomes, and safety events from published manuscripts and unpublished supplemental data. High-quality studies were considered those that described an appropriate method of randomization, allocation concealment, blinding, and completeness of follow-up.

Main Outcomes and Measures Random-effects Mantel-Haenszel risk ratios (RRs) and 95% CIs were derived for composite cardiovascular events, cardiovascular mortality, all-cause mortality,

and individual cardiovascular events. Analyses were stratified by subgroups of patients with and without a history of acute coronary syndrome (ACS) within 1 year of randomization.

**Results** Five published and 1 unpublished randomized clinical trials of 6735 patients (mean age, 67 years; 51.3% women; 36.2% with a cardiac history; mean follow-up time, 7.9 months) were included. Influenza vaccine was associated with a lower risk of composite cardiovascular events (2.9% vs 4.7%; RR, 0.64 [95% CI, 0.48-0.86],  $P = .003$ ) in published trials. A treatment interaction was detected between patients with (RR, 0.45 [95% CI, 0.32-0.63]) and without (RR, 0.94 [95% CI, 0.55-1.61]) recent ACS ( $P$  for interaction = .02). Results were similar with the addition of unpublished data.

**Conclusions and Relevance** In a meta-analysis of RCTs, the use of influenza vaccine was associated with a lower risk of major adverse cardiovascular events. The greatest treatment effect was seen among the highest-risk patients with more active coronary disease. A large, adequately powered, multicenter trial is warranted to address these findings and assess individual cardiovascular end points.

### **JAMA Pediatrics**

October 2013, Vol 167, No. 10

<http://archpedi.jamanetwork.com/issue.aspx>

[Reviewed earlier; No relevant content]

### **Journal of Community Health**

Volume 38, Issue 5, October 2013

<http://link.springer.com/journal/10900/38/5/page/1>

[Reviewed earlier]

### **Journal of Health Organization and Management**

Volume 27 issue 6 - Latest Issue

<http://www.emeraldinsight.com/journals.htm?issn=1477-7266&show=latest>

[No relevant content]

### **Journal of Infectious Diseases**

Volume 208 Issue 10 November 15, 2013

<http://jid.oxfordjournals.org/content/current>

[No relevant content]

### **Journal of Global Infectious Diseases (JGID)**

July-September 2013 Volume 5 | Issue 3 Page Nos. 91-124

<http://www.jgid.org/currentissue.asp?sabs=n>

[No relevant content]

### **Journal of Medical Ethics**

November 2013, Volume 39, Issue 11

<http://jme.bmj.com/content/current>

[No relevant content]

### **Journal of Medical Microbiology**

November 2013; 62 (Pt 11)

<http://jmm.sgmjournals.org/content/current>

[No relevant content]

### **Journal of the Pediatric Infectious Diseases Society (JPIDS)**

Volume 2 Issue 3 September 2013

<http://jpids.oxfordjournals.org/content/current>

[Reviewed earlier]

### **Journal of Pediatrics**

Vol 163 | No. 5 | November 2013 | Pages 1235-1536

<http://www.jpeds.com/current>

#### **Tdap vaccination during pregnancy—no signal of safety concerns for infants**

[Sarah S. Long](#), MD

*Abstract* <http://www.jpeds.com/article/S0022-3476%2813%2901106-2/preview>

Taking advantage of a robust electronic medical record system at Intermountain Healthcare facilities in Utah, Shakib et al performed a retrospective cohort study assessing pregnancy, birth, and infancy outcomes for 138 women who were given tetanus and reduced-content diphtheria toxoids and reduced-content acellular pertussis vaccine (Tdap) compared with 552 randomly selected nonvaccinated pregnant women controls. The study, ending in 2009, was performed before routine recommendation for Tdap administration during pregnancy. The most common reason for Tdap was prophylaxis for open wounds or during acute care visits for trauma. Of pregnant women receiving Tdap, 63% received the vaccine during the first trimester.

#### **Tetanus, Diphtheria, Acellular Pertussis Vaccine during Pregnancy: Pregnancy and Infant Health Outcomes**

[Julie H. Shakib](#), DO, MS, MPH, [Kent Korgenski](#), MS, MT, [Xiaoming Sheng](#), PhD, [Michael W. Varner](#), MD, [Andrew T. Pavia](#), MD, [Carrie L. Byington](#), MD

*Abstract* <http://www.jpeds.com/article/S0022-3476%2813%2900734-8/abstract>

Objective

To assess pregnancy and birth outcomes in infants born to women who did or did not receive tetanus, diphtheria, acellular pertussis (Tdap) vaccine during pregnancy.

Study design

Retrospective cohort. Pregnant women 12–45 years of age who received Tdap at Intermountain Healthcare facilities and their infants were identified and compared with mother-infant pairs without documented Tdap from May 2005 through August 2009. Primary measures included pregnancy outcomes and infant health outcomes at birth through 12 months.

Results

From 162 448 pregnancies we identified 138 women (0.08%) with documented Tdap administration during pregnancy (cases); 552 pregnant women without documented Tdap were randomly selected as controls. Of 138 immunized women, 63% received Tdap in the first

trimester and 37% after. Tdap was given most commonly as wound prophylaxis. The incidence of spontaneous or elective abortion was no greater in Tdap cases than in controls. There were no significant differences in preterm delivery, gestational age, or birth weight between groups. One or more congenital anomaly was identified in 3.7% (95% CI 1.2%-8.5%) of case infants and 4.4% (95% CI 2.7%-6.5%) of control infants ( $P = .749$ ). In infants born to women receiving Tdap during pregnancy, 3.6% (0.8%-10.2%) had International Classification of Diseases, Ninth Revision, Clinical Modification diagnoses consistent with complex chronic conditions within 12 months compared with 10.4% (95% CI 7.2%-14.4%) of infants of controls ( $P = .054$ ).

#### Conclusions

Documented Tdap administration during pregnancy was uncommon and occurred most often in the first trimester as prophylaxis following trauma. No increase in adverse outcomes was identified in infants born to women receiving Tdap compared with infants of controls.

#### **Journal of Public Health Policy**

Volume 34, Issue 4 (November 2013)

<http://www.palgrave-journals.com/jphp/journal/v34/n4/index.html>

[Reviewed earlier]

#### **Journal of the Royal Society – Interface**

January 6, 2014; 11 (90)

<http://rsif.royalsocietypublishing.org/content/current>

[No relevant content]

#### **Journal of Virology**

[November 2013, volume 87, issue 21](#)

<http://jvi.asm.org/content/current>

[No relevant content]

#### **The Lancet**

Oct 26, 2013 Volume 382 Number 9902 p1381 - 1458

<http://www.thelancet.com/journals/lancet/issue/current>

##### **Editorial**

##### **Polio eradication: where are we now?**

The Lancet

[Full Text] <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2813%2962196-0/fulltext>

On Oct 17, WHO received reports of a cluster of acute cases of flaccid paralysis in Syria. [Initial results](#) showed two suspected cases of poliomyelitis, indicating the first apparent outbreak of polio in 14 years in the country. Syria is now considered at high risk for polio and other vaccine-preventable diseases, and this suspected outbreak raises the alarm that the country's health crisis has deepened further. With the appalling conflict in Syria continuing to damage the [health system infrastructure](#) needed for polio eradication, as well as other health

services, this new suspected outbreak is a reminder that political determinants of health underscore the success or failure of eliminating this disease once and for all.

Beyond Syria, [polio campaigns in Pakistan](#) have been damaged by repeated violent attacks and killings of polio workers, lack of public confidence in vaccines because of the false characterisation of vaccination as a plot to sterilise Muslims, and publicly boycotted polio immunisation by the Taliban. Worryingly, the situation in North Waziristan Federally Administered Tribal Areas—where polio vaccines are strictly blocked—is becoming increasingly severe, with the largest number of children being paralysed by poliomyelitis in all of Asia. Compared with this time last year, Pakistan has made little progress with almost identical numbers of polio cases. Clearly, attacks on health workers are unacceptable, and those who engage in them must face prosecution. Furthermore, the reasons why the general community might be suspicious of vaccination should be addressed. While health education is an important part of promoting vaccine uptake, the mistrust of authority that fuels anti-vaccination conspiracy theories must also be examined. The latest sociological and psychological research as to how and why people come to hold such beliefs, as well as the specific cultural milieu in which vaccination programmes operate, should be taken into consideration.

Poliomyelitis also re-emerged in the Horn of Africa this May, with 174 cases in Somalia, 14 in Kenya, six in Ethiopia, and three in South Sudan according to the [most recent reports](#). In Somalia, many polio cases are in areas south of Mogadishu where Al-Shabaab operates. The group refused to admit supplies of polio vaccine and launched a propaganda campaign in areas it controls, spreading falsehoods about the vaccine to scare off parents. Furthermore, Somalia has been so dangerous for health workers that Médecins Sans Frontières pulled out of the country in August of this year, ending an involvement of 22 years.

Continued virus transmission in endemic countries, and the outbreaks of polio in the Horn of Africa and Syria, are pertinent reminders that the most difficult challenges for global polio eradication are the political determinants of health such as weak health systems, public mistrust, political instability, and conflict—rather than medical barriers.

With regard to the technical dimension of ending polio, global eradication efforts led by WHO, UNICEF, and the Rotary Foundation have made remarkable progress. Poliomyelitis cases have been reduced by more than 99% and there are only three remaining polio-endemic countries—Afghanistan, Nigeria, and Pakistan. In 2013, the number of polio cases from the three endemic countries—99 in total—is 40% lower than in 2012. To further strengthen the efforts, the Global Polio Eradication Initiative (GPEI) launched the new [Eradication & Endgame Strategic Plan 2013–18](#) in May, with a detailed budget and a new deadline for polio eradication set for 2018. The plan has four simultaneous objectives: detection and interruption of wild poliovirus, strengthening of routine immunisation and withdrawal of the oral polio vaccine (OPV), containment of all virus samples and certification of interruption of transmission, and legacy planning to benefit other health and development initiatives. Notably, the most ambitious vaccine introduction plan in history has been initiated, which aims to introduce inactivated polio vaccines (IPV) by the end of 2015 in 124 countries to replace OPV and eliminate the rare risk of vaccine-derived cases of polio. In June of this year, the GAVI board agreed to provide financial support and play a lead role in introduction of IPV.

Technical improvements are insufficient, however, unless the political context, which has been paid little attention, is tackled more seriously. World Polio Day on Oct 24 is a reminder of the importance of global polio eradication. To end poliomyelitis at this stage, strong political will from international partners and governments to address the political determinants of disease eradication more vigorously and urgently is key.

**The Lancet Global Health**

Nov 2013 Volume 1 Number 5 e238 - 309

<http://www.thelancet.com/journals/langlo/issue/current>

[No relevant content]

**The Lancet Infectious Diseases**

Nov 2013 Volume 13 Number 11 p907 - 994

<http://www.thelancet.com/journals/laninf/issue/current>

[No relevant content]

**Medical Decision Making (MDM)**

November 2013; 33 (8)

<http://mdm.sagepub.com/content/current>

[Reviewed earlier]

**The Milbank Quarterly**

*A Multidisciplinary Journal of Population Health and Health Policy*

September 2013 Volume 91, Issue 3 Pages 419–65

[http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1468-0009/currentissue](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1468-0009/currentissue)

[Reviewed earlier; No relevant content]

**Nature**

Volume 502 Number 7472 pp409-586 24 October 2013

[http://www.nature.com/nature/current\\_issue.html](http://www.nature.com/nature/current_issue.html)

[No relevant content]

**Nature Immunology**

November 2013, Volume 14 No 11 pp1101-1198

<http://www.nature.com/ni/journal/v14/n11/index.html>

[No relevant content]

**Nature Medicine**

October 2013, Volume 19 No 10 pp1191-1350

<http://www.nature.com/nm/journal/v19/n10/index.html>

[Reviewed earlier]

**Nature Reviews Immunology**

November 2013 Vol 13 No 11

<http://www.nature.com/nri/journal/v13/n11/index.html>

[No relevant content]

## **New England Journal of Medicine**

October 24, 2013 Vol. 369 No. 17

<http://www.nejm.org/toc/nejm/medical-journal>

### ***Perspective***

#### **Access to Patient-Level Trial Data — A Boon to Drug Developers**

Hans-Georg Eichler, M.D., Frank Pétavy, M.Sc., Francesco Pignatti, M.D., and Guido Rasi, M.D.  
N Engl J Med 2013; 369:1577-1579 [October 24, 2013](#) DOI: 10.1056/NEJMp1310771

<http://www.nejm.org/doi/full/10.1056/NEJMp1310771>

#### ***Excerpt***

The provision of access to clinical trial results that include patient-level data is generating much debate. A growing chorus of transparency advocates is pushing for open access to these data, making a case on the basis of respect for patients' altruism, the need to safeguard public health, and distrust in the integrity and completeness of published trial information.<sup>1</sup> We at the European Medicines Agency (EMA) have been actively engaged in this debate, and the EMA has recently published a draft of a policy that would make patient-level data in its possession publicly accessible. The principle of privacy protection will inform the EMA's policy and activities; robust and proportionate measures will be adopted to safeguard patients' privacy, in compliance with applicable data-protection legislation.<sup>2</sup>

Pharmaceutical-industry organizations, however, have expressed concern that "one of the risks to innovation is disclosure to competitors of companies' trade secrets and proprietary information that could allow others to 'free ride' off of the substantial investments of innovators"; they fear "degradation of incentives for companies to invest in biomedical research."<sup>3</sup>

Industry leaders have rightly complained about the unsustainability of the current drug development and business model. The timelines and costs of clinical drug development are increasing relentlessly, and the attrition rate of assets in development remains high. At the same time, growing cost pressures in all health care environments are forcing restrictions on drug use, aiming to limit coverage only to patients who can be expected to benefit from a given intervention and for whom that intervention is clearly cost-effective.

Contrary to industry fears, we argue that access to full — though appropriately deidentified — data sets from clinical trials will benefit the research-based biopharmaceutical industry. We predict that it will help to increase the efficiency of drug development, improve cost-effectiveness, improve comparative-effectiveness analysis, and reduce duplication of effort among trial sponsors...

#### ***Health Law, Ethics, and Human Rights***

#### **Preparing for Responsible Sharing of Clinical Trial Data**

Michelle M. Mello, J.D., Ph.D., Jeffrey K. Francer, J.D., M.P.P., Marc Wilenzick, J.D., Patricia Teden, M.B.A., Barbara E. Bierer, M.D., and Mark Barnes, J.D., LL.M.

N Engl J Med 2013; 369:1651-1658 [October 24, 2013](#) DOI: 10.1056/NEJMhle1309073

*Excerpt* <http://www.nejm.org/doi/full/10.1056/NEJMhle1309073>

Data from clinical trials, including participant-level data, are being shared by sponsors and investigators more widely than ever before. Some sponsors have voluntarily offered data to researchers,<sup>1,2</sup> some journals now require authors to agree to share the data underlying the studies they publish,<sup>3</sup> the Office of Science and Technology Policy has directed federal agencies to expand public access to data from federally funded projects,<sup>4</sup> and the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) have proposed the expansion of

access to data submitted in regulatory applications.<sup>5,6</sup> Sharing participant-level data may bring exciting benefits for scientific research and public health but may also have unintended consequences. Thus, expanded data sharing must be pursued thoughtfully.

We provide a suggested framework for broad sharing of participant-level data from clinical trials and related technical documents. After reviewing current data-sharing initiatives, potential benefits and risks, and legal and regulatory implications, we propose potential governing principles and key features for a system of expanded access to participant-level data and evaluate several governance structure...

### **OMICS: A Journal of Integrative Biology**

October 2013, 17(10)

<http://online.liebertpub.com/toc/omi/17/10>

[Reviewed earlier; No relevant content]

### **Revista Panamericana de Salud Pública/Pan American Journal of Public Health (RPSP/PAJPH)**

September 2013 Vol. 34, No. 3

[http://www.paho.org/journal/index.php?option=com\\_content&view=article&id=132&Itemid=228&lang=en](http://www.paho.org/journal/index.php?option=com_content&view=article&id=132&Itemid=228&lang=en)

[Reviewed earlier]

### **The Pediatric Infectious Disease Journal**

October 2013 - Volume 32 - Issue 10 pp: e383-e413,1045-1158

<http://journals.lww.com/pidj/pages/currenttoc.aspx>

[Reviewed earlier]

### **Pediatrics**

October 2013, VOLUME 132 / ISSUE 4

<http://pediatrics.aappublications.org/current.shtml>

[Reviewed earlier]

### **Pharmaceutics**

Volume 5, Issue 3 (September 2013), Pages 371-

<http://www.mdpi.com/1999-4923/5/3>

[No new relevant content]

### **Pharmacoeconomics**

Volume 31, Issue 10, October 2013

<http://link.springer.com/journal/40273/31/10/page/1>

[Reviewed earlier]

**PLoS One**

[Accessed 26 October 2013]

<http://www.plosone.org/>

[No new relevant content]

**PLoS Medicine**

(Accessed 26 October 2013)

<http://www.plosmedicine.org/>

[No new relevant content]

**PLoS Neglected Tropical Diseases**

September 2013

<http://www.plosntds.org/article/browseIssue.action>

[Reviewed earlier]

**PNAS - Proceedings of the National Academy of Sciences of the United States of America**

(Accessed 26 October 2013)

<http://www.pnas.org/content/early/recent>

[No new relevant content]

**Public Health Ethics**

Volume 6 Issue 2 July 2013

<http://phe.oxfordjournals.org/content/current>

[Reviewed earlier]

**Qualitative Health Research**

October 2013; 23 (10)

<http://qhr.sagepub.com/content/current>

[No relevant content]

**Risk Analysis**

October 2013 Volume 33, Issue 10 Pages 1759–1937

<http://onlinelibrary.wiley.com/doi/10.1111/risa.2013.33.issue-10/issuetoc>

[Reviewed earlier; No relevant content]

**Science**

25 October 2013 vol 342, issue 6157, pages 393-520

<http://www.sciencemag.org/current.dtl>

[No relevant content]

## Science Translational Medicine

23 October 2013 vol 5, issue 208

<http://stm.sciencemag.org/content/current>

[No relevant content]

## Social Science & Medicine

Volume 98, [In Progress](#) (December 2013)

<http://www.sciencedirect.com/science/journal/02779536/93>

[No new relevant content]

## UN Chronicle

Vol. L No. 3 2013 September 2013

<http://unchronicle.un.org/>

### **Theme: Migration**

This issue, which features contributions from twelve leading experts from within and outside of the United Nations system, looks at international migration and development. The articles examine, among other things, lowering the costs and amplifying the benefits of migration; the protection of migrants' rights and State sovereignty; labour migration and inclusive development; leveraging remittances for development; the reintegration of returning migrants; and strengthening migration cooperation.

## Vaccine

Volume 31, Issue 46, Pages 5297-5494 (4 November 2013)

<http://www.sciencedirect.com/science/journal/0264410X>

### **Progress in the establishment and strengthening of national immunization technical advisory groups: Analysis from the 2013 WHO/UNICEF joint reporting form, data for 2012**

Original Research Article

Pages 5314-5320

Philippe Duclos, Laure Dumolard, Nihal Abeyasinghe, Alex Adjagba, Cara Bess Janusz, Richard Mihigo, Liudmila Mosina, Yashohiro Takashima, Murat Hakan Öztürk

#### *Abstract*

The majority of industrialized and some developing countries have established National Immunization Technical Advisory Groups (NITAGs). To enable systematic global monitoring of the existence and functionality of NITAGs, in 2011, WHO and UNICEF included related questions in the WHO/UNICEF Joint Reporting Form (JRF) that provides an official means to globally collect indicators of immunization program performance. These questions relate to six basic process indicators.

According to the analysis of the 2013 JRF, data for 2012, notable progress was achieved between 2010 and 2012 and by the end of 2012, 99 countries (52%) reported the existence of a NITAG with a formal legislative or administrative basis (with a high of 86% in the Eastern Mediterranean Region – EMR), among the countries that reported data in the NITAG section of the JRF.

There were 63 (33%) countries with a NITAG that met six process indicators (47% increase over the 43 reported in 2010) including a total of 38 developing countries. 11% of low income countries reported a NITAG that meets all six process criteria, versus 29% of middle income countries and 57% of the high income ones. Countries with smaller populations reported the existence of a NITAG that meets all six process criteria less frequently than more populated countries (23% for less populated countries versus 43% for more populated ones).

However, progress needs to be accelerated to reach the Global Vaccine Action Plan (GVAP) target of ensuring all countries have support from a NITAG. The GVAP represents a major opportunity to boost the institutionalization of NITAGs. A special approach needs to be explored to allow small countries to benefit from sub-regional or other countries advisory groups.

### **Vaccines against diseases transmitted from animals to humans: A one health paradigm**

Review Article

Pages 5321-5338

Thomas P. Monath

#### *Abstract*

This review focuses on the immunization of animals as a means of preventing human diseases (zoonoses). Three frameworks for the use of vaccines in this context are described, and examples are provided of successes and failures. Framework I vaccines are used for protection of humans and economically valuable animals, where neither plays a role in the transmission cycle. The benefit of collaborations between animal health and human health industries and regulators in developing such products is discussed, and one example (West Nile vaccine) of a single product developed for use in animals and humans is described. Framework II vaccines are indicated for domesticated animals as a means of preventing disease in both animals and humans. The agents of concern are transmitted directly or indirectly (e.g. via arthropod vectors) from animals to humans. A number of examples of the use of Framework II vaccines are provided, e.g. against brucellosis, *Escherichia coli* O157, rabies, Rift Valley fever, Venezuelan equine encephalitis, and Hendra virus. Framework III vaccines are used to immunize wild animals as a means of preventing transmission of disease agents to humans and domesticated animals. Examples are reservoir-targeted, oral bait rabies, *Mycobacterium bovis* and Lyme disease vaccines. Given the speed and low cost of veterinary vaccine development, some interventions based on the immunization of animals could lead to rapid and relatively inexpensive advances in public health. Opportunities for vaccine-based approaches to preventing zoonotic and emerging diseases that integrate veterinary and human medicine (the One Health paradigm) are emphasized.

### **Influenza cost and cost-effectiveness studies globally – A review**

Review Article

Pages 5339-5348

Samuel K. Peasah, Eduardo Azziz-Baumgartner, Joseph Breese, Martin I. Meltzer, Marc-Alain Widdowson

#### *Abstract*

Every year, approximately 10–20% of the world's population is infected with influenza viruses, resulting in a significant number of outpatient and hospital visits and substantial economic burden both on health care systems and society. With recently updated WHO recommendations on influenza vaccination and broadening vaccine production, policy makers in middle- and low-income countries will need data on the cost of influenza disease and the cost effectiveness of vaccination. We reviewed the published literature to summarize estimates of cost and cost-effectiveness of influenza vaccination. We searched PUBMED (MEDLINE),

EMBASE, WEB of KNOWLEDGE, and IGOOGLE using the key words 'influenza', 'economic cost', 'cost effectiveness', and 'economic burden'. We identified 140 studies which estimated either cost associated with seasonal influenza or cost effectiveness/cost-benefit of influenza vaccination. 118 of these studies were conducted in World Bank-defined high income, 22 in upper-middle income, and no studies in low and lower-middle income countries.

The per capita cost of a case of influenza illness ranged from \$30 to \$64. 22 studies reported that influenza vaccination was cost-saving; reported cost-effectiveness ratios were \$10,000/outcome in 13 studies, \$10,000 to \$50,000 in 13 studies, and  $\geq$ \$50,000 in 3 studies. There were no studies from low income countries and few studies among pregnant women. Substantial differences in methodology limited the generalization of results.

Decision makers in lower income countries lack economic data to support influenza vaccine policy decisions, especially of pregnant women. Standardized cost-effectiveness studies of influenza vaccination of WHO-recommended risk groups' methods are urgently needed.

### [\*\*Adolescents and vaccines in the western world\*\*](#)

Review Article

Pages 5366-5374

Nicola Principi, Susanna Esposito

#### *Abstract*

Recent data have shown that the immune protection evoked by vaccines given in the first years of life progressively weakens, and that this is associated with a higher than expected incidence of vaccine-preventable diseases in adolescents and young adults. Furthermore, the greater circulation of pathogens among adolescents and young adults leads to a high risk of infection in unvaccinated or not fully vaccinated younger children. These findings, together with the availability of vaccines specifically developed to prevent infections that typically occur during adolescence, have induced a number of experts to suggest radical changes in the immunisation schedules usually recommended by health authorities. The most important of these relate pertussis, meningococcal and human papillomavirus vaccines but, although they are based on unexceptionable scientific premises, the suggestions have been only slowly and partially received in most countries, even in those in which vaccination programmes are usually adequately implemented and monitored. Adolescence is a particular period of life characterised by changes in intellectual, moral, physical, emotional and psychological development. All of these can have a considerable impact on compliance with immunisation schedules because the approach to any preventive method no longer entirely depends on parents' and pediatricians' judgements as in the first years of life but is the consequence of a more complex process involving the adolescents' thoughts and opinions, their relationships with their parents, friends and physicians, and the information they receive from the mass media. Every effort should be made to overcome the barriers to adolescent immunisation, including those arising from the adolescents themselves.

### [\*\*Cost-effectiveness of targeted vaccination to protect new-borns against pertussis: Comparing neonatal, maternal, and cocooning vaccination strategies\*\*](#)

Original Research Article

Pages 5392-5397

Anna K. Lugnér, Nicoline van der Maas, Michiel van Boven, Frits R. Mooi, Hester E. de Melker

#### *Abstract*

Pertussis (whooping cough) is a severe infectious disease in infants less than 6 months old. Mass vaccination programmes have been unable to halt transmission effectively. Strategies to protect new-borns against infection include vaccination of the neonate or the mother directly after birth (cocooning), or the mother during pregnancy (maternal). Here we investigate the

cost-effectiveness of these three strategies in the Netherlands. Costs for health care utilization and productivity losses, as well as impact on quality of life were calculated for a 10-year vaccination programme, assuming that vaccine-induced immunity lasts 5 years. Cocooning was the most attractive option from a cost-effectiveness viewpoint (€89,000/QALY). However, both cocooning and maternal vaccination would reduce the disease burden in infants and mothers vaccinated (about 17–20 QALY/year). Specifically, with a persistent epidemic as seen in 2012, there is need for reconsidering the vaccination schedules against pertussis in order to increase protection of the vulnerable new-borns.

### **[How parents make decisions about their children's vaccinations](#)**

Original Research Article

Pages 5466-5470

Emily K. Brunson

*Abstract*

Background

Continued parental acceptance of childhood vaccination is essential for the maintenance of herd immunity and disease prevention. As such, understanding parents' decision-making in relation to their children's vaccinations is vitally important.

Objective

This qualitative study sought to develop an understanding of the general process parents go through when making decisions about their children's vaccinations.

Methods

Interviews were conducted with U.S.-born parents living in King County, Washington who had children  $\leq 18$  months of age. These interviews were recorded and transcribed verbatim.

Results

Through the application of grounded theory, a general decision-making process was identified. Stages in this process included: awareness, assessing and choosing, followed by either stasis or ongoing assessment. The greatest variation occurred during the assessing stage, which involved parents examining vaccination-related issues to make subsequent decisions. This research suggests that three general assessment groups exist: acceptors, who rely primarily on general social norms to make their vaccination decisions; reliers, who rely primarily on other people for information and advice; and searchers, who seek for information on their own, primarily from published sources.

Conclusions

These results imply that one-size-fits-all approaches to vaccination interventions are inappropriate. Instead, this research suggests that interventions must be targeted to parents based on how they assess vaccination.

### **Vaccine**

Volume 31, Issue 45, Pages 5147-5296 (25 October 2013)

<http://www.sciencedirect.com/science/journal/0264410X/31/45>

### **["HPV? Never heard of it!": A systematic review of girls' and parents' information needs, views and preferences about human papillomavirus vaccination](#)**

Review Article

Pages 5152-5167

Maggie Hendry, Ruth Lewis, Alison Clements, Sarah Damery, Clare Wilkinso

*Abstract*

Background and objective

Two human papillomavirus vaccines were licenced in 2006/2007 for cervical cancer prevention. National vaccination programmes for schoolgirls were subsequently introduced in some European countries, North America and Australia. To understand factors influencing vaccine uptake and to inform the development of appropriate UK educational materials, we aimed to synthesise evidence of girls' and parents' information needs, views and preferences regarding HPV vaccination.

Design

Systematic review and mixed method synthesis of qualitative and survey data.

Data sources

Twelve electronic databases; bibliographies of included studies 1980 to August 2011.

Review methods

Two reviewers independently screened papers and appraised study quality. Studies were synthesised collaboratively using framework methods for qualitative data, and survey results integrated where they supported, contrasted or added to the themes identified.

Results

Twenty-eight qualitative studies and 44 surveys were included. Where vaccination was offered, uptake was high. Intention to decline was related to a preference for vaccinating later to avoid appearing to condone early sexual activity, concerns about vaccine safety and low perception of risk of HPV infection. Knowledge was poor and there were many misconceptions; participants tried to assess the potential benefits and harms of vaccination but struggled to interpret limited information about HPV in the context of existing knowledge about sexually transmitted infections and cancer.

Conclusion Many girls and their parents have limited understanding to an extent that impinges on their ability to make informed choices about HPV vaccination and could impact on future uptake of cervical screening. This is a considerable challenge to those who design and provide information, but getting the messages right for this programme could help in developing patient information about other HPV related cancers.

[\*\*HPV vaccination among French girls and women aged 14–23 years and the relationship with their mothers' uptake of Pap smear screening: A study in general practice\*\*](#)

Original Research Article

Pages 5243-5249

D. Lutringer-Magnin, C. Cropet, G. Barone, G. Canat, J. Kalecinski, Y. Leocmach, P. Vanhems, F. Chauvin, C. Lasset

*Abstract*

Introduction

HPV vaccination is recommended in France for girls aged 14 and for those aged 15–23 before sexual debut or who have become sexually active within the previous year. The first aim was to describe vaccination practice among 14–23-year-old girls visiting a general practitioner. A second objective was to investigate factors associated with starting vaccination among girls aged 14–18, in particular the regular practice of Pap-smear screening (PSS) by their mothers.

Methods

A cross-sectional study was conducted from June to August 2009. A total of 87 general practitioners from the large Rhône-Alpes region contributed data on 502 girls/women who came for consultation.

Results

231 (46.0%) of these girls/women had begun the process of HPV vaccination (68.2%, 56.9% and 18.7% of the 14–16, 17–20 and 21–23-year-olds respectively) of whom 139 (60.2%) had

received all three doses. 92 girls/women (39.8%) had received only one or two doses at the time of study. However, in 71 (77.2%) cases, the gap between the last dose received and the time of study was within the between-dose interval recommended in the vaccination schedule. GPs reported that 16 (11.5%) had mentioned side effects following injections. Having a mother who practised regular PSS (Odds Ratio 6.2 [1.5–25.8]), having never lived with a partner (4.6 [1.6–13.5]) and vaccination against hepatitis B (3.2 [1.6–6.1]) were found to be independently correlated with the initiation of HPV vaccination among girls/women aged 14–18 years.

#### Conclusion

Two years after the start of the programme, only half of girls/women aged 14–23 years had begun the process of HPV vaccination. HPV vaccination status was correlated with PSS in the mother, family status and hepatitis B vaccination. Such information may help to better target girls who are less likely to be vaccinated.

### **Vaccine: Development and Therapy**

(Accessed 26 October 2013)

<http://www.dovepress.com/vaccine-development-and-therapy-journal>

[No new relevant content]

### **Vaccines — Open Access Journal**

(Accessed 26 October 2013)

<http://www.mdpi.com/journal/vaccines>

*Vaccines (ISSN 2076-393X), an international open access journal, is published by MDPI online quarterly.*

[No new relevant content]

### **Value in Health**

Vol 16 | No. 7 | November 2013

<http://www.valueinhealthjournal.com/current>

[No relevant content]

### **From Google Scholar & other sources: Selected Journal Articles, Newsletters, Dissertations, Theses, Commentary**

#### **[Human papillomavirus vaccine intentions among males: A test of the Parallel Processing Model](#)**

CW Wheldon, ER Buhi, EM Daley, ND Hernandez... - Journal of Health Psychology ..., 2013

#### *Abstract*

We investigated the cognitive and emotional reactions resulting from a human papillomavirus-related illness threat (i.e. testing positive for human papillomavirus) and the potential behavioral implications resulting from these psychosocial processes among men (N = 536). Structural equation modeling was used to explore a theoretical model explaining human papillomavirus vaccine intentions. The model fit the data well and explained 16 percent of the variance in vaccine intentions. Negative emotional response mediated the path between illness

threat and vaccine intentions. Threat of genital warts was a salient concern and was positively associated with negative emotional response and subsequent vaccine intentions. Implications for vaccine promotion are discussed.

### **Media/Policy Watch**

This section is intended to alert readers to substantive news, analysis and opinion from the general media on vaccines, immunization, global; public health and related themes. *Media Watch* is not intended to be exhaustive, but indicative of themes and issues CVEP is actively tracking. This section will grow from an initial base of newspapers, magazines and blog sources, and is segregated from *Journal Watch* above which scans the peer-reviewed journal ecology.

We acknowledge the Western/Northern bias in this initial selection of titles and invite suggestions for expanded coverage. We are conservative in our outlook in adding news sources which largely report on primary content we are already covering above. Many electronic media sources have tiered, fee-based subscription models for access. We will provide full-text where content is published without restriction, but most publications require registration and some subscription level.

### **Al Jazeera**

<http://www.aljazeera.com/Services/Search/?q=vaccine>

*Accessed 26 October 2013*

[No new, unique, relevant content]

### **The Atlantic**

<http://www.theatlantic.com/magazine/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

### **BBC**

<http://www.bbc.co.uk/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

### **Brookings**

<http://www.brookings.edu/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

### **Council on Foreign Relations**

<http://www.cfr.org/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

### **Economist**

<http://www.economist.com/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

## **Financial Times**

<http://www.ft.com>

*Accessed 26 October 2013*

### **Immunology: Vaccine producers flourish in field dominated by multinationals**

By Thalita Carrico

Life-saving injections were once such an alien concept in Brazil that a campaign against smallpox in Rio de Janeiro in 1904 provoked riots that left scores dead.

The common people felt vaccinations, which in many cases were forcibly given, were invasive, and they added to popular anger over other social ills, leading to the unrest today known as the vaccine revolt.

But the vaccinations eradicated smallpox in Rio and the visionary doctor behind the campaign gave his name to one of the country's leading institutions, the Oswaldo Cruz Foundation. The joint work of the foundation and the [Butantan Institute](#) represents 90 per cent of Brazil's vaccine production.

"Brazil is considered one of the biggest producers of vaccines," says Luis Carlos de Souza, a researcher at the University of São Paulo.

In a market dominated by multinationals, Brazilian vaccine makers appear to be flourishing. This is in spite of the country's low funding for research and the control of prices by the Ministry of Health, which buys and distributes most of the vaccines...

<http://www.ft.com/cms/s/0/89666a00-25eb-11e3-8ef6-00144feab7de.html?siteedition=intl&siteedition=uk#axzz2isYQk6uK>

## **Forbes**

<http://www.forbes.com/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

## **Foreign Affairs**

<http://www.foreignaffairs.com/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

## **Foreign Policy**

<http://www.foreignpolicy.com/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

## **The Guardian**

<http://www.guardiannews.com/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

## **The Huffington Post**

<http://www.huffingtonpost.com/>

*Accessed 26 October 2013*

[No new, unique, relevant content]

## Le Monde

<http://www.lemonde.fr/>

Accessed 26 October 2013

[No new, unique, relevant content]

## New Yorker

<http://www.newyorker.com/>

Accessed 26 October 2013

[No new, unique, relevant content]

## New York Times

<http://www.nytimes.com/>

Accessed 26 October 2013

[No new, unique, relevant content]

## Reuters

<http://www.reuters.com/>

Accessed 26 October 2013

[No new, unique, relevant content]

## Wall Street Journal

<http://online.wsj.com/home-page>

Accessed 26 October 2013

[No new, unique, relevant content]

## Washington Post

<http://www.washingtonpost.com/>

Accessed 26 October 2013

[No new, unique, relevant content]

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