

## Center for Vaccine Ethics and Policy

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### Vaccines: The Week in Review 8 September 2012 Center for Vaccine Ethics & Policy (CVEP)

*This weekly summary targets news, events, announcements, articles and research in the global vaccine 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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#### **The European Centre for Disease Prevention and Control (ECDC) published an update to its 2008 guidance on human papillomavirus (HPV) vaccines in Europe**

"in light of the introduction of vaccination programmes in 19 European countries and new evidence from research studies in the past four years." Randomised trials and observations from the field have demonstrated good safety profiles and efficacy against cervical cancer precursors. In spite of this, and that most of these countries are providing the vaccine for free, vaccination rates are lower than expected. Vaccinating girls is shown to be more cost-effective than vaccinating boys. ECDC's guidance is that public health initiatives should continue to focus on vaccinating girls.

Among the deterring factors for the slow uptake are the cost of the vaccine and the regime of three doses in six months. Routine vaccination targets girls between ages 10 to 14 years as the vaccines are clinically proven to be most effective when administered before the onset of sexual activity. These girls require parental permission to be vaccinated therefore the role of parents and healthcare workers is of utmost importance.

Nineteen countries out of the 29 EU/EEA countries have introduced HPV vaccination programmes following the authorisation of the vaccines but vaccination rates in EU countries range from only 17% to 84%. In 2010, only Portugal and the United Kingdom had full vaccination coverage rates above 80% for the target groups out of the seven countries reporting this data.

ECDC Director Marc Sprenger said: "We, public health authorities, frontline healthcare workers and parents alike, have a shared responsibility to protect thousands of women from cervical cancer. We need to work together to ensure that all girls between 10 and 14 years of age are vaccinated. European countries may need to examine why HPV

vaccination coverage rates in their countries are not higher and strengthen their vaccination campaigns accordingly.”

Since its introduction by some European countries in 2006 the inclusion of boys in HPV vaccination programmes has been an open question. Only the quadrivalent HPV vaccine has been evaluated for men but current data shows that it gives the same, if not better, levels of efficacy for boys as girls of the same age groups. But the personal benefit of the vaccine for men in terms of cancer prevention is very low, most likely resulting in few boys being vaccinated and low vaccination coverage rates.

Marc Sprenger said **“ECDC’s conclusion is that including boys in the current HPV vaccination programmes is unlikely to be cost-effective. A better investment of public resources is to focus on immunising all girls. This issue can be re-assessed when vaccination costs are significantly reduced.”**...

<http://www.ecdc.europa.eu/en/press/Press>

[%20Releases/20120905\\_pressrelease\\_HPVGuidanceUpdate%20\(2\).pdf](http://www.ecdc.europa.eu/en/press/Press/%20Releases/20120905_pressrelease_HPVGuidanceUpdate%20(2).pdf)

### **Speech: WHO Director-General Address to the Regional Committee for South-East Asia, Sixty-fifth Session**

Dr Margaret Chan

Director-General of the World Health Organization

Yogyakarta, Indonesia

5 September 2012

[http://www.who.int/dg/speeches/2012/searo\\_20120905/en/index.html](http://www.who.int/dg/speeches/2012/searo_20120905/en/index.html)

Excerpt:

“...Let me begin with some well-deserved praise. On present trends, this region is set to be declared polio-free in January 2014.

India, the skeptics said it could not be done. But you did it. You stopped wild poliovirus transmission dead in its tracks. You have silenced the critics.

You have provided definitive proof that eradication is technically feasible, and you have done so in what was arguably the most challenging of all the remaining strongholds of this virus.

This is what your experience tells the world. The poliovirus is not permanently entrenched. It is not destined to remain a perpetual threat to each new generation of children. It can indeed be driven out of existence.

I fully agree with the assessment of the Independent Monitoring Board. This is a “magnificent” achievement. The Indian government succeeded because of its passionate engagement in a mission to protect its people from a vicious disease.

I appreciate, too, the specific lessons from the Indian experience set out in your report on polio eradication.

The most critical factor for success is ownership of the programme, from the local to the national level. The Indian government owned this programme, operating as the principal source of staff and funds. Other lessons include the importance of tight-knit partnerships, constant innovation, and a relentless drive to improve quality and accountability.

The May World Health Assembly elevated polio eradication to the level of a global public health emergency. This region has the expertise, bolstered by success, to lead the world in such an emergency response.

Medical officers from India, Bangladesh, and Nepal are now directly assisting countries that are still battling polio. I urge you to continue this leadership role. We can and must win.

As the IMB report noted, polio is now at its lowest level worldwide since records began.

Public health faces some heavy challenges, some bad trouble heading our way. Any longstanding problem that can be solved, once and for all, will free much-needed capacity and resources..."

[http://www.who.int/csr/don/2012\\_09\\_08/en/index.html](http://www.who.int/csr/don/2012_09_08/en/index.html)

**Speech: Address to the 65th session of the WHO Regional Committee for South-East Asia**

Helen Evans, Deputy CEO, GAVI Alliance

Yogyakarta, Indonesia

6 September 2012

Full text: <http://www.gavialliance.org/library/news/statements/2012/searo-regional-committee-meeting/>

**GAVI reported that the Government of Japan "underlined its commitment to protecting millions of children from vaccine-preventable diseases today by renewing its funding support for the GAVI Alliance."**

Kimihiro Ishikane, Ambassador Extraordinary and Plenipotentiary Mission of Japan to the Association of Southeast Asian Nations, speaking at the Asia Pacific Development Summit, said, "For the fiscal year 2012, I am hereby happy to announce that Japan will make a contribution of US\$9.07 million. Japan is also ready to make due contribution accordingly from the year 2013 onwards."

<http://www.gavialliance.org/library/news/press-releases/2012/japan-funds-life-saving-vaccines-for-developing-countries/>

The **MMWR Weekly for September 7, 2012** / Vol. 61 / No. 35  
- [National, State, and Local Area Vaccination Coverage Among Children Aged 19–35 Months — United States, 2011](#)

The **Weekly Epidemiological Record (WER) for 7 September 2012**, vol. 87, 36 (pp. 337–344) includes:

Outbreak news

- Cholera, Sierra Leone
- Ebola haemorrhagic fever, Democratic Republic of the Congo
- Ebola haemorrhagic fever, Uganda

Performance of acute flaccid paralysis (AFP) surveillance and incidence of poliomyelitis, 2012

<http://www.who.int/entity/wer/2012/wer8736.pdf>

### **Update: *Polio this week - As of 05 Sep 2012***

Global Polio Eradication Initiative

- **The outbreak in Katsina, northern Nigeria, is continuing, with four new wild poliovirus (WPV) type 1 cases reported this week.** Katsina has reported 16 cases of WPV1 since May, more than any other state in the country. Katsina now accounts for 40% of all WPV1 cases in Nigeria since May. Upwards of one-third of children remain under-immunized in the state. During the most recent supplementary immunization activity (SIA), nearly one-third of children were missed in Katsina city (the most populous part of the state and location of the bulk of cases).
- The Strategic Advisory Group of Experts on immunization (SAGE) Polio Working Group met this week in Geneva, Switzerland. Among other topics, the SAGE Polio Working Group discussed concrete ways to more effectively manage the short- and long-term implications of vaccine-derived polioviruses (VDPVs), including a potential switch from trivalent oral polio vaccine (OPV) to bivalent OPV even before the interruption of the remaining strains of WPV type 1 and WPV type 3. This approach had previously been endorsed in principle by SAGE. In May, the World Health Assembly (WHA) had requested the development of a comprehensive polio eradication and endgame strategy, to feature the potential timing of such a switch. The outcomes of the discussions from the SAGE Polio Working Group, and with continued guidance from SAGE and the WHA, will help inform a comprehensive Polio Eradication and Endgame Strategy 2014-2018.

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

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

*Vaccines: 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)

### **WHO: *World Immunization Week 2012 Evaluation Report pdf, 547kb***

#### **Conference: AIDS Vaccine**

BOSTON 9-12 SEPTEMBER 2012

"...the largest and most diverse international meeting of researchers, advocates, clinicians, private sector partners and public health experts working collaboratively to advance HIV vaccine science. With a focus on new minds and new ideas, AIDS Vaccine 2012 will make a special effort to welcome the most promising young- and early-career researchers to share and debate cutting-edge ideas and approaches to HIV vaccine research and development with their colleagues from around the world"

<http://vaccineenterprise.org/conference/2012/>

### **Symposium: Health and Human Security in the Americas**

PAHO, Japan Center for International Exchange (JCIE)

Lima, Peru, 6-9 September, 2012.

Preliminary Agenda:

[http://new.paho.org/per/images/stories/FtPage/2012/20120905\\_agenda\\_eng.pdf](http://new.paho.org/per/images/stories/FtPage/2012/20120905_agenda_eng.pdf)

"PAHO/WHO and the Japan Center for International Exchange (JCIE) are co-hosting a Regional Meeting on Health and Human Security to be held in Lima, Peru, 6-9 September, 2012. The event will open on September 6th with a Symposium on Health and Human Security in the Americas."

[http://new.paho.org/per/index.php?](http://new.paho.org/per/index.php?option=com_content&task=view&id=1864&Itemid=724)

[option=com\\_content&task=view&id=1864&Itemid=724](http://new.paho.org/per/index.php?option=com_content&task=view&id=1864&Itemid=724)

### ***Journal Watch***

*Vaccines: 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)*

### **Annals of Internal Medicine**

4 September 2012, Vol. 157. No. 5

21 August 2012, Vol. 157. No. 4

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

[No relevant content]

### **British Medical Bulletin**

Volume 103 Issue 8 September 2012

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

[Reviewed earlier]

### **British Medical Journal**

08 September 2012 (Vol 345, Issue 7873)

<http://www.bmj.com/content/345/7873>

#### ***Analysis***

#### **No more disease silos for sub-Saharan Africa**

BMJ 2012; 345 doi: 10.1136/bmj.e5812 (Published 31 August 2012)

Cite this as: BMJ 2012;345:e5812

Patricio V Marquez, lead health specialist, Eastern and Southern Africa Region<sup>1</sup>,  
Jill L Farrington, honorary senior lecturer<sup>2</sup>

*Extract*

Countries in sub-Saharan Africa are facing a double burden of communicable and non-communicable disease. Patricio Marquez and Jill Farrington argue that knowledge of their common determinants and the links between diseases should be used to spur development of coordinated programmes to prevent and treat both

While much of the health focus in sub-Saharan Africa, has been directed at communicable diseases (particularly HIV/AIDS, tuberculosis, and malaria), non-communicable diseases are a growing problem for the region, causing almost one third of total deaths.<sup>1</sup> The May 2012 World Health Assembly resolution on setting a global target for reducing non-communicable diseases<sup>2</sup> and the pronouncements made at the 19th International AIDS Conference in July remind us of the similar challenges faced by these two sets of disease and the potential shared solutions. The theme of the AIDS conference “turning the tide together” seems apt and should give pause for thought in the lead-up to further debate about non-communicable diseases at the UN and other international forums.

The approach to preventing and treating HIV/AIDS—exemplified by an intention to build on lessons learnt, take account of recent scientific advances, and demonstrable ability to scale-up key interventions—seems particularly relevant to non-communicable diseases. But how should sub-Saharan Africa, well represented at the AIDS conference, gear up to the challenge of non-communicable diseases in a way that avoids creating new vertical programmes in competition for scarce resources?

What is the essence of the problem?

Although communicable diseases have traditionally been leading causes of disease and mortality in sub-Saharan Africa, rapid urbanisation, changes in dietary patterns, behavioural and biological factors, and major improvements in the prevention and treatment of communicable diseases, particularly AIDS, that are helping raise life expectancy, are all contributing to a shift in disease patterns. For some countries, such as Mauritius and Seychelles, and some populations, such as people aged over 45 years,

...

<http://www.bmj.com/content/345/bmj.e5812>

**Bulletin of the World Health Organization**

Volume 90, Number 9, September 2012, 633-712

<http://www.who.int/bulletin/volumes/90/9/en/index.html>

[Reviewed earlier]

**Cost Effectiveness and Resource Allocation**

(Accessed 8 September 2012)

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

[No new relevant content]

**Emerging Infectious Diseases**

Volume 18, Number 9—September 2012

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

[Reviewed earlier]

### **Eurosurveillance**

Volume 17, Issue 36, 06 September 2012

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

#### ***Surveillance and outbreak reports***

##### **A report on the large measles outbreak in Lyon, France, 2010 to 2011**

by C Huoi, JS Casalegno, T Bénet, A Neuraz, G Billaud, D Eibach, Y Mekki, R Rudigoz, J Massardier, C Huissoud, M Massoud, P Gaucherand, O Claris, Y Gillet, D Floret, B Lina, P Vanhems

*[Summary]*

In 2010 and 2011, the city of Lyon, located in the Rhône-Alpes region (France), has experienced one of the highest incidences of measles in Europe. We describe a measles outbreak in the Lyon area, where cases were diagnosed at Lyon University hospitals (LUH) between 2010 and mid-2011. Data were collected from the mandatory notification system of the regional public health agency, and from the virology department of the LUH. All patients and healthcare workers who had contracted measles were included. Overall, 407 cases were diagnosed, with children of less than one year of age accounting for the highest proportion (n=129, 32%), followed by individuals between 17 and 29 years-old (n=126, 31%). Of the total cases, 72 (18%) had complications. The proportions of patients and healthcare workers who were not immune to measles were higher among those aged up to 30 years. Consequently, women of childbearing age constituted a specific population at high risk to contract measles and during this outbreak, 13 cases of measles, seven under 30 years-old, were identified among pregnant women. This study highlights the importance of being vaccinated with two doses of measles vaccine, the only measure which could prevent and allow elimination of the disease.

### **Global Health Governance**

[Volume V, Issue 2: Spring 2012](#)

[Reviewed earlier]

### **Globalization and Health**

[Accessed 8 September 2012]

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

[No new relevant content]

### **Health Affairs**

September 2012; Volume 31, Issue 9

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

*Theme: Payment Reform To Achieve Better Health Care*

[No relevant content]



## **Health and Human Rights**

Vol 14, No 1 (2012)

<http://hhrjournal.org/index.php/hhr>

[Reviewed earlier]

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

Volume 7 - Issue 03 - July 2012

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

### **Articles**

#### **Incentives, health promotion and equality**

Kristin Voigt

##### *Abstract*

The use of incentives to encourage individuals to adopt 'healthier' behaviours is an increasingly popular instrument in health policy. Much of the literature has been critical of 'negative' incentives, often due to concerns about equality; 'positive' incentives, however, have largely been welcomed as an instrument for the improvement of population health and possibly the reduction of health inequalities. The aim of this paper is to provide a more systematic assessment of the use of incentives from the perspective of equality. The paper begins with an overview of existing and proposed incentive schemes. I then suggest that the distinction between 'positive' and 'negative' incentives – or 'carrots' and 'sticks' – is of limited use in distinguishing those incentive schemes that raise concerns of equality from those that do not. The paper assesses incentive schemes with respect to two important considerations of equality: equality of access and equality of outcomes. While our assessment of incentive schemes will, ultimately, depend on various empirical facts, the paper aims to advance the debate by identifying some of the empirical questions we need to ask. The paper concludes by considering a number of trade-offs and caveats relevant to the assessment of incentive schemes.

## **Health Policy and Planning**

Volume 27 Issue 6 September 2012

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

[Reviewed earlier]

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

Volume 8, Issue 9 September 2012

<http://www.landesbioscience.com/journals/vaccines/toc/volume/8/issue/8/>

**Special Focus: Cancer Commentary Series Guest Editors: Michael G. Hanna and Alex Kudrin**

### **Short Report**

#### **Varicella vaccine uptake in Shandong province, China**

<http://dx.doi.org/10.4161/hv.20722>

Authors: Aiqiang Xu, Qing Xu, Xueqiang Fang, Stephanie Bialek and Chengbin Wang

##### *Abstract:*

Varicella vaccine has been licensed in China for decade to be used as single dose in



children aged  $\geq 12$  mo of age in private sector. Little data were available on varicella uptake to date in China yet. A cross-sectional study was conducted in Shandong Province in May 2011 to examine varicella vaccination coverage among children aged 16–40 mo and examine factors associated with varicella vaccine uptake. The overall coverage among children eligible for varicella vaccine was 62% (range 16.7–94.7% by county), much lower than the coverage of the eight vaccines included in the national immunization program (all above 97%). Though proximity to immunization services ( $< 5$  km) was linked with higher vaccine uptake (62.6 vs. 37.4%,  $p = 0.02$ ), county-level economic development (77.8, 61.0 and 47.1% for developed, sub-developed and developing regions, respectively,  $p < 0.001$ ) played an even more important role in varicella vaccination. Moreover, there was little variation in coverage of vaccines included in the national immunization program along with county-level economic development. Even though varicella vaccine uptake is relatively high for use on a private basis, the vaccination coverage is not high enough to prevent epidemiology shift to adolescents and adults who are more prone to develop severe outcomes to varicella. Further enhancement on varicella vaccination coverage is necessary and inclusion to national immunization program seems to be a promising option for achieving and maintaining high coverage.

#### ***Research Paper***

#### **Social and cultural determinants of oral cholera vaccine uptake in Zanzibar**

<http://dx.doi.org/10.4161/hv.20901>

Authors: Christian Schaetti, Said M. Ali, Raymond Hutubessy, Ahmed M. Khatib, Claire-Lise Chagnat and Mitchell G. Weiss

#### ***Abstract:***

Effectiveness of mass cholera vaccination campaigns requires not only technical and financial capacity but also consideration of social and cultural factors affecting vaccine acceptance. This study examined the influence of local community views of cholera on oral cholera vaccine (OCV) uptake in a mass vaccination campaign in 2009 in peri-urban and rural areas of Zanzibar. It used data from interviews conducted before the campaign and followed previous research assessing determinants of anticipated OCV acceptance. OCV uptake was lower than the reported anticipated acceptance. Less than half of the 356 adult respondents (49.7%) drank the required two doses of OCV. Variables referring to socio-cultural features of diarrheal illness that respondents identified with a cholera case vignette explained uptake better than analysis only of socio-demographic characteristics. Somatic features of illness not specific for cholera were negative determinants. Recognition of unconsciousness as a serious sign of dehydration and concern that cholera outbreaks would overwhelm the local healthcare system in the rural area were positive determinants of acceptance. Female gender, rural residence and older age were also positive determinants of OCV uptake. For further vaccine action with OCVs, cholera as a cause of severe dehydration should be distinguished from other causes of diarrhea. Planning should acknowledge rural concern about the relationship of limited capacity of the healthcare system to cope with cholera outbreaks and the priority of a cholera vaccine. Findings recommend particular efforts to increase cholera immunization coverage among young adults, in peri-urban areas and for men.

#### ***Research Paper***

#### **Individualism, acceptance and differentiation as attitude traits in the public's response to vaccination**

<http://dx.doi.org/10.4161/hv.21183>

Authors: Baruch Velan, Valentina Boyko, Liat Lerner-Geva, Arnona Ziv, Yaakov Yagar and Giora Kaplan

*Abstract:*

The attitude of the general public to vaccination was evaluated through a survey conducted on a representative sample of the Israeli population (n = 2,018), in which interviewees were requested to express their standpoints regarding five different vaccination programs. These included: pandemic influenza vaccination, seasonal influenza vaccination, travel vaccines, Human Papilloma Virus vaccine and childhood vaccinations. Analysis of the responses reveal three major attitude traits: a) acceptance, characterized by the opinion that targets should be vaccinated; b) individualism, characterized by the opinion that vaccination should be left to personal choice; and c) differentiation, characterized by the tendency to express different attitudes when addressing different vaccination programs. Interestingly, direct opposition to vaccination was found to be a minor attitude trait in this survey. Groups within the population could be defined according to their tendency to assume these different attitudes as Acceptors, Judicious-acceptors, Differentiators, Soft-individualists, and Hard-individualists. These groups expressed different standpoints on all five vaccination programs as well as on other health recommendations, such as screening for early detection of cancer. Attitude traits could be also correlated, to a certain extent, with actual compliance with vaccination programs. Interestingly, attitudes to vaccination were not correlated with social profiles related to income or education, although younger individuals exhibited higher degrees of individualism and differentiation. Taken together, all this is in accordance with the current social settings, underlining the individual's tendency for critical evaluation and self-stirring. This should be taken into consideration by health authorities involved in vaccination programs.

**Research Paper**

**Modeling the economic value of a Chagas' disease therapeutic vaccine**

<http://dx.doi.org/10.4161/hv.20966>

Authors: Bruce Y. Lee, Kristina M. Bacon, Angela R. Wateska, Maria Elena Bottazzi, Eric Dumonteil and Peter J. Hotez

*Abstract:*

The health burden of Chagas' disease (resulting from *Trypanosoma cruzi* infection) in Latin America (estimated to outweigh that of malaria by 5-fold and affect 2–6 million people in Mexico alone) has motivated development of therapeutic vaccines to prevent infection progression to severe disease. Our economic model for a Chagas' therapeutic vaccine in Mexico suggests that a vaccine would be highly cost-effective and in many cases economically dominant (providing both cost savings and health benefits) throughout a range of protection durations, severe adverse event risk, and dosing regimens and would be most likely to provide a positive return on investment if the vaccine prevented (rather than delayed) the onset of cardiomyopathy.

**Cancer Commentary Series**

**SPECIAL FOCUS REVIEW**

[\*Reimbursement challenges with cancer immunotherapeutics\*](#)

Alex Kudrin

<http://dx.doi.org/10.4161/hv.20550>

[\*Abstract\*](#) |

**SPECIAL FOCUS COMMENTARIES**

### **Overview of cancer vaccines: Considerations for development**

Alex Kudrin

<http://dx.doi.org/10.4161/hv.20518>

[Abstract](#) |

### **Cancer immunotherapy products: Regulatory aspects in the European Union**

Jorge Camarero and Sol Ruiz

<http://dx.doi.org/10.4161/hv.21142>

[Abstract](#) |

### **Cancer vaccines and immunotherapeutics: Challenges for pricing, reimbursement and market access**

Bengt Jönsson and Nils Wilking

[Abstract](#) |

## **International Journal of Infectious Diseases**

[September 2012](#), [Vol. 16](#), [No. 9](#)

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

[Reviewed earlier]

## **JAMA**

September 05, 2012, Vol 308, No. 9

<http://jama.ama-assn.org/current.dtl>

### ***Viewpoint / September 5, 2012 ONLINE FIRST***

### **Ethical Challenges of Preexposure Prophylaxis for HIV**

Jonathan S. Jay, JD, MA; Lawrence O. Gostin, JD

JAMA. 2012;308(9):867-868. doi:10.1001/2012.jama.10158

#### ***Extract***

On July 16, 2012, emtricitabine/tenofovir (Truvada; Gilead Sciences) became the first drug approved by the US Food and Drug Administration (FDA) for preexposure prophylaxis (PrEP) of human immunodeficiency virus (HIV) for adults at high risk. Clinical trials have demonstrated that daily use of oral antiretroviral drugs can reduce the risk of HIV acquisition through sexual intercourse. With 50 000 new HIV infections per year in the United States<sup>1</sup> and 2 million per year worldwide,<sup>2</sup> PrEP could become a major component of “combination prevention” along with condoms, counseling, testing, and treatment...

#### ***...EQUITY AND JUSTICE***

Despite empowering patients and promoting the public's health, PrEP could exacerbate health care inequalities. High cost and intense medical monitoring could exclude individuals with low income, unstable housing, drug dependence, or mental illness. This challenge is even greater in low-income countries with limited resources and infrastructure.

Early PrEP adopters are likely to include gay and bisexual men and heterosexual serodiscordant couples with greater education and resources. Extending PrEP to other groups will require effective public health governance, along with research and innovation. Fortunately, a blueprint exists: antiretroviral strategies for both HIV treatment and preventing mother-to-child transmission have relied on advances in science, financing, access, and health care to achieve remarkable success globally.

**Underserved Populations.** Reaching populations with disproportionate HIV incidence, including young black men who engage in male-to-male sexual contact, is crucial to reduce HIV burdens and promote equity. Although the Affordable Care Act will expand coverage, it cannot ensure testing and PrEP for all vulnerable individuals. Prevention programs should explore synergies with HIV testing campaigns, which currently link to treatment, but they could also link to PrEP for HIV-negative, high-risk individuals.

**Women.** The FDA approval includes at-risk women, despite mixed evidence of PrEP effectiveness but clear need: 25% of new HIV infections in the United States<sup>1</sup> and half worldwide<sup>2</sup> occur in women. PrEP addresses the need for a female-controlled prevention mechanism that can be used without a male partner's consent. The efficacy of oral PrEP remains less certain for women than for men, although the results of the VOICE study (clinicaltrials.gov [NCT00705679](#)) are expected in 2013 and could alleviate concerns raised by the FEM-PrEP study, which closed early due to futility.<sup>7</sup> A female-specific prevention method such as vaginal microbicide could enhance the effectiveness of chemoprophylaxis among women. The CAPRISA 004 trial found that topical tenofovir gel, used before and after sexual contact, reduced HIV acquisition by 39%.<sup>8</sup>

**Generalized Epidemics.** Most new HIV infections worldwide occur in developing countries experiencing generalized epidemics. Although the United States is the only country to have approved a PrEP indication, others may soon follow. PrEP rollout represents a vital test for governments, global health programs (eg, PEPFAR and the Global Fund to Fight AIDS, Tuberculosis and Malaria), and normative bodies (World Health Organization). Cost and health care infrastructure could represent major barriers to widespread PrEP availability. Planning for regulatory review, financing, and implementation must therefore continue.

**Ethical Resource Allocation.** Thousands of Americans with HIV are currently on waiting lists for drug treatment, even though effective treatment significantly reduces the risk of transmission.<sup>9</sup> Given scarce resources, what are the relative priorities between PrEP for healthy individuals and treatment for currently infected individuals? Although these 2 uses may appear to entail inescapable trade-offs, expanding treatment for all infected individuals (which is now recommended),<sup>10</sup> while selectively offering PrEP to high-risk individuals, is the best public health strategy and could lower health care costs in the long term.

**Ethical Research.** The FDA's approval of PrEP will trigger scrutiny of HIV prevention trials using placebo controls. Beneficence requires researchers to minimize risks to study participants—and while regulatory approval alone does not determine the appropriate standard of care, it signals a strong evidence base and shifting clinical norms. Offering PrEP to study participants, however, presents scientific and logistical research challenges, with no consensus on how to balance conflicting obligations. Multistakeholder deliberations should proceed on this topic.

### ***Viewpoint / September 5, 2012***

#### **Clinical Trial Data as a Public Good**

Marc A. Rodwin, JD, PhD; John D. Abramson, MD, MS

JAMA. 2012;308(9):871-872. doi:10.1001/jama.2012.9661

#### ***Extract***

Knowledge of the benefits and risks of prescription drugs is based mainly on published reports of clinical trials, yet the medical literature may present an incomplete and potentially biased sample of clinical trials.<sup>1</sup> Trials with positive results generally are published more frequently than studies that conclude that a new drug poses greater

risks or is no more effective than standard therapy or a placebo. Furthermore, some articles may distort trial findings by omitting important data or by modifying prespecified outcome measures. Lack of access to detailed information about clinical trials can undermine the integrity of medical knowledge...

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

Volume 26 issue 6 - Published: 2012

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

[Reviewed earlier; No relevant content]

### **Journal of Infectious Diseases**

Volume 206 Issue 7 October 1, 2012

<http://www.journals.uchicago.edu/toc/jid/current>

#### **EDITORIAL COMMENTARY**

#### **Keeping the M in Medical Exemptions: Protecting Our Most Vulnerable Children**

[Daniel A. Salmon](#) and [Neal A. Halsey](#)

*(See the brief report by Stadlin et al, on pages 989–92.)*

In this issue of the journal, Stadlin et al report that, although the rates of medical exemptions to school immunization requirements are rather modest, easier processes for offering medical exemptions were associated with higher rates of medical exemptions [1]. This finding is consistent with previous studies that found that the ease of obtaining nonmedical religious or philosophical exemptions was associated with higher rates of exemptions [2, 3]. Interestingly, states with more difficult procedures for nonmedical exemptions had higher rates of medical exemptions, suggesting that some parents may be opting for medical exemptions when it is difficult to obtain nonmedical exemptions. This observation is consistent with our unpublished ...

#### **MAJOR ARTICLES AND BRIEF REPORTS**

#### **PUBLIC POLICY**

Stephanie Stadlin, Robert A. Bednarczyk, and Saad B. Omer

#### **Editor's choice: Medical Exemptions to School Immunization Requirements in the United States—Association of State Policies With Medical Exemption Rates (2004–2011)**

J Infect Dis. (2012) 206(7): 989–992 doi:10.1093/infdis/jis436

#### *Abstract*

All 50 US states allow medical exemptions from school entry immunization requirements. The extent to which medical exemptions are granted and the relationship with ease of obtaining these exemptions has not previously been examined in detail. We evaluated counts and rates of state-level medical exemptions to kindergarten entry requirements over 7 school years (2004–2005 through 2010–2011). During this period, 0.26%–0.41% of enrolled children received medical exemptions. In states with easier medical exemption criteria, medical exemption rates were significantly higher (adjusted incidence rate ratio: 6.4 [95% confidence interval: 2.7–15.6]). Routine evaluation of medical exemption rates is needed to ensure their appropriate use.

**Journal of Global Infectious Diseases (JGID) July-September 2012**

Volume 4 | Issue 3 Page Nos. 139-186

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

**ORIGINAL ARTICLE**

**Re-emergence of cholera in the Americas: Risks, susceptibility, and ecology**

[Mathieu JP Poirier](#)<sup>1</sup>, [Ricardo Izurieta](#)<sup>1</sup>, [Sharad S Malavade](#)<sup>1</sup>, [Michael D McDonald](#)<sup>2</sup>

USA DOI: 10.4103/0974-777X.100576

Background: The re-emergence of cholera in Haiti has established a new reservoir for the seventh cholera pandemic which threatens to spread to other countries in the Americas. Materials and Methods: Statistics from this new epidemic are compared to the 1991 Peru epidemic, which demonstrated the speed and complexity with which this disease can spread from country to country. Environmental factors implicated in the spread of *Vibrio cholerae* such as ocean currents and temperatures, as well as biotic factors from zooplankton to waterfowl pose a risk for many countries in the Americas. Results: The movement of people and goods from Hispaniola are mostly destined for North America, but occur to some degree throughout the Americas. These modes of transmission, and the probability of uncontrolled community spread beyond Hispaniola, however, are completely dependent upon risk factors within these countries such as water quality and availability of sanitation. Although North America has excellent coverage of these deterrents to the spread of infectious gastrointestinal diseases, many countries throughout Latin America and the Caribbean lack these basic services and infrastructures. Conclusions : In order to curb the immediate spread of cholera in Hispaniola, treatment availability should be expanded to all parts of the island and phase II epidemic management initiatives must be developed.

**Journal of Medical Ethics**

September 2012, Volume 38, Issue 9

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

**Brief report**

**It is the lifetime that matters: public preferences over maximising health and reducing inequalities in health**

[Paul Dolan](#)<sup>1</sup>, [Akil Tsuchiya](#)<sup>2</sup>

Received 8 September 2011

Revised 10 February 2012

Accepted 3 March 2012

Published Online First 6 April 2012

**Abstract**

Scarce healthcare resources can be allocated in many ways. The National Institute for Health and Clinical Excellence in the UK focuses on the size of the benefit relative to costs, yet we know that there is support among clinicians and the general public for reducing inequalities in health. This paper shows how the UK general public trade-off these sometimes competing objectives, and the data we gather allow us to show the weight given to different population groups, for example, 1 extra year of life in full health to someone who would otherwise die at the age of 60 years is worth more than twice as much as an additional year of life to someone who would otherwise die at the age of 70 years. Such data can help inform the rationing decisions faced by all healthcare systems around the world.

**Journal of Medical Microbiology**

September 2012; 61 (Pt 9)

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

[Reviewed earlier; No relevant content]

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

Volume 1 Issue 3 September 2012

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

[Reviewed earlier; No relevant content]

**The Lancet**

Sep 08, 2012 Volume 380 Number 9845 p859 - 948

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

**Editorial****The struggle for universal health coverage**

The Lancet

*Preview*

Certain concepts resonate so naturally with the innate sense of dignity and justice within the hearts of men and women that they seem an insuppressible right. That health care should be accessible to all is surely one such concept. Yet in the past, this notion has struggled against barriers of self-interest and poor understanding. Building on several previous Lancet Series that have examined health and health systems in Mexico, China, India, southeast Asia, Brazil, and Japan, today we try to challenge those barriers with a collection of papers that make the ethical, political, economic, and health arguments in favour of universal health coverage (UHC), and which will be presented in New York on Sept 26, to coincide with the UN General Assembly.

**The future of the Global Fund**

The Lancet

*Preview*

Good news about the Global Fund to Fight AIDS, Tuberculosis and Malaria has been sorely lacking these past few years as the organisation has faced corruption allegations, financial woes, and internal reform. Yet, despite these challenging times, the Fund remains operational and continues its important work. Last week, it announced that its Board had approved 45 new 2 year grants, from 37 countries, totalling US\$419.2 million.

**Comment****Universal health coverage: the third global health transition?**

Judith Rodin, David de Ferranti

[Preview](#) |

**Universal health coverage: good health, good economics**

Julio Frenk, David de Ferranti

[Preview](#) |

**Universal health coverage is a development issue**

David B Evans, Robert Marten, Carissa Etienne



[Preview](#) |

### **Profile**

#### **Margaret Chan: committed to universal health coverage**

David Holmes

#### *Extract*

Margaret Chan is a woman who needs little introduction. As WHO Director-General, her face is a fixture on news bulletins whenever there is a serious disease outbreak, drug safety issue, or food scare. But it was the less sensational—although some would argue more important—work that Chan and WHO are doing to promote universal health coverage that she was keen to talk about when she spoke to The Lancet.

Universal health coverage is, Chan says, “part of her DNA”, and has become an important part of WHO's agenda under her stewardship. After her appointment for a second 5-year term as Director-General in May this year, Chan used her speech to the World Health Assembly to issue a stern rebuke to those “bitter observers” who say that the financial crisis “derailed the best chance ever to alleviate poverty and give this lopsided world greater fairness and balance”. Instead, Chan argued that “the best days for health are ahead of us, not behind us”, in large part because of the critical momentum that has built behind the move towards universal health coverage.

The launch in 2010 of WHO's Health Systems Financing: the Path to Universal Coverage led to “more than 60 middle-income and low-income countries requesting technical assistance and advice to move towards universal health coverage”, Chan told The Lancet. She points to the “amazing achievement” of Mexico as a measure of what progress can be made. Universal health coverage is, Chan says, “the most powerful unifying single concept that public health has to offer, because you can realise the dream and the aspiration of health for every person irrespective of what class you belong to, whether you are a woman, or whether you are poor”.

Chan's commitment to universal health coverage has been shaped by personal experience. Born in 1947 and brought up in Hong Kong under British rule, Chan says she “benefited from a similar system to the National Health Service in the UK”. Her mother, she says, was very “liberal minded”, and always told her to “follow her heart”, but it was following her “childhood sweetheart” (now her husband, David) that led her into medicine. After working as a teacher, Chan followed David to Canada and the University of Western Ontario in the early 1970s, where he was to study medicine. There, Chan was delighted to win a place to train in a Canadian health system already on the last leg of its journey towards universal health coverage...

### **Series**

#### **Universal Health Coverage**

#### **Does progress towards universal health coverage improve population health?**

Rodrigo Moreno-Serra, Peter C Smith

[Preview](#) |

#### **Universal Health Coverage**

#### **Political and economic aspects of the transition to universal health coverage**

William D Savedoff, David de Ferranti, Amy L Smith, Victoria Fan

[Preview](#) |

#### **Universal Health Coverage**

#### **Moving towards universal health coverage: health insurance reforms in nine developing countries in Africa and Asia**

Gina Lagomarsino, Alice Garabrant, Atikah Adyas, Richard Muga, Nathaniel Otoo

[Preview](#) |

### **Viewpoint**

#### **Achieving universal health coverage in low-income settings**

Jeffrey D Sachs

[Preview](#) |

The goal of universal health coverage is deeply embedded in politics, ethics, and international law. Article 25 of the 1948 Universal Declaration of Human Rights states that everyone has the right to a standard of living adequate for health, including medical care, and the right to security in the event of sickness or disability.<sup>1</sup> Motherhood and childhood are to be afforded special care and assistance. In the same year, the Constitution of the World Health Organization came into force, declaring that “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

### **The Lancet Infectious Disease**

Sep 2012 Volume 12 Number 9 p647 - 736

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

[Reviewed earlier]

### **Medical Decision Making (MDM)**

July–August 2012; 32 (4)

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

*Theme: Patients’ Choices: Perceived Risk, Health State Values, and Decisions*

*Original Articles/Presenting Probabilities to Patients*

[Reviewed earlier]

### **The Milbank Quarterly**

June 2012 Volume 90, Issue 2 Pages 215–416

<http://onlinelibrary.wiley.com/doi/10.1111/milq.2012.90.issue-2/issuetoc>

[Reviewed earlier]

### **Nature**

Volume 489 Number 7414 pp5-170 6 September 2012

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

#### **Nature | Editorial**

#### **Accountable and transparent**

Nature 489, 5 (06 September 2012)

doi:10.1038/489005a

Published online

05 September 2012

The US government has changed how biomedical scientists disclose their financial interests. The revised rules are welcome, but Internet access to the identified conflicts should be a requirement.

Toughened rules for how US biomedical scientists report financial interests came into force last month. The changes, which affect scientists who receive grants from the government, are welcome — although in one respect they do not go far enough. About 38,000 researchers, most of them recipients of grants from the US National Institutes of Health (NIH), the world's largest medical-research funder, will need to comply with the beefed-up rules. The changes update regulations put in place in 1995 to ensure that investigator bias doesn't sway the design, conduct or reporting of research.

There are several important changes. First, investigators must now disclose to their institutions every "significant financial interest" belonging to themselves or their immediate family that is related to any of their institutional responsibilities — from teaching and seeing patients to lab research and service on ethics committees. This requirement appropriately casts a broader net than the previous rules, which generally asked for disclosure on only a project-specific basis.

The change ends ambiguity that, for instance, might have allowed a researcher to conclude that paid service on the board of a major pharmaceutical company drew only on clinical expertise, and therefore was not relevant to a government-funded research project that used one of the company's experimental compounds. Under the updated rules, there will be no question that such income must be disclosed, and institutions will have a more complete picture of their scientists' potentially relevant financial interests.

*"Public trust in the medical enterprise is at risk and must be built, not undermined."*

It takes only one example to drive home the significance of this change. Between January 2000 and January 2006, high-profile psychiatrist Charles Nemeroff, then at Emory University in Atlanta, Georgia, received more than US\$800,000 in payments from drug-maker GlaxoSmithKline for over 250 speeches that he gave to psychiatrists. He failed to disclose this income to Emory administrators. After being discovered, Nemeroff argued that the rules on whether such income was reportable were ambiguous.

The tougher rules, crucially, give institutions prime responsibility for determining whether a given financial interest — company-paid speaking honoraria, consulting fees, paid authorship, travel reimbursements and stock ownership all qualify — is related to a government-funded grant, and whether it constitutes a conflict. Under the old regime, the scientist was charged with deciding whether a given interest was related to the research and thus whether it was reportable. That arrangement did not inspire confidence — a problem in an era in which public trust in the medical enterprise is at risk and must be built, not undermined.

The updated rules also lower the threshold at which an interest is defined as significant, from \$10,000 under the old rules to \$5,000. In a moribund economy with many US taxpayers struggling to make ends meet, this is fitting.

The rules have also been strengthened in other important ways. For instance, far more detail will now be reported by institutions to the NIH about each identified conflict, including the approximate dollar value of the interest and the measures being taken to manage or eliminate the conflict. There is also, importantly, an explicit exception to the disclosure requirements for income that scientists earn from universities or government agencies for teaching, serving on advisory or review panels and giving seminars or lectures.

The new rules fall down, however, in one significant regard. When it first published the proposed changes, the NIH described what it called "an important and significant new requirement to...underscore our commitment to fostering transparency, accountability, and public trust".

That requirement was that institutions would post details of their investigators' financial conflicts of interest on a publicly accessible website that was updated every year. In the final iteration of the new rules, the website has been made optional, and institutions faced with requests for information may instead respond in writing, within five business days. This is an outdated approach to transparency. It will not advance the public's faith in timely, comprehensive and truly accessible disclosure, at a time when the boundary between academia and industry has become ever more porous, and when the average citizen's trust in government-funded medical research is ever more crucial. The NIH should revise the rules again to make the website mandatory. It is within the agency's power to insist on this standard, and it is the right thing to do.

### **Nature Immunology**

September 2012, Volume 13 No 9 pp797-899

<http://www.nature.com/ni/journal/v13/n9/index.html>

[Reviewed earlier; No relevant content]

### **Nature Medicine**

September 2012, Volume 18 No 9 pp1305-1445

<http://www.nature.com/nm/journal/v18/n9/index.html>

[No relevant content]

### **Nature Reviews Immunology**

September 2012 Vol 12 No 9

<http://www.nature.com/nri/journal/v12/n9/index.html>

[Reviewed earlier]

### **New England Journal of Medicine**

September 6, 2012 Vol. 367 No. 10

<http://content.nejm.org/current.shtml>

#### ***Review Article***

#### ***200th Anniversary Article***

#### **Tuberculosis, Drug Resistance, and the History of Modern Medicine**

Salmaan Keshavjee, M.D., Ph.D., and Paul E. Farmer, M.D., Ph.D.

N Engl J Med 2012; 367:931-936 [September 6, 2012](#)

#### ***Extract***

Tuberculosis is a treatable airborne infectious disease that kills almost 2 million people every year. Multidrug-resistant (MDR) tuberculosis — by convention, a disease caused by strains of *Mycobacterium tuberculosis* that are resistant to isoniazid and rifampin, the backbone of first-line antituberculosis treatment — afflicts an estimated 500,000 new patients annually. Resistance to antituberculosis agents has been studied since the 1940s; blueprints for containing MDR tuberculosis were laid out in the clinical literature and in practice, in several settings, more than 20 years ago.<sup>1,2</sup> Yet today, barely 0.5% of persons with newly diagnosed MDR tuberculosis worldwide receive treatment that is considered the standard of care in the United States.<sup>3</sup> Those who have not received

appropriate treatment continue to fuel a global pandemic that now includes strains resistant to most — and by some accounts all — classes of drugs tested. [4,5](#) Despite the enormity of the threat, investments to contain the epidemic and to cure infected patients have been halting and meager when compared, for example, with those made to address the acquired immunodeficiency syndrome (AIDS) pandemic. In this essay we seek to elucidate the reasons for the anemic response to drug-resistant tuberculosis by examining the recent history of tuberculosis policy...

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

**Ethical Considerations in Studying Drug Safety — The Institute of Medicine Report**

Michelle M. Mello, J.D., Ph.D., Steven N. Goodman, M.D., M.H.S., Ph.D., and Ruth R. Faden, Ph.D., M.P.H.

N Engl J Med 2012; 367:959-964 [September 6, 2012](#)

*Extract*

The tumult arising from revelations of serious safety risks associated with widely prescribed drugs, including rosiglitazone (Avandia, GlaxoSmithKline), rofecoxib (Vioxx, Merck), and celecoxib (Celebrex, Pfizer), has led to widespread recognition that improvement is needed in our national system of ensuring drug safety. Notwithstanding federal legislation in 2007 that strengthened the authority of the Food and Drug Administration (FDA) in the postmarketing period, [1](#) critical weaknesses in the national system persist.

Central to these weaknesses are dilemmas surrounding not only the science but also the ethics of drug-safety research, [2](#) many of which came to the fore in the heated public debate about the Thiazolidinedione Intervention with Vitamin D Evaluation (TIDE) trial, which compared the cardiovascular outcomes of long-term treatment with rosiglitazone with those of pioglitazone (Actos, Takeda) in patients with type 2 diabetes. [3](#) At the request of the FDA, an Institute of Medicine (IOM) committee, on which we served, was convened to examine the ethics and science of FDA-required postmarketing safety research. In this article, we review the key ethics findings from the committee's May 1, 2012, report [4](#) and offer some reflections on the challenges ahead...

**OMICS: A Journal of Integrative Biology**

July – August 2012, 16(7-8)

<http://online.liebertpub.com/toc/omi/16/7-8>

[No relevant content]

**The Pediatric Infectious Disease Journal**

September 2012 - Volume 31 - Issue 9 pp: A7-A8,889-1002,e141-e175

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

[Reviewed earlier]

**Pediatrics**

September 2012, VOLUME 130 / ISSUE 3

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

[Reviewed earlier]

## Pharmacoeconomics

September 1, 2012 - Volume 30 - Issue 9 pp: 749-858

<http://adisonline.com/pharmacoeconomics/pages/currenttoc.aspx>

[Reviewed earlier]

## PLoS One

[Accessed 8 September 2012]

<http://www.plosone.org/article/browse.action;jsessionid=577FD8B9E1F322DAA533C413369CD6F3.ambra01?field=date>

### **Is Universal HBV Vaccination of Healthcare Workers a Relevant Strategy in Developing Endemic Countries? The Case of a University Hospital in Niger**

Gérard Pellissier, Yazdan Yazdanpanah, Eric Adehossi, William Tosini, Boubacar Madougou, Kaza Ibrahima, Isabelle Lolom, Sylvie Legac, Elisabeth Rouveix, Karen Champenois, Christian Rabaud, Elisabeth Bouvet

PLoS ONE: Research Article, published 07 Sep 2012 10.1371/journal.pone.0044442

#### *Abstract*

##### Background

Exposure to hepatitis B virus (HBV) remains a serious risk to healthcare workers (HCWs) in endemic developing countries owing to the strong prevalence of HBV in the general and hospital populations, and to the high rate of occupational blood exposure. Routine HBV vaccination programs targeted to high-risk groups and especially to HCWs are generally considered as a key element of prevention strategies. However, the high rate of natural immunization among adults in such countries where most infections occur perinatally or during early childhood must be taken into account.

##### Methodology/Principal Findings

We conducted a cross sectional study in 207 personnel of 4 occupational groups (medical, paramedical, cleaning staff, and administrative) in Niamey's National Hospital, Niger, in order to assess the prevalence of HBV markers, to evaluate susceptibility to HBV infection, and to identify personnel who might benefit from vaccination. The proportion of those who declared a history of occupational blood exposure ranged from 18.9% in the administrative staff to 46.9% in paramedical staff. Only 7.2% had a history of vaccination against HBV with at least 3 injections. Ninety two percent were anti-HBc positive. When we focused on 170 HCWs, only 12 (7.1%) showed no biological HBV contact. Twenty six were HBsAg positive (15.3%; 95% confidence interval: 9.9%–20.7%) of whom 8 (32%) had a viral load >2000 IU/ml.

##### Conclusions/Significance

The very small proportion of HCWs susceptible to HBV infection in our study and other studies suggests that in a global approach to prevent occupational infection by bloodborne pathogens, a universal hepatitis B vaccination of HCWs is not priority in these settings. The greatest impact on the risk will most likely be achieved by focusing efforts on primary prevention strategies to reduce occupational blood exposure. HBV screening in HCWs and treatment of those with chronic HBV infection should be however considered.

## **PLoS Medicine**

(Accessed 8 September 2012)

<http://www.plosmedicine.org/article/browse.action?field=date>

### **Point-of-Care Testing for Infectious Diseases: Diversity, Complexity, and Barriers in Low- And Middle-Income Countries**

Nitika Pant Pai, Caroline Vadnais, Claudia Denking, Nora Engel, Madhukar Pai Policy Forum, published 04 Sep 2012

doi:10.1371/journal.pmed.1001306

#### *Summary Points*

- Enthusiasm and hope are increasing around point-of-care (POC) diagnostics for diseases of global health importance.
- The mere availability of rapid or simple tests does not automatically ensure their adoption or scale-up. A range of barriers prevent the successful use of POC testing—economic, regulatory, and policy-related, as well as user/provider perceptions and cultural barriers.
- Technology as such does not define a POC test. Rather, it is the successful use at the POC that defines a diagnostic process as POC testing. Thus, the focus must be on POC testing programs, rather than POC technologies.
- We discuss a framework that envisions POC testing as a spectrum of technologies (simplest to more sophisticated), users (lay persons to highly trained), and settings (homes, communities, clinics, peripheral laboratories, and hospitals).
- A deeper appreciation of this diversity in target product profiles, and likely barriers in each setting, might help test developers and public health managers to identify the most impactful product and delivery model.

## **PLoS Neglected Tropical Diseases**

August 2012

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

[No relevant content]

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

(Accessed 8 September 2012)

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

[No new relevant content]

## **Public Health Ethics**

Volume 5 Issue 1 April 2012

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

[Reviewed earlier]

## **Trends in Molecular Medicine**

Volume 18, Issue 9, Pages 503-574 (September 2012)

<http://www.sciencedirect.com/science/journal/14714914>



[Reviewed earlier]

## **Science**

7 September 2012 vol 337, issue 6099, pages 1137-1264

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

[No relevant content]

## **Science Translational Medicine**

5 September 2012 vol 4, issue 150

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

[No relevant content]

## **Vaccine**

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

### **Volume 30, Issue 44, Pages 6225-6340 (28 September 2012)**

<http://www.sciencedirect.com/science/journal/0264410X/30/44>

#### **Technology transfer in human vaccinology: A retrospective review on public sector contributions in a privatizing science field**

Review Article

Pages 6230-6240

Jan Hendriks

#### *Abstract*

As health intervention, vaccination has had a tremendous impact on reducing mortality and morbidity caused by infectious diseases. Traditionally vaccines were developed and made in the western, industrialised world and from there on gradually and with considerable delay became available for developing countries. Today that is beginning to change. Most vaccine doses are now produced in emerging economies, although industrialised countries still have a lead in vaccine development and in manufacturing innovative vaccines. Technology transfer has been an important mechanism for this increase in production capacity in emerging economies. This review looks back on various technology transfer initiatives and outlines the role of WHO and other public and private partners. It goes into a more detailed description of the role of the National Institute of Public Health and the Environment (RIVM) in Bilthoven, the Netherlands. For many decades RIVM has been providing access to vaccine technology by capacity building and technology transfer initiatives not only through multilateral frameworks, but also on a bilateral basis including a major project in China in the 90s of the previous century.

Looking forward it is expected that, in a globalizing world, the ambition of BRICS countries to play a role in global health will lead to an increase of south-south technology transfers. Further, it is argued that push approaches including technology transfer from the public domain, connecting innovative enabling platforms with competent developing country vaccine manufacturers (DCVM), will be critical to ensure a sustainable supply of affordable and quality vaccines to national immunization programmes in developing countries.

## **Cost-effectiveness of tick-borne encephalitis vaccination in Slovenian adults**

Original Research Article

Pages 6301-6306

Renata Šmit

### *Abstract*

#### Background

Slovenia is an endemic country with a high incidence rate of tick-borne encephalitis (TBE) and low vaccination coverage. TBE causes high costs for the health care insurances as well as the society due to hospitalization and frequent long term or permanent neurological sequelae. Vaccination is effective and a safe prophylaxis against TBE.

#### Objective

The purpose of this study was to evaluate the incremental cost-effectiveness ratio (ICER) between vaccination and no vaccination in Slovenia. The results are shown as cost per quality-adjusted life year (QALY) gained from the view of the health care payer and the society.

#### Methods

Based on the natural course of the disease, the Markov model was used for comparing the economic and health outcomes of vaccinated and unvaccinated groups from 18 to 80 years of age.

#### Results

The incremental cost-effectiveness ratio from the current Slovenian vaccination programme for FSME-Immun® compared to no vaccination amounts to €15,128 per QALY gained and for Encepur® €20,099 per QALY gained from the view of the health care payer. From the view of the society vaccination is cost saving, mainly due to avoiding the high indirect costs.

#### Conclusions

According to the cost-effectiveness threshold as proposed by the Slovenian Health Council, the current Slovenian vaccination programme against TBE is cost-effective from the health care payer's perspective and also economical from the society's perspective.

## **Vaccine**

**Volume 30, Issue 43, Pages 6111-6224 (21 September 2012)**

<http://www.sciencedirect.com/science/journal/0264410X/30/43>

## **Vaccine and Immunization Surveillance in Ontario (VISION) – Using linked health administrative databases to monitor vaccine safety**

Review Article

Pages 6115-6120

Kumanan Wilson, Steven Hawken, Jeffrey C. Kwong, Shelley L. Deeks, Natasha S. Crowcroft, Douglas Manuel

### *Abstract*

Vaccine safety surveillance is a critical component of any population-wide vaccination program. In the province of Ontario, Canada we developed a vaccine safety surveillance system utilizing linked health administration databases. VISION (Vaccine and Immunization Surveillance in Ontario) has conducted population based self-controlled case series analyses to evaluate the safety of recommended pediatric vaccines in the general population and in specific subgroups. We present our experiences with

developing this system including preliminary findings and challenges. Key methodological observations include: (1) aggregate health services data as an endpoint appears useful (2) graphical description of events following vaccination are valuable and (3) relative incidence ratios are helpful for overcoming the healthy vaccinee effect.

### **Disability among US Army Veterans vaccinated against anthrax**

Original Research Article

Pages 6150-6156

Sandra I. Sulsky, Rose Luippold, Patrick Garman, Hayley Hughes, Edward J. Boyko, Charles Maynard, Paul J. Amoroso

#### *Abstract*

##### Context

To protect troops against the use of anthrax as a biological weapon, the US Department of Defense began an anthrax vaccination program in 1998. 14 years after the inception of the vaccination program, there is no evidence suggesting vaccination against anthrax carries long-term health risks for Active Duty Soldiers.

##### Objective

To investigate the association between Anthrax Vaccine Adsorbed (AVA) received while on Active Duty and subsequent disability determined by the Veterans Benefits Administration.

##### Design, setting and participants

Case-control study nested in the cohort of all Active Duty personnel known to have separated from the US Army between December 1, 1997 and December 31, 2005. Cases were  $\geq 10\%$  disabled, determined either by the Army prior to separation ( $N = 5846$ ) or by the Veterans Benefits Administration (VBA) after separation ( $N = 148,934$ ). Controls ( $N = 937,705$ ) separated from the Army without disability, and were not receiving pensions from the VBA as of April 2007. Data were from the Total Army Injury and Health Outcomes Database and the VBA Compensation and Pension and Benefits database.

##### Main outcomes

Disability status (yes/no); for primary disability, percent disabled ( $\geq 10\%$ ,  $20\%$ ,  $>20\%$ ) and type of disability.

##### Results

Vaccination against anthrax was four times more likely among disabled Veterans with hostile fire pay records (HFP, a surrogate for deployment). Vaccinated Soldiers with HFP had lower odds of disability separation from the Army 0.89 (0.80, 0.98); there was no association between vaccine and receiving Army disability benefits among those without HFP (OR = 1.05, CI: 0.96, 1.14). Vaccination was negatively associated with receiving VA disability benefits for those with HFP (OR = 0.66, CI: 0.65, 0.67), but there was little or no association between vaccine and receipt of VA disability benefits for those without HFP (OR = 0.95, CI: 0.93, 0.97).

##### Conclusions

Risk of disability separation from the Army and receipt of disability compensation from the VA were not increased in association with prior exposure to AVA. This study provides evidence that vaccination against anthrax is not associated with long term disability.

### **The pediatric vaccine stockpiling problem**

Original Research Article

Pages 6175-6179

Van-Anh Truong

### *Abstract*

The U.S. has experienced many major interruptions of its pediatric vaccine production in the past decade. The Centers for Disease Control and Prevention (CDC) copes with these shortages by building a national stockpile of pediatric vaccines, which it makes accessible to the public in the event of a shortage. The management of this stockpile is difficult due to limited production capacity and long and unpredictable production interruptions. In this paper, we address policies for managing the stockpile. We provide sufficient conditions for the optimal policy to be a modified state-dependent base-stock policy, with the base-stock level decreasing in the pipeline inventory. Since the optimal policy is in general difficult to evaluate, we derive bounds on the optimal decision in each period. We develop an efficient policy that performs on average within 1% of optimality in simulations. We show that stocking the same supply of vaccine of every type can be over-conservative in some cases, and inadequate in others by large factors. We also quantify the substantial reduction in inventory level that can be achieved when there are multiple suppliers in the market.

### **Vaccine**

**Volume 30, Issue 42, Pages 6007-6110 (14 September 2012)**

<http://www.sciencedirect.com/science/journal/0264410X/30/42>

**Report of the ad-hoc consultation on aging and immunization for a future WHO research agenda on life-course immunization**

Pages 6007-6012

Judith Thomas-Crusells, Janet E. McElhaney, M. Teresa Aguado

### *Abstract*

WHO convened a meeting of around 30 experts to address the topic of aging and immunization in March 2011 in Geneva. The purpose of the meeting was to develop a global research agenda to eventually inform WHO policy recommendations regarding immunization beyond childhood and into old age. This issue is becoming more critical, since the population aged 60 and above will reach two billion people – three-quarters of whom will be in developing countries – in the next 40 years. The meeting reviewed current knowledge and gaps in information about: (1) the epidemiology of infectious diseases in the elderly in developed and developing countries and their contribution to disability in old age; (2) the deterioration of the immune system with age (“immune senescence”) and possible ways to measure and counteract it; and (3) immunization approaches to maintain or improve health in older persons. These approaches include the concept of a “life-course vaccination” schedule to help sustain immunity to vaccine-preventable diseases beyond childhood and into old age; strategies to strengthen older persons’ responses to vaccines (e.g., by adding adjuvants to vaccines, increasing vaccine dosage, and intradermal vaccine administration); and the possible development of new vaccines targeted specifically for older adults. Participants proposed priority research topics as well as strategies to facilitate and coordinate the research, including the establishment of networks of collaborators, with WHO playing a key coordinating role.

**Cost-effectiveness of hepatitis A vaccination for adults in Belgium**

Original Research Article

Pages 6070-6080

Jeroen Luyten, Stefaan Van de Sande, Koen de Schrijver, Pierre Van Damme, Philippe Beutels

### *Abstract*

Hepatitis A vaccination targeting adults (or adult risk-groups like e.g. travellers, health care workers, soldiers or teachers) could be considered an alternative to a universal infant or adolescent vaccination program in low endemic countries. We estimated the current disease burden of hepatitis A in Belgium, and evaluated whether adult vaccination is cost-effective. We used a Markov cohort model to simulate the costs and effects of (1) vaccination of adults and (2) serological screening of adults and vaccination of susceptibles and compared these with the current situation. The results indicated that these expanded vaccination strategies are not cost-effective in the epidemiological circumstances of a typical low-endemic western country. In order to gain 1 quality-adjusted life year the health care payer would have to pay 185,000€ for vaccination and 223,000€ for screening and vaccination of seronegatives. For adult vaccination to be cost-effective, risk-groups would need to be exposed to a force of infection that is 3.5–4 times higher than currently estimated in the general population; or the total costs of vaccination would have to drop with approximately 75%.

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

(Accessed 8 September 2012)

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

[No new relevant content]

### **Value in Health**

Vol 15 | No. 5 | July-August 2012 | Pages 593-790

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

[Reviewed earlier]

### ***From Google Scholar: Dissertations, Theses, Selected Journal Articles***

#### **American Journal of Infection Control, 2012**

[PDF] [From 51% to 100%: Mandatory seasonal influenza vaccination](#)

M Lewis -

We believe we are the first union hospital to succeed in mandating the seasonal influenza vaccine for employees and physicians. We relate the process that we used to achieve this success. ...

#### **Current Infectious Disease Reports, 2012**

[Health-Care Worker Vaccination for Influenza: Strategies and Controversies](#)

CJ Derber, S Shankaran -

### *Abstract*

Influenza infections cause significant morbidity and mortality throughout the world, and vaccination rates of health-care workers remain well below target goals. Strategies for increasing vaccination rates include mandatory vaccination of health-care workers, mandatory declination, employee incentives, intensive education, increased access to vaccines, and the use of social media to inform employees of the safety and efficacy of vaccination. While these strategies in combination have been shown to be effective in

increasing vaccination rates, personal and religious objections, as well as the potential for infringing on individual autonomy, remain challenges in our efforts to bring health-care worker vaccination rates up to target goals.

### **BMC Health Services Research, 2012**

[PDF] [Using financial incentives to increase initial uptake and completion of HPV vaccinations: protocol for a randomised controlled trial](#)

E Mantzari, F Vogt, TM Marteau -

#### *Abstract*

##### Background

HPV vaccination reduces the risk of cervical cancer. Uptake however, of the “catch-up” campaign in England for 17-18 year old girls is below the 80% NHS target. The aim of this randomized controlled trial is to assess the impact of financial incentives on (a) the uptake and completion of an HPV vaccination programme and (b) the quality of the decisions to undertake the vaccination.

##### Method/Design

One thousand (n = 1000) 16-18 year-old girls will be invited to participate in an HPV vaccination programme: Five-hundred (n = 500) will have received a previous invitation to get vaccinated but will have failed to do so (previous non-attenders) and 500 will not have previously received an invitation (first-time invitees). Girls will be randomly selected from eligible participants who are registered with a GP in areas covered by the Birmingham East and North (BEN) and Heart of Birmingham Primary Care Trusts. The two samples of girls will be randomised to receive either a standard vaccination invitation letter or an invitation letter including the offer of vouchers worth £45 for receiving three vaccinations. Girls will also complete a questionnaire to assess the quality of their decisions to be vaccinated. The primary outcome will be uptake of the 1st and 3rd vaccinations. The secondary outcome will be the quality of the decisions to undertake the vaccination, measured by assessing attitudes towards and knowledge of the HPV vaccination.

##### Discussion

The key results will be: a) the effectiveness of financial incentives in increasing uptake of the 1st and 3rd vaccinations; b) the role of participants’ socio-economic status in the moderation of the impact of incentives on uptake; and c) the impact of incentives on the quality of decisions to undertake the HPV vaccinations.

### ***Media Watch***

Beginning in June 2012, *Vaccines: The Week in Review* expanded 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 CVERP 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. Most publications require either a registration or a fee-based subscription for access. We will provide full-text where content is published without restriction, but most publications require registration and some subscription level.

## **Economist**

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

*Accessed 8 September 2012*

### **Flowering Asia welfare states draw upon lessons from the West**

#### *Extract*

ASIA'S economies have long wowed the world with their dynamism. Thanks to years of spectacular growth, more people have been pulled from abject poverty in modern Asia than at any other time in history. But as they become more affluent, the region's citizens want more from their governments. Across the continent pressure is growing for public pensions, national health insurance, unemployment benefits and other hallmarks of social protection. As a result, the world's most vibrant economies are shifting gear, away from simply building wealth towards building a welfare state.

The speed and scale of this shift are mind-boggling (see [article](#)). Last October Indonesia's government promised to provide all its citizens with health insurance by 2014. It is building the biggest "single-payer" national health scheme—where one government outfit collects the contributions and foots the bills—in the world. In just two years China has extended pension coverage to an additional 240m rural folk, far more than the total number of people covered by Social Security, America's public-pension system. A few years ago about 80% of people in rural China had no health insurance. Now virtually everyone does. In India some 40m households benefit from a government scheme to provide up to 100 days' work a year at the minimum wage, and the state has extended health insurance to some 110m poor people, more than double the number of uninsured in America...

<http://www.economist.com/node/21562195>

## **Financial Times**

<http://www.ft.com>

*Accessed 8 September 2012*

[No new unique, relevant content]

## **Forbes**

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

Pharma & Health

9/05/2012 @ 2:38PM |

### **When Americans Rejected Small Pox Vaccines**

#### *Extract*

When I lived in [Ann Arbor](#), my children attended a public school where upwards of 15% of kids were not vaccinated for mumps because their left-wing parents didn't trust the vaccine industry. Meanwhile on the right end of the political spectrum, Tea Party heart throb Michelle Bachman famously accused vaccines of causing autism. How is it that such an advanced technologic country harbors so many vaccine luddites?

A quick glance at the U.S. small pox epidemic of 1900 offers a clue...

<http://www.forbes.com/sites/peterubel/2012/09/05/when-americans-rejected-small-pox-vaccines/>

## **Foreign Affairs**

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



September/October 2012 Volume 91, Number 5

*Accessed 8 September 2012*

[No new unique, relevant content]

### **Foreign Policy**

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

*Accessed 8 September 2012*

[No new unique, relevant content]

### **The Guardian**

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

*Accessed 8 September 2012*

[No new unique, relevant content]

### **The Huffington Post**

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

*Accessed 8 September 2012*

[No new unique, relevant content]

### **New Yorker**

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

*Accessed 8 September 2012*

[No new unique, relevant content]

### **New York Times**

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

*Accessed 8 September 2012*

[No new unique, relevant content]

### **Wall Street Journal**

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

*Accessed 8 September 2012*

[No new unique, relevant content]

### **Washington Post**

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

*Accessed 8 September 2012*

[No new unique, relevant content]

### ***Twitter Watch*** *[accessed 8 September 2012 15:08]*

Items of interest from a variety of twitter feeds associated with immunization, vaccines and global public health. This capture is highly selective and is by no means intended to be exhaustive.

[GAVI Alliance @GAVIAlliance](#)

Is [@GAVIAlliance](#) delivering on its promises? Track GAVI's progress against its targets for the 2011-2015 strategy! <http://ht.ly/dyRVd>  
2:00 PM - 8 Sep 12

[UNICEF MENA @UNICEFmena](#)

UNICEF [#Jordan](#) health specialist reports on the first immunization clinic for young Syrian children at Za'atari camp. <http://pic.twitter.com/jSCzZz4q>  
Retweeted by [UNICEF](#)  
5:10 AM - 5 Sep 12

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***Vaccines: The Week in Review*** is a service of the Center for Vaccines Ethics and Policy (CVEP) which is solely responsible for its content. Support for this service is provided by its governing institutions – [Department of Medical Ethics, NYU Medical School](#); [The Wistar Institute Vaccine Center](#) and the [Children's Hospital of Philadelphia Vaccine Education Center](#). Additional support is provided by [PATH Vaccine Development Program](#) and the [International Vaccine Institute](#) (IVI), and by vaccine industry leaders including GSK, Merck, Pfizer, and sanofi pasteur (list in formation), as well as the Developing Countries Vaccine Manufacturers Network ([DCVMN](#)). Support is also provided by a growing list of individuals who use this service to support their roles in public health, clinical practice, government, NGOs and other international institutions, academia and research organizations, and industry.

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