#### Vaccines: The Week in Review 19 September 2011 Center for Vaccine Ethics & Policy (CVEP)

http://centerforvaccineethicsandpolicy.wordpress.com/

A program of

- Center for Bioethics, University of Pennsylvania http://www.bioethics.upenn.edu/
- The Wistar Institute Vaccine Center http://www.wistar.org/vaccinecenter/default.html
- Children's Hospital of Philadelphia, Vaccine Education Center http://www.chop.edu/consumer/jsp/microsite/microsite.jsp

This weekly summary targets news and events in global vaccines ethics and policy gathered from key governmental, NGO and industry sources, key journals and other sources. This summary supports ongoing initiatives of the Center for Vaccine Ethics & Policy, and is not intended to be exhaustive in its coverage. Vaccines: The Week in Review is now also posted in pdf form and as a set of blog posts at <u>http://centerforvaccineethicsandpolicy.wordpress.com/</u>. This blog allows full-texting searching of some 2,000 content items. Comments and suggestions should be directed to David R. Curry, MS Editor and

Ealtor and Executive Director Center for Vaccine Ethics & Policy david.r.curry@centerforvaccineethicsandpolicy.org

**The Bill & Melinda Gates Foundation announced that Dr. Trevor Mundel has been named president of the foundation's Global Health Program**. Dr. Mundel is currently global head of development for Novartis Pharma AG and is based in Basel, Switzerland. Bill Gates, co-chair of the foundation, said, "We are very pleased that Dr. Mundel has agreed to lead our global health program. He brings tremendous scientific and medical credentials, in the lab and in the clinic. We look forward to working with him to help improve the health of people in the world's poorest countries." In this role, Dr. Mundel "will lead the foundation's efforts to develop and deliver drugs, vaccines, and other tools to fight developing-world diseases, such as HIV/AIDS, tuberculosis, and malaria, and take the world closer to the goal of polio eradication. He will oversee the foundation's global health grant portfolio, which includes more than \$14.7 billion in grants to date."

http://www.prnewswire.com/news-releases/gates-foundation-names-dr-trevor-mundelto-lead-global-health-program-129717323.html

The European Commission (EC) announced a commitment of "an additional 20 million Euros" to the GAVI Alliance. GAVI CEO Dr Seth Berkley commented, "We are grateful for the European Commission's confidence in GAVI. This donation, combined with the evident commitment from developing countries to expand immunisation programmes, will further support our efforts to protect children from death and disability. All children have a right to a healthy start in life and vaccination is critical to this."

http://www.gavialliance.org/library/news/press-releases/2011/ec-makes-furthercommitment-to-saving-lives/

The Global Fund said it welcomed a report by an "independent panel of distinguished individuals" recommending "major changes in the way the Global Fund does its business and manages its grants." The panel was co-chaired by former U.S. Health and Human Services Secretary Michael O. Leavitt and former President of Botswana Festus Mogae and found that the Global Fund "needs to focus much more on its core business of managing grants to save and protect lives. It recommends improving financial and Board oversight, simplifying grant application processes, and putting in place a robust risk management framework." Simon Bland, Chair of the Global Fund's Board, commented, "The panel's report provides a great opportunity to sharpen the focus of the Global Fund and make it fit for the future. We commissioned the panel to give us an honest, hard look at the institution from the outside and that is exactly what we have got. The panel's findings will play a central role in accelerating reform. As an organization we are totally committed to making the necessary changes to strengthen oversight, improve impact, value for money and sustainability." The Global Fund said its Board will hold a special meeting on 26 September in Geneva to "consider the report's findings and prepare an action plan and will meet again in November for its regular meeting to consider larger changes to the organization's governance structure, strategy and work processes." http://www.theglobalfund.org/en/mediacenter/pressreleases/2011-09-19 Global Fund welcomes call by Independent High Level Panel for stronger financ

ial\_safeguards/

WHO released the draft agenda for the Meeting of the Strategic Advisory Group of Experts on Immunization (SAGE) to be held 8 - 10 November 2011, in Geneva http://www.who.int/entity/immunization/sage/AGENDA\_Nov\_SAGE\_with\_timings\_13\_Se p\_2011.pdf

NIH launched an "initiative that will facilitate the ability of start-up companies to license inventions for groundbreaking medical technologies for drugs, vaccines and therapeutics developed by intramural scientists at NIH." As part of this program, the NIH "is reducing both the costs and paperwork requirements for start-up companies to obtain an exclusive option agreement to license the extensive patent portfolio developed by intramural research laboratories at both NIH and the U.S. Food and Drug Administration." The new start-up license agreements have been developed the Office of Technology Transfer (OTT) at NIH: Companies that are less than five years old, have fewer than 50 employees and received investment of less than \$5 million are eligible to use the new, short-term exclusive Start-Up Evaluation License Agreement and the new Start-Up Commercial License Agreement. Starting on 1 October 2011, "biomedical entrepreneurs will be able to apply for any of the available patents and patent applications relating to drugs, vaccines or therapeutics in the NIH/FDA portfolio by submitting a business plan for how they propose to use them." http://www.nih.gov/news/health/sep2011/od-16a.htm

## Meeting Profile: United Nations high-level meeting on noncommunicable disease prevention and control

Place: New York, USA

Date: 19-20 September 2011

The four main noncommunicable diseases - cardiovascular disease, cancer, chronic lung diseases and diabetes - kill three in five people worldwide, and cause great socioeconomic harm within all countries, particularly developing nations.

The United Nations General Assembly is convening a high-level meeting on the prevention and control noncommunicable diseases, which presents a unique opportunity for the international community to take action against the epidemic, save millions of lives and enhance development initiatives.

The high-level meeting will address the prevention and control of noncommunicable diseases worldwide, with a particular focus on developmental and other challenges and social and economic impacts, particularly for developing countries.

WHO has facilitated regional consultations of Member States to give governments the opportunity to contribute, particularly by identifying the challenges posed by noncommunicable diseases in their countries and the measures that exist to start reversing the epidemic.

#### http://www.who.int/mediacentre/events/meetings/2011/ncd\_prevention\_control/en/inde x.html

#### The Pharmaceutical Research and Manufacturers of America (PhRMA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) made separate announcements coordinated to the United Nations NCD meeting.

PhRMA reported that "America's biopharmaceutical research companies have 901 biotechnology medicines and vaccines in development to target more than 100 debilitating and life-threatening diseases, such as cancer, arthritis and diabetes, according to a new report. The medicines in development—all in either clinical trials or under Food and Drug Administration review—include 353 for cancer and related conditions, 187 for infectious diseases, 69 for autoimmune diseases and 59 for cardiovascular diseases."

http://www.phrma.org/media/releases/over-900-biotechnology-medicines-developmenttargeting-more-100-diseases

IFPMA "outlined the steps it is taking to address the rise of NCDs in the developing world," noting "top line findings of the research [see *Rand Occasional Paper* below] show that effective first-line NCD medicines exist and are now available in generic form, but, in many instances, these medicines are still failing to reach many people living in the developing world." The study identified four priority areas for the research-based pharmaceutical industry to consider:

- innovative ways to improve NCD medicine adherence

- overcoming barriers to availability in poor and remote areas where large mark-ups, tax and duties, along the supply chain, as well as counterfeit products, are an issue

- improving access to primary care

- removing regulatory restrictions that hamper medicine availability in developing countries.

These priority areas provide the basis for the next four studies in the IFPMA NCD research series. The aim is that the studies will help the research-based pharmaceutical industry and its partners develop and carry out the actions that will most effectively improve access to NCD medicines in developing countries.

http://www.ifpma.org/fileadmin/content/News/2011/all/IFPMA\_News\_Release\_UN\_NCD s\_Summit\_19Sept2011.pdf

#### **Improving Access to Medicines for Non-Communicable Diseases in the Developing World** [Rand Occasional Paper]

by Soeren Mattke, Marla C. Haims, Nono Ayivi-Guedehoussou, Emily M. Gillen, Lauren Hunter, Lisa Klautzer, Tewodaj Mengistu

#### Abstract [full text]

Non-communicable diseases (NCDs) now account for the majority of global morbidity and mortality and are increasingly affecting developing countries whose under-resourced health care systems also have to handle a high burden of infectious disease. To counter the global devastation caused by NCDs, the United Nations General Assembly decided to "set a new global agenda" and is convening a high-level meeting on NCDs in September 2011. In connection with this meeting, the authors of this paper took a first step toward developing a policy research agenda for improving access to NCD medicines in developing countries, a step that the research-based pharmaceutical industry, in particular, can carry forward as part of broader global efforts to combat NCD. The authors provide a framework for understanding the obstacles to access for NCD medicines, review specific issues to be confronted within each obstacle in the developing world, identify promising ideas for improving access to NCD medicines, and point to several highly promising areas for the research-based pharmaceutical industry to focus on as it develops its NCD policy research program in close collaboration with other key stakeholders.

http://www.rand.org/content/dam/rand/pubs/occasional\_papers/2011/RAND\_OP349.pdf

The **MMWR Weekly for September 16, 2011** / Vol. 60 / No. 36 includes: - Influenza-Associated Pediatric Deaths --- United States, September 2010--August 2011 Update: Influenza Activity --- United States and Worldwide, May 22--September 3, 2011 http://www.cdc.gov/mmwr/pdf/wk/mm6036.pdf

The **Weekly Epidemiological Record (WER) for 16 September 2011**, vol. 86, 38 (pp 417–424) includes: InterAmerican Conference on Onchocerciasis, 2010: progress towards eliminating river blindness in the WHO Region of the Americas http://www.who.int/entity/wer/2011/wer8638.pdf

#### Twitter Watch

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

#### GAVIAlliance GAVI Alliance

Wondering why GAVI's attending <u>@UN #NCD</u> Summit? <u>@GAVISeth</u> shares why preventing <u>#NCDs</u> is directly related to our mission. <u>http://ht.ly/6xZ9S</u>

#### GAVIAlliance GAVI Alliance

We are in NYC for the kick-off of the Global Strategy for Women and Children's Health! <u>http://ht.ly/6xJNW</u>

#### pahowho PAHO/WHO

<u>**#NCDs</u>** "This is a global epidemic and this is why we need global actions." Highlighted at Global Atlas on Prevention and Control <u>**#NYC**</u></u>

#### NIHforHealth NIH for Health

News: NIH launches program to facilitate drug, vaccine and therapeutic license agreements for start-up companies <u>1.usa.gov/mP4onV</u>

#### TheLancet The Lancet

First global analysis of breast and cervical cancer estimates 2 million new cases worldwide <u>bit.ly/qGiOgx</u>

#### Eurovaccine ECDC Eurovaccine

ECDC starts coordinating EUVAC.NET, the European surveillance network for vaccinepreventable diseases <u>bit.ly/qTflg] #vaccine</u>

<u>ArthurCaplan</u> Arthur Caplan More from me about the challenge on HPV and vaccine safety from Medscape <u>bit.ly/rgBznB</u>

<u>GAVIAlliance</u> GAVI Alliance T-5: In 10 years, GAVI support has averted more than 5 million future deaths. <u>#socialgood http://ht.ly/6u6EA</u>

gatesfoundation Gates Foundation by globalfundnews .@GlobalFundNews has saved 6.5M lives since 2001. Learn more: gates.ly/o7Z6Wj #malaria #AIDS

Journal Watch [Editor's Note] *Vaccines: The Week in Review* continues its weekly scanning of key 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

#### **Annals of Internal Medicine**

September 6, 2011; 155 (5) http://www.annals.org/content/current [Reviewed earlier; No relevant content]

#### **British Medical Bulletin**

Volume 99 Issue 1 September 2011 http://bmb.oxfordjournals.org/content/current [Reviewed earlier; No relevant content]

#### **British Medical Journal**

17 September 2011 Volume 343, Issue 7823 http://www.bmj.com/content/current *Editorial* 

#### UN meeting for non-communicable diseases

Tracey Pérez Koehlmoos, programme head [Extract]

Long term commitment within countries is needed, with support from global development partners and strong leadership from the UN

On 19-20 September 2011, the United Nations will host a general assembly high level meeting on the control and prevention of non-communicable disease (NCD). Although the meeting will be held in New York, the eyes of developing country leaders, decision makers, civil society groups, industry, non-governmental organisations, and researchers will be focused on the event and its outcomes. Previous UN summits have provided the catalyst for change. The summit on HIV/AIDS in 2001 resulted in substantial funding and political commitments. 1

The UN meeting is a crucial moment. This is especially true because it developed in the shadow of global efforts to achieve the millennium development goals, which do not include NCD. NCD is by far the largest killer on the planet and has continued to advance in low and middle income countries, so that the cause of 63% of all global deaths receives less than 3% of international development assistance for health. 2 About 80% of deaths caused by NCD occur in developing countries and generally in a younger population than in high income countries. 3 4 Over the next 10 years, the World Health Organization predicts that deaths from NCD will increase by 17% globally, with the greatest increases in the ...

#### **Clinical Infectious Diseases**

Volume 53 Issue 8 October 15, 2011 http://www.journals.uchicago.edu/toc/cid/current

## Correspondence

#### Human Papillomavirus Vaccination Programs and Human Immunodeficiency Virus Epidemics

Seema Yasmin, David J. Gerberry, and Sally Blower

TO THE EDITOR—In a recent article, Tracy et al [1] use mathematical modeling to predict the potential impact of human papillomavirus (HPV) vaccination programs in developing countries; HPV is the primary causative agent for cervical cancer. The analysis is timely, given the recent announcement that Rwanda will soon launch Africa's first HPV vaccination program [2]. Tracy and colleagues focused on challenges associated with HPV vaccination in Mali (eg, female circumcision, marriage at younger ages, polygamy, cultural and economic factors), but they did not assess the potential effect of human immunodeficiency virus (HIV) on HPV vaccination programs. Rwanda and many other countries in Sub-Saharan Africa have a significant burden of HPV and HIV. HIV infection increases a woman's susceptibility to HPV infection, boosts the chances that infection is from high-risk subtypes ...

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

(accessed 19 September 2011) http://www.resource-allocation.com/ [No new relevant content]

## **Emerging Infectious Diseases**

Volume 17, Number 9–September 2011 http://www.cdc.gov/ncidod/EID/index.htm [Reviewed earlier; No relevant content]

## **Health Affairs**

September 2011; Volume 30, Issue 9 *The New Urgency To Lower Costs* <u>http://content.healthaffairs.org/content/current</u> [Reviewed earlier; No relevant content]

#### Health Economics, Policy and Law

Volume 6 - Issue 04 - 01 October 2011 <u>http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue</u> [Reviewed earlier]

#### **Human Vaccines**

Volume 7, Issue 9 September 2011 http://www.landesbioscience.com/journals/vaccines/toc/7/9/ [Reviewed earlier]

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

Volume 15, Issue 9 pp. e583-e654 (September 2011) http://www.sciencedirect.com/science/journal/12019712 [Reviewed earlier]

#### JAMA

September 14, 2011, Vol 306, No. 10, pp 1055-1158 http://jama.ama-assn.org/current.dtl [No relevant content]

#### Journal of Infectious Diseases

Volume 204 Issue 8 October 15, 2011 http://www.journals.uchicago.edu/toc/jid/current

## EDITORIAL COMMENTARIES

## **Broadening Indications for Maternal Influenza Vaccination**

W. Paul Glezen

[Extract: full text here: http://jid.oxfordjournals.org/content/204/8/1151.full ] The primary indication for influenza vaccination of pregnant women is to decrease the risk of serious complications during pregnancy [1]. The case fatality rates for pregnant women during the influenza pandemics of 1918 and 1957 ranged from 20% to 50% in various reports [2]. As a consequence, pregnancy—with or without comorbidities—was considered a high-risk condition by the Surgeon General's Advisory Committee. A large collaborative perinatal project sponsored by the National Institute for Neurological and Communicative Disorders and Stroke from 1959 to 1965 enrolled over 50 000 pregnant women and their offspring who were intensively followed for all events prior to and after delivery found that influenza vaccine administered to 2291 women during pregnancy had no untoward effects [3, 4]. From this study, it can be estimated that about 2 million women received influenza vaccine during pregnancy between 1959 and 1965. Despite the evidence of safety, influenza vaccine was no longer recommended for pregnant women without chronic underlying conditions after 1966 because "influenzaassociated excess mortality among pregnant women has not been documented except in the pandemics..." [5]. Reports of influenza-related deaths continued to occur, and the sensitivity of the data derived from death certificates was guestioned [6, 7]. In the early 1990s, investigators looked at risk of influenza-associated hospitalizations during pregnancy and found significant excess occurrence of pneumonia that increased as the pregnancy progressed. This led to reconsideration of the indication for ...

#### The Lancet

Sep 17, 2011 Volume 378 Number 9796 p1049 - 1116 http://www.thelancet.com/journals/lancet/issue/current

[No relevant content]

#### **The Lancet Infectious Disease**

Sep 2011 Volume 11 Number 9 p651 - 720 http://www.thelancet.com/journals/laninf/issue/current [Reviewed earlier]

#### Medical Decision Making (MDM)

September/October 2011; 31 (5) http://mdm.sagepub.com/content/current

#### Editorials

Katrina Brown and Nick Sevdalis

#### Lay Vaccination Narratives on the Web: Are They Worth Worrying About?

Med Decis Making September/October 2011 31: 707-709, doi:10.1177/0272989X11419664

#### Extract

The Internet allows us more access than ever before to the unadulterated anecdotes and opinions of our fellow laypeople. Our decisions—about health care or parenting, for example—were once based on advice from experts, plus perhaps testimonies from a small pool of friends and family, or a finite number of narratives filtered through the press or television. Now the proliferation of social networking and user-generated content in the age of Web 2.0 1 puts at our disposal a huge and often unmoderated bank of online material. Google searches in June 2011 for "health discussion forum" and "mothers discussion forum" yielded 310 million and 62 million hits, respectively—and we know that decision makers do access these online resources. 2, 3

What is less clear is whether, why, and exactly how lay narratives from online forums are associated with real-life decisions. In this issue of Medical Decision Making (MDM), Betsch and colleagues 4 report an investigation of how lay narratives are used in decision making about vaccination. Using a fictional disease and vaccine context, a mock Internet bulletin board setup, and an undergraduate sample, the authors varied the relative frequency, emotionality, richness, and correlation with official risk estimates of narratives reporting vaccine adverse events and assessed perceived adverse event risk and vaccine uptake intention. Betsch and others found that a higher frequency of narratives reporting vaccine adverse events increased perceived vaccine risk and decreased vaccine uptake intention, that narrative frequency affected risk perception and uptake intention to a greater extent than did statistical information, and that emotionality in narratives increased risk perception, whereas richness had no impact. Cornelia Betsch, Corina Ulshöfer, Frank Renkewitz, and Tilmann Betsch **The Influence of Narrative v. Statistical Information on Perceiving Vaccination Risks** 

Med Decis Making September/October 2011 31: 742-753, first published on March 29, 2011 doi:10.1177/0272989X11400419

#### Abstract

Background. Health-related information found on the Internet is increasing and impacts patient decision making, e.g. regarding vaccination decisions. In addition to statistical information (e.g. incidence rates of vaccine adverse events), narrative information is

also widely available such as postings on online bulletin boards. Previous research has shown that narrative information can impact treatment decisions, even when statistical information is presented concurrently.

Objectives. As the determinants of this effect are largely unknown, we will vary features of the narratives to identify mechanisms through which narratives impact risk judgments. Methods. An online bulletin board setting provided participants with statistical information and authentic narratives about the occurrence and nonoccurrence of adverse events. Experiment 1 followed a single factorial design with 1, 2, or 4 narratives out of 10 reporting adverse events. Experiment 2 implemented a 2 (statistical risk 20% vs. 40%)  $\times$  2 (2/10 vs. 4/10 narratives reporting adverse events)  $\times$  2 (high vs. low richness)  $\times$  2 (high vs. low emotionality) between-subjects design. Dependent variables were perceived risk of side-effects and vaccination intentions. Results. Experiment 1 shows an inverse relation between the number of narratives reporting adverse-events and vaccination intentions, which was mediated by the perceived risk of vaccinating. Experiment 2 showed a stronger influence of the number of narratives than of the statistical risk information. High (vs. low) emotional narratives had a greater impact on the perceived risk, while richness had no effect. Implications. The number of narratives influences risk judgments can potentially override statistical information about risk.

#### Nature

Volume 477 Number 7364 pp249-364 15 September 2011 http://www.nature.com/nature/current\_issue.html [No relevant content]

#### **Nature Medicine**

September 2011, Volume 17 No 9 http://www.nature.com/nm/index.html [Reviewed earlier]

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

September 15, 2011 Vol. 365 No. 11 http://content.nejm.org/current.shtml

## **Original Articles**

## A Field Trial to Assess a Blood-Stage Malaria Vaccine

M.A. Thera and Others

Background Blood-stage malaria vaccines are intended to prevent clinical disease. The malaria vaccine FMP2.1/AS02A, a recombinant protein based on apical membrane antigen 1 (AMA1) from the 3D7 strain of Plasmodium falciparum, has previously been shown to have immunogenicity and acceptable safety in Malian adults and children. Methods

In a double-blind, randomized trial, we immunized 400 Malian children with either the malaria vaccine or a control (rabies) vaccine and followed them for 6 months. The primary end point was clinical malaria, defined as fever and at least 2500 parasites per

cubic millimeter of blood. A secondary end point was clinical malaria caused by parasites with the AMA1 DNA sequence found in the vaccine strain. Results

The cumulative incidence of the primary end point was 48.4% in the malaria-vaccine group and 54.4% in the control group; efficacy against the primary end point was 17.4% (hazard ratio for the primary end point, 0.83; 95% confidence interval [CI], 0.63 to 1.09; P=0.18). Efficacy against the first and subsequent episodes of clinical malaria, as defined on the basis of various parasite-density thresholds, was approximately 20%. Efficacy against clinical malaria caused by parasites with AMA1 corresponding to that of the vaccine strain was 64.3% (hazard ratio, 0.36; 95% CI, 0.08 to 0.86; P=0.03). Local reactions and fever after vaccination were more frequent with the malaria vaccine. Conclusions

On the basis of the primary end point, the malaria vaccine did not provide significant protection against clinical malaria, but on the basis of secondary results, it may have strain-specific efficacy. If this finding is confirmed, AMA1 might be useful in a multicomponent malaria vaccine. (Funded by the National Institute of Allergy and Infectious Diseases and others; ClinicalTrials.gov number, <u>NCT00460525</u>.)

#### **Review Article**

## Genomic Medicine: Genomics, Health Care, and Society

K.L. Hudson

[Initial text from free full text here:

## http://www.nejm.org/doi/full/10.1056/NEJMra1010517

A new generation of genomic technologies permits the increased collection of data on large study populations. 1,2 New methods in informatics facilitate the integration of diverse types of information with genomic data in disease research. As a result, researchers are learning more about the genetic bases of disease and response to drugs. 3-6 Genetic tests, including many that are offered directly to the consumer, are growing in number and clinical relevance. Genomic knowledge and technologies are also being adopted in areas distant from human health. Here, I describe evolving policies pertinent to genetic and genomic research, the integration of genetics into clinical care, and the broader issues raised by genetic technologies and information....

#### The Pediatric Infectious Disease Journal

October 2011 - Volume 30 - Issue 10 pp: A7-A8,821-918,e179-e202 http://journals.lww.com/pidj/pages/currenttoc.aspx *History of Medicine* Smallpox Variolation During the Revolutionary War Cantey, Joseph B. Pediatric Infectious Disease Journal. 30(10):821, October 2011. doi: 10.1097/INF.0b013e318227759a [No abstract]

#### Pediatrics

September 2011, VOLUME 128 / ISSUE 3 <u>http://pediatrics.aappublications.org/current.shtml</u> [Reviewed earlier]

#### **Pharmacoeconomics**

October 1, 2011 - Volume 29 - Issue 10 pp: 823-911 http://adisonline.com/pharmacoeconomics/pages/currenttoc.aspx *Original Research Articles* <u>Does the Market Share of Generic Medicines Influence the Price Level?: A</u> <u>European Analysis</u>

Dylst, Pieter; Simoens, Steven Pharmacoeconomics. 29(10):875-882, October 1, 2011. doi: 10.2165/11585970-000000000-00000 *Abstract:* 

Background: After the expiry of patents for originator medicines, generic medicines can enter the market, and price competition may occur. This process generates savings to the healthcare payer and to patients, but knowledge about the factors affecting price competition in the pharmaceutical market following patent expiry is still limited. Objective: This study aimed to investigate the relationship between the market share of generic medicines and the change of the medicine price level in European off-patent markets.

Methods: Data on medicine volumes and values for 35 active substances were purchased from IMS Health. Ex-manufacturer prices were used, and the analysis was limited to medicines in immediate-release, oral, solid dosage forms. Countries included were Austria, Belgium, Denmark, Germany, France, Italy, the Netherlands, Spain, Sweden and the UK, which constitute a mix of countries with low and high generic medicines market shares. Data were available from June 2002 until March 2007. Results: Market volume has risen in both high and low generic market share countries (+29.27% and +27.40%, respectively), but the cause of the rise is different for the two markets. In low generic market share countries, the rise was caused by the increased use of generic medicines and a shift of use from originator to generic medicines. Market value was substantially decreased in high generic market share countries (-26.6%), while the decrease in low generic market share countries was limited (-0.06%). In high generic market share countries, medicine prices dropped by -43.18% versus -21.56% in low market share countries.

Conclusions: The extent to which price competition from generic medicines leads to price reductions appears to vary according to the market share of generic medicines. High generic market share countries have seen a larger decrease in medicine prices than low market share countries.

#### PLoS One

[Accessed 19 September 2011]

http://www.plosone.org/article/browse.action;jsessionid=577FD8B9E1F322DAA533C413 369CD6F3.ambra01?field=date

Maintaining Vaccine Delivery Following the Introduction of the Rotavirus and Pneumococcal Vaccines in Thailand

Bruce Y. Lee, Tina-Marie Assi, Korngamon Rookkapan, Angela R. Wateska, Jayant Rajgopal, Vorasith Sornsrivichai, Sheng-I Chen, Shawn T. Brown, Joel Welling, Bryan A.

Norman, Diana L. Connor, Rachel R. Bailey, Anirban Jana, Willem G. Van Panhuis, Donald S. Burke Diseases Computer Science Maintaining Vaccine ... Maintaining Vaccine Delivery Following the Introduction of the Rotavirus and Pneumococcal Vaccines in Thailand ... and Pneumococcal Vaccines in Thailand Introducing Rotavirus and Pneumococcal Vaccines Bruce Y. Lee 1 \* Tina PLoS ONE: Research Article, published 13 Sep 2011 10.1371/journal.pone.0024673

## Abstract

Although the substantial burdens of rotavirus and pneumococcal disease have motivated many countries to consider introducing the rotavirus vaccine (RV) and heptavalent pneumococcal conjugate vaccine (PCV-7) to their National Immunization Programs (EPIs), these new vaccines could affect the countries' vaccine supply chains (i.e., the series of steps required to get a vaccine from their manufacturers to patients). We developed detailed computational models of the Trang Province, Thailand, vaccine supply chain to simulate introducing various RV and PCV-7 vaccine presentations and their combinations. Our results showed that the volumes of these new vaccines in addition to current routine vaccines could meet and even exceed (1) the refrigerator space at the provincial district and sub-district levels and (2) the transport cold space at district and sub-district levels preventing other vaccines from being available to patients who arrive to be immunized. Besides the smallest RV presentation (17.1 cm3/dose), all other vaccine introduction scenarios required added storage capacity at the provincial level (range: 20 L–1151 L per month) for the three largest formulations, and district level (range: 1 L-124 L per month) across all introduction scenarios. Similarly, with the exception of the two smallest RV presentation (17.1 cm3/dose), added transport capacity was required at both district and sub-district levels. Added transport capacity required across introduction scenarios from the provincial to district levels ranged from 1 L-187 L, and district to sub-district levels ranged from 1 L-13 L per shipment. Finally, only the smallest RV vaccine presentation (17.1 cm3/dose) had no appreciable effect on vaccine availability at sub-districts. All other RV and PCV-7 vaccines were too large for the current supply chain to handle without modifications such as increasing storage or transport capacity. Introducing these new vaccines to Thailand could have dynamic effects on the availability of all vaccines that may not be initially apparent to decisionmakers.

#### **Resource Allocation for Epidemic Control in Metapopulations**

Martial L. Ndeffo Mbah, Christopher A. Gilligan vaccination to prevent or mitigate the spread of an outbreak ..., they show that when vaccine supplies are limited ..., it is optimal to target vaccination toward the more PLoS ONE: Research Article, published 13 Sep 2011 10.1371/journal.pone.0024577

#### Abstract

Deployment of limited resources is an issue of major importance for decision-making in crisis events. This is especially true for large-scale outbreaks of infectious diseases. Little is known when it comes to identifying the most efficient way of deploying scarce resources for control when disease outbreaks occur in different but interconnected regions. The policy maker is frequently faced with the challenge of optimizing efficiency (e.g. minimizing the burden of infection) while accounting for social equity (e.g. equal opportunity for infected individuals to access treatment). For a large range of diseases described by a simple SIRS model, we consider strategies that should be used to minimize the discounted number of infected individuals during the course of an epidemic. We show that when faced with the dilemma of choosing between socially

equitable and purely efficient strategies, the choice of the control strategy should be informed by key measurable epidemiological factors such as the basic reproductive number and the efficiency of the treatment measure. Our model provides new insights for policy makers in the optimal deployment of limited resources for control in the event of epidemic outbreaks at the landscape scale.

## **PLoS Medicine**

(Accessed 19 September 2011)

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

Strengthening the Informed Consent Process in International Health Research through Community Engagement: The KEMRI-Wellcome Trust

**Research Programme Experience** Mwanamvua Boga, Alun Davies, Dorcas Kamuya, Samson M. Kinyanjui, Ester Kivaya, Francis Kombe, Trudie Lang, Vicki Marsh, Bibi Mbete, Albert Mlamba, Sassy Molyneux, Stephen Mulupi, Salim Mwalukore Health in Action, published 13 Sep 2011

doi:10.1371/journal.pmed.1001089

Summary Points

- Informed consent is fundamental to ethical health research.

- Significant challenges are experienced in obtaining consent for research, particularly in poor settings.

- Consenting processes can be strengthened by taking into account local social, cultural, and economic contexts in the design and administration of consent forms.

Institutional wide support is important in ensuring consistency in the consenting process for all studies within a given institution.

# Proceedings of the National Academy of Sciences of the United States of America

(Accessed 19 September 2011) http://www.pnas.org/content/early/recent [No new relevant content]

## Science

16 September 2011 vol 333, issue 6049, pages 1537-1668 http://www.sciencemag.org/current.dtl

## Perspectives

## AIDS/HIV

## Converging on an HIV Vaccine

Bette Korber and S. Gnanakaran Science 16 September 2011: 1589-1590. *Summary* 

Three decades after the discovery of AIDS we still do not have a vaccine against the causative agent, the human immunodeficiency virus (HIV). Multidrug therapy can extend life and health for those with HIV, but only holds the virus at bay, making treatment a lifetime proposition. Access to treatment or other promising infection prevention measures such as topical microbicides (1) are an economic and social challenge (2). A

vaccine would be a simple and direct strategy for prevention. On pages 1593 and 1633 of this issue, Wu et al. (3) and Scheid et al. (4) detail the trajectory of an immune response to natural HIV infection that may provide a path to a vaccine.

## **Science Translational Medicine**

14 September 2011 vol 3, issue 100 http://stm.sciencemag.org/content/current [No relevant content]

#### **Tropical Medicine & International Health**

October 2011 Volume 16, Issue 10 Pages 1191–1352 http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1365-3156/currentissue Implementation research Research capacity for institutional collaboration in implementation research on diseases of poverty (pages 1285–1290)

M. A. González-Block, E. M. Vargas-Riaño, N. Sonela, A. J. Idrovo, O. Ouwe-Missi-Oukem-Boyer and J. J. Monot

*Article first published online: 18 JUL 2011 | DOI: 10.1111/j.1365-3156.2011.02834.x Summary* 

Objective To assess the capacity for research collaboration and implementation research in strengthening networks and institutions in developing countries.

Methods Bibliometric analysis of implementation research on diseases of poverty in developing countries from 2005 to 2010 through systematically searching bibliographic databases. Methods identified publication trends, participating institutions and countries and the cohesion and centrality of networks across diverse thematic clusters.

Results Implementation research in this field showed a steadily growing trend of networking, although networks are loose and a few institutions show a high degree of centrality. The thematic clusters with greatest cohesion were for tuberculosis and malaria.

Conclusions The capacity to produce implementation research on diseases of poverty is still low, with the prominence of institutions from developed countries. Wide ranges of collaboration and capacity strengthening strategies have been identified which should be put into effect through increased investments.

#### Child health

**Reaching Millennium Development Goal 4 – The Gambia (pages 1314–1325)** Momodou Jasseh, Emily L. Webb, Shabbar Jaffar, Stephen Howie, John Townend, Peter G. Smith, Brian M. Greenwood and Tumani Corrah

Article first published online: 24 JUN 2011 | DOI: 10.1111/j.1365-3156.2011.02809.x *Summary* 

Objective To describe how, through a DSS in a rural area of The Gambia, it has been possible to measure substantial reductions in child mortality rates and how we investigated whether the decline paralleled the registered fall in malaria incidence in the country.

Methods Demographic surveillance data spanning 19.5 years (1 April 1989–30 September 2008) from 42 villages around the town of Farafenni, The Gambia, were used to estimate childhood mortality rates for neonatal, infant, child (1–4 years) and

under-5 age groups. Data were presented in five a priori defined time periods, and annual rates per 1000 live births were derived from Kaplan–Meier survival probabilities.

Results From 1989–1992 to 2004–2008, under-5 mortality declined by 56% (95% CI: 48–63%), from 165 (95% CI: 151–181) per 1000 live births to 74 (95% CI: 65–84) per 1000 live births. In 1- to 4-year-olds, mortality during the period 2004–2008 was 69% (95% CI: 60–76%) less than in 1989–1992. The corresponding mortality decline in infants was 39% (95% CI: 23–52%); in neonates, it was 38% (95% CI: 13–66%). The derived annual under-5 mortality rates declined from 159 per 1000 live births in 1990 to 45 per 1000 live births in 2008, thus implying an attainment of MDG4 seven years in advance of the target year of 2015.

Conclusion Achieving MDG4 is possible in poor, rural areas of Africa through widespread deployment of relatively simple measures that improve child survival, such as immunisation and effective malaria control.

#### Vaccine

http://www.sciencedirect.com/science/journal/0264410X Volume 29, Issue 42 pp. 7219-7284 (23 September 2011) The Development of Dengue Vaccines Edited by Beth-Ann Coller, Alan D.T. Barrett and Stephen J. Thomas Volume 29, Issue 41 pp. 7115-7218 (22 September 2011) Vaccine Technology III: Advances in Vaccine Technology [Reviewed last week]

#### Value in Health

September 2011, Vol. 14, No. 6 http://www.valueinhealthjournal.com/home [No relevant content]