Vaccines: The Week in Review

25 April 2011

Center for Vaccine Ethics & Policy

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 http://centerforvaccineethicsandpolicy.wordpress.com/. This blog allows full-texting searching of some 1,200 items.

Comments and suggestions should be directed to
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WHO promoted *World Malaria Day — A Day to Act* (25 April 2011) as which "heralds the international community's renewed efforts make progress towards zero malaria deaths by 2015." WHO said malaria stakeholders "will continue to report on the remaining challenges to reach the 2010 target of universal coverage of malaria treatment and prevention," as called for by the UN Secretary-General, Ban Ki-moon.

http://www.rollbackmalaria.org/worldmalariaday/index.html

NIH statement on World Malaria Day

April 25, 2011

http://www.nih.gov/news/health/apr2011/niaid-20.htm

WHO outlined details of what was described as a "landmark" agreement "to ensure that, in a pandemic, influenza virus samples will be shared with partners who need the information to take steps to protect public health." The agreement was reached by the WHO Open-Ended Working Group of Member States on Pandemic Influenza Preparedness (OEWG/PIP), convened under the authority of the World Health Assembly and coordinated by WHO. The new framework includes "certain binding legal regimes for WHO, national influenza laboratories around the world and industry partners in both developed and developing countries that will strengthen how the world responds more effectively with the next flu pandemic. By making sure that the roles and obligations among key players are better established than in the past -

including through the use of contracts - the framework will help increase and expedite access to essential vaccines, antivirals and diagnostic kits, especially for outbreak areas."

The WHO overview noted that "during an influenza outbreak, knowing the exact makeup of the virus is critical for monitoring the spread of the disease, for knowing the potential of the virus to cause a pandemic and for creating the life-saving vaccines as well as other technological benefits. However, developing countries often have limited access to these vaccines for several reasons:

- they often do not have their own manufacturing capacity,
- global supplies can be limited when there is a surge in demand as is seen during pandemics.
- vaccines can often be priced out of the reach of some countries.

"The new framework will help ensure more equitable access to affordable vaccines and at the same time, also guarantee the flow of virus samples into the WHO system so that the critical information and analyses needed to assess public health risks and develop vaccines are available." Dr Margaret Chan, Director-General of WHO, commented, "This has been a long journey to come to this agreement, but the end result is a very significant victory for public health. It has reinforced my belief that global health in the 21st century hinges on bringing governments and key stakeholders like civil society and industry together to find solutions."

WHO said the working group was co-chaired by Ambassador Juan José Gomez-Camacho (Mexico) and Ambassador Bente Angell-Hansen (Norway) and included the participation of WHO Member States, industry representatives, civil society and other organizations involved in influenza pandemic preparedness. The agreed upon framework will be presented to the World Health Assembly in May for its consideration and approval. The negotiations by 193 WHO Member States began in November 2007 amid concerns that the avian influenza (H5N1) virus in South-East Asia could become a human pandemic, WHO said.

The text of the agreement is available at:

http://www.who.int/entity/csr/disease/influenza/pip framework 16 april 2011.pdf http://www.who.int/mediacentre/news/releases/2011/pandemic_influenza_prep_201104 17/en/index.html

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) said it welcomes the outcome of the WHO Open-Ended Working Group of Member States on Pandemic Influenza Preparedness (OEWG/PIP). The Working Group has reached a decision that will result in an effective global system to prepare for potential future influenza pandemics, recognizing a shared responsibility to help secure the world against future pandemic influenza outbreaks. The IFPMA supports the reported principles of the decision, and awaits with interest the final report of the OEWG/PIP in order to comment on the detail of the framework. It will be crucial to have a system that allows for rapid access to pandemic viruses and for benefits to be allocated to those countries most in need...."

- "...IFPMA members made a commitment to the OEWG to ensure that vaccines and antivirals are made available for developing country use in the event of a future pandemic, pledging to:
- reserve at least 10% of pandemic vaccine manufacturing capacity on a real-time basis, for donation to the WHO and/or supply at tiered prices, to developing countries;
- reserve at least 10% of antiviral manufacturing capacity for donation to the WHO

and/or supply at tiered prices to developing countries.

"In addition, IFPMA members recognised the importance of local production of vaccines and antivirals in pandemic preparedness. Many research-based pharmaceutical companies are already investing in establishing manufacturing in several countries (Mexico, Brazil, China, Indonesia, Thailand) and funding significant capacity increases in developed countries – also to enable developing country supply. IFPMA members have given assurances to the OEWG/PIP that they will continue to explore such opportunities.

"During the OEWG/PIP consultations, individual IFPMA members confirmed that they were also willing to undertake voluntarily a selection of actions, including production capacity expansion and access to reverse genetics technology, dependent upon skills, knowledge, financial management, public health policy and national regulation.

"It would appear that the OEWG/PIP's approach to intellectual property rights is in line with WHO reports that have concluded that IPRs have presented no barrier to supply of vaccines and antivirals to developing countries. IFPMA members will continue to ensure that intellectual property rights do not present a barrier at the next pandemic. The IFPMA gave the Working Group assurances that their members were prepared to consider, when appropriate, flexible approaches to meet this goal.

"The commitments tabled at the OEWG/PIP by IFPMA members have considerable monetary value and represent a highly significant contribution to global preparedness for a future pandemic. "It is important that they are built upon with proportionate action by other stakeholders. We believe that national governments should play a crucial role in ensuring vaccines reach their populations, including immunization policy of seasonal influenza as advised by the WHO" said Eduardo Pisani, adding "This would need to be accompanied by regulatory procedures, country surveillance, health system infrastructure, and rules for transfer of viruses to build on the significant contributions to the global pandemic made by IFPMA members."

http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=13824

WHO announced details of Immunization Week noting that "for the first time, about 180 countries and territories across the WHO regions of Africa, the Americas, Eastern Mediterranean, Europe and the Western Pacific are taking part. WHO said that during immunization week "outreach teams visit communities with limited access to regular health services such as those living in remote areas, urban fringes and internally displaced people to administer vaccines. Teams carry out large-scale vaccination campaigns against diseases like measles and polio."

- <u>WHO Director-General video message on immunization week</u> [Streaming wmv 03:15]

Related links

- Immunization Week 2011
- African Vaccination Week
- Vaccination Week in the Americas
- Vaccination Week in the Eastern Mediterranean
- European Immunization Week
- Vaccination Week in the Western Pacific

http://www.who.int/features/2011/immunization_week/en/index.html

Assistant surgeon general and director of the Centers for Disease Control and Prevention's National Center for Immunization and Respiratory Diseases **Dr. Anne Schuchat announced National Infant Immunization Week (NIIW) 2011 kicking off Saturday, 23 April 23.** Dr. Schuchat noted, "Infant immunizations have had an enormous impact on improving children's health over the past century. Vaccine-preventable diseases can be serious—even deadly—especially for infants and young children. Fortunately, most parents today have never seen first-hand the devastating consequences that vaccine-preventable diseases have on a family or community. Today, immunization rates are at or near record highs and routine childhood immunizations save 42,000 lives, prevent 20 million cases of disease and save 13.6 billion dollars in medical costs for each birth cohort.

"While vaccine-preventable diseases are not common in the U.S., they persist around the world, so it is important that we continue to protect our children with vaccines. Outbreaks of vaccine-preventable diseases can and do occur in this country. Last year in the U.S., there were more than 22,000 cases of whooping cough, and 26 deaths were reported – 22 of these deaths were in children younger than 1 year old. Outbreaks of measles are at record levels in Europe and the US is experiencing a record number of imported cases this year, raising the threat of spread in our own communities.

"These outbreaks serve as important reminders to ensure that all children are fully immunized on time according to the recommended immunization schedule. "Not receiving all doses of a vaccine leaves your child vulnerable to serious diseases like measles and whooping cough."

http://www.cdc.gov/media/releases/2011/s0422 infantimmunization.html

Alex Palacios, GAVI Special Representative, delivered a statement before the House Appropriations Sub-committee on State and Foreign Operations, United States House of Representatives, requesting "that the **Subcommittee recommend at least US\$115** million under the Global Health account for a **U. S. Contribution to the GAVI** Alliance in fiscal year 2012. The Administration for fiscal year 2012 has requested funding for GAVI at the \$115 million level. He also requested that the Subcommittee recommend "at least the Administration's request of US\$849 million for the Global Health account for Child Survival and Maternal Health..."

"...GAVI and its partners now face a serious challenge to secure the financing necessary to essentially meet the aspirations of poor countries and to improve the health and wellbeing of their children. Globally, GAVI will require on average an additional \$750 million per year from all sources worldwide between now and 2015 to introduce new vaccines to prevent pneumonia and diarrhea while sustaining other immunization programs.

"With additional resources GAVI can, over the next five years, ensure that four million future deaths will be averted, and over 256 million additional children vaccinated against diseases that kill or disable. We recognize this represents a significant challenge for the U.S. and other donors facing fiscal deficits and constraints. However, we know also that the U.S. Congress and the administration are seeking to support effective and efficient development programs and GAVI, with only 5 % overhead and a small staff, represents,

as Bill Gates would say, good value for the money and a good investment for the American people...."

http://www.gavialliance.org/media_centre/statements/alex_palacios.php

GAVI issued a statement on its strategy for 2011-2015 which "includes an explicit goal to shape vaccine markets," noting that with its procurement partners it will achieve this goal "through efficient procurement of quality vaccines while ensuring sustainable supply at affordable prices to GAVI countries." GAVI-funded vaccines "now account for nearly half of the total value of UNICEF's vaccine procurement, where UNICEF itself represents about 40% of the global volume of vaccine doses. These large volumes have helped promote the entry of vaccine manufacturers, particularly from emerging economies. Over the period 2000-2009, GAVI increased its supply base from eight manufacturers to 18 manufacturers in 2009, including 8 based in emerging markets."

GAVI said that to move towards "a more active market management approach," it is in the process of revising its supply and procurement strategy which will be reviewed by the GAVI Programme and Policy Committee in May 2011 and the GAVI Alliance Board in July 2011. GAVI also said it "recognizes the importance of timely, transparent and accurate information sharing on expected vaccine demand and supply dynamics. It therefore welcomes vaccine suppliers' agreement to make pricing information more transparent. UNICEF publishes the vaccine prices paid to individual manufacturers. A few suppliers have not agreed at this stage to share their price information, but UNICEF hopes to add this information in the future."

http://www.gavialliance.org/vision/supply/index.php

WHO released initial chapters of *The World Medicines Situation Report 2011* noting that this third edition "brings together new data on 24 key topics relating to pharmaceutical production and consumption, innovation, regulation and safety - in one place...Each chapter of this report is written by a different author. Chapters are being published electronically, in batches, between April and December 2011. The new report updates the 1988 and 2004 reports."

Table of Contents

Chapters

- Introduction
- Global health trends: global burden of disease and pharmaceutical needs
- Pharmaceutical consumption Expected June 2011
- Medicine expenditures Expected June 2011
- Financing medicines
- Medicines prices, availability and affordability pdf. 657 kb Released April 2011
- Access to medicines at the household level (access to health care and medicines: burden of expenditures and risk protection)
- Research and development of medicines
- Intellectual property, trade and medicines
- Regulation of medicines

- Quality of medicines: the challenge of globalization
- Pharmacovigilance & safety of medicines Expected June 2011
- Selection of essential medicines Expected June 2011
- Rational use of medicines pdf. 245 kb -- Annexes Released April 2011
- Medicines Information and regulation of promotion
- Procurement of medicines Expected June 2011
- Storage and supply chain management of medicines
- <u>Traditional medicines: global situation, issues and challenges pdf. 180 kb</u> Released April 2011
- Access to controlled medicines pdf. 262 kb Released April 2011
- Good governance of pharmaceutical Sector pdf. 221 kb Released April 2011
- Human resources in pharmaceuticals
- Access to medicines as part of the right to health Expected June 2011
- National medicines policy
- Conclusion

http://www.who.int/medicines/areas/policy/world_medicines_situation/en/index.html

The U.S. Food and Drug Administration released *Strategic Priorities 2011 – 2015: Responding to the Public Health Challenges of the 21st Century,*

described as the final version of a strategic priorities document outlining the goals that will guide the agency and its 12,000 employees through 2015. The document "provides a vision of the FDA that includes:

- a modernized field of regulatory science that draws on innovations in science and technology to help ensure the safety and effectiveness of medical products throughout their life cycles,
- an integrated global food safety system focused on prevention and improved nutrition
- expanded efforts to meet the needs of special populations.

View PDF of full document

http://www.prnewswire.com/news-releases/fda-strategic-priorities-2011---2015-now-available-120302174.html

The **Weekly Epidemiological Record (WER) for 22 April 2011**, vol. 86, 17 (pp 161–172) includes:

- Update on human cases of highly pathogenic avian influenza A(H5N1) virus infection, 2010
- Summary analysis of 2010 survey of National Influenza Centres in the WHO Global Influenza Surveillance Network
- Executive Summary of the third meeting of National Influenza Centres, 30 November 3 December 2010
- Monthly report on dracunculiasis cases, January— February 2011http://www.who.int/entity/wer/2011/wer8617.pdf

The MMWR for April 22, 2011 / Vol. 60 / No. 15

- Grand Rounds: The Opportunity for and Challenges to Malaria Eradication
- Announcements: World Malaria Day --- April 25, 2011
- <u>Announcements: National Infant Immunization Week --- April 23--30, 2011</u> http://www.cdc.gov/mmwr/pdf/wk/mm6015.pdf

Twitter Watch

A selection of items of interest this week from a variety of twitter feeds. This capture is highly selective and by no means intended to be exhaustive.

globalfundnews The Global Fund

eBangladesh: 4th World Malaria Day 2011: Zero malaria deaths by 2015 http://bit.ly/faNPs9

gatesfoundation Gates Foundation

Bill Gates Asks Families to Celebrate <u>#Immunization</u> Week 2011: http://gates.ly/i3JLed
#vaccines

MalariaVaccine PATH MVI

A perspective on World <u>#Malaria</u> Day from MVI Director Dr. Christian Loucq: http://bit.ly/f6q3fm

CDCgov CDC.gov

Next week is National Infant Immunization Week! Protect your baby from serious diseases—find out how! #NIIW http://go.usa.gov/bil

CDCgov CDC.gov

Apr 24 is World Meningitis Day. Do you know symptoms of the disease? http://go.usa.gov/Thl

NIAIDNews NIAID News

The road to an <u>#AIDS</u> vaccine: New NIAID article proposes adaptive <u>#clinicaltrial</u> designs to speed vaccine development: http://go.usa.gov/TLm

rotary Rotary International

by EndPolioNow

Give a talk on polio based on The Rise and Fall of Poliomyelitis. Includes timeline, charts & case for eradication. http://cot.ag/dOSnCx

FightingMalaria Malaria Consortium

Financial Times special report on combating malaria out tomorrow: http://tinyurl.com/4xmel9c

GAVIAlliance GAVI Alliance

News Update: GAVI request for US funding... - GAVI request for US funding...

http://ow.ly/1cgvHo

GAVIAlliance GAVI Alliance

We need 24,187 more signers to reach our goal. Act now and help us spread the word: http://one.org/international/actnow/vaccines/

sabinvaccine Sabin Vaccine Inst.

Dengue Vaccine Initiative partner discusses the demand for a <u>#dengue</u> vaccine: http://bit.ly/hjPQ5S

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

April 19, 2011; 154 (8) http://www.annals.org/content/current [No relevant content]

British Medical Bulletin

Volume 97 Issue 1 March 2011 http://bmb.oxfordjournals.org/content/current [Reviewed earlier]

British Medical Journal

23 April 2011 Volume 342, Issue 7803 http://www.bmj.com/content/current

News

"Vaccine hesitancy" means scientists need to be more honest about risks

Matthew Limb

Extract

Global vaccination programmes are on the brink of a successful new era, but they could yet be undermined by challenges, including a potential crisis of public trust, say experts. A seminar heard how "vaccine hesitancy," poor healthcare systems, and "unfair" pricing must be tackled to stop preventable diseases claiming millions more lives. The debate, on vaccines and the opportunities they offer for global health, was held at the London

School of Hygiene and Tropical Medicine on 13 April. Speakers included specialists in the fields of vaccines development, immunisation strategy, and international aid and development....

Clinical Infectious Diseases

Volume 52 Issue 10 May 15, 2011

http://www.journals.uchicago.edu/toc/cid/current

ARTICLES AND COMMENTARIES

Advances in Pneumococcal Disease Prevention: 13-Valent Pneumococcal Conjugate Vaccine for Infants and Children

Peter R. Paradiso

Abstract

A 13-valent pneumococcal conjugate vaccine (PCV13), developed with the same chemistry used for the 7-valent PCV vaccine (PCV7) and with the goal of expanding serotype coverage, was clinically evaluated in the United States and Europe and found to induce capsular-specific antibody responses comparable to those of PCV7 for the common serotypes, with robust responses to the 6 additional serotypes. In addition, PCV13 has a similar safety profile to PCV7 and can be given routinely to infants and children, ideally as a 3-dose primary series in the first year of life, with a booster dose in the second year. Children who have initiated their vaccination program with PCV7 can transition to PCV13 at any point in the schedule. Children aged ≥15 months who have been completely vaccinated with PCV7 can receive a single dose of PCV13 to induce immunity to the 6 additional serotypes.

Cost Effectiveness and Resource Allocation

(accessed 24 April 2011) http://www.resource-allocation.com/ [No relevant content]

Emerging Infectious Diseases

Volume 17, Number 4-April 2011 http://www.cdc.gov/ncidod/EID/index.htm [Reviewed earlier]

Health Affairs

April 2011; Volume 30, Issue 4 http://content.healthaffairs.org/content/30/2.toc [Reviewed earlier; No relevant content]

Health Economics, Policy and Law

Volume 6 - Issue 02

http://journals.cambridge.org/action/displayJournal?jid=HEP

[Reviewed earlier; No relevant content]

Human Vaccines

Volume 7, Issue 4 April 2011 http://www.landesbioscience.com/journals/vaccines/toc/volume/7/issue/4/ [Reviewed earlier]

JAMA

April 20, 2011, Vol 305, No. 15, pp 1511-1610 http://jama.ama-assn.org/current.dtl

Commentary Medicine and Law

ONLINE FIRST

JAMA. 2011;305(15):1585-1586. Published online March 29, 2011. doi: 10.1001/jama.2011.418

Reforming the World Health Organization

Devi Sridhar, DPhil; Lawrence O. Gostin, JD

In December 2010, Jack Chow, 1 the former World Health Organization (WHO) assistant director-general, asked, "Is the WHO becoming irrelevant?" A month later, the WHO's executive board considered the agency's future within global health governance. After a year-long consultation with member states on its financing, Director-General Margaret Chan called the WHO overextended and unable to respond with speed and agility to today's global health challenges. 2

The crisis in leadership is not surprising to those familiar with the WHO. As its first specialized agency, the United Nations (UN) endowed the WHO with extensive normative powers to act as the directing and coordinating authority on international health. Yet modern global health initiatives (eg, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the GAVI Alliance [formerly the Global Alliance for Vaccines and Immunisation]), bilateral programs (eg, US President's Emergency Plan for AIDS Relief [PEPFAR]), and well-funded philanthropies (eg, the Bill & Melinda Gates Foundation) often overshadow the agency. The WHO can be subject to political pressure, and its relationship with industry and civil society is uncertain. 3

Given the importance of global health cooperation, few would dispute that a stronger, more effective WHO would benefit all. The WHO's internal reform agenda must be bold to ensure its future. In this Commentary, we offer 5 proposals for reestablishing the agency's leadership....

http://jama.ama-assn.org/content/305/15/1585.full

Journal of Infectious Diseases

Volume 203 Issue 10 May 15, 2011
http://www.journals.uchicago.edu/toc/jid/current
[Reviewed earlier; No relevant content]

The Lancet

Apr 23, 2011 Volume 377 Number 9775 Pages 1379 - 1464

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

Comment

Pay-for-performance and the Millennium Development Goals

Dominic Montagu, Gavin Yamey

Only 23 countries are on course to reach Millennium Development Goal (MDG) 5: to reduce maternal mortality ratio by 75% by 2015.1 One reason for this slow progress is that, in many low-income and middle-income countries, most poor women deliver at home without skilled attendance, and thus face a high rate of obstetric complications. Our recent analysis, for example, found that in sub-Saharan Africa, from 2003 to the present, 78% of births among the poorest women occurred at home, of which 56% were unattended.

Health Policy

Priority actions for the non-communicable disease crisis

Robert Beaglehole, Ruth Bonita, Richard Horton, Cary Adams, George Alleyne, Perviz Asaria, Vanessa Baugh, Henk Bekedam, Nils Billo, Sally Casswell, Michele Cecchini, Ruth Colagiuri, Stephen Colagiuri, Tea Collins, Shah Ebrahim, Michael Engelgau, Gauden Galea, Thomas Gaziano, Robert Geneau, Andy Haines, James Hospedales, Prabhat Jha, Ann Keeling, Stephen Leeder, Paul Lincoln, Martin McKee, Judith Mackay, Roger Magnusson, Rob Moodie, Modi Mwatsama, Sania Nishtar, Bo Norrving, David Patterson, Peter Piot, Johanna Ralston, Manju Rani, K Srinath Reddy, Franco Sassi, Nick Sheron, David Stuckler, Il Suh, Julie Torode, Cherian Varghese, Judith Watt, for NCD Action Group and the NCD Alliance

Preview

The UN High-Level Meeting on Non-Communicable Diseases (NCDs) in September, 2011, is an unprecedented opportunity to create a sustained global movement against premature death and preventable morbidity and disability from NCDs, mainly heart disease, stroke, cancer, diabetes, and chronic respiratory disease. The increasing global crisis in NCDs is a barrier to development goals including poverty reduction, health equity, economic stability, and human security. The Lancet NCD Action Group and the NCD Alliance propose five overarching priority actions for the response to the crisis—leadership, prevention, treatment, international cooperation, and monitoring and accountability—and the delivery of five priority interventions—tobacco control, salt reduction, improved diets and physical activity, reduction in hazardous alcohol intake, and essential drugs and technologies...

The Lancet Infectious Disease

Apr 2011 Volume 11 Number 4 Pages 253 - 332 http://www.thelancet.com/journals/laninf/issue/current [Reviewed earlier]

Medical Decision Making (MDM)

March/April 2011; 31 (2) http://mdm.sagepub.com/content/current [Reviewed earlier]

Nature

Volume 472 Number 7343 pp259-384 21 April 2011 http://www.nature.com/nature/current_issue.html [No relevant content]

Nature Medicine

April 2011, Volume 17 No 4 http://www.nature.com/nm/index.html [Reviewed earlier]

New England Journal of Medicine

April 21, 2011 Vol. 364 No. 16

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

Perspective

Safety, Supply, and Suits — Litigation and the Vaccine Industry

Aaron Kesselheim, M.D., J.D., M.P.H.

N Engl J Med 2011; 364:1485-1487 April 21, 2011

[Free full text: http://www.nejm.org/doi/full/10.1056/NEJMp1102182

The Pediatric Infectious Disease Journal

May 2011 - Volume 30 - Issue 5 pp: A9-A10,365-450,e75-e87 http://journals.lww.com/pidj/pa ges/currenttoc.aspx [No relevant content]

Pediatrics

April 2011 / VOLUME 127 / ISSUE 4 http://pediatrics.aappublications.org/current.shtml [Reviewed earlier; No relevant content]

Pharmacoeconomics

May 1, 2011 - Volume 29 - Issue 5 pp: 361-454

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

Commentaries

<u>Health Economic and Infectious Disease Modelling: A Guide to Merging</u>
Streams

Anonychuk, Andrea; Krahn, Murray

Pharmacoeconomics. 29(5):367-369, May 1, 2011.

doi: 10.2165/11589240-000000000-00000

Practical Application

Modelling the Epidemiology of Infectious Diseases for Decision Analysis: A Primer

Jit, Mark; Brisson, Marc

Pharmacoeconomics. 29(5):371-386, May 1, 2011.

doi: 10.2165/11539960-0000000000-00000

PLoS Medicine

(Accessed 24 April 2011)

http://medicine.plosjournals.org/perlserv/?request=browse&issn=1549-1676&method=pubdate&search_fulltext=1&order=online_date&row_start=1&limit=10&document_count=1533&ct=1&SESSID=aac96924d41874935d8e1c2a2501181c#results

Decline in Diarrhea Mortality and Admissions after Routine Childhood

Rotavirus Immunization in Brazil: A Time-Series Analysis

Greice Madeleine Ikeda do Carmo, Catherine Yen, Jennifer Cortes, Alessandra Araújo Siqueira, Wanderson Kleber de Oliveira, Juan José Cortez-Escalante, Ben Lopman, Brendan Flannery, Lucia Helena de Oliveira, Eduardo Hage Carmo, Manish Patel Research Article, published 19 Apr 2011

doi:10.1371/journal.pmed.1001024

Abstract

Background

In 2006, Brazil began routine immunization of infants <15 wk of age with a single-strain rotavirus vaccine. We evaluated whether the rotavirus vaccination program was associated with declines in childhood diarrhea deaths and hospital admissions by monitoring disease trends before and after vaccine introduction in all five regions of Brazil with varying disease burden and distinct socioeconomic and health indicators. Methods and Findings

National data were analyzed with an interrupted time-series analysis that used diarrhearelated mortality or hospitalization rates as the main outcomes. Monthly mortality and admission rates estimated for the years after rotavirus vaccination (2007–2009) were compared with expected rates calculated from pre-vaccine years (2002–2005), adjusting for secular and seasonal trends. During the three years following rotavirus vaccination in Brazil, rates for diarrhea-related mortality and admissions among children <5 y of age were 22% (95% confidence interval 6%–44%) and 17% (95% confidence interval 5%–27%) lower than expected, respectively. A cumulative total of \sim 1,500 fewer diarrhea deaths and 130,000 fewer admissions were observed among children <5 y during the three years after rotavirus vaccination. The largest reductions in deaths (22%–28%) and admissions (21%–25%) were among children younger than 2 y, who had the highest rates of vaccination. In contrast, lower reductions in deaths (4%) and admissions (7%) were noted among children two years of age and older, who were not age-eligible for vaccination during the study period.

Conclusions

After the introduction of rotavirus vaccination for infants, significant declines for three full years were observed in under-5-y diarrhea-related mortality and hospital admissions for diarrhea in Brazil. The largest reductions in diarrhea-related mortality and hospital admissions for diarrhea were among children younger than 2 y, who were eligible for vaccination as infants, which suggests that the reduced diarrhea burden in this age group was associated with introduction of the rotavirus vaccine. These real-world data are consistent with evidence obtained from clinical trials and strengthen the evidence base for the introduction of rotavirus vaccination as an effective measure for controlling severe and fatal childhood diarrhea.

Science

22 April 2011 vol 332, issue 6028, pages 383-500 http://www.sciencemag.org/current.dtl [No relevant content]

Science Translational Medicine

20 April 2011 vol 3, issue 79

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

Perspectives - HIV

HIV-1 Vaccines and Adaptive Trial Designs

Lawrence Corey, Gary J. Nabel, Carl Dieffenbach, Peter Gilbert, Barton F. Haynes, Margaret Johnston, James Kublin, H. Clifford Lane, Giuseppe Pantaleo, Louis J. Picker, and Anthony S. Fauci

20 April 2011: 79ps13

Abstract

Developing a vaccine against the human immunodeficiency virus (HIV) poses an exceptional challenge. There are no documented cases of immune-mediated clearance of HIV from an infected individual, and no known correlates of immune protection. Although nonhuman primate models of lentivirus infection have provided valuable data about HIV pathogenesis, such models do not predict HIV vaccine efficacy in humans. The combined lack of a predictive animal model and undefined biomarkers of immune protection against HIV necessitate that vaccines to this pathogen be tested directly in clinical trials. Adaptive clinical trial designs can accelerate vaccine development by rapidly screening out poor vaccines while extending the evaluation of efficacious ones, improving the characterization of promising vaccine candidates and the identification of correlates of immune protection.

Vaccine

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

Volume 29, Issue 21 pp. 3725-3826 (12 May 2011) Short Communication

Awareness, attitudes and behavior of hospital healthcare workers towards a mandatory vaccination directive: Two years on

Pages 3734-3737

Holly Seale, Julie Leask, C. Raina MacIntyre

Abstract

In 2007, the state of New South Wales, Australia instituted a policy directive with compulsory provisions for health care workers to be vaccinated. This study sought to identify staff awareness and attitudes two years after it was implemented. It involved a self administered paper-based questionnaire of HCWs in two tertiary-referral teaching hospitals in Sydney, Australia in 2009. In the early phase, general awareness of the policy was incomplete and detailed knowledge was poor. However, support levels were high. Two years later, while the respondents indicated that they were aware that there was a policy in place, very few of the respondents were able to accurately describe its

requirements. Regardless of the level of knowledge, support for the policy was still high (83% vs. 91%, respectively). Despite the high levels of general support for the vaccine policy directive in NSW, this study indicates that including influenza vaccination into the policy could be challenging.

Regular Papers

Poliomyelitis outbreaks in Angola genetically linked to India: Risk factors and implications for prevention of outbreaks due to wild poliovirus importations

Original Research Article

Pages 3760-3766

Sarah Kidd, James L. Goodson, Javier Aramburu, Alda Morais, Abou Gaye, Kathleen Wannemuehler, Joanna Buffington, Sue Gerber, Steven Wassilak, Amra Uzicanin *Abstract*

We conducted an investigation of two outbreaks of poliomyelitis in Angola during 2007–2008 due to wild poliovirus (WPV) genetically linked to India. A case-control study including 27 case-patients and 76 age- and neighborhood-matched control-subjects was conducted to assess risk factors associated with paralytic poliomyelitis, and epidemiologic links to India were explored through in-depth case-patient interviews. In multivariable analysis, case-patients were more likely than control-subjects to be undervaccinated with fewer than four routine doses of oral poliovirus vaccine (adjusted matched odds ratio [aMOR], 4.1; 95% confidence interval [CI], 1.2–13.6) and have an adult household member who traveled outside the province of residence in the 2 months preceding onset of paralysis (aMOR, 3.2; 95% CI, 1.2–8.6). No epidemiologic link with India was identified. These findings underscore the importance of routine immunization to prevent outbreaks following WPV importations and suggest a possible role of adults in sustaining WPV transmission.

<u>Human papillomavirus (HPV) vaccine uptake and completion at an urban</u> hospital

Original Research Article

Pages 3767-3772

Nicholas H. Schluterman, Mishka Terplan, Alison D. Lydecker, J. Kathleen Tracy Abstract

Background

Despite the benefit of the human papillomavirus (HPV) vaccine in preventing cervical cancer, fewer than half of eligible young women in the United States have initiated the three-vaccine series. Among those who initiate HPV vaccination, large proportions do not complete the three-dose regimen.

Purpose

To evaluate racial and health insurance-related disparities in HPV vaccination. Methods

We analyzed outpatient claims data for 8069 patients, ages 9–26 years, who had gynecologic visits at the University of Maryland Medical Center outpatient clinic from August 2006 to January 2010.

Results

Thirty-five percent of our sample initiated the vaccine series, including 91% of those ages 9–13. Only 11% of the sample and 33% of the 9–13 age group completed the 3 dose series. A higher proportion of blacks than whites (38% vs. 32%; p < 0.01) initiated, and 11% and 12%, respectively, of each race completed. Lower age was strongly correlated with uptake. After adjustment for insurance, blacks were less than

half as likely as whites to complete the series in all age groups, and had 0.35 the odds (95% CI 0.26–0.46) of adherence. The uninsured had much lower race-adjusted odds than insured groups for initiation, but had similar adherence rates. Publicly insured individuals were more likely than the privately insured to complete all 3 doses. Conclusions

Of the population of gynecologic service seekers seen at our university-based outpatient practice clinics, a significant minority initiate but do not complete the HPV vaccine series. More blacks than whites initiate the series, but similar proportions of the two races complete. Lack of insurance appears to be a major barrier to initiation, despite free vaccination programs.

Vaccine

Volume 29, Issue 20 pp. 3625-3724 (9 May 2011)
2009-2010 seasonal and pandemic A (H1N1) influenza vaccination among healthcare workers

Original Research Article

Pages 3703-3707

Maria Teresa del Campo, Villamor José Miguel, Cáceres Susana, Gómez Ana, Ledesma Gregoria, Mahíllo-Fernández Ignacio

Abstract

Influenza vaccination recommendations are traditionally met with low compliance by healthcare workers (HCWs). The aim of this study is to analyze influenza vaccination among HCWs following a vaccination strategy characterized by an increased effort to maximize the hospital vaccination rate. For this, 2009-2010 seasonal and pandemic influenza vaccination rates among 2739 HCWs at a tertiary university hospital were evaluated. The seasonal influenza vaccination rate was 26.7% (48.3% increase vs. 2008-2009, p=0.0000), and 14.8% in the case of pandemic influenza. HCWs with direct patient contact showed similar seasonal (25.7%) and pandemic (15.4%) influenza vaccination rates compared to the overall rates. Physician vaccination displayed the highest rate, showing significant differences vs. total rate (38.3%, p=0.0007 for seasonal, and 32.2%, p=0.0000 for pandemic influenza). The areas in which the vaccination strategy was most active reflected a significant increase (32.6%, p=0.0056 for seasonal, and 25.2%, p=0.0000 for pandemic influenza). It therefore appears that more active campaigns might increase influenza vaccination among HCWs.

Vaccine

Volume 29, Issue 19 pp. 3513-3624 (27 April 2011)

Regular Papers

Estimating the cost-effectiveness of a national program to eliminate disparities in influenza vaccination rates among elderly minority groups

Original Research Article

Pages 3525-3530

Constantinos I. Michaelidis, Richard K. Zimmerman, Mary Patricia Nowalk, Kenneth J. Smith

Abstract

Influenza is a major cause of preventable morbidity and mortality in the United States, particularly among the elderly. Yet, there remain large disparities in influenza vaccination rates across elderly Caucasian (70%), African-American (50%) and Hispanic

(55%) populations, with substantial mortality consequences. In this study, we built a decision-analysis model to estimate the cost-effectiveness of a hypothetical national vaccination program designed to eliminate these disparities in influenza vaccination rates. Taking a societal perspective, we developed a Markov model with a one-year cycle length and lifetime time horizon. In the base case, we conservatively assumed that the cost of promoting the vaccination program was \$10 per targeted elder per year and that by year 10, the vaccination rate of the elderly African-American and Hispanic populations would equal the vaccination rate of the elderly Caucasian population (70%). The cost-effectiveness of the vaccination program compared to no vaccination program was \$48,617 per QALY saved. Probabilistic sensitivity analyses suggested that at willingness-to-pay thresholds of \$50,000 and \$100,000 per QALY saved, the likelihood of the vaccination program being cost-effective was 38% and 92%, respectively. In an analysis using conservative assumptions, we found that a hypothetical program to ameliorate disparities in influenza vaccination rates has a moderate to high likelihood of being cost-effective.

<u>Is vaccination coverage a good indicator of age-appropriate vaccination? A prospective study from Uganda</u>

Original Research Article

Pages 3564-3570

Lars T. Fadnes, Victoria Nankabirwa, Halvor Sommerfelt, Thorkild Tylleskär, James K. Tumwine, Ingunn M.S. Engebretsen and for the PROMISE-EBF Study Group Abstract

Background

Timely vaccination is important to protect children from common infectious diseases. We assessed vaccination timeliness and vaccination coverage as well as coverage of vitamin A supplementation in a Ugandan setting.

Methods and findings

This study used vaccination information gathered during a cluster-randomized trial promoting exclusive breastfeeding in Eastern Uganda between 2006 and 2008 (ClinicalTrials.gov no. NCT00397150). Five visits were carried out from birth up to 2 years of age (median follow-up time 1.5 years), and 765 children were included in the analysis. We used Kaplan–Meier time-to-event analysis to describe vaccination coverage and timeliness. Vaccination coverage at the end of follow-up was above 90% for all vaccines assessed individually that were part of the Expanded Program on Immunization (EPI), except for the measles vaccine which had 80% coverage (95%CI 76–83). In total, 75% (95%CI 71–79) had received all the recommended vaccines at the end of follow-up. Timely vaccination according to the recommendations of the Ugandan EPI was less common, ranging from 56% for the measles vaccine (95%CI 54–57) to 89% for the Bacillus Calmette–Guérin (BCG) vaccine (95%CI 86–91). Only 18% of the children received all vaccines within the recommended time ranges (95%CI 15–22). The children of mothers with higher education had more timely vaccination. The coverage for vitamin A supplementation at end of follow-up was 84% (95%CI 81–87).

Conclusions

Vaccination coverage was reasonably high, but often not timely. Many children were unprotected for several months despite being vaccinated at the end of follow-up. There is a need for continued efforts to optimise vaccination timeliness.

HPV vaccination in France: Uptake, costs and issues for the National Health Insurance

Original Research Article

Pages 3610-3616

Jean-Paul Fagot, Aurélie Boutrelle, Philippe Ricordeau, Alain Weill, Hubert Allemand Abstract

Introduction

Two vaccines for primary prevention of cervical cancer are available in France, Gardasil® and Cervarix®, since 2007 and 2008 respectively. Currently, the French guidelines indicate vaccination of girls aged 14 with a catch-up program for females from 15 to 23 years old. In France, the reimbursement rate for these vaccines is 65% of the vaccine price, resulting in Gardasil® being the fifth highest drug expenditure of the main scheme of the French National Health Insurance in 2008. The purpose of this study is to provide data on vaccination coverage and costs in France until 31 December 2009. In addition, the current vaccination coverage rate is compared with the coverage rates assumed in cost-effectiveness studies.

Methods

Data were extracted from the National Health Insurance Information System (SNIIRAM). The SNIIRAM records all reimbursements of medical costs to patients – including drugs – by the French public Health Insurance Schemes since 2004. The analysis was performed for the period of July 2007 until December 2009 using the data of the general scheme of National Health Insurance covering about 88% of the French population, i.e., 56.5 million people. Vaccination rates for one or three doses were determined for the target and catch-up population using the 2009 reference population from the general health insurance scheme as the denominator. Results

The cumulative number of doses reached 2,900,000 at the end of 2009. About 1,200,000 girls and young women have been reimbursed for at least one vaccine dose, of these 96.5% females aged 14–23 years. Among the target group, reimbursement for at least one dose remained low, from 50.8% for girls aged 14 years in 2007 to 41.7% and 20.5% for girls aged 14 years in 2008 and 2009 respectively. In terms of complete vaccination, only 33.3% of girls of the age of 14 years in 2007 and 23.7% in 2008 were reimbursed for 3 doses of HPV vaccine. The maximum uptake in the catch-up group for both 1 and 3 doses was observed for women born in 1992 (15 years in 2007) with 52.5% and 35.6% respectively.

Conclusion

Low rates of coverage have been observed both in the target and catch-up groups in France. Considering this, the cost-effectiveness of vaccination in combination with opportunistic screening or organized screening needs to be re-evaluated.

Are Kenyan healthcare workers willing to receive the pandemic influenza vaccine? Results from a cross-sectional survey of healthcare workers in Kenya about knowledge, attitudes and practices concerning infection with and vaccination against 2009 pandemic influenza A (H1N1), 2010

Original Research Article

Pages 3617-3622

Prisca A. Oria, Wycliffe Matini, Ian Nelligan, Gideon Emukule, Martha Scherzer, Beryl Oyier, Hezron N. Ochieng, Laura Hooper, Anne Kanyuga, Phillip Muthoka, Kathleen F. Morales, Charles Nzioka, Robert F. Breiman, Mark A. Katz *Abstract*

Over 1200 cases of 2009 pandemic influenza A H1N1 (pH1N1) have been identified in Kenya since the first case in June 2009. In April 2010 the Kenyan government launched a program to immunize high-risk groups and healthcare workers (HCWs) with pH1N1 vaccines donated by the World Health Organization. To characterize HCWs' knowledge, attitudes and practices regarding pH1N1 vaccination, we conducted a quantitative and qualitative survey in 20 healthcare facilities across Kenya between January 11 and 26, 2010. Of 659 HCWs interviewed, 55% thought there was a vaccine against pH1N1, and 89% indicated that they would receive pH1N1 vaccine if it became available. In focus group discussions, many HCWs said that pH1N1 virus infection did not cause severe disease in Kenyans and questioned the need for vaccination. However, most were willing to accept vaccination if they had adequate information on safety and efficacy. In order for the influenza vaccination campaign to be successful, HCWs must understand that pH1N1 can cause severe disease in Kenyans, that pH1N1 vaccination can prevent HCWs from transmitting influenza to their patients, and that the vaccine has been widely used globally with few recognized adverse events.

Value in Health

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