Vaccines: The Week in Review
21 February 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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Editor's Note: With this week's edition, we add three journals to our *Journal Watch* section below. Please share your suggestions for additional journals for coverage.
- Health Affairs is "the leading journal of health policy thought and research" which "explores health policy issues of current concern in both domestic and international spheres."
- Medical Decision Making (MDM) is "a peer-reviewed bi-monthly journal offering rigorous and systematic approaches to decision making that are designed to improve the health and clinical care of individuals and to assist with health policy development. MDM presents theoretical, statistical, and modeling techniques and methods from disciplines including decision psychology, health economics, clinical epidemiology, and evidence synthesis."
- Value in Health is "a multidisciplinary peer-reviewed journal reporting on evaluations of medical technologies including pharmaceuticals, biologics, devices, procedures, and other health care interventions. The Journal provides a scientific forum for communicating health economics and outcomes research methods and findings…"

The U.S. Department of Health and Human Services released a new National Vaccine Plan to "enhance coordination of all aspects of federal vaccine and immunization activities (and) to ensure that all Americans can access the preventive benefits of vaccines." HHS described that new plan as "a wide-ranging guide to innovating the nation's vaccine system. It addresses such issues as research and development, supply, financing, distribution, safety, global cooperation, and informed

decision-making among consumers and health care providers." This is the first update of the National Vaccine Plan since the original version in 1994.

Bruce Gellin, M.D., M.P.H., Director of the National Vaccine Program Office and Deputy Assistant Secretary for Health, said, "This plan is a 10-year vision for the nation to more effectively prevent infectious diseases and reduce adverse reactions to vaccines. The plan is national in scope. Implementation will require a well-organized effort among stakeholders, including federal, state and local policymakers, health care providers, manufacturers, academia, philanthropic organizations, and the public." HHS said next steps include "a series of regional meetings with stakeholders in the spring and summer of 2011, which will focus on how to implement the strategies laid out in the National Vaccine Plan. The final implementation plan will be completed by the end of 2011." Text of the new National Vaccine Plan: http://www.hhs.gov/nvpo/vacc_plan/. http://www.businesswire.com/news/home/20110216006036/en/HHS-releases-strategic-plan-advance-vaccine-immunization

The Bill & Melinda Gates Foundation announced that Dr. Tachi Yamada president of the Foundation's Global Health Program intends to retire from his position after serving for five years. Bill Gates, co-chair of the Gates Foundation, commented, "Tachi has done a great job of focusing our ability to create and deliver vaccines and other interventions to the people who need them the most. He has put our global health programs on a path to success, and we look forward to building on his work." Dr. Margaret Chan, Director-General of the World Health Organization, said, "Tachi's leadership has helped keep the global health community focused on results. He has built a long-lasting partnership with the WHO and we look forward to remaining deeply engaged with the Gates Foundation." The Foundation said Dr. Yamada will remain in his role until June and that a global search for his successor is underway. Dr. Yamada said, "It has been my greatest privilege to be able to impact the lives of so many people in need. I will always cherish the friendship and collaboration of my outstanding colleagues who have been my partners in this endeavor." http://www.gatesfoundation.org/press-releases/Pages/tachi-yamada-to-leave-110214.aspx

Dr. Rajiv Shah, Administrator of the United States Agency for International Development (USAID) presented the most recent David E. Barmes Global Health Lecture on Tuesday, 15 February 2011 at NIH in Bethesda, Maryland. In his remarks, Dr. Shah noted USAID is:

- Recommitting to the Millennium Development Goals by building sustainable governance and delivery systems to support healthy and productive lives.
- Investing in country-owned models of inclusive growth and development in a focused set of countries that are well-governed, economically stable, globally connected and market-oriented.
- Developing and delivering scientific and technological breakthroughs.

The recorded videocast of Dr. Shah's lecture is available here: Addressing Grand Challenges: The Role of Science in Global Health Development [VIDEO] The transcript is available here: Remarks by USAID Administrator Dr. Rajiv Shah
http://www.fic.nih.gov/news/events/barmeslecture.htm

The American Public Health Association adopted 17 policies at its 138th Annual Meeting 6-10 November 2010 in Denver. The newly adopted policies "address a broad range of public health concerns, from environmental health issues and public health education and workforce challenges to oral health prevention strategies and implications of immigration policy on public health outcomes." Included was:

201014 **Influenza vaccination of health workers** — Supports implementation of requirements for all health workers to receive an annual influenza vaccination. Urges providers, employers and other organizations to implement comprehensive infection control programs, including vaccination training and education, housekeeping and standard respiratory precautions in keeping with infection control standards. Emphasizes that vaccination of health workers is important for their own protection, not just patient safety.

The full text of all policies are available at:
http://www.apha.org/advocacy/policy/policysearch/
http://www.apha.org/about/news/pressreleases/2011/2010adoptedpolciesrelease.htm

The **Weekly Epidemiological Record (WER) for 18 February 2011**, vol. 86, 8 (pp 61–72) includes: Influenza A(H1N1) 2009 virus: current situation and postpandemic recommendations; Safety of rotavirus vaccines: postmarketing surveillance in the WHO Region of the Americas.
http://www.who.int/entity/wer/2011/wer8608.pdf

Twitter Watch

A selection of items of interest this week from a variety of twitter feeds from NGOs and other sources

gatesfoundation Gates Foundation
"We need a higher sense of urgency." --@BillGates on the fight against #HIV and #AIDS: http://bit.ly/gQvhLj

PATHtweets PATH
"Relenting in the effort to finally defeat #malaria would be an abdication of our responsibility."~ Dr. Christian Loucq http://ow.ly/3YEjM

CDCgov CDC.gov
Read the vision for vaccine science and policy over the next decade in @HHSgov's National #VaccinePlan http://bit.ly/wvW0p

PATHtweets PATH
Injections without needles? PATH and partners are bringing "jet injection" to developing-country immunization programs. http://ow.ly/3XGth

EndPolioNow EndPolioNow
A longtime skeptic in the war against polio, Dr. Henderson has changed his mind. #polio http://cot.ag/gIVdm9

TBVI_EU TBVI
by TropMed_IntHlth
How can we eliminate #tuberculosis? Progress in TB vaccine research - New blogs http://tiny.cc/c8ch8

PATHtweets PATH
@MalariaVaccine RTS,S is the first malaria vaccine candidate to ever reach large-scale Phase 3 clinical testing. http://ow.ly/3XFed

WHO_Europe WHO/Europe
by whonews
WHO Epidemiological Brief 12: Importation of Wild Poliovirus and Response Measures in the European Region http://bit.ly/i7m8OY

nytimeshealth NYTimes Health
by gatesfoundation
Can Polio Be Eradicated? A Skeptic Now Thinks So http://nyti.ms/f3bIgu

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. Our initial scan list includes the journals below. If you would like to suggest other titles, please write to David Curry at david.r.curry@centerforvaccineethicsandpolicy.org

Annals of Internal Medicine
February 15, 2011; 154 (4)
http://www.annals.org/content/current
[No relevant content]

British Medical Journal
19 February 2011 Volume 342, Issue 7794
http://www.bmj.com/content/current
Features
Vaccines: Global HPV vaccination
Sophie Arie
[Initial article language]

Most deaths from cervical cancer occur in countries without the resources to screen, treat, or vaccinate against the disease. Sophie Arie explores what's being done to make HPV vaccination available to low income countries

In roughly five years since they arrived on the market, vaccines against human papillomavirus (HPV), which causes cervical cancer, have been rapidly and widely adopted in countries that can afford to do so.

The United States and much of Europe have introduced vaccines for school age girls in addition to existing well established screening programmes for women. The vaccines —Cervarix, made by GlaxoSmithKline (GSK), and Gardasil, made by Merck—protect against the most common types of virus, which cause around 70% of all cervical cancers, but they are among the most expensive of all vaccines. Both companies say their prices reflect a major investment in research and development and relatively complex manufacturing processes. Pricing varies from country to country but the current price in the US for a three dose course of Cervarix is a little under $300 (£187; €222) for government health service providers and close to $360 for private healthcare providers.

In the developing world, however, the situation is very different. Nearly 530 000 women each year develop cervical cancer and 275 000 die from it. 2 More than 85% of those deaths occur in low and middle income countries, where cervical cancer is the most common type of cancer in women, but screening is usually available only to women who can afford it privately, and where there is little or no capacity to treat the disease, let alone the resources to invest in a vaccine.

More than 60% of women who contract the disease in the developing world die of it because of late detection. According to the World Health Organization, if current trends continue, the …

Clinical Infectious Diseases
Volume 52 Issue 5 March 1, 2011
http://www.journals.uchicago.edu/toc/cid/current
[Reviewed earlier]

Emerging Infectious Diseases
Volume 17, Number 2–February 2011
http://www.cdc.gov/ncidod/EID/index.htm
[Reviewed earlier]

Health Affairs
February 2011; Volume 30, Issue 2
http://content.healthaffairs.org/content/30/2.toc

Policy & Pharmaceuticals

What Are The Respective Roles Of The Public And Private Sectors In Pharmaceutical Innovation?

Bhaven N. Sampat and Frank R. Lichtenberg

Health Aff February 2011 30:2332-339; doi:10.1377/hlthaff.2009.0917

Abstract

What are the respective roles of the public and private sectors in drug development? This question is at the heart of some policy proposals, such as those that would give the government a share of profits from drugs at least partly developed with federal research dollars. This paper provides empirical data on these issues, using information included in the patents on drugs approved between 1988 and 2005. Overall, we find that direct government funding is more important in the development of "priority-review" drugs—sometimes described as the most innovative new drugs—than it is for "standard-review" drugs. Government funding has played an indirect role—for example, by funding basic underlying research that is built on in the drug discovery process—in almost half of the drugs approved and in almost two-thirds of priority-review drugs. Our analyses should help inform thinking about the returns on public research funding—a topic of long-standing interest to economists, policy makers, and health advocates.

Human Vaccines

Volume 7, Issue 2 February 2011

http://www.landesbioscience.com/journals/vaccines/toc/volume/7/issue/2/

[Reviewed earlier]

JAMA

February 16, 2011, Vol 305, No. 7, pp 645-732

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

Commentaries

A Historical Perspective on Clinical Trials Innovation and Leadership: Where Have the Academics Gone?

David L. DeMets,

Robert M. Califf

JAMA. 2011;305(7):713-714.doi:10.1001/jama.2011.175

[No abstract; initial article text per JAMA convention]

The randomized controlled trial (RCT), the gold standard for evaluating the balance of risk and benefit in medical therapies, first emerged as a key clinical research tool in the mid-20th century thanks to visionary leadership of agencies such as the US National Institutes of Health (NIH), the UK Medical Research Council, and academic research institutions. Since then, clinical trials activity has shifted from the NIH and academia into the purviews of the medical products industry and regulatory authorities. Recent emphasis on evidence-based medicine, patient-centered outcomes research, 1 and learning 2 and accountable 3 health care systems underscores the fact that most clinical trials fail to provide the evidence needed to inform medical decision making. However, the serious implications of this deficit are largely absent from public discourse, and a better balance between commercial interests and public health is critically needed….

Journal of Infectious Diseases
Volume 203 Issue 5 March 1, 2011
http://www.journals.uchicago.edu/toc/jid/current
[Reviewed earlier]

The Lancet
Feb 19, 2011 Volume 377 Number 9766 Pages 611 - 690
http://www.thelancet.com/journals/lancet/issue/current
[No relevant content]

The Lancet Infectious Disease
Feb 2011 Volume 11 Number 2 Pages 73 - 152
http://www.thelancet.com/journals/laninf/issue/current
[Reviewed earlier]

Medical Decision Making (MDM)
January/February 2011; 31 (1)
http://mdm.sagepub.com/content/current
Cost-Effectiveness Analysis: Methods
Steven M. Shechter
Treatment Evolution and New Standards of Care: Implications for Cost-Effectiveness Analysis
Med Decis Making January/February 2011 31: 35-42, first published on March 30, 2010
doi:10.1177/0272989X10364849
Abstract
Background. Traditional approaches to cost-effectiveness analysis have not considered the downstream possibility of a new standard of care coming out of the research and development pipeline. However, the treatment landscape for patients may change significantly over the course of their lifetimes. Objective. To present a Markov modeling framework that incorporates the possibility of treatment evolution into the incremental cost-effectiveness ratio (ICER) that compares treatments available at the present time.
Design. Markov model evaluated by matrix algebra. Measurements. The author evaluates the difference between the new and traditional ICER calculations for patients with chronic diseases facing a lifetime of treatment. Results. The bias of the traditional ICER calculation may be substantial, with further testing revealing that it may be either positive or negative depending on the model parameters. The author also performs probabilistic sensitivity analyses with respect to the possible timing of a new treatment discovery and notes the increase in the magnitude of the bias when the new treatment is likely to appear sooner rather than later. Limitations. The modeling framework is intended as a proof of concept and therefore makes simplifying assumptions such as time stationarity of model parameters and consideration of a single new drug discovery.
Conclusions. For diseases with a more active research and development pipeline, the possibility of a new treatment paradigm may be at least as important to consider in sensitivity analysis as other parameters that are often considered.
Infectious Disease Modeling

Joseph R. Egan, Ian M. Hall, and Steve Leach
Stamping Out Fires! Controlling Smallpox with Targeted Mass Vaccination
Med Decis Making January/February 2011 31: 69-78, first published on May 18, 2010
doi:10.1177/0272989X10369003
Abstract

Background. More than 30 years have now passed since the last naturally occurring case of smallpox; however, the variola virus still exists in at least 2 locations. The possibility that any clandestine stocks could be used for bioterrorism is a continuing concern for the public health community.

Objective. Mathematical modeling is used to assess the impact of mass vaccination following a smallpox release when either standard public health controls are failing or political/public opinion is urging more comprehensive methods. Two mass vaccination strategies are considered: a blanket nationwide campaign v. an approach targeted only at those geographic areas that experience smallpox cases. The study evaluates which intervention strategy results in the fewest combined disease and vaccine-related deaths.

Results. Outbreaks that go unnoticed until up to 50 cases have occurred are optimally controlled with targeted mass vaccination of the affected administrative districts in the majority of scenarios considered. The number of people vaccinated is approximately two thirds fewer than when implementing a nationwide campaign. Similar results arise when contact tracing is either highly unsuccessful or reduced in favor of reallocating limited resources for a policy of mass vaccination.

Conclusions. Reactive nationwide mass vaccination remains a suboptimal strategy for controlling an expanding smallpox outbreak in all but the most extreme circumstances. Rather, targeted mass vaccination of affected areas is likely to result in fewer deaths. The vaccines administered are also likely to be much fewer because they would probably be distributed to a much smaller number of districts, thus relieving pressure on potentially stretched public health systems.

Nature
Volume 470 Number 7334 pp305-430 17 February 2011
http://www.nature.com/nature/current_issue.html
[No relevant content]

Nature Medicine
February 2011, Volume 17 No 2
http://www.nature.com/nm/index.html
[Reviewed earlier]

New England Journal of Medicine
February 17, 2011 Vol. 364 No. 7
http://content.nejm.org/current.shtml
Original Articles
Safety of Influenza A (H1N1) Vaccine in Postmarketing Surveillance in China
X.-F. Liang and Others
Background

On September 21, 2009, China began administering vaccines, obtained from 10 different manufacturers, against 2009 pandemic influenza A (H1N1) virus infection in priority populations. We aimed to assess the safety of this vaccination program.
Full Text of Background...
Methods
We designed a plan for passive surveillance for adverse events after immunization with the influenza A (H1N1) vaccine. Physicians or vaccination providers were required to report the numbers of vaccinees and all adverse events to their local Center for Disease Control and Prevention (CDC), which then reported the data to the Chinese CDC through the online National Immunization Information System's National Adverse Event Following Immunization Surveillance System. Data were collected through March 21, 2010, and were verified and analyzed by the Chinese CDC.
Full Text of Methods...
Results
A total of 89.6 million doses of vaccine were administered from September 21, 2009, through March 21, 2010, and 8067 vaccinees reported having an adverse event, for a rate of 90.0 per 1 million doses. The age-specific rates of adverse events ranged from 31.4 per 1 million doses among persons 60 years of age or older to 130.6 per 1 million doses among persons 9 years of age or younger, and the manufacturer-specific rates ranged from 4.6 to 185.4 per 1 million doses. A total of 6552 of the 8067 adverse events (81.2%; rate, 73.1 per 1 million doses) were verified as vaccine reactions; 1083 of the 8067 (13.4%; rate, 12.1 per 1 million doses) were rare and more serious (vs. common, minor events), most of which (1050) were allergic reactions. Eleven cases of the Guillain–Barré syndrome were reported, for a rate of 0.1 per 1 million doses, which is lower than the background rate in China.
Full Text of Results...
Conclusions
No pattern of adverse events that would be of concern was observed after the administration of influenza A (H1N1) vaccine, nor was there evidence of an increased risk of the Guillain–Barré syndrome.
Full Text of Discussion...

The Pediatric Infectious Disease Journal
March 2011 - Volume 30 - Issue 3 pp: A9-A10,187-272,e38-e55
http://journals.lww.com/pidj/pa ges/currenttoc.aspx
[Reviewed earlier]

Pediatrics
February 2011 / VOLUME 127 / ISSUE 2
http://pediatrics.aappublications.org/current.shtml
[Reviewed earlier]

Pharmacoeconomics
March 1, 2011 - Volume 29 - Issue 3 pp: 173-268
http://adisonline.com/pharmacoeconomics/pages/currenttoc.aspx

[Reviewed earlier]

Pharmacoeconomics & Outcomes News
February 19, 2011 - Volume - Issue 622 pp: 1-11
http://adisonline.com/pecnews/pages/currenttoc.aspx
[No relevant content]

PLoS Medicine
(Accessed 20 February 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
[No relevant content]

Science
18 February 2011 vol 331, issue 6019, pages 807-974
http://www.sciencemag.org/current.dtl
[No relevant content]

Science Translational Medicine
16 February 2011 vol 3, issue 70
http://stm.sciencemag.org/content/current
[No relevant content]

Vaccine
Volume 29, Issue 10 pp. 1855-2004 (24 February 2011)
http://www.sciencedirect.com/science/journal/0264410X
Regular Papers
Emerging and continuing trends in vaccine opposition website content
Original Research Article Pages 1874-1880
Sandra J. Bean
Abstract
Context
Anti-vaccination websites appeal to persons searching the Internet for vaccine information that reinforces their predilection to avoid vaccination for themselves or their children. Few published studies have systematically examined these sites.
Objectives
The aim of this study was to employ content analysis as a useful tool for examining and comparing anti-vaccination websites for recurring and changing emphases in content, design, and credibility themes since earlier anti-vaccination website content analyses were conducted.
Methods

Between February and May 2010, using a commonly available search engine followed by a deep web search, 25 websites that contained anti-vaccination content were reviewed and analyzed for 24 content, 14 design, and 13 credibility attributes.
Results
Although several content claims remained similar to earlier analyses, two new themes emerged: (1) the 2009 H1N1 epidemic threat was "manufactured," and (2) the increasing presence of so-called "expert" testimony in opposing vaccination.
Conclusion
Anti-vaccination websites are constantly changing in response to the trends in public health and the success of vaccination. Monitoring the changes can permit public health workers to mount programs more quickly to counter the opposition arguments. Additionally, opposition claims commonly appeal to emotions whereas the supporting claims appeal to reason. Effective vaccine support may be better served by including more emotionally compelling content.

Value in Health
December 2010 Volume 13, Issue 8 Pages 863–1065
http://onlinelibrary.wiley.com/doi/10.1111/vhe.2010.13.issue-8/issuetoc
Policy Analysis
Willingness to Pay for a Quality-Adjusted Life-Year: The Individual Perspective (pages 1046–1055)
Ana Bobinac, N. J. A. Van Exel, Frans F. H. Rutten and Werner B. F. Brouwer
Article first published online: 3 SEP 2010 | DOI: 10.1111/j.1524-4733.2010.00781.x
ABSTRACT
Objective: The aim of this study was to elicit the individual willingness to pay (WTP) for a quality-adjusted life-year (QALY).
Methods: In a Web-based questionnaire containing contingent valuation exercises, respondents valued health changes in five scenarios. In each scenario, the respondents first valued two health states on a visual analog scale (VAS) and expressed their WTP for avoiding a decline in health from the better health state to the worse, using a payment scale followed by a bounded open contingent valuation question.
Analysis: WTP per QALY was calculated for QALY gains calculated using VAS valuations, as well as the Dutch EQ-5D tariffs, the two steps in the WTP estimations and each scenario. Heterogeneity in WTP per QALY ratios was examined from the perspective of: 1) household income; and 2) the level of certainty in WTP indicated by respondents. Theoretical validity was analyzed using clustered multivariate regressions.
Results: A total of 1091 respondents, representative of the Dutch population, participated in the survey. Mean WTP per QALY was €12,900 based on VAS valuations, and €24,500 based on the Dutch EuroQoL tariffs. WTP per QALY was strongly associated with income, varying from €5000 in the lowest to €75,400 in the highest income group. Respondents indicating higher certainty exhibited marginally higher WTP. Regression analyses confirmed expected relations between WTP per QALY, income, and other personal characteristics.
Conclusion: Individual WTP per QALY values elicited in this study are similar to those found in comparable studies. The use of individual valuations in social decision-making deserves attention, however.