Vaccines: The Week in Review
28 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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The U.S. Supreme Court decided 6-2 to affirm a lower court ruling upholding the National Childhood Vaccine Injury Act. The Act prevents civil suits against manufacturers of FDA-approved childhood vaccines "based on a claim that a particular vaccine should have been designed differently." The opinion of the Court in the case – Bruesewitz v. Wyeth – stated that "[The Vaccine Act] reflects a sensible choice to leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries." In an amicus brief, the American Academy of Pediatrics and over 20 other professional and public health organizations argued that a ruling against Wyeth could "precipitate the same crisis that Congress sought to avert in passing the Vaccine Act: 'the very real possibility of vaccine shortages, and, in turn increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases.'" The court's opinion is available at: http://www.supremecourt.gov/opinions/10pdf/09-152.pdf.

The International Vaccine Institute (IVI) and Sanofi Pasteur announced "their intent to work together towards creating the conditions to make a dengue vaccine widely accessible to countries where this disease is endemic." Dr. Ragnar Norrby, Chairman of the IVI Board of Trustees, said, "A dengue vaccine represents the most viable prevention tool in our quest to reduce the growing number of dengue infections occurring globally each year. We thank Sanofi Pasteur for their commitment to reducing the considerable burden placed on communities and health systems around the world due to dengue and dengue hemorrhagic fever." Earlier this

month, the IVI announced the launch of the Dengue Vaccine Initiative, in collaboration with the Sabin Vaccine Institute, the Johns Hopkins University, and the World Health Organization. Through a $6.9 million grant from the Bill & Melinda Gates Foundation, DVI "will accelerate the availability and utilization of safe, affordable and broadly protective vaccines to combat dengue."
http://www.ivi.org/event_news/news_view.asp?enid=118

WHO released the priorities for vaccine evaluations for prequalification for 2011-2012. The prioritization list below "is a tool published every two years by the WHO by the prequalification programme to guide decisions as to the vaccines on which to focus resources." Vaccines are categorized in four groups: high, medium, low and no priority. The priority list was developed by consultation between WHO and the two United Nations purchasing agencies (UNICEF and the Pan American Health Organization Revolving Fund) which use the prequalification service for vaccines. The prioritization exercise takes into account needs from WHO programmes (e.g. polio, measles, rabies) and the International Health Regulations, as well as vaccines defined globally as priority for accelerated introduction.

WHO said that in the consultation process for the current list, vaccines were considered if, based on information available to the UN purchasing agencies and WHO, they were already available in the market or were expected to become available during the biennium 2011-2012. The criteria used to assign priorities include:
a) Demand in the respective UN-supplied markets, with consideration given to plans for introduction;
b) WHO programmatic needs;
c) recommendations of WHO's Strategic Advisory Group of Experts (SAGE) on immunization ; and
d) security of supplies: number, diversity, and production capacity of suppliers in the market.

Vaccines prequalification priority list 2011-12

- High priority vaccines
- Bivalent oral polio (bOPV1+3)
- DTwP based pentavalent combination (fully liquid DTwP-Hep B-Hib)
- Inactivated polio (IPV)
- Meningococcal A-containing conjugate
- Meningoccocal AC-containing polysaccharide
- Meningococcal W-containing polysaccharide
- Meningococcal W-containing conjugate
- Pneumococcal conjugate
- Rotavirus
- Trivalent oral polio (tOPV)
- Yellow fever

Vaccines of high programmatic interest but not available for supply in January 2011 (e.g. dengue; malaria; and new formulations of current vaccine types with enhanced stability outside of the currently accepted storage conditions) may be considered as high priority if they become available before the end of the period for which the list is in force.

http://www.who.int/immunization_standards/vaccine_quality/pq_priorities/en/index.html

WHO released the newest issue of Global Immunization News (25 February 2011) http://www.who.int/entity/immunization/GIN_February_2011.pdf Included in this issue:
ANNOUNCEMENTS FROM THE SIVAC INITIATIVE
25/02/2011 from Julia Blau, AMP
The briefing described below is available in the Center of Expertise on the NITAG Resource
- The "Introduction to Health Economic Evaluations for NITAG members briefing" is an e-learning tool that provides NITAG members with a basic background on health economic evaluations applied to immunization. It contains 4 modules of 10 to 40 minutes each:
- Module 1: The usefulness of economic evaluations for public health
- Module 2: The different types of economic evaluations
- Module 3: The main methodological issues of an economic evaluation
- Module 4: Interpretation of cost-effectiveness ratios
http://www.nitag-resource.org/en/training/rapid-briefing.php

Twitter Watch

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

SingerPeter Peter Singer
Great photo of polio vaccination @gatesfoundation! Is there an ethical obligation to complete polio eradication? Yes! http://bit.ly/dfbjT2
26 Feb

CDCgov CDC.gov
Protect your child against #rotavirus. #Vaccinate beginning at 2 months of age. http://go.usa.gov/g7A
25 Feb

USAID USAID
Podcast of Deputy Assistant Admin for Global Health Amie Batson on the importance of #vaccines: @GLOBALHEALTHorg http://tinyurl.com/643gtse
24 Feb

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

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 Bulletin
Volume 96 Issue 1 December 2010
http://bmb.oxfordjournals.org/content/current
Articles
Sarah J. Whitehead and
Shehzad Ali
Health outcomes in economic evaluation: the QALY and utilities
Br Med Bull (2010) 96(1): 5-21 first published online October 29, 2010
doi:10.1093/bmb/ldq033
Abstract
The quality-adjusted life year (QALY) is routinely used as a summary measure of health outcome for economic evaluation, which incorporates the impact on both the quantity and quality of life. Key studies relating to the QALY and utility measurement are the sources of data. Areas of agreement include the need for a standard measure of health outcome to enable comparisons across different disease areas and populations, and the methods used for valuing health states in utility measurement. Areas of controversy include the limitation of the QALY approach in terms of the health benefits it can capture, its blindness towards equity concerns, the underlying theoretical assumptions and the most appropriate generic preference-based measure of utility. There is growing debate relating to whether a QALY is the same regardless of who accrues it, and also the issue as to who should value health states. Research is required to further enhance the QALY approach to deal with challenges relating to equity-weighted utility maximization and testing the validity of underlying assumptions. Issues around choosing between condition-specific measures and generic instruments also merit further investigation.

British Medical Journal

26 February 2011 Volume 342, Issue 7795
http://www.bmj.com/content/current

Editorials

Pandemic influenza vaccines

John M Watson,
Richard G Pebody
BMJ 342:doi:10.1136/bmj.d545 (Published 8 February 2011

Extract

Are protective, but are limited by delays in availability

Almost as soon as the new influenza A/H1N1 2009 virus was identified in April 2009, its pandemic potential was realised. 1 Immediate steps were taken by vaccine manufacturers, working with the World Health Organization's network of influenza reference laboratories, and with regulatory and standardisation authorities, to develop a pandemic specific vaccine and manufacture enough to meet global needs. To make best use of the H1N1 antigen, low dose monovalent vaccines were developed with the addition of adjuvant to enhance immunogenicity. These vaccines became available towards the end of 2009. The first of several studies to assess the effectiveness of these pandemic influenza A/H1N1 vaccines, including the linked study (doi: 10.1136/bmj.c7297) by Skowronski and colleagues, 2 are now being published.

On the basis of the emerging epidemiological picture, pandemic vaccines were given to subsets of the population at higher risk of infection and severe disease according to national immunisation policies. In the United Kingdom, people with underlying health conditions that place them at increased risk from the complications of influenza, including those aged 65 years and over …

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
[Reviewed earlier]

Human Vaccines
Volume 7, Issue 2 February 2011
http://www.landesbioscience.com/journals/vaccines/toc/volume/7/issue/2/
[Reviewed earlier]

JAMA
February 23, 2011, Vol 305, No. 8, pp 743-844
http://jama.ama-assn.org/current.dtl
[No relevant content]

Journal of Infectious Diseases
Volume 203 Issue 6 March 15, 2011
http://www.journals.uchicago.edu/toc/jid/current
[No relevant content]

The Lancet
Feb 26, 2011 Volume 377 Number 9767 Pages 691 - 782
http://www.thelancet.com/journals/lancet/issue/current
Editorial
Better spending needed for neglected diseases
The Lancet
Preview
Over the past decade, there has been a concerted effort, mainly by public and philanthropic organisations, to counter the neglect of developing world diseases by increasing funding for research and development. The Global Funding of Innovation for Neglected Diseases (G-FINDER) survey, now in its third year, does the valuable job of tracking this global investment. The latest survey covers 31 neglected diseases, including HIV, malaria, and tuberculosis as well as conditions such as leprosy and trachoma.
Series
Towards achievement of universal health care in India by 2020: a call to action
K Srinath Reddy, Vikram Patel, Prabhat Jha, Vinod K Paul, AK Shiva Kumar, Lalit Dandona, for The Lancet
Preview
To sustain the positive economic trajectory that India has had during the past decade, and to honour the fundamental right of all citizens to adequate health care, the health of all Indian people has to be given the highest priority in public policy. We propose the creation of the Integrated National Health System in India through provision of universal health insurance, establishment of autonomous organisations to enable accountable and evidence-based good-quality health-care practices and development of appropriately trained human resources, the restructuring of health governance to make it coordinated and decentralised, and legislation of health entitlement for all Indian people.

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
[Reviewed earlier]

Nature
Volume 470 Number 7335 pp435-568 24 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 24, 2011 Vol. 364 No. 8
http://content.nejm.org/current.shtml
[No relevant content]

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
[Reviewed earlier]

PLoS Medicine
(Accessed 27 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

Dengue Vaccines Regulatory Pathways: A Report on Two Meetings with Regulators of Developing Countries

Richard Mahoney, Liliana Chocarro, James Southern, Donald P. Francis, John Vose, Harold Margolis Policy Forum, published 22 Feb 2011
doi:10.1371/journal.pmed.1000418

Summary Points

- Because a dengue vaccine should be tetravalent in nature and provide protection against all four dengue serotypes, regulatory agencies need to address additional issues associated with multi-valent vaccines such as interference between the vaccine serotypes.
- Safety assessment needs to account for the potential risk of inducing antibody-enhanced diseases (antibody-dependent enhancement).
- Because of the varying epidemiology and disease impact in different countries and regions, dengue vaccines will likely need to be evaluated in diverse populations initially in both the Americas and the Asia Pacific region.
- Several national regulatory authorities (NRAs) in endemic developing countries are likely to be engaged in review of both applications for clinical evaluation and for marketing of vaccines and they should receive support as appropriate.
- Manufacturers can submit a dossier to the European Medicines Agency for the Evaluation of Medicinal Products (EMA) for review (Scientific Opinion). This is possible due to the introduction of Article 58 of EMA's regulation 726/2004 (within which the example of dengue is specifically mentioned). This Opinion could facilitate the review process by NRAs in developing countries. Manufacturers may also obtain scientific advice and protocol assistance from the EMA, which may facilitate later Article 58 review.
- The Developing Countries' Vaccine Regulators Network recommends that consideration be given to agreements for joint reviews of clinical trial applications by similarly affected NRAs and also the review of applications for licensure in order to accelerate the launch and introduction of dengue vaccines. The NRAs would need to have access to the necessary expertise to review the quality and safety aspects of the license application.
- It is critical that improved standardized tests be introduced as soon as possible for the diagnosis of early infection and for the measurement of immune protection (requiring identification of a correlate of protection). The World Health Organization (WHO), through its Expert Committee on Biological Standardization, can evaluate and standardize such tests; in addition, WHO and its Collaborating Centers may also help ensure availability of necessary standards and reagents for use in the field.

Science
25 February 2011 vol 331, issue 6020, pages 975-1098
http://www.sciencemag.org/current.dtl

EDITORIAL:

Advancing Regulatory Science

Margaret A. Hamburg, Commissioner of the U.S. Food and Drug Administration
Summary
Ensuring the safety and quality of food and medical products has never been more complicated. Societies around the world face increasingly complex challenges that require harnessing the best available science and technology on behalf of patients and consumers. This effort requires a strong field of regulatory science to develop new tools, standards, and approaches that efficiently and consistently assess the safety, efficacy, quality, and performance of products. Yet, despite being a critical component of the scientific enterprise, regulatory science has long been underappreciated and underfunded.

Science Translational Medicine
23 February 2011 vol 3, issue 71
http://stm.sciencemag.org/content/current
[No relevant content]

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

Volume 29, Issue 12 pp. 2227-2348 (9 March 2011)
Regular Papers
Human papillomavirus vaccine initiation among adolescent girls in high-risk communities Original Research Article
Pages 2235-2241
Sarah L. Guerry, Christine J. De Rosa, Lauri E. Markowitz, Susan Walker, Nicole Liddon, Peter R. Kerndt, Sami L. Gottlieb
Abstract
Background
We assessed human papillomavirus (HPV) vaccine uptake among adolescent girls, parents' intentions to vaccinate daughters, and barriers and facilitators of vaccination in a population at elevated risk for cervical cancer.
Methods
Between October 2007 and June 2008, telephone surveys were conducted with randomly selected parents/guardians of 11–18 year old girls attending public middle and high schools serving economically disadvantaged populations in Los Angeles County.
Results
We surveyed 509 predominantly Hispanic (81%) and African American (16%) parents; 71% responded in Spanish. Overall, 23% reported their daughter had received ≥1 dose of HPV vaccine. Although 93% of daughters had seen a doctor in the past year, only 30% reported that a provider recommended HPV vaccine. Characteristics positively associated with odds of having initiated HPV vaccine were having heard of the vaccine (adjusted odds ratio [aOR] 2.6), belief in vaccine effectiveness (aOR 2.9), and doctor recommendation (aOR 48.5). Negative attitudes toward HPV vaccine (aOR 0.2) and needing more information about it (aOR 0.1) were negatively associated with vaccine initiation. Of those with unvaccinated daughters (n = 387), 62% said they

"probably/definitely will" vaccinate within the next year and 21% were undecided or didn't know; only 11% said they definitely won't.
Conclusions
About one-quarter of adolescent girls in this at-risk community had initiated HPV vaccine by mid-2008. Provider recommendation was the single most important factor associated with vaccination. Because a substantial proportion of parents remain undecided about HPV vaccine, health care providers can play a key role by providing needed information and offering HPV vaccine to all eligible adolescents.

Vaccine
http://www.sciencedirect.com/science/journal/0264410X
Volume 29, Issue 11 pp. 2005-2226 (3 March 2011)
Meeting Report
Lessons from smallpox eradication campaign in Bihar State and in India
Pages 2005-2007
Mahendra Dutta, R.N. Basu
Abstract

Following several key breakthroughs during the mid-1960s under the global smallpox eradication programme namely, development of a thermo-stable vaccine, efficient and acceptable technique of it's delivery by bifurcated needle and evolution of a strategy (in lieu of mass vaccination) of active case search and containment, an intensified campaign of smallpox eradication from India was successfully implemented during 1973–1975. A formidable battle was fought, particularly in Bihar state leading to the occurrence of last indigenous case on 17 May 1975. The rapid achievement of eradication of the scourge from India in a record time was hailed as unprecedented in public health history. The single key factor in the achievement was the sustained efforts of a band of national and international epidemiologists, supported by young medical interns heading mobile containment teams, working under trying field conditions.

Through the campaign several important lessons were learnt and innovations made. Important among these were: (i) need for refinement of tools, techniques, and strategies for attaining the objective; (ii) implementation of a time and target oriented campaign; (iii) support of adequate and dedicated short term personnel to supplement supervision and field activities; (iv) providing of flexible funding and a convenient disbursement procedure; (v) building private-public partnership; (vi) devising of simple innovations, based on feedback from field, to support activities; (vii) development of political commitment; (viii) improved communication from field to higher levels to enable action on recent information; (ix) regular periodic staff meetings at each administrative level to facilitate early recognition and correction of deficiencies; (x) mobilization of support from international community, whenever required.
Regular Papers
Vaccine eligibility and acceptance among ambulatory obstetric and gynecologic patients Original Research Article
Pages 2024-2028
Wendy S. Vitek, Aletha Akers, Leslie A. Meyn, Galen E. Switzer, Bruce Y. Lee, Richard H. Beigi
Abstract
Objective

To assess vaccine eligibility and factors associated with vaccine acceptance among ambulatory obstetric and gynecologic patients.
Methods
An anonymous office-based survey was administered to women seeking ambulatory obstetric and gynecologic care at a large women's hospital from December 2007 to July 2008. Information collected included: demographics, medical and vaccination history, interest in receiving vaccines and attitudes towards vaccine providers. Vaccine eligibility was based on age and/or self-reported risk factors in accord with the 2007–2008 Center for Disease Control and Prevention (CDC) adult immunization schedule. Vaccine eligibility was examined using descriptive statistics, and demographic characteristics were compared using chi-squared analysis. A multivariable logistic regression model was developed to assess factors associated with participants' willingness to accept vaccines from their obstetrician–gynecologist.
Results
A total of 1441 women completed the survey. The majority of participants (87%) would accept vaccines if recommended by their obstetrician–gynecologist. The primary factors associated with vaccine acceptance were having less than a high school education, being privately insured, currently being pregnant, reporting a history of vaccinations and previously receiving vaccinations from an obstetrician–gynecologist. A significant portion of participants were eligible for the hepatitis B, influenza and HPV vaccines (≥50% for each). The type of vaccine did not influence willingness to accept vaccines from an obstetrician–gynecologist.
Conclusion
A majority of women appear eligible for, and will accept, vaccinations regardless of specific vaccine, if recommended by their obstetrician–gynecologist. These findings justify ongoing efforts to expand immunization services offered by obstetrician–gynecologists.

From the patient perspective: The economic value of seasonal and H1N1 influenza vaccination Original Research Article
Pages 2149-2158
Bruce Y. Lee, Kristina M. Bacon, Julie M. Donohue, Ann E. Wiringa, Rachel R. Bailey, Richard K. Zimmerman
Abstract
Although studies have suggested that a patient's perceived cost-benefit of a medical intervention could affect his or her utilization of the intervention, the economic value of influenza vaccine from the patient's perspective remains unclear. Therefore, we developed a stochastic decision analytic computer model representing an adult's decision of whether to get vaccinated. Different scenarios explored the impact of the patient being insured versus uninsured, influenza attack rate, vaccine administration costs and vaccination time costs. Results indicated that the cost of avoiding influenza was fairly low (with one driver being required vaccination time). To encourage vaccination, decision makers may want to focus on ways to reduce this time, such as vaccinating at work, churches, or other normally frequented locations.

Pandemic influenza A/H1N1 vaccination uptake among health care workers in Qatar: Motivators and barriers Original Research Article
Pages 2206-2211
Mohamed Ghaith Alkuwari, Nagah A. Aziz, Zaher A.S. Nazzal, Saad A. Al-Nuaimi
Abstract

Influenza A/H1N1 new vaccine helps control disease spread. Cross-sectional survey was conducted at PHC & Emergency Departments in Qatar to determine influenza A/H1N1 vaccination rate among HCWs and associated factors, 523 HCWs were enrolled. The study showed that 13.4% HCWs received vaccination. Feeling protected strongly influenced vaccination decision (OR = 14.5). Uncertainty about vaccine efficacy and fear of side effects strongly influenced decision to reject the vaccine (OR = 0.3 and 0.2 respectively). Vaccination coverage was very low. The most common barriers were uncertainty about vaccine efficacy and fear of side effects. Health authorities should build message highlighting how the benefit of vaccination outweighs risk.

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
[Reviewed earlier]