Vaccines: The Week in Review
23 May 2011
Center for Vaccine Ethics & Policy (CVEP)
http://centerforvaccineethicsandpolicy.wordpress.com/
A program of
- Center for Bioethics, University of Pennsylvania
http://www.bioethics.upenn.edu/
- The Wistar Institute Vaccine Center
http://www.wistar.org/vaccinecenter/default.html
- Children's Hospital of Philadelphia, Vaccine Education Center
http://www.chop.edu/consumer/jsp/microsite/microsite.jsp

This weekly summary targets news and events in global vaccines ethics and policy gathered from key governmental, NGO and industry sources, key journals and other sources. This summary supports ongoing initiatives of the Center for Vaccine Ethics & Policy, and is not intended to be exhaustive in its coverage. Vaccines: The Week in Review is now also posted in pdf form and as a set of blog posts at 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 **Sixty-fourth World Health Assembly (16–24 May 2011) continues in Geneva**. WHO Media Center meeting documentation available here:
http://www.who.int/mediacentre/events/2011/wha64/en/index.html
Twitter updates by whonews and tags #worldhealthassembly #globalhealth
Speeches
Dr Margaret Chan
WHO Director-General
Opening address
Opening address video
Streaming wmv, 00:32:50
Bill Gates
Co-chair of the Bill & Melinda Gates Foundation
Read the speech
Video of speech
Streaming wmv, 00:28:42
Her Excellency Sheikh Hasina
Prime Minister of Bangladesh
Read the speech
Video of speech
Streaming wmv, 00:27:23

Dr Christos Patsalides
President, Sixty-fourth World Health Assembly
Video of speech
Streaming wmv, 00:19:22
Complete documentation of WHAT actions are included in the daily WHA Journal here:
http://apps.who.int/gb/e/e_wha64.html

Bill Gates addressed the 64th World Health Assembly during its first week.
The full text of the Gates Foundation media release is below:
GENEVA, May 17, 2011 /PRNewswire/ —

Bill Gates, co-chair of the Bill & Melinda Gates Foundation, called on government leaders to increase their investments in vaccines and to hold themselves accountable for extending the benefits of vaccines to every child.

In a keynote address at the 64th World Health Assembly, an annual gathering of health ministers and global health leaders, Gates laid out his vision for the impact that broadening access to vaccines can have on the world. "Strong immunization systems will put an end to polio and help us reach all children with five to six new vaccines," Gates said. "We can save four million lives by 2015, and 10 million lives by 2020."

Gates is more optimistic than ever about the impact of vaccines. "Vaccines are inexpensive, they are easy to deliver, and they are proven to protect children from disease," he declared.

Recognizing that leadership is essential to achieving his vision, Gates announced that starting in 2012, his foundation would bestow an award on an individual or organization that has made a uniquely innovative contribution to the Decade of Vaccines. The innovation could be in the science, the delivery, or the financing of vaccines.

"The best immunization systems work because leaders hold themselves accountable for results," he said. "Leaders diagnose weaknesses, innovate to address them, and spread the best ideas."

Gates cited leaders in India and Nigeria who are responsible for increasing immunization rates in their states, and praised the success of the new Meningitis A vaccine that was rolled out in Burkina Faso, Mali and Niger last December, to emphasize the importance of commitments to immunization.

Gates also called on pharmaceutical manufacturers to commit to making sure vaccines are affordable for poor countries.

"I believe we have the opportunity to make a new future in which global health is the cornerstone of global prosperity," he said.

Achieving his vision for the next decade would depend on doing difficult, necessary things.
Specifically, Gates called on:
- Donor countries to increase their investment in vaccines and immunization, even though they are coping with budget crises. He cited the GAVI Alliance pledging meeting in London on June 13 as an opportunity to show their support.
- Pharmaceutical companies to make sure vaccines are affordable for poor countries. Specifically, they must make a commitment to affordable pricing. Gates said he was confident that the combined price of the pentavalent, pneumococcus, and rotavirus vaccines can be cut in half by 2015.

- All 193 member states to make vaccines a central focus of their health systems. He said they must pledge to meet vaccine coverage targets of 90 percent at the country level with no district below 80 percent, and ensure that all children have access to existing vaccines and to new ones as they become available.
http://multivu.prnewswire.com/mnr/gatesfoundation/49363/

Special WHA Focus: Among key issues CVEP is tracking includes WHA on the Pandemic Influenza Preparedness (PIP) Framework addressing "sharing of influenza viruses and access to vaccines and other benefits from base documents: A64/8 and A64/8 Corr.1 As reported in the WHA Journal: N° 6 21 May 2011:
http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_JOUR6-en.pdf
*

Eighth meeting of Committee A
Chairman: Dr Walid Ammar (Lebanon)
– – Draft third report of Committee A
The Chairman opened the meeting and called upon the Rapporteur (Dr-Mast Kulzhanov [Kazakhstan]) to read out the third draft report of Committee A, document (draft) A64/57 containing one resolution entitled:
– Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits
The resolution http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_57Draft-en.pdf was approved and the first report of the Committee was adopted.
*

[Editor's Note: At the recent symposium Global Vaccins 202X: Access, Equity, Ethics, 2-4 May 2011, an update on details and open issues associated with the PIP Framework was presented by Michael Watson, sanofi pasteur, and Chair IFPMA Biotherapeutics & Vaccines Committee. The video is available here: Part I, Part II]

Special WHA Focus: CVEP is tracking the response to the GIVS update session at WHA, which included discussion of the Decade of Vaccines Collaboration and planned global vaccine action plan. The WHA Journal reports this as:
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Item 13 (continued) Technical and health matters
Item 13.5 (continued) – **Global immunization vision and strategy**
Discussion of this subitem resumed with the Chairman inviting comments from the floor. The Secretariat was invited to respond to the issues raised. The report of the Secretariat contained in document A64/14 was noted, closing the agenda subitem.
*

The WHO reported on this WHA GIVS discussion as below [full text]:
20 May 2011 - Fifty-five speakers — including country delegates, partners such as UNICEF and the GAVI Alliance, as well as five civil society organizations meeting at the 64th World Health Assembly — took the floor in massive support of the Global Immunization Vision and Strategy and its impact in guiding national immunization strategies to reach child survival goals. The immunization agenda item was debated over

five hours by delegates from WHO's 193 Member States and elicited the highest number of interventions on technical and health matters reviewed so far at this year's Health Assembly.

Several countries spoke of their achievements in: increasing immunization coverage; reaching more children with existing vaccines; eliminating maternal and neonatal tetanus; reducing measles cases and deaths; using new vaccines against diarrhoea and pneumonia thanks to innovative financing; and implementing advocacy events such as the regional immunization weeks to highlight the importance of vaccines and immunization in saving lives.

But several complex challenges need to be addressed by countries and the international community including:

- mobilizing more resources to strengthen national immunization programmes and calling for increased support from the GAVI Alliance and other donors;
- ensuring a balanced approach towards competing priorities such as strengthening immunization systems, introducing new vaccines and eradicating polio;
- preventing a resurgence of measles through high vaccination coverage to reach the 2015 target of 95% measles mortality reduction and with the eventual goal of eradicating the disease;
- facilitating vaccine technology transfer to developing countries and promoting strategies to bring down vaccine prices; and
- strengthening surveillance for vaccine-preventable diseases.

Member States commend WHO's leadership on the Decade of Vaccines, a vision for using the next 10 years to achieve immunization goals and reach important milestones in vaccine research, development, financing and public support. There was strong backing for the objectives proposed by WHO and UNICEF to improve delivery of immunization services in the next decade. Member States request that countries and relevant stakeholders are involved in the consultation process in developing the global vaccine action plan.

Other immunization-related topics for discussion by delegates at the Health Assembly include the control and prevention of cholera, managing the potential risks to polio eradication and access to influenza vaccines as a benefit of sharing of virus strains.
http://www.who.int/immunization/newsroom/newsstory_increased_investment_global_goals/en/index.html
*

[Editor's Note: At the recent symposium Global Vaccines 202X: Access, Equity, Ethics, 2-4 May 2011, an update on the Decade of Vaccines Collaboration and the status of its four Working Groups was presented and discussed. Video of these presentations is available as below:

Decade of Vaccines Collaboration: Overview/Update
Moderator: Chris Elias, PATH
[video: Part I, Part II]

DoV Work Group Updates:
Delivery: JM Okwo-Bele, WHO, IVB
[video: Part I, Part II]
Global Access: Sandy Wrobel, Applied Strategies
[video: here]
Public/Political Support: Lauren Leahy, MRC Global
[video: here]

R&D: David Salisbury, UK Department of Health
[video: here]
Keynote: Global Vaccine Access – Why Now?
Chris Elias, PATH
[video: Part I, Part II]
Keynote: Priorities, policies, perceptions & the public
David Salisbury, Department of Health, United Kingdom
[video: Part I, Part II, Part III, Part IV]

The **Weekly Epidemiological Record (WER) for 20 May 2011**, vol. 86, 21 (pp 205–220) includes: Meeting of the Strategic Advisory Group of Experts on immunization, April 2011.
http://www.who.int/entity/wer/2011/wer8621.pdf

Sabin Vaccine Institute awarded its 2011 Albert B. Sabin Gold Medal Award to Drs. Douglas R. Lowy and John T. Schiller recognizing "several watershed discoveries that advanced the development of vaccines against human papillomavirus (HPV)." Dr. Peter Hotez, President of Sabin, commented, "The Sabin Vaccine Institute is honored to bestow Drs. Lowy and Schiller with the 2011 Albert B. Sabin Gold Medal Award for their pioneering work in the fields of vaccinology and oncology. Millions of lives will be positively affected by Lowy and Schiller's dedication in developing the world's first vaccines against cervical cancer. We applaud their efforts to rid the world of this silent killer." Sabin noted that its Gold Medal Award, awarded annually since 1994, "commemorates the legacy of Dr. Sabin, who developed the oral live virus polio vaccine that is widely heralded with contributing to the near elimination of polio worldwide. Dr. Sabin, in whose honor the Sabin Vaccine Institute was founded in 1993, was also an advocate of using science to reduce poverty."
http://sabin.org/news-resources/releases/2011/05/18/drs-douglas-r-lowy-and-john-t-schiller-receive-2011-albert-b-sabi

The GAVI Alliance said it has concluded that US$563,000 was misused in two of its cash-based programmes in Mali. GAVI said that "sixty percent of the misused amount, or $335,000, was judged by investigators as ineligible expenses, which although used in the health sector, were outside the scope of GAVI's funding agreement. The remaining 40% of the funds, $228,000, were spent on nonexistent activities or on fictitious procurement of goods and services." GAVI added that the Malian Government, which fully cooperated in the investigation, has committed to reimburse the total amount to GAVI and has arrested four individuals under suspicion for the misuse. Helen Evans, interim GAVI CEO, said, "We appreciate the partnership with the Malian government in this investigation and the speed at which it is reacting to ensure that the missing funds are promptly repaid," said. "GAVI vigorously condemns

any misuse of its funding. Children's lives are jeopardised when GAVI funds are not used as they are intended."
http://www.gavialliance.org/media_centre/statements/mali.php

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.

PIH Partners In Health
"When unjust systems or structures prevent people from achieving good health, this is structural violence in action" http://ow.ly/4ZbUU

pahowho PAHO/WHO
TDR Wins 2011 Gates Award for Global Health new.paho.org/hq/index.php?o…

PATHtweets PATH
A first: PATH receives a grant for tuberculosis work through Vietnam's Ministry of Health. http://ow.ly/4ZwSR #globalhealth #TB

MalariaNoMore Malaria No More
Hey @NASCAR fans! Bid on tickets and meet&greet w/ Carl Edwards for May 29 race in Concord, NC to fight malaria! http://bit.ly/jh7LGy

pahowho PAHO/WHO
55 speakers, delegates, UNICEF, GAVI Alliance took the floor in massive support of Global Immunization Vision/Strategy http://bit.ly/mGXYE8

GAVIAlliance GAVI Alliance
10 Facts on Immunisation http://ht.ly/4Z7GF

AIDSvaccine IAVI
#India #Science & #Tech Min calls for global partnerships to address scientific challenges on path to an #HIV #vaccine http://bit.ly/luXfNS

VaxEthicsPolicy CVEP:UPenn
#globalvaccines202X Art Caplan keynote - Vaccination: Personal Responsibility; Community Imperative http://tinyurl.com/3hvqlco

GAVIAlliance GAVI Alliance
Quotes on GAVI from BillGates, Dr.Chan, MinistersOfHealth, HillaryClinton, AndrewMitchell, BanKi-moon,Bono,Sarkozy&more! http://ht.ly/4Y3fA

RWJF_PubHealth RWJF PublicHealth
Today is #HIV #Vaccine Awareness Day: http://bit.ly/l0KIsZ #HVAD
18 May

sabinvaccine Sabin Vaccine Inst.
Congratulations Drs. Douglas Lowy & John Schiller, 2011 Albert B. Sabin Gold Medal Award recipients!: http://bit.ly/mumF9a #HPV

gatesfoundation Gates Foundation
Bill Gates' vision: #polio eradication & affordable #vaccines for every child. http://gates.ly/mEp27v #worldhealthassembly

GAVIAlliance GAVI Alliance
Dr. Wecker writes on "Multilateral partnerships help protect children from deadly diseases" @PATH @ONE #Vaccines http://ht.ly/4Vz3H

AIDSvaccine IAVI
@IAVISeth's keynote "Realizing the Potential of Global #Vaccines" at #globalvaccines202X conf via @vaxethicspolicy http://bit.ly/mQg3Yq #HIV

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
May 17, 2011; 154 (10)
http://www.annals.org/content/current
Ideas and Opinions
Advancing the Science of Patient Safety
Paul G. Shekelle, Peter J. Pronovost, Robert M. Wachter, Stephanie L. Taylor, Sydney M. Dy, Robbie Foy, Susanne Hempel, Kathryn M. McDonald, John Ovretveit, Lisa V. Rubenstein, Alyce S. Adams, Peter B. Angood, David W. Bates, Leonard Bickman, Pascale Carayon, Sir Liam Donaldson, Naihua Duan, Donna O. Farley, Trisha Greenhalgh, John Haughom, Eileen T. Lake, Richard Lilford, Kathleen N. Lohr, Gregg S. Meyer, Marlene R. Miller, Duncan V. Neuhauser, Gery Ryan, Sanjay Saint, Kaveh G. Shojania, Stephen M. Shortell, David P. Stevens, and Kieran Walshe
Ann Intern Med May 17, 2011 154:693-696;
Abstract
Despite a decade's worth of effort, patient safety has improved slowly, in part because of the limited evidence base for the development and widespread dissemination of successful patient safety practices. The Agency for Healthcare Research and Quality

sponsored an international group of experts in patient safety and evaluation methods to develop criteria to improve the design, evaluation, and reporting of practice research in patient safety. This article reports the findings and recommendations of this group, which include greater use of theory and logic models, more detailed descriptions of interventions and their implementation, enhanced explanation of desired and unintended outcomes, and better description and measurement of context and of how context influences interventions. Using these criteria and measuring and reporting contexts will improve the science of patient safety.

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

British Medical Journal
21 May 2011 Volume 342, Issue 7807
http://www.bmj.com/content/current

Inadequate reporting of research ethics review and informed consent in cluster randomised trials: review of random sample of published trials

Monica Taljaard, Andrew D McRae, Charles Weijer, Carol Bennett, Stephanie Dixon, Julia Taleban, Zoe Skea, Martin P Eccles, Jamie C Brehaut, Allan Donner, Raphael Saginur, Robert F Boruch, Jeremy M Grimshaw
BMJ 2011;342:doi:10.1136/bmj.d2496 (Published 11 May 2011)
[Free full text]

Abstract

Objectives To investigate the extent to which authors of cluster randomised trials adhered to two basic requirements of the World Medical Association's Declaration of Helsinki and the International Committee of Medical Journal Editors' uniform requirements for manuscripts (namely, reporting of research ethics review and informed consent), to determine whether the adequacy of reporting has improved over time, and to identify characteristics of cluster randomised trials associated with reporting of ethics practices.

Design Review of a random sample of published cluster randomised trials from an electronic search in Medline.

Setting Cluster randomised trials in health research published in English language journals from 2000 to 2008.

Study sample 300 cluster randomised trials published in 150 journals.

Results 77 (26%, 95% confidence interval 21% to 31%) trials failed to report ethics review. The proportion reporting ethics review increased significantly over time (P<0.001). Trials with data collection interventions at the individual level were more likely to report ethics review than were trials that used routine data sources only (79% (n=151) v 55% (23); P=0.008). Trials that accounted for clustering in the design and analysis were more likely to report ethics review. The median impact factor of the journal of publication was higher for trials that reported ethics review (3.4 v 2.3; P<0.001). 93 (31%, 26% to 36%) trials failed to report consent. Reporting of consent increased significantly over time (P<0.001). Trials with interventions targeting

participants at the individual level were more likely to report consent than were trials with interventions targeting the cluster level (87% (90) v 48% (41); P<0.001). Trials with data collection interventions at the individual level were more likely to report consent than were those that used routine data sources only (78% (146) v 29% (11); P<0.001).

Conclusions Reporting of research ethics protections in cluster randomised trials is inadequate. In addition to research ethics approval, authors should report whether informed consent was sought, from whom consent was sought, and what consent was for.

Clinical Infectious Diseases
Volume 52 Issue 11 June 1, 2011
http://www.journals.uchicago.edu/toc/cid/current
Mark H. Eckman, Tiffany E. Kaiser, and Kenneth E. Sherman
The Cost-effectiveness of Screening for Chronic Hepatitis B Infection in the United States
Clin Infect Dis. (2011) 52(11): 1294-1306 doi:10.1093/cid/cir199
Abstract
(See the editorial commentary by Lo Re III, on pages 1307–1309.)
Background. Hepatitis B virus (HBV) continues to cause significant morbidity and mortality in the United States. Current guidelines suggest screening populations with a prevalence of ≥2%. Our objective was to determine whether this screening threshold is cost-effective and whether screening lower-prevalence populations might also be cost-effective.

Methods.We developed a Markov state transition model to examine screening of asymptomatic outpatients in the United States. The base case was a 35-year-old man living in a region with an HBV infection prevalence of 2%. Interventions (versus no screening) included screening for Hepatitis B surface antigen followed by treatment of appropriate patients with (1) pegylated interferon-α2a for 48 weeks, (2) a low-cost nucleoside or nucleotide agent with a high rate of developing viral resistance for 48 weeks, (3) prolonged treatment with low-cost, high-resistance nucleoside or nucleotide, or (4) prolonged treatment with a high-cost nucleoside or nucleotide with a low rate of developing viral resistance. Effectiveness was measured in quality-adjusted life years (QALYs) and costs in 2008 US dollars.

Results. Screening followed by treatment with a low-cost, high-resistance nucleoside or nucleotide was cost-effective ($29,230 per QALY). Sensitivity analyses revealed that screening costs <$50,000 per QALY in extremely low-risk populations unless the prevalence of chronic HBV infection is <.3%.

Conclusions.The 2% threshold for prevalence of chronic HBV infection in current Centers for Disease Control and Prevention/US Public Health Service screening guidelines is cost-effective. Furthermore, screening of adults in the United States in lower-prevalence populations (eg, as low as .3%) also is likely to be cost-effective, suggesting that current health policy should be reconsidered.
Received November 10, 2010.
Accepted February 2, 2011
Vincent Lo Re III

Editorial Commentary: Economic Analysis of Hepatitis B Screening and Treatment

Clin Infect Dis. (2011) 52(11): 1307-1309 doi:10.1093/cid/cir238

Extract

Approximately 350 million people worldwide are living with chronic hepatitis B virus (HBV) infection, and an estimated 620,000 die annually from complications of HBV-related liver disease [1]. In the United States, the incidence of acute HBV infection has declined substantially since 1985 as a result of the availability of effective HBV vaccines and widespread immunization of infants and high-risk populations [2]. Nevertheless, approximately 43,000 new cases of acute HBV infection occur each year in the United States [3]. Further, although vaccination programs have successfully reduced the incidence, the prevalence of chronic HBV infection has not declined, primarily because of the immigration of chronically infected persons from countries with high or intermediate HBV endemicity [4]. National surveys indicate that approximately 1.25 million US residents have chronic HBV infection (prevalence, 0.3%–0.5%) [5], and many are likely unaware of their infection status [6].

The public health impact of chronic HBV infection is almost entirely related to its long-term effects on liver-related complications [7, 8]. Specifically, chronic HBV infection is a major cause of cirrhosis, hepatic decompensation, and hepatocellular carcinoma, and the risk of these complications increases with higher HBV DNA levels [9, 10]. The number of hospitalizations, outpatient visits, and expenditures associated with chronic HBV infection has persistently increased over the past 20 years [4, 11], and as the influx of patients with chronic HBV infection in the United States continues, utilization of HBV-related health care …

James B. Wing, Lynne Smart, Ray Borrow, Jamie Findlow, Helen Findlow, Andrew W. Heath, and Robert C. Read

Editor's Choice: Kinetics of Immune Responses to Nasal Challenge With Meningococcal Polysaccharide One Year After Serogroup-C Glycoconjugate Vaccination

Clin Infect Dis. (2011) 52(11): 1317-1323 doi:10.1093/cid/cir198

Abstract

Background. Recipients of serogroup-C glycoconjugate meningococcal vaccine (MCC) exhibit waning of serum bactericidal antibody (SBA) titers, but the rate of decline and the speed of their immunological memory in response to new meningococcal nasopharyngeal colonization are unknown.

Methods.In a prospective challenge study, we measured persistence of SBA and anti–Neisseria meningitidis serogroup-C (MenC) immunoglobulin (Ig) G and IgA in adults aged 18–39, 28 days and 12 months after receiving MCC. Volunteers were then challenged intranasally with 50 μg MenC polysaccharide to mimic meningococcal colonization, and systemic and mucosal antibody responses were measured.

Results.All subjects had protective SBA titers (≥8) 28 days after MCC vaccination, but 12.3% and 20.2% had unprotective (<8) or low (<128) levels, respectively, after 12 months. Following rechallenge (12 months postvaccination) and measurement of antibody responses after 4, 7, and 10 days, rises in SBA titers were only observed in subjects with low (<128) or nonprotective (<8) prerechallenge SBA titers. In subjects with pre rechallenge SBA titers <8, the majority did not reach a protective SBA titer until 7 days post-rechallenge. MenC-specific IgG levels rose in both serum and saliva in correlation with SBA titers. No detectable rise in salivary IgA was observed.

Conclusions. In those individuals who fail to retain protective SBA 12 months after MCC, immunological memory fails to generate protective systemic and mucosal antibodies until 7 days post intranasal challenge with cognate meningococcal polysaccharide. This is likely too slow to protect from natural meningococcal infection. MCC vaccinees rely on persistence of antibody levels rather than immunological memory for sustained protection.

Vaccines

Sunheang Shin, Sachin N. Desai, Binod K. Sah, and John D. Clemens

Oral Vaccines Against Cholera

Clin Infect Dis. (2011) 52(11): 1343-1349 doi:10.1093/cid/cir141

Abstract

The current seventh pandemic of cholera, caused by serogroup O1, El Tor biotype, has now involved almost the entire developing world. The ongoing dynamic epidemiology of cholera, involving evolution of new strains, prolonged and more frequent epidemics, increased antimicrobial resistance, and awareness of the role of climate change upon the global burden has returned cholera to the forefront of global public health discussions. Improved water and sanitation should continue to be the mainstays of cholera-prevention efforts, but major improvements are a far-off goal for much of the cholera-affected developing world. The advent of safe and effective, new-generation oral vaccines against cholera has created renewed interest in the use of vaccines as a tool to control cholera.

Cost Effectiveness and Resource Allocation

(accessed 22 May 2011)

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

[No relevant content]

Emerging Infectious Diseases

Volume 17, Number 5–May 2011

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

[Reviewed earlier]

Health Affairs

May 2011; Volume 30, Issue 5

Environmental Challenges For Health

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

[No relevant content]

Health Economics, Policy and Law

Volume 6 - Issue 02

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

[Reviewed earlier; No relevant content]

Human Vaccines
Volume 7, Issue 5 May 2011
http://www.landesbioscience.com/journals/vaccines/toc/volume/7/issue/5/
[Reviewed earlier]

JAMA
May 18, 2011, Vol 305, No. 19, pp 1937-2024
http://jama.ama-assn.org/current.dtl
Commentaries
From Efficacy to Effectiveness in the Face of Uncertainty: Indication Creep and Prevention Creep
Benjamin Djulbegovic, Ash Paul
JAMA. 2011;305(19):2005-2006.doi:10.1001/jama.2011.650
Extract
Therapeutic and prevention clinical research is typically performed to address questions of efficacy ("Can intervention work in the ideal study setting?"), effectiveness ("Does it work, generalized to real-world settings and applied to individual patients?"), and cost-effectiveness ("Is it worth it and should it be paid for?"). To date, both public and private research enterprise has predominantly funded efficacy research. Comparative effectiveness research holds promise to generate much-needed effectiveness data. However, given the large number of important clinical questions, it will not be possible to provide reliable empirical efficacy, effectiveness, and cost-effectiveness data for every question to help guide individual decision-making. 1 Instead, practitioners will continue to rely on inductive reasoning to apply the results of the study ("group averages" from an efficacy trial) to individual patients who often differ in important ways from patients enrolled in the efficacy trial (eg, these patients may be older, have comorbid conditions, or might …

Journal of Infectious Diseases
Volume 203 Issue 11 June 1, 2011
http://www.journals.uchicago.edu/toc/jid/current
EDITORIAL COMMENTARIES
Stephen M. Ostroff
Editor's Choice: Measles: Going, Going, But Not Gone
J Infect Dis. (2011) 203(11): 1507-1509 doi:10.1093/infdis/jir125
Extract
For those of us engaged in disease investigation and response at the state and local level, the report by Chen and colleagues [1] in this issue of the Journal makes for sobering reading. It describes an outbreak of measles in Arizona where virus transmission predominantly occurred in the health care setting, a scenario of great concern to us all. In reading through the report, I was repeatedly reminded of the adage "What a fool does in the end, the wise do in the beginning." One hopes that a report of this nature will spur at least some health care systems, hospitals, and physicians' offices to act wisely before they too are confronted with a case of measles in their facilities. The Tucson outbreak also highlights many of the challenges faced by public health departments around the country with respect to a disease that, vaccine controversies

notwithstanding, has been receding in memory and importance for many health care practitioners, institutions, and the public

In the United States, we entered the "postelimination" era in 2000 [2]. But in the context of measles, "elimination" does not mean that there are no cases occurring. This is because the disease continues to be still too common in other parts of the world, and international travels produce opportunities for continued introduction [3]. As a result, between 2000 and 2008, an average of 56 cases per year have been confirmed in the United States [3]. And paradoxically, the number of cases may actually be rising as segments of the population increasingly opt out of vaccination, producing uneven vaccination rates and pockets of susceptibility [4]. This raises concerns that …
[Full Text of this Article]

Mark R. Schleiss

Editor's Choice: Could Therapeutic Vaccination of Cytomegalovirus-Seropositive Persons Prevent Reinfection and Congenital Virus Transmission?

J Infect Dis. (2011) 203(11): 1513-1516 doi:10.1093/infdis/jir144

Extract

In the developed world, cytomegalovirus (CMV) is the most common congenital viral infection, with an overall birth prevalence of ~0.6% [1]. Approximately 10% of congenitally infected infants have signs and symptoms of disease at birth, and these symptomatic infants have been reported to have a 40%–90% risk of subsequent neurologic sequelae, including mental retardation, microcephaly, development delay, seizure disorders, and cerebral palsy [2– 4]. Seven percent –to 20% of asymptomatically infected newborns will also demonstrate sequelae, particularly sensorineural hearing loss [5– 7]. The public health impact of congenital CMV infection is substantial and underrecognized; although more children suffer from long-term neurodevelopmental handicaps as a result of congenital CMV infection than either Down syndrome or fetal alcohol syndrome [8], awareness unfortunately remains low, particularly among women of childbearing age [9, 10]. An effective vaccine could, by preventing neurological sequelae and other disabilities, provide a newborn with a lifetime of benefit. For that reason, a report from the Institute of Medicine (IOM) of the National Academy of Sciences placed CMV in its highest priority category for vaccine development, concluding that a vaccine would be strongly cost saving [11, 12]. Among the various CMV vaccine candidates currently in clinical trials [13], the most encouraging results to date have been observed in studies of a vaccine based on the immunodominant envelope glycoprotein B (gB). Several clinical trials have been performed using a recombinant form of this protein expressed in Chinese hamster ovary cells, purified and combined with an oil-in-water adjuvant known as MF59 [14– 17]. Pass et al recently reported the results of a seminal phase II efficacy trial of the gB-MF59 …

VIRUSES

Sanny Y. Chen, Shoana Anderson, Preeta K. Kutty, Francelli Lugo, Michelle McDonald, Paul A. Rota, Ismael R. Ortega-Sanchez, Ken Komatsu, Gregory L. Armstrong, Rebecca Sunenshine, and Jane F. Seward

Editor's Choice: Health Care–Associated Measles Outbreak in the United States After an Importation: Challenges and Economic Impact

J Infect Dis. (2011) 203(11): 1517-1525 doi:10.1093/infdis/jir115

[Free full text]

Abstract

(See the editorial commentary by Ostroff, on pages 1507–9.)
Background. On 12 February 2008, an infected Swiss traveler visited hospital A in Tucson, Arizona, and initiated a predominantly health care–associated measles outbreak involving 14 cases. We investigated risk factors that might have contributed to health care–associated transmission and assessed outbreak-associated hospital costs.
Methods. Epidemiologic data were obtained by case interviews and review of medical records. Health care personnel (HCP) immunization records were reviewed to identify non–measles-immune HCP. Outbreak-associated costs were estimated from 2 hospitals.
Results. Of 14 patients with confirmed cases, 7 (50%) were aged ≥18 years, 4 (29%) were hospitalized, 7 (50%) acquired measles in health care settings, and all (100%) were unvaccinated or had unknown vaccination status. Of the 11 patients (79%) who had accessed health care services while infectious, 1 (9%) was masked and isolated promptly after rash onset. HCP measles immunity data from 2 hospitals confirmed that 1776 (25%) of 7195 HCP lacked evidence of measles immunity. Among these HCPs, 139 (9%) of 1583 tested seronegative for measles immunoglobulin G, including 1 person who acquired measles. The 2 hospitals spent US$799,136 responding to and containing 7 cases in these facilities.
Conclusions. Suspecting measles as a diagnosis, instituting immediate airborne isolation, and ensuring rapidly retrievable measles immunity records for HCPs are paramount in preventing health care–associated spread and in minimizing hospital outbreak–response costs.

The Lancet

May 21, 2011 Volume 377 Number 9779 Pages 1719 - 1806
http://www.thelancet.com/journals/lancet/issue/current

Editorial

HIV treatment as prevention—it works

The Lancet

Preview

Last week any doubts around treatment as an approach to halt the spread of the HIV epidemic were allayed. An international study showed that antiretroviral treatment can prevent the sexual transmission of HIV among heterosexual couples in whom one partner is HIV-infected and the other is not. UNAIDS described the result as a "serious game changer" for HIV prevention.

Articles

Long-term protection against malaria after experimental sporozoite inoculation: an open-label follow-up study

Meta Roestenberg, Anne C Teirlinck, Matthew BB McCall, Karina Teelen, Krystelle Nganou Makamdop, Jorien Wiersma, Theo Arens, Pieter Beckers, GeertJan van Gemert, Marga van de Vegte-Bolmer, André JAM van der Ven, Adrian JF Luty, Cornelus C Hermsen, Robert W Sauerwein

Preview

Artificially induced immunity lasts longer than generally recorded after natural exposure; providing a new avenue of research into the mechanisms of malaria immunity.

The Lancet Infectious Disease

May 2011 Volume 11 Number 5 Pages 333 - 416
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 473 Number 7347 pp253-414 19 May 2011
http://www.nature.com/nature/current_issue.html
[No relevant content]

Nature Medicine
May 2011, Volume 17 No 5
http://www.nature.com/nm/index.html
[Reviewed earlier]

New England Journal of Medicine
May 19, 2011 Vol. 364 No. 20
http://content.nejm.org/current.shtml
[No relevant content]

The Pediatric Infectious Disease Journal
May 2011 - Volume 30 - Issue 5 pp: A9-A10,365-450,e75-e87
http://journals.lww.com/pidj/pages/currenttoc.aspx
[Reviewed earlier; No relevant content]

Pediatrics
May 2011 / VOLUME 127 / ISSUE 5
http://pediatrics.aappublications.org/current.shtml
[No relevant content]

Pharmacoeconomics
June 1, 2011 - Volume 29 - Issue 6 pp: 455-547
http://adisonline.com/pharmacoeconomics/pages/currenttoc.aspx
Review Articles
Health Technology Funding Decision-Making Processes Around the World: The Same, Yet Different
Stafinski, Tania; Menon, Devidas; Philippon, Donald J.; McCabe, Christopher
Pharmacoeconomics. 29(6):475-495, June 1, 2011.
doi: 10.2165/11586420-000000000-00000
Abstract:

All healthcare systems routinely make resource allocation decisions that trade off potential health gains to different patient populations. However, when such trade-offs relate to the introduction of new, promising health technologies, perceived 'winners' and 'losers' are more apparent. In recent years, public scrutiny over such decisions has intensified, raising the need to better understand how they are currently made and how they might be improved. The objective of this paper is to critically review and compare current processes for making health technology funding decisions at the regional, state/provincial and national level in 20 countries.

A comprehensive search for published, peer-reviewed and grey literature describing actual national, state/provincial and regional/institutional technology decision-making processes was conducted. Information was extracted by two independent reviewers and tabulated to facilitate qualitative comparative analyses. To identify strengths and weaknesses of processes identified, websites of corresponding organizations were searched for commissioned reviews/evaluations, which were subsequently analysed using standard qualitative methods.

A total of 21 national, four provincial/state and six regional/institutional-level processes were found. Although information on each one varied, they could be grouped into four sequential categories: (i) identification of the decision problem; (ii) information inputs; (iii) elements of the decision-making process; and (iv) public accountability and decision implementation. While information requirements of all processes appeared substantial and decision-making factors comprehensive, the way in which they were utilized was often unclear, as were approaches used to incorporate social values or equity arguments into decisions.

A comprehensive inventory of approaches to implementing the four main components of all technology funding decision-making processes was compiled, from which areas for future work or research aimed at improving the acceptability of decisions were identified. They include the explication of decision criteria and social values underpinning processes

PLoS Medicine
(Accessed 22 May 2011)
http://www.plosmedicine.org/article/browse.action?field=date
[No relevant content]

Science
20 May 2011 vol 332, issue 6032, pages 881-996
http://www.sciencemag.org/current.dtl
[No relevant content]

Science Translational Medicine
18 May 2011 vol 3, issue 83
http://stm.sciencemag.org/content/current
[No relevant content]

Tropical Medicine & International Health
June 2011 Volume 16, Issue 6 Pages 661–772
http://onlinelibrary.wiley.com/doi/10.1111/tmi.2011.16.issue-6/issuetoc
[Reviewed last week]

Vaccine
Volume 29, Issue 24 pp. 4079-4182 (31 May 2011)
http://www.sciencedirect.com/science/journal/0264410X
Short Communications
Patent data mining: A tool for accelerating HIV vaccine innovation
Pages 4086-4093
K. Clark, J. Cavicchi, K. Jensen, R. Fitzgerald, A. Bennett, S.P. Kowalski
Abstract
Global access to advanced vaccine technologies is challenged by the interrelated components of intellectual property (IP) management strategies, technology transfer (legal and technical) capabilities and the capacity necessary for accelerating R&D, commercialization and delivery of vaccines. Due to a negative association with the management of IP, patents are often overlooked as a vast resource of freely available, information akin to scientific journals as well as business and technological information and trends fundamental for formulating policies and IP management strategies. Therefore, a fundamental step towards facilitating global vaccine access will be the assembly, organization and analysis of patent landscapes, to identify the amount of patenting, ownership (assignees) and fields of technology covered. This is critical for making informed decisions (e.g., identifying licensees, building research and product development collaborations, and ascertaining freedom to operate). Such information is of particular interest to the HIV vaccine community where the HIV Vaccine Enterprise, have voiced concern that IP rights (particularly patents and trade secrets) may prevent data and materials sharing, delaying progress in research and development of a HIV vaccine. We have compiled and analyzed a representative HIV vaccine patent landscape for a prime-boost, DNA/adenoviral vaccine platform, as an example for identifying obstacles, maximizing opportunities and making informed IP management strategy decisions towards the development and deployment of an efficacious HIV vaccine.
Addressing the needs and gaps in safety assessment of vaccines during clinical trials in resource limited countries
Pages 4173-4174
Agnes Kisser, Ulrich Heininger, Vasee S. Moorthy, Bartholomew D. Akanmori, Odile Lero
[No abstract]
Economic burden of rotavirus disease in children under 5 years in Kazakhstan
Pages 4175-4180
Renat Latipov, Aynagul Kuatbaeva, Olga Kristiansen, Saltanat Aubakirova, Ulbosin Akhanaeva, Ivar Sønbø Kristiansen, Elmira Flem
Abstract
Background
We aimed to estimate the societal costs of rotavirus cases among children less than 5 years in Kazakhstan, an upper-middle income country in Central Asia.
Methods

Data on medical, non-medical and indirect costs were collected for 190 patients less than 5 years, hospitalized with severe diarrhea in 2009 in two pediatric hospitals. Data on resource use for moderate and mild diarrhea cases were obtained from published sources. A probabilistic sensitivity analysis was performed to explore uncertainty in cost estimates.

Results

Approximately 4,000 severe, 30,700 moderate, and 122,900 mild rotavirus cases were estimated annually in children <5 years old. The mean societal cost of a severe, moderate and mild rotavirus case was estimated at US$ 454, 82, and 21, respectively. The total annual cost of rotavirus disease was $37.53 million or on average $107.36 for a child under 5 years old in Kazakhstan. Ninety-four percent of total costs (35.13 million) are indirect costs (productivity losses) from fatal cases and parents' job absenteeism, while direct medical costs account for 2.04 million (5.4%), and direct non-medical for 0.46 million (1.2%).

Conclusions

Rotavirus-associated diarrhea represents a significant economic burden in Kazakhstan, largely due to indirect costs. The costs of rotavirus infections should be considered when planning further preventive actions, including the introduction of rotavirus vaccination.