

Vaccines: The Week in Review
14 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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WHO announced the introduction of pneumococcal conjugate vaccine by the Government of Kenya with support from WHO and partners. Kenya is the fourth country to include the vaccine into its national immunization programme in the past three months, after Nicaragua, Sierra Leone and Yemen. WHO said the introduction comes less than two years after the same vaccine was introduced in industrialized countries. Dr Margaret Chan, WHO Director-General, commented, "The rapid roll-out of new-generation pneumococcal vaccine shows how innovation and technology can be harnessed, at affordable prices, to save lives in the developing world. The payback, as measured by reduced childhood mortality, will be enormous."

http://www.who.int/immunization/newsroom/newsstory_new_gen_pneumo_vaccine_feb_2011/en/index.html

IVI (International Vaccine Institute) announced the launch of the Dengue Vaccine Initiative (DVI), in collaboration with the Sabin Vaccine Institute, the Johns Hopkins University, and the World Health Organization "to support development of vaccines to control dengue fever, a widespread and expanding hemorrhagic fever that is endemic in most tropical and subtropical regions of the world." DVI is supported by a US\$6.9 million grant from the Bill & Melinda Gates Foundation, and "will accelerate the development and utilization of safe, affordable and broadly protective vaccines to combat dengue, a mosquito-borne infection which causes severe flu-like symptoms, and its potentially lethal complication dengue hemorrhagic fever, characterized by bleeding, plasma fluid leakage, and in severe cases shock and death." Each year, an estimated 2

million people with dengue hemorrhagic fever require hospitalization representing a significant burden on the fragile healthcare systems of developing and endemic nations.

Dr. John Clemens, Director-General of IVI, commented, "We are extremely grateful for the Gates Foundation's continued support of our critical work to promote the development of life-saving dengue vaccines and ensure their effective introduction. Dengue is an infection whose burden has increased sharply around the world. The global dengue community is on the eve of many important breakthroughs in dengue research and development, and I believe that we'll make significant progress in controlling dengue within the decade."

<http://sabin.org/news-resources/releases/2011/02/10/dengue-vaccine-initiative-launched-raise-profile-dengue-and-promo>

IFPMA "expressed the research-based pharmaceutical industry's support for calls to extend the deadline for Least-Developed Countries to comply with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)." Mr. David Brennan, President of the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) and CEO of AstraZeneca, said, "We recognize the significant development challenges experienced by Least-Developed Countries and believe that an extension would be useful to allow for effective TRIPS implementation. Such an extension should be used to align implementation across all areas of technology, to ensure a consistent approach. Our industry continues to believe that effective Intellectual Property Rights are a crucial component of long-term economic development within these countries, and international organizations and national bodies should continue to provide technical assistance, based on specific in-country needs."

<http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=13819>

The **Weekly Epidemiological Record (WER) for 11 February 2011**, vol. 86, 7 (pp 53–60) includes: Meeting of the International Task Force for Disease Eradication – October 2010

<http://www.who.int/entity/wer/2011/wer8607.pdf>

GAVI's Phase III (2011-15) Strategic Plan is posted. GAVI notes that the plan has four goals, each supporting GAVI's overall mission:

- Strategic goal 1: accelerate the uptake and use of underused and new vaccines;
- Strategic goal 2: contribute to strengthening the capacity of integrated health systems to deliver immunisation;
- Strategic goal 3: increase the predictability of global financing and improve the sustainability of national financing for immunisation;
- Strategic goal 4: shape vaccine markets.

The strategy also includes two cross-cutting areas: Monitoring and Evaluation, and Advocacy, Communication and Public Policy.

In November 2010, the GAVI Board approved a business plan designed to implement the strategy and ensure that GAVI's day-to-day activities deliver on its overall mission. The 2011-15 business plan includes:

- defined targets and goal-level indicators;
- 26 programme objectives with measurable deliverables;
- detailed activities and 2011-2012 budgets.

Strategy Table: http://www.gavialliance.org/resources/Strategy_2011_2015_Table.pdf

Business Plan: http://www.gavialliance.org/resources/Business_Plan_2011_2015.pdf

<http://www.gavialliance.org/vision/strategy/phase3/index.php>

Twitter Watch

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

[GAVIAlliance](#) GAVI Alliance

T-1: 1 million children could be saved every year by fighting pneumonia. Find Out How:

<http://ht.ly/3VDEy>

[sabinvaccine](#) Sabin Vaccine Inst.

[#Dengue](#) Vaccine Initiative formed 2 develop vaccines against infection which impacts 55% of the world: <http://bit.ly/gAPEED>

[gatesfoundation](#) Gates Foundation

Contest: Raise awareness on [#vaccines](#) & win \$5K from @GOOD. Sky is the limit--start thinking now: <http://bit.ly/dEuhIM>

[AIDSvaccine](#) IAVI

Saddened by passing of HIV prevention advocate Matilda Mogale of Soweto. We honor her commitment to find an HIV vaccine <http://bit.ly/h9dGoO>

[CDCgov](#) CDC.gov

Be part of the U.S. polio success story: immunize & protect against polio.

<http://go.usa.gov/gli>

[malariaday2011](#) World Malaria Day

by FightingMalaria

[#WorldMalariaDay2011](#) WHO Focus is capturing results achieved by all partners in the fight against [#malaria](#) <http://bit.ly/g4M16f>

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 1, 2011; 154 (3)

<http://www.annals.org/content/current>

[Reviewed last week]

British Medical Journal

12 February 2011 Volume 342, Issue 7793

<http://www.bmj.com/content/current>

Editorials

Postmarketing studies of drug safety

Sebastian Schneeweiss,

Jerry Avorn

A European initiative could help bring more transparency and rigour to pharmacoepidemiology

In the early days of randomised clinical trials, their results could be manipulated in several ways—protocols could be altered in light of early findings, sponsors could exert undue influence over what could be published, and some “unfavourable” results could be suppressed entirely. In the United States, the creation of the government clinical trials website (www.clinicaltrials.gov) greatly contributed to minimising these threats to honest science. 1 But requiring similar consistency, rigour, and transparency has been more difficult with observational studies, because any person or company with modest resources can purchase a large database of health insurance claims and perform a variety of epidemiological analyses with little or no accountability for the transparency, rigour, or visibility of such work ↓ .

In 2006, the European Medicines Agency took on this problem by creating the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) to provide registration, standardisation, and quality assurance for observational studies of the effects of drugs (www.encepp.eu/). To qualify for the “ENCePP seal,” study organisers must agree to a code of conduct and transparency, meet a checklist of methodological standards, and agree to publicly post the study protocol as well as its results. 2

“Best practices” for the conduct of epidemiological studies of the safety of drugs are less well standardised than those developed over the ...

Clinical Infectious Diseases

Volume 52 Issue 5 March 1, 2011

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

[Reviewed last week]

Emerging Infectious Diseases

Volume 17, Number 2–February 2011

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

[Reviewed last week]

Human Vaccines

Volume 7, Issue 2 February 2011

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

[Reviewed last week]

JAMA

February 9, 2011, Vol 305, No. 6, pp 535-634

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

Original Contributions

Maternal HIV Infection and Antibody Responses Against Vaccine-Preventable Diseases in Uninfected Infants

Christine E. Jones, Shalena Naidoo, Corena De Beer, Monika Esser, Beate Kampmann, Anneke C. Hesselning

JAMA. 2011;305(6):576-584.doi:10.1001/jama.2011.100

Abstract

Context

Altered immune responses might contribute to the high morbidity and mortality observed in human immunodeficiency virus (HIV)–exposed uninfected infants.

Objective

To study the association of maternal HIV infection with maternal- and infant-specific antibody levels to Haemophilus influenzae type b (Hib), pneumococcus, Bordetella pertussis antigens, tetanus toxoid, and hepatitis B surface antigen.

Design, Setting, and Participants

A community-based cohort study in Khayelitsha, Western Cape Province, South Africa, between March 3, 2009, and April 28, 2010, of 109 HIV-infected and uninfected women and their infants. Serum samples from 104 women and 100 infants were collected at birth and samples from 93 infants were collected at 16 weeks.

Main Outcome Measure

Level of specific antibody in mother-infant pairs at delivery and in infants at 16 weeks, determined by enzyme-linked immunosorbent assays.

Results

At birth, HIV-exposed uninfected infants (n = 46) had lower levels of specific antibodies than unexposed infants (n = 54) did to Hib (0.37 [interquartile range {IQR}, 0.22-0.67] mg/L vs 1.02 [IQR, 0.34-3.79] mg/L; P < .001), pertussis (16.07 [IQR, 8.87-30.43] Food and Drug Administration [FDA] U/mL vs 36.11 [IQR, 20.41-76.28] FDA U/mL; P < .001), pneumococcus (17.24 [IQR, 11.33-40.25] mg/L vs 31.97 [IQR, 18.58-61.80] mg/L; P = .02), and tetanus (0.08 [IQR, 0.03-0.39] IU/mL vs 0.24 [IQR, 0.08-0.92] IU/mL; P = .006). Compared with HIV-uninfected women (n = 58), HIV-infected women (n = 46) had lower specific antibody levels to Hib (0.67 [IQR, 0.16-1.54] mg/L vs 1.34

[IQR, 0.15-4.82] mg/L; P = .009) and pneumococcus (33.47 [IQR, 4.03-69.43] mg/L vs 50.84 [IQR, 7.40-118.00] mg/L; P = .03); however, no differences were observed for antipertussis or antitetanus antibodies. HIV-exposed uninfected infants (n = 38) compared with HIV-unexposed infants (n = 55) had robust antibody responses following vaccination, with higher antibody responses to pertussis (270.1 [IQR, 84.4-355.0] FDA U/mL vs 91.7 [IQR, 27.9-168.4] FDA U/mL; P = .006) and pneumococcus (47.32 [IQR, 32.56-77.80] mg/L vs 14.77 [IQR, 11.06-41.08] mg/L; P = .001).

Conclusion

Among South African infants, antenatal HIV exposure was associated with lower specific antibody responses in exposed uninfected infants compared with unexposed infants at birth, but with robust responses following routine vaccination.

Journal of Infectious Diseases

Volume 203 Issue 5 March 1, 2011

<http://www.journals.uchicago.edu/toc/jid/current>

[Reviewed earlier; No relevant content]

The Lancet

Feb 12, 2011 Volume 377 Number 9765 Pages 527 - 610

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

Series

Emerging infectious diseases in southeast Asia: regional challenges to control

Richard J Coker, Benjamin M Hunter, James W Rudge, Marco Liverani, Piya Hanvoravongchai

Summary

Southeast Asia is a hotspot for emerging infectious diseases, including those with pandemic potential. Emerging infectious diseases have exacted heavy public health and economic tolls. Severe acute respiratory syndrome rapidly decimated the region's tourist industry. Influenza A H5N1 has had a profound effect on the poultry industry. The reasons why southeast Asia is at risk from emerging infectious diseases are complex. The region is home to dynamic systems in which biological, social, ecological, and technological processes interconnect in ways that enable microbes to exploit new ecological niches. These processes include population growth and movement, urbanisation, changes in food production, agriculture and land use, water and sanitation, and the effect of health systems through generation of drug resistance. Southeast Asia is home to about 600 million people residing in countries as diverse as Singapore, a city state with a gross domestic product (GDP) of US\$37 500 per head, and Laos, until recently an overwhelmingly rural economy, with a GDP of US\$890 per head. The regional challenges in control of emerging infectious diseases are formidable and range from influencing the factors that drive disease emergence, to making surveillance systems fit for purpose, and ensuring that regional governance mechanisms work effectively to improve control interventions.

The Lancet Infectious Disease

Feb 2011 Volume 11 Number 2 Pages 73 - 152

<http://www.thelancet.com/journals/laninf/issue/current>

[Reviewed earlier]

Nature

Volume 470 Number 7333 pp139-300 10 February 2011

http://www.nature.com/nature/current_issue.html

World View

Pharmaceutical industry must take its medicine

To fix the drug pipeline, governments must take on drug-makers instead of capitulating to their every demand, says Colin Macilwain.

Nature Medicine

February 2011, Volume 17 No 2

<http://www.nature.com/nm/index.html>

[Reviewed last week]

New England Journal of Medicine

February 10, 2011 Vol. 364 No. 6

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

Perspective

Developing the Sentinel System — A National Resource for Evidence

Development

R.E. Behrman and Others

[Free Full-Text]

The Food and Drug Administration (FDA) now has the capacity to “query” the electronic health information of more than 60 million people, posing specific questions in order to monitor the safety of approved medical products. This pilot program, called Mini-Sentinel, uses a distributed data network (rather than a centralized database) that allows participating health plans and other organizations to create data files in a standard format and to maintain possession of those files. These organizations perform most analyses of their own data by running computer programs distributed by a coordinating center, and they provide consistent summarized results for the FDA's review.¹ The principles and practices involved in this effort to improve the safety of medical products can inform other uses of electronic health information to answer additional important questions about health and health care.

When the FDA announced the Sentinel Initiative in May 2008, it established a vision and objectives for the program, including the development of the Sentinel System, which will eventually be able to search the electronic health data of a minimum of 100 million patients.² Laying the groundwork for that system has required an extraordinary range of input from public and private organizations. Under a cooperative agreement with the FDA, the Engelberg Center for Health Care Reform at the Brookings Institution has been convening an ongoing series of discussions among stakeholders to address the near- and long-term challenges inherent in implementing the Sentinel System.³ In 2009, the FDA gave the Harvard Pilgrim Health Care Institute the lead role in fulfilling a 5-year contract to establish a system — the Mini-Sentinel — for developing and testing

approaches and methods that could be used to inform the structure and operations of the full Sentinel System. The institute is now leading a diverse partnership of approximately 200 epidemiologists, clinical content experts, statisticians, and data specialists from 27 institutions that are participating in this pilot system (www.minisentinel.org).

Through the Mini-Sentinel, capabilities are being developed for actively monitoring the safety of approved medical products using the electronic health information in claims systems, inpatient and outpatient medical records, and patient registries. The Mini-Sentinel builds on the work of the Vaccine Safety Datalink project (managed by the Centers for Disease Control and Prevention), the HMO Research Network, the Population Medicine Distributed Research Network (PopMedNet, funded by the Agency for Healthcare Research and Quality), and the Observational Medical Outcomes Partnership, among others.⁴

In the first year of the Mini-Sentinel project, its leaders established a network of data partners and a system with robust patient-privacy policies that could be used in querying the network's databases. The initiative's distributed data network allows each data partner to maintain physical and operational control over its own patient-level data, while providing the aggregated information needed to address the FDA's questions. Source data reside behind the data partners' institutional firewalls, where they are transformed into a standard format. This approach allows each data partner to answer the FDA's queries by executing standardized computer programs distributed by the Mini-Sentinel Operations Center. A typical result might include the number of new users of a product who experience a particular outcome, grouped according to age, sex, other treatments, and health status. This use of distributed analysis — whenever possible — eliminates or greatly reduces the exchange of protected health information. The data partners can obtain full-text medical records when necessary to confirm diagnoses or exposures and to determine the existence or severity of risk factors.

The initial focus of Mini-Sentinel has been on developing the ability to use claims data. In the next year, laboratory-test results and vital signs, derived from electronic health records and clinical laboratory records, will be added. The partnership is also evaluating procedures whereby Mini-Sentinel data partners will be able to link to data held by other organizations, such as state immunization registries and device registries.

The FDA will soon begin to actively monitor the data, seeking answers to specific questions about the performance of medical products, such as the frequency of myocardial infarction among users of oral hypoglycemic agents (a topic selected because it has been difficult to identify drug-induced myocardial infarction through existing prospective surveillance mechanisms). The FDA will also monitor the occurrence of adverse events associated with select routinely administered vaccines. Using the Mini-Sentinel system, the FDA will also be able to obtain rapid responses to new questions about medical products and, eventually, to evaluate the health effects of its regulatory actions. This monitoring portfolio will expand as the FDA and its collaborators acquire experience and develop operational efficiencies and as additional data resources become available.

The distributed-database-and-analysis model and the infrastructure of the Mini-Sentinel data network can be extended to other forms of evidence development. Provisions in the economic stimulus and health care reform legislation, and a recent report from the President's Council of Advisors on Science and Technology,⁵ envision expanded use of electronic health information for other types of public health

surveillance, quality measurement, comparative effectiveness research, and biomedical research — all of which are essential to improving the country's health and health care delivery system.

Issues relevant to other secondary uses of electronic health information include recruitment of appropriate data partners, development and refinement of analytic methods, implementation of standards to ensure that analytic methods are consistent across the data sources, and above all, protection for the rights and privacy of patients. Data privacy and security are top priorities that were key considerations in the decision to build Mini-Sentinel as a system that uses a distributed data system and distributed analysis whenever possible. The committed collaboration among representatives of patients and consumers, health care professionals, Mini-Sentinel's data partners and safety scientists, and the medical-products industry has been essential to the Sentinel Initiative's progress.

It is particularly challenging to establish appropriate governance for a distributed data network that can support multiple secondary uses for health information. The current infrastructure is supported by a single federal agency, the FDA, and all the data are provided by private organizations, yet potential users of such a system reside not only broadly in government but also in academia, the private sector, and other user communities. To facilitate the development of this infrastructure into a national resource, this distributed system may ultimately be best managed by a consortium of interested parties operating as a public–private partnership. For example, specialized network-coordinating centers might rely on a consistent infrastructure to use the same sources of health information for various purposes, including public health uses, effectiveness research, quality measurement, and health services research.

The envisioned Sentinel System will build on the knowledge, partnerships, data resources, privacy protections, and technical capabilities that are being developed in the Mini-Sentinel program. Success in the form of improved safety of medical products will depend on the continued engagement of all concerned stakeholders and on ensuring that patients, consumers, and health care providers understand that all medical products pose risks and that postmarketing surveillance is critical to expanding the limited evidence base that exists when products are approved. Success also depends on the continued development of surveillance methods and on increasing the workforce of scientists who are trained to develop and interpret this evidence effectively.

Health care data represent a precious resource that must be used to the fullest possible extent to promote the public health, while the rights of patients and consumers are protected. As an early working model for secondary uses of data produced in the routine delivery of health care, the Sentinel System can and should become a national resource for evidence development and a cornerstone of a learning health care system.

This article (10.1056/NEJMp1014427) was published on January 12, 2011, at NEJM.org.

Special Article

[The Role of Public-Sector Research in the Discovery of Drugs and Vaccines](#)

A.J. Stevens and Others

Background

Historically, public-sector researchers have performed the upstream, basic research that elucidated the underlying mechanisms of disease and identified promising points of intervention, whereas corporate researchers have performed the downstream, applied research resulting in the discovery of drugs for the treatment of diseases and have

carried out development activities to bring them to market. However, the boundaries between the roles of the public and private sectors have shifted substantially since the dawn of the biotechnology era, and the public sector now has a much more direct role in the applied-research phase of drug discovery.

[Full Text of Background...](#)

Methods

We identified new drugs and vaccines approved by the Food and Drug Administration (FDA) that were discovered by public-sector research institutions (PSRIs) and classified them according to their therapeutic category and potential therapeutic effect.

[Full Text of Methods...](#)

Results

We found that during the past 40 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in PSRIs. These drugs included 93 small-molecule drugs, 36 biologic agents, 15 vaccines, 8 in vivo diagnostic materials, and 1 over-the-counter drug. More than half of these drugs have been used in the treatment or prevention of cancer or infectious diseases. PSRI-discovered drugs are expected to have a disproportionately large therapeutic effect.

[Full Text of Results...](#)

Conclusions

Public-sector research has had a more immediate effect on improving public health than was previously realized.

The Pediatric Infectious Disease Journal

March 2011 - Volume 30 - Issue 3 pp: A9-A10,187-272,e38-e55

<http://journals.lww.com/pidj/pages/currenttoc.aspx>

Commentary

[Anthroposophy: A Risk Factor for Noncompliance With Measles Immunization](#)

Ernst, Edzard

Pediatric Infectious Disease Journal. 30(3):187-189, March 2011.

doi: 10.1097/INF.0b013e3182024274

[No abstract available]

[Measles in the United States During the Postelimination Era: Fiebelkorn AP, et al. J Infect Dis. 2010;202: 1520–1528](#)

Pediatric Infectious Disease Journal. 30(3):226, March 2011.

doi: 10.1097/INF.0b013e31820b93c0

[Primary Care Pediatricians' Perceptions of Vaccine Refusal in Europe](#)

Grossman, Zachi; van Esso, Diego; del Torso, Stefano; Hadjipanayis, Adamos; Drabik, Anna; Gerber, Andreas; Miron, Dan

Pediatric Infectious Disease Journal. 30(3):255-256, March 2011.

doi: 10.1097/INF.0b013e3181faaaa3

Abstract:

An electronic survey assessing primary care pediatricians' estimations and practices regarding parents' vaccination refusal was sent to 395 members of the European Academy of Pediatrics Research in Ambulatory Setting network, with a response rate of 87%. Of respondents who vaccinate in the clinic, 93% estimated the total vaccine refusal rate as <1%. Of all respondents, 69% prefer a shared decision-making approach to handle refusing parents.

Pediatrics

February 2011 / VOLUME 127 / ISSUE 2

<http://pediatrics.aappublications.org/current.shtml>

[Reviewed last week]

Pharmacoeconomics

March 1, 2011 - Volume 29 - Issue 3 pp: 173-268

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

Commentary

Including Indirect Medical Care Costs from Survivor Years of Life in Economic Evaluations

Nyman, John A.; Jalal, Hawre J.

Pharmacoeconomics. 29(3):173-174, March 1, 2011.

doi: 10.2165/11588790-000000000-00000

Leading Article

Standardizing the Inclusion of Indirect Medical Costs in Economic Evaluations

van Baal, Pieter H.M.; Wong, Albert; Slobbe, Laurentius C.J.; Polder, Johan J.; Brouwer, Werner B.F.; de Wit, G. Ardine

Pharmacoeconomics. 29(3):175-187, March 1, 2011.

Abstract

A shortcoming of many economic evaluations is that they do not include all medical costs in life-years gained (also termed indirect medical costs). One of the reasons for this is the practical difficulties in the estimation of these costs. While some methods have been proposed to estimate indirect medical costs in a standardized manner, these methods fail to take into account that not all costs in life-years gained can be estimated in such a way. Costs in life-years gained caused by diseases related to the intervention are difficult to estimate in a standardized manner and should always be explicitly modelled. However, costs of all other (unrelated) diseases in life-years gained can be estimated in such a way.

We propose a conceptual model of how to estimate costs of unrelated diseases in life-years gained in a standardized manner. Furthermore, we describe how we estimated the parameters of this conceptual model using various data sources and studies conducted in the Netherlands. Results of the estimates are embedded in a software package called 'Practical Application to Include future Disease costs' (PAID 1.0). PAID 1.0 is available as a Microsoft® Excel tool (available as Supplemental Digital Content via a link in this article) and enables researchers to 'switch off' those disease categories that were already included in their own analysis and to estimate future healthcare costs of all other diseases for incorporation in their economic evaluations.

We assumed that total healthcare expenditure can be explained by age, sex and time to death, while the relationship between costs and these three variables differs per disease. To estimate values for age- and sex-specific per capita health expenditure per disease and healthcare provider stratified by time to death we used Dutch cost-of-illness (COI) data for the year 2005 as a backbone. The COI data consisted of age- and sex-specific per capita health expenditure uniquely attributed to 107 disease categories and eight healthcare provider categories. Since the Dutch COI figures do not distinguish

between costs of those who die at a certain age (decedents) and those who survive that age (survivors), we decomposed average per capita expenditure into parts that are attributable to decedents and survivors, respectively, using other data sources.

Review Article

Cost Effectiveness of Pneumococcal Conjugate Vaccination against Acute Otitis Media in Children: A Review

Boonacker, Chantal W.B.; Broos, Pieter H.; Sanders, Elisabeth A.M.; Schilder, Anne G.M.; Rovers, Maroeska M.

Pharmacoeconomics. 29(3):199-211, March 1, 2011.

doi: 10.2165/11584930-000000000-00000

Abstract:

While pneumococcal conjugate vaccines have shown to be highly effective against invasive pneumococcal disease, their potential effectiveness against acute otitis media (AOM) might become a major economic driver for implementing these vaccines in national immunization programmes. However, the relationship between the costs and benefits of available vaccines remains a controversial topic. Our objective is to systematically review the literature on the cost effectiveness of pneumococcal conjugate vaccination against AOM in children.

We searched PubMed, Cochrane and the Centre for Reviews and Dissemination databases (Database of Abstracts of Reviews of Effects [DARE], NHS Economic Evaluation Database [NHS EED] and Health Technology Assessment database [HTA]) from inception until 18 February 2010. We used the following keywords with their synonyms: 'otitis media', 'children', 'cost-effectiveness', 'costs' and 'vaccine'. Costs per AOM episode averted were calculated based on the information in this literature.

A total of 21 studies evaluating the cost effectiveness of pneumococcal conjugate vaccines were included. The quality of the included studies was moderate to good. The cost per AOM episode averted varied from €168 to €4214, and assumed incidence rates varied from 20 952 to 118 000 per 100 000 children aged 0–10 years. Assumptions regarding direct and indirect costs varied between studies. The assumed vaccine efficacy of the 7-valent pneumococcal CRM197-conjugate vaccine was mainly adopted from two trials, which reported 6–8% efficacy. However, some studies assumed additional effects such as herd immunity or only took into account AOM episodes caused by serotypes included in the vaccine, which resulted in efficacy rates varying from 12% to 57%. Costs per AOM episode averted were inversely related to the assumed incidence rates of AOM and to the estimated costs per AOM episode. The median costs per AOM episode averted tended to be lower in industry-sponsored studies.

Key assumptions regarding the incidence and costs of AOM episodes have major implications for the estimated cost effectiveness of pneumococcal conjugate vaccination against AOM. Uniform methods for estimating direct and indirect costs of AOM should be agreed upon to reliably compare the cost effectiveness of available and future pneumococcal vaccines against AOM.

Pharmacoeconomics & Outcomes News

February 5, 2011 - Volume - Issue 621 pp: 1-11

<http://adisonline.com/pecnews/pages/currenttoc.aspx>

[Reviewed earlier; No relevant content]

PLoS Medicine

(Accessed 13 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

A Surprising Prevention Success: Why Did the HIV Epidemic Decline in

Zimbabwe? Daniel T. Halperin, Owen Mugurungi, Timothy B. Hallett, Backson Muchini, Bruce Campbell, Tapuwa Magure, Clemens Benedikt, Simon Gregson Policy Forum, published 08 Feb 2011

doi:10.1371/journal.pmed.1000414

Summary Points

- There is growing recognition that primary prevention, including behavior change, must be central in the fight against HIV/AIDS. The earlier successes in Thailand and Uganda may not be fully relevant to the severely affected countries of southern Africa.
- We conducted an extensive multi-disciplinary synthesis of the available data on the causes of the remarkable HIV decline that has occurred in Zimbabwe (29% estimated adult prevalence in 1997 to 16% in 2007), in the context of severe social, political, and economic disruption.
- The behavioral changes associated with HIV reduction—mainly reductions in extramarital, commercial, and casual sexual relations, and associated reductions in partner concurrency—appear to have been stimulated primarily by increased awareness of AIDS deaths and secondarily by the country's economic deterioration. These changes were probably aided by prevention programs utilizing both mass media and church-based, workplace-based, and other inter-personal communication activities.
- Focusing on partner reduction, in addition to promoting condom use for casual sex and other evidence-based approaches, is crucial for developing more effective prevention programs, especially in regions with generalized HIV epidemics.

Science

11 February 2011 vol 331, issue 6018, pages 639-806

<http://www.sciencemag.org/current.dtl>

[No relevant content]

Science Translational Medicine

9 February 2011 vol 3, issue 69

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

Commentaries

Data Sharing

Power to the People: Participant Ownership of Clinical Trial Data

Sharon F. Terry and

Patrick F. Terry

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Abstract

Participation in clinical trials is dismally low. In this age of electronic sharing of information of all sorts, trial participants can easily share clinical trial data. The benefits of participant ownership and sharing of trial data appear to outweigh the risks. Thus, the time has come to crowd-source data for diagnostic and therapy development.

Health Information Technology

Electronic Consent Channels: Preserving Patient Privacy Without Handcuffing

Researchers

Robert H. Shelton

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Abstract

Advances in health information technology and electronic medical records have the tremendous potential to accelerate translational and clinical research. However, privacy concerns threaten to be a rate-limiting factor. By recognizing and responding to patient privacy concerns, policy-makers, researchers, and information technology leaders have the opportunity to transform trial recruitment and make it safer to electronically locate and convey sensitive health information.

Vaccine

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