## Vaccines: The Week in Review

#### 21 November 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/service/vaccine-education-center/home.html

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 <u>http://centerforvaccineethicsandpolicy.wordpress.com/</u>. This blog allows full-texting searching of some 2,000 content items. Comments and suggestions should be directed to David R. Curry, MS Editor and

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The GAVI Board said it "will take the first steps towards the introduction of HPV and rubella vaccines in developing countries." Regarding HPV vaccine, GAVI said that "if negotiations to secure a sustainable price from manufacturers are successful and countries can demonstrate their ability to deliver the vaccines, up to two million women and girls in nine countries could be protected from cervical cancer by 2015." Regarding rubella, GAVI said that "responding to projected demand from 30 countries and World Health Organization (WHO) recommendations, the Board also agreed to open a funding window for vaccines against the rubella virus, which threatens pregnancies and child health. The plan is to reach 588 million children by 2015." Seth Berkley MD, CEO of GAVI, commented, "These two initiatives have huge potential impact for women and families in the developing world...The HPV vaccine is critical to women and girls in poorer countries because they usually do not have access to screening to prevent cervical cancer and treatment taken for granted in richer nations. Today, we have taken deliberate first steps to correct this inequity." GAVI-funded rubella vaccines will be combined for easy delivery with measles vaccines in a single measles-rubella (MR) shot, supporting the global measles immunisation effort. If contracted by pregnant women, rubella can lead to multiple severe birth defects that cause lifelong disabilities. Some 90,000 birth defects occur each year in GAVI-eligible countries, equivalent to 80% of the global burden. It can also lead to miscarriage and stillbirth. The GAVI Board also said it

will consider funding a vaccine against Japanese encephalitis once an appropriate vaccine is prequalified by WHO, and that it "looked forward to the development of an appropriate conjugate vaccine against typhoid."

http://www.gavialliance.org/library/news/press-releases/2011/gavi-takes-first-steps-tointroduce-vaccines-against-cervical-cancer-and-rubella/

## WHO recommended that countries with high or intermediate endemic rates of meningococcal disease and countries with frequent epidemics introduce large scale vaccination programmes, using meningococcal conjugate

**vaccines.** The recommendation was made in a position paper published in the *Weekly Epidemiological Record*. In countries where meningococcal disease occurs less frequently, vaccination is recommended for defined risk groups such as children and young adults living in closed communities, for instance in boarding schools or military camps. Laboratory workers at risk of exposure to meningococci and travellers to high-endemic areas should also be vaccinated. For all countries, knowledge of meningococcal disease burden is critical in ensuring that available vaccines are appropriately used. Countries considering the use of meningococcal vaccines should develop the surveillance systems to characterize meningococcal disease epidemiology. And continued surveillance should dictate the need and timing of repeat mass vaccination campaigns.

WHO noted that in Africa, major epidemics have been occurring over the past 100 years, most of them attributed to serogroup A and occurring in the African "meningitis belt", a large area that spans sub-Saharan Africa from Senegal in the west to Ethiopia in the east. In 1996 to 1997, the largest epidemic in history swept across the belt, causing over 250,000 cases, an estimated 25,000 deaths, and disability in 50,000 people. Large epidemics recur in the meningitis belt on a regular basis. In December 2010, the first meningococcal A conjugate vaccine to be developed specifically for countries in the African meningitis belt was introduced in Burkina Faso, Mali and Niger. Three additional countries — Cameroon, Chad and Nigeria — are introducing the vaccine in December 2011. Position paper on meningococcal vaccines:

http://www.who.int/entity/wer/2011/wer8647.pdf

http://www.who.int/immunization/newsroom/newsstory\_countries\_menin\_high\_vacc\_pr\_ogrammes/en/index.html

**PATH announced that Cameroon, Chad, and Nigeria will MenAfriVac™ meningitis vaccine campaigns in December**. These countries in Africa's meningitis belt are "poised to vaccinate 22 million people against epidemic meningitis next month" and become the fourth, fifth, and sixth countries to introduce the vaccine. MenAfriVac<sup>™</sup> targets the strain of meningitis that has plagued sub-Saharan Africa with deadly and debilitating epidemics for more than a century.

http://www.path.org/news/an111115-meningitis-vaccine.php

PAHO/WHO said it is collecting examples of cell phones and other mobile devices being used to improve vaccine coverage and data collection as part of efforts to promote exchange of information and best practices in 'mHealth' among its member countries. Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Guatemala, Honduras, Mexico, Panama, Peru, the United States and Uruguay are among the countries in the Americas that are using devices such as personal digital assistants (PDAs) and mobile phones in their immunization programs. The countries "are at different stages in their use of these technologies, ranging from pilot projects focused on improving management of the vaccine cold chain and supplies, to comprehensive electronic patient records systems."

http://new.paho.org/hq/index.php?

option=com\_content&task=view&id=6212&Itemid=1926

#### Sweden released its most current assessment of multilateral organisations

noting that four organisations have been assessed: The Global Alliance for Vaccines and Immunisation (GAVI), the International Fund for Agricultural Development (IFAD), the UN Office for the Coordination of Humanitarian Affairs (OCHA) and the United Nations Children's Fund (UNICEF). The assessments are described as "a key tool in strengthening Sweden's involvement in multilateral organisations. They are also part of the Government's efforts to more clearly show the results of our international development cooperation." In 2008, assessments of 23 organisations were conducted, and assessments since have averaged five organisations annually.

The summary document highlights the assessments <u>http://www.sweden.gov.se/sb/d/15331/a/180674</u>

#### GAVI

GAVI is a partnership and an alliance that brings together governments, multilateral organisations, philanthropists, the private sector, research institutions and civil society. Its overall objective is to save children's lives and protect people's health by increasing access to immunisation in the world's poorest countries.

GAVI is assessed as highly relevant to Swedish development policy. It has an explicit poverty focus and a clear role in contributing to the achievement of the UN's Millennium Development Goals.

GAVI is assessed as having a very high level of internal effectiveness, due partly to the fact that its structure is well suited to its activities and it has a distinct results culture. It is also considered a swift-footed and responsive organisation with a small and efficient secretariat.

GAVI is assessed as having a very high level of external effectiveness. This may be partly explained by the fact that it has a clearly defined and limited mandate that is relatively easy to measure. GAVI has unquestionably achieved important development results. From its launch in 2000 and up to the end of 2009, the organisation financed the vaccination of 257 million children and helped prevent some 5.4 million future deaths.

#### UNICEF

UNICEF, the United Nations Children's Fund, is mandated by the UN General Assembly to promote children's rights, i.e. the right of the child to survival, development,

protection and participation. Its activities encompass both long-term development work and humanitarian action.

UNICEF is assessed as highly relevant to Swedish development goals. The organisation has a unique mandate and contributes significantly to the achievement of the Millennium Development Goals. UNICEF focuses on supporting the poorest and least developed countries and on reaching the most vulnerable and marginalized children.

UNICEF is assessed as having a high level of internal effectiveness. Several aspects of the organisation's internal effectiveness have been significantly improved. Sweden's assessment is that the changes already introduced or currently in the pipeline will pave the way for greater accountability, improved risk management and better tools and mechanisms for results-based management, and will also simplify and improve working procedures. It is too soon, however, to assess the extent to which the reforms and systems that UNICEF has recently introduced work in practice. This is one of the reasons why UNICEF cannot be awarded top marks for internal effectiveness.

UNICEF is assessed as having a high level of external effectiveness. The organisation enjoys a good reputation at country level, and this has impacted favourably on its chances of achieving practical results. Swedish embassies emphasise that UNICEF has high credibility and has performed well in the area of capacity-building. The fact that the organisation is not rated as having a 'very high' level of external effectiveness is due to the varying quality of its work in different countries and the somewhat scattered nature of its country programmes.

http://www.sweden.gov.se/download/3aa5503d.pdf? major=1&minor=180567&cn=attachmentPublDuplicator 0 attachment

Sanofi Pasteur, announced a new education campaign – ImmYounity(SM) – "designed to help answer parents' questions about immunization and to offer health-care professionals a reference tool to supplement their discussions about vaccination with patients." The new campaign "provides consumer-friendly, accurate and science-based information about immunization that can be easily accessed at www.vaccines.com. The site contains useful facts and resources, including visuals that can be easily shared via social media and email, and is supplemented by educational brochures offered for use by health-care providers." Sanofi noted that "while a majority of parents are committed to childhood vaccination, a rising tide of questions has emerged over the past 20 years regarding the benefit and safety of vaccines. Many parents have questions about vaccines and are looking for credible sources of information that respect their desire to come to a decision on their own terms. While parents continue to look to health-care professionals for information, they also have more access than ever before to many other sources of information that can be confusing, conflicting, and ultimately make it more difficult for parents to come to a well-informed decision about what is best for their children." Phil Hosbach, vice president, Immunization Policy, Sanofi Pasteur, said, "From listening to parents" concerns about the current vaccine environment, we began to think about what else we could do to support them. We concluded that it is critical to enhance our commitment to educate parents about the importance of vaccines."

http://www.prnewswire.com/news-releases/sanofi-pasteur-launches-nationwideeducation-campaign-to-help-parents-make-informed-decisions-about-immunization-134030683.html

**BIO Ventures for Global Health (BVGH) announced that Don Joseph, JD, currently Chief Operating Officer, will assume the role of CEO effective 1 February 2012.** Prior to joining BVGH, Mr. Joseph served as the Chief Operating Officer at the Institute for OneWorld Health, a non-profit, global health organization engaged in drug development for neglected tropical diseases. Carl Feldbaum, Chair of the Board at BVGH, commented, "We are very pleased to name Don Joseph to this position and are confident that BVGH will continue to benefit from his leadership, in light of his deep ties with the biotech community and experience in global health. This leadership transition will allow the organization to continue the momentum that has built over the past two years under Melinda Moree's leadership." Moree will continue her involvement with BVGH in the new role of Executive Chair of the Board of Directors. http://www.prnewswire.com/news-releases/don-joseph-to-succeed-dr-melinda-moreeas-ceo-of-bio-ventures-for-global-health-moree-to-become-executive-chair-of-the-boardof-directors-134111973.html

The **Weekly Epidemiological Record (WER) for 18 November 2011**, vol. 86, 47 (pp 521–540) includes: Meningococcal vaccines: WHO position paper, November 2011; Monthly report on dracunculiasis cases, January–August 2011 <a href="http://www.who.int/entity/wer/2011/wer8647.pdf">http://www.who.int/entity/wer/2011/wer8647.pdf</a>

#### Twitter Watch

A selection of items of interest from a variety of twitter feeds associated with immunization, vaccines and global public health. This capture is highly selective and by no means intended to be exhaustive.

GAVIAlliance GAVI Alliance

Have you seen <u>@unfoundation</u>'s @shot@life campaign? They highlight the <u>#powerofvaccines</u>! <u>ht.ly/7vV0q</u> <u>6 hours ago</u>

GAVIAlliance GAVI Alliance GAVI's support for yellow fever <u>#vaccine</u> has averted 140,000 future deaths- <u>ht.ly/7vZJz</u> <u>19 Nov</u>

<u>sabinvaccine</u> Sabin Vaccine Inst. Today on the blog read about innovations in vaccine R&D! <u>bit.ly/ttOLYE</u> <u>18 Nov</u>

#### MeaslesInit Measles Initiative

GAVI's new rubella funding will protect hundreds of millions against measles and rubella wp.me/p1UXPA-1I

<u>17 Nov</u>

#### WHOnews WHO

MT <u>@GAVIAlliance</u> takes first steps to protect women & children from cervical cancer & rubella <u>bit.ly/uDBKRf #HPV #vaccine</u> 17 Nov

#### preventdengue DVI

"Dengue anywhere is a threat everywhere." Govts must lay the groundwork now to implement a future <u>#dengue</u> <u>#vaccine</u> <u>bit.ly/v0ciAQ</u> 16 Nov

#### unfoundation UN Foundation

<u>#Pneumonia</u>: one disease, two <u>@UNFoundation</u> solutions - <u>@cookstoves</u> & <u>@ShotAtLife</u>. Read more from our CEO, Kathy Calvin: <u>ow.ly/7wKkn</u> <u>17 Nov</u>

#### GAVISeth Seth Berkley

Delighted that GAVI board in Dhaka decided to take first steps to introduce vaccines against cervical cancer & rubella <u>bit.ly/rT6bMS</u> 17 Nov

#### <u>GAVIAlliance</u> GAVI Alliance News Update: GAVI takes first steps to introduce vaccines against cervical cancer and rubella. <u>ht.ly/7wm4L</u> 17 Nov

## GAVIAlliance GAVI Alliance A step in the eradication of <u>#polio</u>! Millions of children get polio <u>#vaccine</u> in UN-backed campaign in South-Sudan- <u>ht.ly/7vYMk</u> <u>16 Nov</u>

## PATHtweets PATH

Don't remember diphtheria? Maybe that's because you got vaccinated against it. See our new video. <u>ow.ly/7odHj #powerofvaccines</u> <u>16 Nov</u>

# <u>Journal Watch</u>

[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: <u>david.r.curry@centerforvaccineethicsandpolicy.org</u>

#### Annals of Internal Medicine

November 15, 2011; 155 (10) http://www.annals.org/content/current [No relevant content]

## **British Medical Bulletin**

Volume 99 Issue 1 September 2011 http://bmb.oxfordjournals.org/content/current [Reviewed earlier; No relevant content]

#### **British Medical Journal**

19 November 2011 (Vol 343, Issue 7832) http://www.bmj.com/content/current [No relevant content]

#### **Cost Effectiveness and Resource Allocation**

(accessed 20 November 2011) http://www.resource-allocation.com/ [No new relevant content]

#### **Emerging Infectious Diseases**

Volume 17, Number 11—November 2011 http://www.cdc.gov/ncidod/EID/index.htm [Reviewed earlier]

#### **Health Affairs**

November 2011; Volume 30, Issue 11 http://content.healthaffairs.org/content/current *Theme: Linking Community Development & Health* [No relevant content]

## Health Economics, Policy and Law

Volume 6 - Issue 04 - 01 October 2011 http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue [Reviewed earlier]

#### **Health Policy and Planning**

Volume 26 Issue 6 November 2011 http://heapol.oxfordjournals.org/content/current [Reviewed earlier]

#### Human Vaccines

Volume 7, Issue 11 November 2011 http://www.landesbioscience.com/journals/vaccines/toc/volume/7/issue/11/ Special Focus: Neglected Vaccines - Developing World [Reviewed earlier]

## International Journal of Infectious Diseases

Volume 15, Issue 11 pp. e731-e806 (November 2011) http://www.sciencedirect.com/science/journal/12019712 [Reviewed earlier; No relevant content]

## JAMA

November 16, 2011, Vol 306, No. 19, pp 2059-2175 http://jama.ama-assn.org/current.dtl [No relevant content]

#### Journal of Infectious Diseases

Volume 204 Issue 12 December 15, 2011 http://www.journals.uchicago.edu/toc/jid/current [No relevant content]

#### The Lancet

Nov 19, 2011 Volume 378 Number 9805 p1757 – 1824 e8 http://www.thelancet.com/journals/lancet/issue/current Comment

# The Global Fund: getting the reforms right

Richard GA Feachem

Preview

As its Board meets this month in Accra, Ghana, for its 25th meeting, the Global Fund to fight AIDS, Tuberculosis, and Malaria finds itself at a crossroads.1 Major reforms are needed to ensure its survival. The final report of a High-Level Independent Review Panel, which was tasked to examine the Global Fund's operations in light of allegations of fraud, made six recommendations.2 The Global Fund, it argued, must transition from an emergency to a sustainable response; develop new risk-management approaches; strengthen internal governance; institute a new grant-approval process; strengthen decision making by middle management; and "get serious about results".

#### The Lancet Infectious Disease

Nov 2011 Volume 11 Number 11 p801 - 886 <u>http://www.thelancet.com/journals/laninf/issue/current</u> (Reviewed earlier]

## Medical Decision Making (MDM)

November/December 2011; 31 (6) http://mdm.sagepub.com/content/current [No relevant content]

## Nature

Volume 479 Number 7373 pp267-438 17 November 2011 http://www.nature.com/nature/current\_issue.html [No relevant content]

#### **Nature Medicine**

November 2011, Volume 17 No 11 http://www.nature.com/nm/index.html [No relevant content]

## **New England Journal of Medicine**

November 17, 2011 Vol. 365 No. 20 http://content.nejm.org/current.shtml Perspective **Global Health** Global Health: War, Drought, Malnutrition, Measles — A Report from Somalia Jean-Clement Cabrol, M.D. N Engl J Med 2011; 365:1856-1858November 17, 2011 Free Full Text **Original Articles** First Results of Phase 3 Trial of RTS,S/AS01 Malaria Vaccine in African Children The RTS, S Clinical Trials Partnership Background An ongoing phase 3 study of the efficacy, safety, and immunogenicity of candidate malaria vaccine RTS,S/AS01 is being conducted in seven African countries. Full Text of Background... Methods From March 2009 through January 2011, we enrolled 15,460 children in two age categories — 6 to 12 weeks of age and 5 to 17 months of age — for vaccination with

either RTS,S/AS01 or a non-malaria comparator vaccine. The primary end point of the

analysis was vaccine efficacy against clinical malaria during the 12 months after

vaccination in the first 6000 children 5 to 17 months of age at enrollment who received all three doses of vaccine according to protocol. After 250 children had an episode of severe malaria, we evaluated vaccine efficacy against severe malaria in both age categories.

## Full Text of Methods...

## Results

In the 14 months after the first dose of vaccine, the incidence of first episodes of clinical malaria in the first 6000 children in the older age category was 0.32 episodes per person-year in the RTS,S/AS01 group and 0.55 episodes per person-year in the control group, for an efficacy of 50.4% (95% confidence interval [CI], 45.8 to 54.6) in the intention-to-treat population and 55.8% (97.5% CI, 50.6 to 60.4) in the per-protocol population. Vaccine efficacy against severe malaria was 45.1% (95% CI, 23.8 to 60.5) in the intention-to-treat population and 47.3% (95% CI, 22.4 to 64.2) in the per-protocol population. Vaccine efficacy against severe malaria in the combined age categories was 34.8% (95% CI, 16.2 to 49.2) in the per-protocol population during an average follow-up of 11 months. Serious adverse events occurred with a similar frequency in the two study groups. Among children in the older age category, the rate of generalized convulsive seizures after RTS,S/AS01 vaccination was 1.04 per 1000 doses (95% CI, 0.62 to 1.64).

## Full Text of Results...

## Conclusions

The RTS,S/AS01 vaccine provided protection against both clinical and severe malaria in African children. (Funded by GlaxoSmithKline Biologicals and the PATH Malaria Vaccine Initiative; RTS,S ClinicalTrials.gov number, <u>NCT00866619</u>.)

## Editorial

## A Vaccine for Malaria

Nicholas J. White, F.R.S. N Engl J Med 2011; 365:1926-1927<u>November 17, 2011</u> [Free full-text]

It's been a long time coming, and indeed we are still not there yet, but it is becoming increasingly clear that we really do have the first effective vaccine against a parasitic disease in humans. If there are no unforeseen disasters, the RTS,S/AS01 Plasmodium falciparum malaria vaccine should become available in just over 3 years. The World Health Organization (WHO) has already taken the unusual step of indicating that it could recommend this first malaria vaccine for use in some African countries as early as 2015, depending on the full phase 3 trial results that will become available in 2014.1 The vaccine has been developed by a public-private partnership between GlaxoSmithKline and the Program for Appropriate Technology in Health (PATH) Malaria Vaccine Initiative, supported by the Bill and Melinda Gates Foundation, primarily for use in infants and young children in sub-Saharan Africa. RTS,S/AS01 is a hybrid construct of the hepatitis B surface antigen fused with a recombinant antigen derived from part of the circumsporozoite protein. This is the protein coat of the sporozoite, the parasite stage that is inoculated by the feeding anopheline mosquito, which then invades liver cells and multiplies there before entering the bloodstream. Keys to the success of the vaccine are the immunogenic polymeric nature of RTS,S particles and the proprietary adjuvant AS01. A large number of other potential malaria vaccines are in various stages of development, but the RTS, S/AS01 vaccine is considerably further along the path to registration and potential deployment than the others.

In this issue of the Journal, the RTS,S Clinical Trials Partnership provides an interim report of a large, multicenter phase 3 trial of this vaccine. A total of 15,460 children in two age categories — 6 to 12 weeks and 5 to 17 months — were enrolled. The report describes vaccine efficacy against P. falciparum malaria in the first 6000 of 8923 children in the older age category, together with an evaluation of the first 250 cases of severe malaria from the two age groups. It is not usual practice to publish the results of trials in pieces, and there does not seem to be a clear scientific reason why this trial has been reported with less than half the efficacy results available. The target population for this vaccine is young infants who would receive the malaria vaccine together with routine immunizations, but the critical efficacy results in this subgroup will not be reported for another year. Even then, only results on short-term efficacy will be available, findings that will be insufficient to assess the public health role of this vaccine.

The interim results are broadly in line with those reported previously in extended phase 2 studies. <u>3-5</u> Protective efficacy against P. falciparum malaria (55% protection against all malaria episodes) was at the upper end of expectations from earlier studies, whereas the overall reduction in severe malaria (35% protection) was slightly less than anticipated.

Trials often throw up unexpected findings. In this trial, there were significantly more cases of meningitis among children receiving the RTS,S/AS01 vaccine than among those receiving the comparator vaccines. There seems to be no plausible explanation for this, and it may well turn out to be a chance finding, but it cannot be ignored. On the other hand, the increased risk of febrile reactions or seizures among RTS,S/AS01 recipients may be real, reflecting the reactogenicity of this highly immunogenic vaccine. Such questions highlight the importance of phase 4 studies of both safety and effectiveness with active surveillance if this vaccine is deployed.

What does this vaccine mean for the future of the control and elimination of malaria? The considerable increase in global funding is paying dividends. In places where effective interventions (insecticide-treated bed nets, insecticides, and artemisinin-combination treatments) are being intensively deployed, malaria morbidity and mortality are falling. Several new, simple, affordable interventions, such as seasonal chemoprevention among young children in areas of seasonally high malaria transmission and the use of artesunate in patients with severe malaria, can also provide substantial reductions in mortality. The very low rate of death from malaria in this large trial (only 10 deaths directly attributed to malaria) testifies to the benefits of providing early diagnosis and effective antimalarial treatment. But there are real dangers ahead. How will the necessary funding be sustained in the face of a global economic downturn, along with a reduction in political pressure associated with declining mortality from malaria? In addition, artemisinin resistance in malaria parasites and pyrethroid resistance in anopheline mosquito vectors pose very serious threats.

All the investigators who have labored long and hard in the development and evaluation of this malaria vaccine deserve congratulations. It is a great achievement and an important advance, but they know that this partially protective vaccine is not the sole solution to the control and elimination of malaria. After registration, the definitive WHO guidance, expected in 2015, may recommend that the inclusion of RTS,S/AS01 in the multipronged attack against malaria is justified. The key question of how long the protection against malaria lasts, particularly in the anticipated context of declining malaria transmission, remains open. An assessment of an 18-month booster dose will not be available until 2014. Another key issue is whether efficacy varies according to the

intensity of transmission. We also do not know yet how much the vaccine will cost. All these factors are essential components of the objective assessments of cost-effectiveness that should form the basis of future global and national policy decisions.

## The Pediatric Infectious Disease Journal

November 2011 - Volume 30 - Issue 11 pp: A7-A8,921-1016,e203-e224 http://journals.lww.com/pidj/pages/currenttoc.aspx [Reviewed earlier; No relevant content]

## **Pediatrics**

November 2011, VOLUME 128 / ISSUE 5 <u>http://pediatrics.aappublications.org/current.shtml</u> [Reviewed earlier]

## Pharmacoeconomics

December 1, 2011 - Volume 29 - Issue 12 pp: 1011-1014 http://adisonline.com/pharmacoeconomics/pages/currenttoc.aspx *Current Opinion* <u>QALYs and Carers</u>

Al-Janabi, Hareth; Flynn, Terry N.; Coast, Joanna Pharmacoeconomics. 29(12):1015-1023, December 1, 2011. doi: 10.2165/11593940-000000000-00000 *Abstract:* 

When going 'beyond the patient', to measure QALYs for unpaid carers, a number of additional methodological considerations and value judgements must be made. While there is no theoretical reason to restrict the measurement of QALYs to patients, decisions have to be made about which carers to consider, what instruments to use and how to aggregate and present QALYs for carers and patients. Current, albeit limited, practice in measuring QALY gains to carers in economic evaluation varies, suggesting that there may be inconsistency in judgements about whether interventions are deemed cost effective.

While conventional health-related quality-of-life tools can, in theory, be used to estimate QALYs, there are both theoretical and empirical concerns over the suitability of their use with carers. Measures that take a broader view of health or well-being may be more appropriate. Incorporating QALYs of carers in economic evaluations may have important distributional consequences and, therefore, greater normative discussion over the appropriateness of incorporating these impacts is required. In the longer term, more flexible forms of cost-per-QALY analysis may be required to take account of the broader impacts on carers and the weight these impacts should receive in decision making.

# PLoS One

[Accessed 20 November 2011] http://www.plosone.org/article/browse.action;jsessionid=577FD8B9E1F322DAA533C413 369CD6F3.ambra01?field=date

#### Burden of Pneumonia and Meningitis Caused by Streptococcus pneumoniae in China among Children under 5 Years of Age: A Systematic Literature Review

Ying Chen, Wei Deng, Song-Mei Wang, Qi-Mei Mo, Huan Jia, Qun Wang, Song-Guang Li, Xiang Li, Bao-Dong Yao, Cheng-Jun Liu, Yi-Qiang Zhan, Chen Ji, Anna Lena Lopez, Xuan-Yi Wang

PLoS ONE: Research Article, published 16 Nov 2011 10.1371/journal.pone.0027333 Abstract

#### Background and Methods

To understand the burden and epidemiology of Streptococcus pneumoniae disease among children between 1 and 59 months of age in China, we conducted a review of literature published between 1980 and 2008 applying standardized algorithms. Because of the absence of population-based surveillance for pneumococcal disease (PD), we identified all-cause pneumonia, bacteremia and meningitis burden, syndromes most commonly associated with S. pneumoniae, and applied the proportion of disease attributable to S. pneumoniae from studies that determined the etiology of these three syndromes to calculate PD burden. Because of the microbiologic difficulties in identifying S. pneumoniae–attributable pneumonia which likely underestimates the pneumonia burden, we also used the proportion obtained from vaccine efficacy trials. Results

Between 1980 and 2008, there were 12,815 cases/100,000/year of all-cause pneumonia among children between 1 month and 59 months, with 526 deaths/100,000 annually. There were 14 meningitis cases/100,000/year. We estimate that as of 2000, there were 260,768 (113,000 to 582,382) and 902 (114–4,463) cases of pneumococcal pneumonia and meningitis, respectively with 10,703 (4,638–23,904) and 75 (9–370) pneumococcal pneumonia cases and deaths were more than two-fold higher, 695,382 (173,845–1,216,918) and 28,542 (7,136–49,949), respectively, when parameters from efficacy trials were used. Serotypes 19F, 19A and 14 were the most common serotypes obtained from pneumonia/meningitis patients. Currently available vaccines are expected to cover 79.5% to 88.4% of the prevalent serotypes. With high antibiotic resistance, introducing pneumococcal vaccines to the routine immunization program should be considered in China. Population-based studies are warranted.

## **Estimation of the Health Impact and Cost-Effectiveness of Influenza** Vaccination with Enhanced Effectiveness in Canada

David N. Fisman, Ashleigh R. Tuite

PLoS ONE: Research Article, published 14 Nov 2011 10.1371/journal.pone.0027420 Abstract

#### Introduction

The propensity for influenza viruses to mutate and recombine makes them both a familiar threat and a prototype emerging infectious disease. Emerging evidence suggests that the use of MF59-adjuvanted vaccines in older adults and young children enhances protection against influenza infection and reduces adverse influenza-attributable outcomes compared to unadjuvanted vaccines. The health and economic impact of such vaccines in the Canadian population are uncertain.

#### Methods

We constructed an age-structured compartmental model simulating the transmission of influenza in the Canadian population over a ten-year period. We compared projected health outcomes (quality-adjusted life years (QALY) lost), costs, and incremental cost-

effectiveness ratios (ICERs) for three strategies: (i) current use of unadjuvanted trivalent influenza vaccine; (ii) use of MF59-adjuvanted influenza vaccine adults  $\geq$ 65 in the Canadian population, and (iii) adjuvanted vaccine used in both older adults and children aged < 6.

Results

In the base case analysis, use of adjuvanted vaccine in older adults was highly costeffective (ICER = \$2111/QALY gained), but such a program was "dominated" by a program that extended the use of adjuvanted vaccine to include young children (ICER = \$1612/QALY). Results were similar whether or not a universal influenza immunization program was used in other age groups; projections were robust in the face of wideranging sensitivity analyses.

Interpretation

Based on the best available data, it is projected that replacement of traditional trivalent influenza vaccines with MF59-adjuvanted vaccines would confer substantial benefits to vaccinated and unvaccinated individuals, and would be economically attractive relative to other widely-used preventive interventions.

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