

Vaccines: The Week in Review

11 April 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 and partners were honored with the Ludwig Rajchman Prize of the Committee of the Scientific Council of the National Institute of Public Health of Poland for the research work validating the shake test for detecting freeze damage to adsorbed vaccines. WHO noted that "good temperature control during the storage and transport of vaccines is critical to ensure their potency and safety. Liquid formulations of aluminium-based vaccines against diphtheria, pertussis, tetanus, hepatitis B and Haemophilus influenzae type b, alone or in combination, should not be frozen. However, practices that expose vaccines to sub-zero temperatures are widespread in both developed and developing countries.

"The shake test is designed to determine whether adsorbed vaccines have been affected by freezing. Although widely practiced in the field by staff at all levels of the health system, prior to this research it had never been validated as a reference test by comparison to a "gold standard", i.e. visual observation under a phase contrast microscope. The concordance in establishing the status of a vaccine as frozen or non-frozen was 100% between the microscopy test and the shake test performed by health-care workers. The results of the study fully support the hypothesis that the accuracy of the shake test does not vary by product, type of vaccine, vaccine manufacturer, aluminium content or expiry date.

The Ludwig Rajchman Prize "was established to commemorate Ludwig Rajchman, the first Director of the National Institute of Hygiene of Poland, in order to promote original achievements in public health research."

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

GAVI said the Democratic Republic of Congo (DRC) enhanced its immunization programme by including pneumococcal vaccines, initiating the expanded programme in two of the country's 11 provinces.

http://www.gavialliance.org/media_centre/press_releases/drc_pneumococcal.php

German Development Minister, Dirk Niebel, and Bill Gates, co-chair of the Bill & Melinda Gates Foundation, met in Berlin and signed an agreement "for close cooperation between the Federal Ministry for Economic Cooperation and Development, BMZ*, and the Gates Foundation" in the areas of "global health policy, agriculture and rural development, water and sanitation, urban development, as well as microfinance." The Partnership "will commence with a joint increase to the GAVI Alliance with the commitment of the BMZ to increase its contribution through innovative bilateral contributions. The ministry will increase its funding by €14m in 2011 for childhood immunization. In turn, the Gates Foundation will match this amount through multilateral contributions to GAVI; the foundation will also match any further increase in funds for 2012 and 2013 should Germany announce these contributions ahead of the June GAVI Pledging Conference."

<http://www.gatesfoundation.org/press-releases/Pages/close-cooperation-bmz-110406.aspx>

WHO noted World Malaria Day - 25 April 2011, stating that "approximately half of the world's population is at risk of malaria, particularly those living in lower-income countries. It infects more than 500 million people per year and kills more than 1 million. The burden of malaria is heaviest in sub-Saharan Africa but the disease also afflicts Asia, Latin America, the Middle East and even parts of Europe."

<http://www.who.int/mediacentre/events/annual/malaria/en/index.html>

Related links

[More about World Malaria Day](#)

[Roll Back Malaria Partnership](#)

[WHO Global Malaria Programme](#)

[Topical overview: malaria](#)

Sabin Vaccine Institute and Eisai Co., Ltd. announced a memorandum of understanding (MOU) "to advance the development of vaccines to combat neglected tropical diseases (NTDs), a group of parasitic and bacterial infections that afflict more than 1.4 billion people who live on less than \$1.25 a day." Sabin and Eisai "will collaborate on research and development for NTD vaccines and help deepen the pharmaceutical industry's role in global health initiatives for NTDs. In addition, Sabin Vaccine Development-a product development partnership of the Sabin Vaccine Institute-intends to test Eisai's vaccine adjuvant technology in preclinical studies with antigens

that are currently in development. Eisai's adjuvant technology may serve as a valuable tool for enhancing immunogenicity of Sabin's vaccine antigens for human hookworm infection and schistosomiasis."

<http://sabin.org/news-resources/releases/2011/04/05/sabin-vaccine-institute-and-eisai-co-ltd-announce-collaboration-a>

The **Weekly Epidemiological Record (WER) for 8 April 2011**, vol. 86, 15 (pp 141–152) includes: Outbreak news – Outbreak of poliomyelitis, Republic of the Congo, September 2010–February 2011; Meningitis in Burkina Faso, Chad, Niger, Nigeria and Ghana: 2010 epidemic season

<http://www.who.int/entity/wer/2011/wer8615.pdf>

The MMWR for April 8, 2011 / Vol. 60 / No. 13 includes:

- [Measles Imported by Returning U.S. Travelers Aged 6--23 Months, 2001--2011](#)
- [Assessment of ESSENCE Performance for Influenza-Like Illness Surveillance After an Influenza Outbreak --- U.S. Air Force Academy, Colorado, 2009](#)
- [Assessing Completeness of Perinatal Hepatitis B Virus Infection Reporting Through Comparison of Immunization Program and Surveillance Data --- United States](#)
- [Notes from the Field: Measles Outbreak --- Hennepin County, Minnesota, February--March 2011](#)

<http://www.cdc.gov/mmwr/pdf/wk/mm6013.pdf>

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.

[ClintonTweet](#) Clinton Foundation

PHOTO: President Clinton announces National Cholera Education & Awareness Campaign in [#Haiti](#): <http://ow.ly/i/a9Iw>

[SingerPeter](#) Peter Singer

Future MDGs? Rohinton Medhora has some interesting ideas:
<http://blog.idrc.ca/medhora/> @IDRC_CRDI

[eurovaccine](#) ECDC Eurovaccine

Public health & illegal migration are interconnected say EU Health Ministers; seeking EU-wide help <http://bit.ly/earMDV>

[GAVIAlliance](#) GAVI Alliance

Introduction of pneumococcal [#vaccines](#) in Yemen <http://ht.ly/4urx5>

[GAVIAlliance](#) GAVI Alliance

RT @unfoundation: UN-backed partners including @GAVIAAlliance @UNICEF @whonews help DR Congo introduce #pneumonia vaccine <http://ow.ly/4sP0P>

[VaccinesToday](#) VaccinesToday

Interesting speech by @ECDC_EU chief Marc Sprenger addressing EU Health Ministers <http://tinyurl.com/6ebd2b9>

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

April 5, 2011; 154 (7)

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

[No relevant content]

British Medical Bulletin

Volume 97 Issue 1 March 2011

<http://bmb.oxfordjournals.org/content/current>

[Reviewed earlier]

British Medical Journal

9 April 2011 Volume 342, Issue 7801

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

[No relevant content]

Clinical Infectious Diseases

Volume 52 Issue 9 May 1, 2011

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

[No relevant content]

Cost Effectiveness and Resource Allocation

(accessed 10 April 2011)

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

[No relevant content]

Emerging Infectious Diseases

Volume 17, Number 4–April 2011

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

[Reviewed last week]

Health Affairs

April 2011; Volume 30, Issue 4

<http://content.healthaffairs.org/content/30/2.toc>

[No relevant content]

Health Economics, Policy and Law

Volume 6 - Issue 02

<http://journals.cambridge.org/action/displayJournal?jid=HEP>

[Reviewed earlier; No relevant content]

Human Vaccines

Volume 7, Issue 4 April 2011

<http://www.landesbioscience.com/journals/vaccines/toc/volume/7/issue/4/>

[Reviewed last week]

JAMA

April 6, 2011, Vol 305, No. 13, pp 1269-1372

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

[No relevant content]

Journal of Infectious Diseases

Volume 203 Issue 9 May 1, 2011

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

[No relevant content]

The Lancet

Apr 09, 2011 Volume 377 Number 9773 Pages 1211 - 1288

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

Comment

A cytomegalovirus vaccine tames the troll of transplantation

Mark R Schleiss

Health-systems strengthening: current and future activities

Jesper Sundewall, R Chad Swanson, Arvind Betigeri, David Sanders, Téa E Collins, George Shakarishvili, Ruairi Brugha

There is strong consensus in the global health community, among donors, recipient countries, and policy makers, about the need for health-system strengthening in low-income and middle-income countries.^{1,2} Traditional donors and new disease-specific aid initiatives, such as the GAVI Alliance, the US President's Emergency Plan for AIDS Relief (PEPFAR), and the Global Fund to Fight AIDS, Tuberculosis and Malaria, are directly or indirectly funding health-system strengthening. The need for greater capacity to produce a better evidence-base for health-system strengthening has resulted in the first global symposium on health-systems research, to be held in Montreux, Switzerland, in November, 2010.

Articles

Cytomegalovirus glycoprotein-B vaccine with MF59 adjuvant in transplant recipients: a phase 2 randomised placebo-controlled trial

Paul D Griffiths, Anna Stanton, Erin McCarrell, Colette Smith, Mohamed Osman, Mark Harber, Andrew Davenport, Gareth Jones, David C Wheeler, James O'Beirne, Douglas Thorburn, David Patch, Claire E Atkinson, Sylvie Pichon, Paul Sweny, Marisa Lanzman, Elizabeth Woodford, Emily Rothwell, Natasha Old, Ruth Kinyanjui, Tanzina Haque, Sowsan Atabani, Suzanne Luck, Steven Prideaux, Richard SB Milne, Vincent C Emery, Andrew K Burroughs

Summary

Background

Cytomegalovirus end-organ disease can be prevented by giving ganciclovir when viraemia is detected in allograft recipients. Values of viral load correlate with development of end-organ disease and are moderated by pre-existing natural immunity. Our aim was to determine whether vaccine-induced immunity could do likewise.

Methods

We undertook a phase-2 randomised placebo controlled trial in adults awaiting kidney or liver transplantation at the Royal Free Hospital, London, UK. Exclusion criteria were pregnancy, receipt of blood products (except albumin) in the previous 3 months, and simultaneous multiorgan transplantation. 70 patients seronegative and 70 seropositive for cytomegalovirus were randomly assigned from a scratch-off randomisation code in a 1:1 ratio to receive either cytomegalovirus glycoprotein-B vaccine with MF59 adjuvant or placebo, each given at baseline, 1 month and 6 months later. If a patient was transplanted, no further vaccinations were given and serial blood samples were tested for cytomegalovirus DNA by real-time quantitative PCR (rtqPCR). Any patient with one blood sample containing more than 3000 cytomegalovirus genomes per mL received ganciclovir until two consecutive undetectable cytomegalovirus DNA measurements. Safety and immunogenicity were coprimary endpoints and were assessed by intention to treat in patients who received at least one dose of vaccine or placebo. This trial is registered with ClinicalTrials.gov, [NCT00299260](https://www.clinicaltrials.gov/ct2/show/study?term=NCT00299260).

Findings

67 patients received vaccine and 73 placebo, all of whom were evaluable. Glycoprotein-B antibody titres were significantly increased in both seronegative (geometric mean titre 12 537 (95% CI 6593—23 840) versus 86 (63—118) in recipients of placebo recipients; $p < 0.0001$) and seropositive (118 395; 64 503—217 272) versus 24 682 (17 909—34 017); $p < 0.0001$) recipients of vaccine. In those who developed viraemia after transplantation, glycoprotein-B antibody titres correlated inversely with duration of

viraemia ($p=0.0022$). In the seronegative patients with seropositive donors, the duration of viraemia ($p=0.0480$) and number of days of ganciclovir treatment ($p=0.0287$) were reduced in vaccine recipients.

Interpretation

Although cytomegalovirus disease occurs in the context of suppressed cell-mediated immunity post-transplantation, humoral immunity has a role in reduction of cytomegalovirus viraemia. Vaccines containing cytomegalovirus glycoprotein B merit further assessment in transplant recipients.

Funding

National Institute of Allergy and Infectious Diseases, Grant R01AI051355 and Wellcome Trust, Grant 078332. Sponsor: University College London (UCL).

Seminar

Viral pneumonia

Olli Ruuskanen, Elina Lahti, Lance C Jennings, David R Murdoch

Summary

About 200 million cases of viral community-acquired pneumonia occur every year—100 million in children and 100 million in adults. Molecular diagnostic tests have greatly increased our understanding of the role of viruses in pneumonia, and findings indicate that the incidence of viral pneumonia has been underestimated. In children, respiratory syncytial virus, rhinovirus, human metapneumovirus, human bocavirus, and parainfluenza viruses are the agents identified most frequently in both developed and developing countries. Dual viral infections are common, and a third of children have evidence of viral-bacterial co-infection. In adults, viruses are the putative causative agents in a third of cases of community-acquired pneumonia, in particular influenza viruses, rhinoviruses, and coronaviruses. Bacteria continue to have a predominant role in adults with pneumonia. Presence of viral epidemics in the community, patient's age, speed of onset of illness, symptoms, biomarkers, radiographic changes, and response to treatment can help differentiate viral from bacterial pneumonia. However, no clinical algorithm exists that will distinguish clearly the cause of pneumonia. No clear consensus has been reached about whether patients with obvious viral community-acquired pneumonia need to be treated with antibiotics. Apart from neuraminidase inhibitors for pneumonia caused by influenza viruses, there is no clear role for use of specific antivirals to treat viral community-acquired pneumonia. Influenza vaccines are the only available specific preventive measures. Further studies are needed to better understand the cause and pathogenesis of community-acquired pneumonia. Furthermore, regional differences in cause of pneumonia should be investigated, in particular to obtain more data from developing countries.

The Lancet Infectious Disease

Apr 2011 Volume 11 Number 4 Pages 253 - 332

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

[Reviewed last week]

Medical Decision Making (MDM)

March/April 2011; 31 (2)

<http://mdm.sagepub.com/content/current>

[Reviewed earlier]

Nature

Volume 472 Number 7341 pp5-130 7 April 2011

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

Rare-disease project has global ambitions

Consortium aims for hundreds of new therapies by 2020.

Alison Abbott

Prader–Willi syndrome. Fabry renal disease. Spinocerebellar ataxia. Few people have heard of these and the other 'rare diseases', some of which affect only hundreds of patients worldwide. Drug companies searching for the next blockbuster pay them little attention. But the diseases are usually incurable — and there are thousands of them.

This week, the US National Institutes of Health (NIH) and the European Commission launch a joint assault on these conditions, whose small numbers of patients make it difficult to test new treatments and develop diagnostic methods. The International Rare Disease Research Consortium being formed under the auspices of the two bodies has the ambitious goal of developing a diagnostic tool for every known rare disease by 2020, along with new therapies to treat 200 of them. At the launch meeting in Bethesda, Maryland, on 6–8 April, prospective partners will map out research strategies to identify diagnostic biomarkers, design clinical trials and coordinate genome sequencing in these diseases. Nearly all the rare diseases, of which there are an estimated 6,000–8,000, are the result of small genetic changes.

Nature Medicine

April 2011, Volume 17 No 4

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

News

Straight talk with...Seth Berkley - p404

Roxanne Khamsi

doi:10.1038/nm0411-404

On 13 June, donors to the GAVI Alliance will gather in London to affirm their commitment to fund immunizations in the developing world. At the meeting, participants will address the estimated \$3.7 billion financing gap needed over the next four years to scale up childhood vaccination efforts to meet the demand forecasts for those countries that receive assistance from the Geneva-based organization. But attendees of the pledging conference will also be discussing something not on the formal agenda: the announcement last month that Seth Berkley, who founded and heads the International AIDS Vaccine Initiative (IAVI), will take over the helm of the alliance in August.

Berkley will lead a unique chapter in GAVI's development as the organization narrows in on the looming deadline set by Millennium Development Goal 4, which aims to reduce child mortality by two thirds by 2015. Yet, in a sense, these efforts will be a continuation of the work Berkley has fostered at IAVI since he formally launched the New York-based nonprofit in 1996. Berkley, an epidemiologist who previously held jobs with the Rockefeller Foundation, the Carter Center and the US Centers for Disease Control and Prevention, has witnessed ups and downs in the vaccination field, from the disappointing STEP trial in 2007 to the more recent good news from the 2009 Thai

study, which reported as much as 31% protection against HIV. Roxanne Khamisi spoke with Berkley about what he has learned in his quest for a preventative shot against AIDS.

New England Journal of Medicine

April 7, 2011 Vol. 364 No. 14

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

Perspective

[Determining the Value of Drugs — The Evolving British Experience](#)

Ruth R. Faden, Ph.D., M.P.H., and Kalipso Chalkidou, M.D., Ph.D.

N Engl J Med 2011; 364:1289-1291 [April 7, 2011](#)

[An Inactivated Cell-Culture Vaccine against Yellow Fever](#)

T.P. Monath and Others

The Pediatric Infectious Disease Journal

April 2011 - Volume 30 - Issue 4

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

[Reviewed earlier]

Pediatrics

April 2011 / VOLUME 127 / ISSUE 4

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

[Reviewed last week; No relevant content]

Pharmacoeconomics

April 1, 2011 - Volume 29 - Issue 4 pp: 269-359

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

[Reviewed earlier]

Pharmacoeconomics & Outcomes News

April 2, 2011 - Volume - Issue 625 pp: 1-11

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

[Reviewed earlier]

PLoS Medicine

(Accessed 10 April 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&SESSION=aac96924d41874935d8e1c2a2501181c#results
[Effect of Pneumococcal Conjugate Vaccination on Serotype-Specific Carriage and Invasive Disease in England: A Cross-Sectional Study](#)

Stefan Flasche, Albert Jan Van Hoek, Elizabeth Sheasby, Pauline Waight, Nick Andrews, Carmen Sheppard, Robert George, Elizabeth Miller Research Article, published 05 Apr 2011
doi:10.1371/journal.pmed.1001017

Science

8 April 2011 vol 332, issue 6026, pages 133-270
<http://www.sciencemag.org/current.dtl>
[No relevant content]

Science Translational Medicine

6 April 2011 vol 3, issue 77
<http://stm.sciencemag.org/content/current>
[No relevant content]

Vaccine

<http://www.sciencedirect.com/science/journal/0264410X>
Volume 29, Issue 16 pp. 2823-3092 (5 April 2011)
[Reviewed last week]

Value in Health

December 2010 Volume 13, Issue 8 Pages 863–1065
<http://onlinelibrary.wiley.com/doi/10.1111/vhe.2010.13.issue-8/issuetoc>
[Reviewed earlier]