Center for Vaccine Ethics and Policy
NYU | Wistar Institute | CHOP

Vaccines: The Week in Review
6 October 2012
Center for Vaccine Ethics & Policy (CVEP)

This weekly summary targets news, events, announcements, articles and research in the global vaccine ethics and policy space and is aggregated from key governmental, NGO, international organization and industry sources, key peer-reviewed journals, and other media channels. This summary proceeds from the broad base of themes and issues monitored by the Center for Vaccine Ethics & Policy in its work: it is not intended to be exhaustive in its coverage. Vaccines: The Week in Review is also posted in pdf form and as a set of blog posts at http://centerforvaccineethicsandpolicy.wordpress.com/. This blog allows full-text searching of over 3,500 entries.

Comments and suggestions should be directed to
David R. Curry, MS
Editor and
Executive Director
Center for Vaccine Ethics & Policy
david.r.curry@centerforvaccineethicsandpolicy.org

Update: *Polio this week - As of 03 Oct 2012*
Global Polio Eradication Initiative
[Editor's Extract]
Afghanistan
One new case was reported in the past week (WPV1 from the previously-uninfected province of Ghor), bringing the total number of cases for 2012 to 19. It was the most recent case, with onset of paralysis on 31 August.
Pakistan
Three new cases were reported in the past week (2 WPV1 from Khyber Pakhtunkhwa and 1 from Gilgit Baltistan) bringing the total number of cases for 2012 to 40. The most recent case was a WPV1 from Khyber Pakhtunkhwa with onset of paralysis on 13 September.

The Weekly Epidemiological Record (WER) for 5 October 2012, vol. 87, 40 (pp. 381–388) includes:
- Progress towards eradicating poliomyelitis: Afghanistan and Pakistan, January 2011–August 2012
http://www.who.int/entity/wer/2012/wer8740.pdf

The World Bank's Board of Directors approved a US$24 million second additional financing for the Third Partnership for Polio Eradication Project (TPPEP) "to support the Government of Pakistan's efforts to immunize 34.8 million children against the crippling effects of polio with the goal of eradicating the disease from the country." Rachid

Benmessaoud, World Bank Country Director for Pakistan, commented, "Although Pakistan has seen great progress in the reduction of polio over the last 20 years, it remains one of the few countries where polio still impacts lives and recent cases are worrying. Pakistan still has a large role to play to aggressively stop transmission of polio virus to help achieve the global public good of polio eradication in the world". The announcement noted that the recent floods also forced large scale population movements, resulting in large population groups living together in temporary housing with inadequate water and sanitation facilities. This, in turn, has led to exposure of people who had not been previously exposed to the polio virus. In addition, the prevailing security situation affecting the population in areas of Khyber Pakhtunkhwa (KP) and the Federally Administered Tribal Areas (FATA) has seriously affected immunization coverage, with an estimated 90% of children under 5 years no longer receiving adequate immunization. More: http://www.worldbank.org/en/news/2012/10/02/world-bank-help-immunize-34-8-million-children-pakistan-polio

WHO: Global Vaccine Safety Initiative website launched

The GVSI promotes efforts to strengthen "vaccine pharmacovigilance" worldwide. This means identifying any "adverse events" that may occur following immunization and investigating them to see if they are related to the vaccine or the immunization procedure. The Blueprint refers to vaccine pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, prevention and communication of adverse events following immunization, or of any other vaccine- or immunization-related issues", as defined by CIOMS/WHO (2012). Adverse events are also sometimes referred to as "side-effects". Vaccine pharmacovigilance is not just a scientific exercise. Its purpose is to ensure that vaccines are safe and to follow up if a case arises where a vaccination may be linked to harm.

This site provides a wide range of information about vaccine safety in general and the GVSI in particular. The site includes:

- information on established untoward effects of vaccines and estimates of their rates of occurrence;
- advice from an Expert Advisory Group on vaccine safety issues of global importance;
- links to tools and methods for enhancing local capacity in vaccine safety;
- up-to-date information on the management of the GVSI.

The GVSI is a global collaborative effort to ensure that everyone everywhere can be protected from serious infectious diseases with minimal untoward effects from the best available vaccines. Training materials, tools for investigating vaccine safety concerns, and links to the web sites of other organizations are also provided.
http://www.who.int/vaccine_safety/initiative/en/index.html

WHO SEAR: *Partners of Harmonization for Health in Africa discuss action plans for high quality, affordable healthcare and implementation of Tunis Declaration*

"3 October 2012, Nairobi, Kenya – Partners in the Harmonization for Health in Africa (HHA) initiative are convening in Nairobi this week as a follow-up to the recent Tunis ministerial conference for African health and finance ministers. Regional Directors, senior representatives and a multidisciplinary group of technical experts from the HHA partner agencies will use this opportunity to discuss how to further strengthen their support to countries in providing quality and affordable healthcare to African populations, particularly the under-served…"

More:
http://www.afro.who.int/en/media-centre/pressreleases/item/5000-partners-of-harmonization-for-health-in-africa-discuss-action-plans-for-high-quality-affordable-healthcare-and-implementation-of-tunis-declaration.html

PAHO: ***PAHO/WHO Pushes Forward Roadmap to Support Parliamentary Activity on Health in the Americas***
(10/03/2012)
"With the aim of supporting parliamentary work on health in the Americas, the Pan American Health Organization/World Health Organization (PAHO/WHO) will present a portal with information on legislative processes in health policy in the region and also convene roundtables where parliamentarians of all countries will be able to exchange experiences on parliamentary procedures for health issues."
http://new.paho.org/hq/index.php?option=com_content&view=article&id=7294&Itemid=1926

WHO: ***GIN (Global Immunization News) 30 September 2012***
http://www.who.int/immunization/GIN_September_2012.pdf

WHO: New immunization approach in Ethiopia reaches more children
October 2012
"A new approach to routine immunization in the rural Afar region in north-eastern Ethiopia nearly quadrupled the numbers of children vaccinated against measles, diphtheria, pertussis, tetanus, polio and other diseases in 2010 (from as low as 22% to nearly 80% coverage in the target area). The immunization activity used "community champions" to encourage nomadic, pastoral families to have their children vaccinated and introduced new approaches such as task shifting to improve service delivery to these hard-to-reach populations.
"The Enhanced Routine Immunization Activity (ERIA) had already generated strong results among nomadic, pastoral families on a small scale in the neighbouring Somali region. With support from WHO and partners, health officials replicated the approach on a larger scale in Afar to reach more children."
http://www.who.int/features/2012/immunization_ethiopia/en/index.html

GAVI said it welcomed the 2012 aid transparency index that acknowledges the global health partnership for its increasing dedication to aid transparency. GAVI said the index gave it high marks for the "publication of high quality, current activity data" and calls on the organisation "to continue to lead on aid transparency". The index – produced annually by Publish What You Fund – ranks 72 aid organisations across the world, from country donors to private foundations. GAVO CEO Dr Seth Berkley said, "Accountability for results in country is the highest order of what we do; therefore communicating effectively on what is being spent where, by whom, and with what results is the basic foundation of the GAVI model." GAVI noted that it was a founding signatory to the International Aid Transparency Initiative (IATI) in 2008, and uses this global standard for publishing aid information to make information about aid spending easier to find, use and compare.

http://www.gavialliance.org/library/news/statements/2012/gavi-alliance-recognised-for-aid-transparency/

Conferences/Reports/Research/Analysis/Book Watch

Vaccines: The Week in Review has expanded its coverage of new reports, books, research and analysis published independent of the journal channel covered in Journal Watch below. Our interests span immunization and vaccines, as well as global public health, health governance, and associated themes. If you would like to suggest content to be included in this service, please contact David Curry at: david.r.curry@centerforvaccineethicsandpolicy.org

Speech/Panel/Webcast: *Malaria: History, Past Decade's Achievements, and Future Priorities*

Center for Strategic and International Studies
Wednesday, October 17th 3:00 - 5:00pm (EST)
The first hour, Sir Richard Feachem will speak to the historical patterns of malaria control, the outcomes of accelerated global efforts in the past decade, outstanding challenges, and policy priorities for the next Administration and Congress. The second hour will include a moderated discussion with Sir Richard Feachem and Rear Admiral Tim Ziemer on the U.S. anti-malaria agenda moving forward.
This event will be webcast live at: www.SmartGlobalHealth.org/Live
http://smartglobalhealth.org/page/s/malaria---history-past-decade-s-achievements-and-future-priorities

Global Fund: *Final Report of the Independent Evaluation of AMFm Phase 1*

The Global Fund to Fight AIDS, Tuberculosis and Malaria
4 October 2012

The Global Fund made public the final report of an independent evaluation of the pilot phase of the Affordable Medicines Facility–malaria, also known as AMFm. The report was commissioned to provide an independent evaluation to assess the extent to which AMFm has achieved the main objectives laid out for its pilot phase, which ends in December 2012. The independent evaluation was mandated by the Global Fund Board and will inform its decision in November 2012, when the Board is expected to consider the future of AMFm beyond the pilot phase.

The goal of AMFm is to improve access to artemisinin-based combination therapies (ACTs), the most effective anti-malaria treatment. The AMFm pilot phase was launched in April 2009 and began operations in July 2010. It set out to increase availability, particularly through private outlets where most people seek their treatments, and drive down the price of ACTs through a factory-gate global subsidy of ACTs combined with country-level measures to support its implementation.

The AMFm pilot phase currently operates in eight countries: Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania, and Uganda. The independent evaluation assessed the program in each of the pilot countries that was operational at the time of the endline survey.
Links to Executive Summary and Full Report here:
http://www.theglobalfund.org/en/amfm/independentevaluation/

Journal Watch

Vaccines: The Week in Review continues its weekly scanning of key peer-reviewed 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

American Journal of Public Health

Volume 102, Issue 10 (October 2012)

http://ajph.aphapublications.org/toc/ajph/current

[Reviewed earlier]

Annals of Internal Medicine

2 October 2012, Vol. 157. No. 7

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

What Primary Care Providers Need to Know About Preexposure Prophylaxis for HIV Prevention: A Narrative Review

Douglas Krakower, MD; and Kenneth H. Mayer, MD

*Abstract [*Free full-text]

As HIV prevalence climbs globally, including more than 50,000 new infections per year in the United States, we need more effective HIV prevention strategies. The use of antiretrovirals for preexposure prophylaxis (PrEP) among high-risk persons without HIV is emerging as one such strategy. Randomized, controlled trials have demonstrated that once-daily oral PrEP decreased HIV incidence among at-risk men who have sex with men and African heterosexuals, including serodiscordant couples. An additional randomized, controlled trial of a topical pericoital antiretroviral microbicide gel decreased HIV incidence among at-risk heterosexual South African women. Two other studies in African women did not demonstrate the efficacy of oral or topical PrEP, raising concerns about adherence patterns and efficacy in this population.

The U.S. Food and Drug Administration (FDA) Antiviral Drugs Advisory Committee reviewed these studies and additional data in May 2012 and voted to advise the approval of oral tenofovir–emtricitabine for PrEP in high-risk populations. On 16 July 2012, the FDA recommended that this combination medication be approved for use as PrEP in high-risk persons without HIV. Patients may seek PrEP from their primary care providers, and those receiving PrEP require monitoring. Thus, primary care providers should become familiar with PrEP. This review outlines current knowledge about PrEP as it pertains to primary care, including identifying persons likely to benefit from PrEP; counseling to maximize adherence and reduce potential increases in risky behavior; and monitoring for potential drug toxicities, HIV acquisition, and antiretroviral drug resistance. Issues related to cost and insurance coverage are also discussed. Recent data suggest that PrEP, combined with other prevention strategies, holds promise in helping to curtail the HIV epidemic.

Human immunodeficiency virus continues to spread, with more than 2 million new infections globally (1) and 50,000 new infections in the United States per year (2). Thus, more effective HIV prevention strategies are urgently needed. Administration of antiretroviral medications to uninfected persons at high risk to protect against HIV acquisition, known as preexposure prophylaxis (PrEP), has recently emerged as a promising prevention strategy.
Over the past 2 years, randomized, controlled trials have demonstrated that PrEP can decrease HIV incidence in high-risk populations (3 - 6). With the FDA's approval of oral tenofovir–emtricitabine for PrEP in high-risk populations (7), clinicians can now prescribe PrEP to prevent HIV acquisition in their at-risk patients. Thus, it is important that practicing physicians understand this new evidence and its implications.

British Medical Bulletin
Volume 103 Issue 1 September 2012
http://bmb.oxfordjournals.org/content/current
[Reviewed earlier]

British Medical Journal
06 October 2012 (Vol 345, Issue 7877)
http://www.bmj.com/content/345/7877
[No relevant content]

Bulletin of the World Health Organization
Volume 90, Number 10, October 2012, 713-792
http://www.who.int/bulletin/volumes/90/10/en/index.html
EDITORIAL
Stockpiling oral cholera vaccine
Stephen Martin a, Alejandro Costa a & William Perea a
a. Control of Epidemic Diseases Unit, Pandemic and Epidemic Diseases Department, World Health Organization, 20 avenue Appia, 1211 Geneva 27, Switzerland.
Bulletin of the World Health Organization 2012;90:714-714. doi: 10.2471/BLT.12.112433
Cholera is re-emerging as a threat on the global public health stage. The number of reported cases worldwide is back at the peak level observed two decades ago,1 new Vibrio cholerae strains have appeared and antimicrobial resistance has increased. Weak surveillance systems and the possibility of travel and trade sanctions contribute to widespread underreporting of cholera cases, which results in great uncertainty surrounding global disease burden estimates. Such estimates suggest that about 1.4 billion people are at risk of cholera and that the risk is highest among children under five years of age. Annually 2.8 million cases and 91 000 deaths from cholera occur in endemic countries; non-endemic countries contribute another 87 000 cases and 2500 deaths.2 Although effective preventive and therapeutic regimens are well established, clearly cholera remains poorly controlled in both outbreak and endemic contexts.
Cholera-related morbidity and mortality are particularly high during humanitarian crises. Large cholera epidemics in Zimbabwe (2008–2009), Haiti (2011) and now Sierra Leone (2012) have made the international community aware of the need to not merely control endemic disease, but also to strengthen epidemic preparedness and response capacity. In 2011, the Sixty-fourth World Health Assembly issued a resolution calling for a reinvigorated focus on cholera and

defined a range of actions required of the World Health Organization (WHO) and its Member States towards creating an integrated, comprehensive strategy for cholera prevention and control.3 As part of this strategy, WHO is facilitating a multi-partner initiative aimed at establishing a stockpile of oral cholera vaccine (OCV) for use in outbreak response as an adjunct to established prevention and control measures. This approach was endorsed in September 2011 by global cholera experts, who affirmed that such a stockpile is both necessary and feasible.4 There are currently two stockpile candidate oral cholera vaccines, both prequalified by WHO.

A WHO technical working group convened in April 2012 and defined the required characteristics of a stockpiled vaccine, the epidemiological and operational considerations for deployment, and the mechanisms for stockpile governance, replenishment and appraisal.5 This working group agreed on an initial OCV stockpile of 2 million annual doses to be available for epidemic response in low-income countries. The International Coordinating Group (ICG) has a decade of experience as a decision-making partnership that oversees the meningococcal and yellow fever vaccine stockpiles and their deployment. The ICG is composed of experts from four organizations: Médecins sans Frontières, the International Federation of the Red Cross and Red Crescent Societies, the United Nations Children's Fund and WHO, which is both a decision-making partner and the ICG's secretariat. All members of the ICG, including WHO, will oversee the proposed OCV stockpile.

The WHO technical working group emphasized that deployment of the stockpiled vaccine must be guided by epidemiological, technical and operational evidence, some of which remains incomplete and must be consolidated as experience is gained. While acknowledging the difficulties in predicting outbreaks and the need for more detailed empirical data, the working group created an advisory framework for assessing outbreak severity based on three criteria: the biological susceptibility of the population, the social vulnerability of the population and the risk of spatial extension. For each of these criteria, the working group defined epidemiological and demographic indicators, thresholds for deciding when to deploy the vaccine and indicators for determining the anticipated impact of a vaccination campaign. The framework proposed by the working group is intended only to inform decision-making; actual deployment of the OCV from the stockpile would follow not only an analysis of these indicators, but also an assessment of programmatic factors, such as local capacity to organize a mass vaccination campaign and prevailing security conditions.

Progress is being made on the working group's action plans for 2012. The work streams are focused on advocacy for funding, negotiations with vaccine producers and preparedness planning for countries and regions. A stockpile evaluation group has been established to define and implement the detailed monitoring required. As experience and data accrue, the results of this evaluation should enable continuous improvement in the structure and functioning of the stockpile. Successful assessment of a stockpile vaccination campaign will require reinforcement of surveillance systems in most locations where an epidemic is likely to arise.

Public health interventions, such as case management, enhanced environmental control, improved hygiene and sanitation and social mobilization, should form the backbone of all cholera control programmes. In turn, these interventions depend on effective surveillance and strong health-care systems. This initial, necessarily small, OCV stockpile will not constitute sufficient preparedness for a large or sustained epidemic, its use should complement existing measures as part of a reinvigorated and comprehensive approach to meeting the new challenges involved in global cholera control and prevention.

References

Cholera annual report 2011. Wkly Epidemiol Rec 2012; 87: 289-304 pmid: 22905370.

Ali M, Lopez AL, You YA, Kim YE, Sah B, Maskery B, et al., et al. The global burden of cholera. Bull World Health Organ 2012; 90: 209-218 doi: 10.2471/BLT.11.093427 pmid: 22461716.
Resolution WHA64.15. Cholera: mechanism for control and prevention. In: Sixty-fourth World Health Assembly, Geneva, 16–24 May 2011. Volume 1. Resolutions, decisions and annexes. Geneva: World Health Organization; 2011 (WHA64/2011/REC/1). Available from: www.who.int/entity/cholera/.../Resolution_CholeraA64_R15-en.pdf [accessed 5 September 2012].

WHO Consultation on oral cholera vaccine (OCV) stockpile strategic framework: potential objectives and possible policy options. Geneva: Department of Immunization, Vaccines and Biologicals, World Health Organization; 2012 (WHO/IVB/12.05). Available from: http://www.who.int/immunization/documents/innovation/WHO_IVB_12.05/en/ [accessed 4 September 2012].

World Health Organization [Internet]. WHO Technical Working Group on creation of an oral cholera vaccine stockpile. Geneva: World Health Organization; 2012 (WHO/HSE/PED/2012.2). Available from: http://www.who.int/cholera/publications/oral_cholera_vaccine/en/index.html [accessed 1 September 2012].

LESSONS FROM THE FIELD

A new entity for the negotiation of public procurement prices for patented medicines in Mexico

Octavio Gómez-Dantés, Veronika J Wirtz, Michael R Reich, Paulina Terrazas & Maki Ortiz

Problem

As countries expand health insurance coverage, their expenditures on medicines increase. To address this problem, WHO has recommended that every country draw up a list of essential medicines. Although most medicines on the list are generics, in many countries patented medicines represent a substantial portion of pharmaceutical expenditure.

Approach

To help control expenditure on patented medicines, in 2008 the Mexican Government created the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM), whose role, as the name suggests, is to enter into price negotiations with drug manufacturers for patented drugs on Mexico's list of essential medicines.

Local setting

Mexico's public expenditure on pharmaceuticals has increased substantially in the past decade owing to government efforts to achieve universal health-care coverage through Seguro Popular, an insurance programme introduced in 2004 that guarantees access to a comprehensive package of health services and medicines.

Relevant changes

Since 2008, the CCPNM has improved procurement practices in Mexico's public health institutions and has achieved significant price reductions resulting in substantial savings in public pharmaceutical expenditure.

Lessons learnt

The CCPNM has successfully changed the landscape of price negotiation for patented medicines in Mexico. However, it is also facing challenges, including a lack of explicit indicators to assess CCPNM performance; a shortage of permanent staff with sufficient technical expertise; poor coordination among institutions in preparing background materials for the annual negotiation process in a timely manner; insufficient communication among committees and institutions; and a lack of political support to ensure the sustainability of the CCPNM.

Cost Effectiveness and Resource Allocation
(Accessed 6 October 2012)
http://www.resource-allocation.com/
[No new relevant content]

Emerging Infectious Diseases
Volume 18, Number 10—October 2012
http://www.cdc.gov/ncidod/EID/index.htm
[Reviewed earlier; No relevant content]

Eurosurveillance
Volume 17, Issue 40, 04 October 2012
http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678
[No relevant content]

Global Health Governance
Volume V, Issue 2: Spring 2012
[Reviewed earlier]

Globalization and Health
[Accessed 6 October 2012]
http://www.globalizationandhealth.com/
[No new relevant content]

Health Affairs
September 2012; Volume 31, Issue 9
http://content.healthaffairs.org/content/current
Theme: Payment Reform To Achieve Better Health Care
[No relevant content]

Health and Human Rights
Vol 14, No 1 (2012)
http://hhrjournal.org/index.php/hhr
[Reviewed earlier]

Health Economics, Policy and Law
Volume 7 - Issue 03 - July 2012
http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue
[Reviewed earlier]

Health Policy and Planning
Volume 27 Issue 6 September 2012
http://heapol.oxfordjournals.org/content/current
[Reviewed earlier]

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)
Volume 8, Issue 10 October 2012
http://www.landesbioscience.com/journals/vaccines/toc/volume/8/issue/10/
SPECIAL FOCUS: Allergy Vaccines and Immunotherapeutics
Research Papers
Impact of rotavirus vaccination in regions with low and moderate vaccine uptake in Germany
Sandra Dudareva-Vizule, Judith Koch, Matthias an der Heiden, Doris Oberle, Brigitte Keller-Stanislawski and Ole Wichmann
http://dx.doi.org/10.4161/hv.21593
Abstract:
In Germany, routine RV-vaccination is not adopted into the national immunization schedule as of 2012. Because RV-vaccines were already on the market since 2006, in 2010 a moderate (58%) and low (22%) vaccine uptake was observed in the 5 eastern federal states (EFS) and the 11 western federal states (WFS), respectively. To assess the impact of RV-vaccination, we compared the incidence rates (IR) of RV-related hospitalizations before (2004–2006) and in seasons after (2008/09–2010/11) RV-vaccine introduction in Germany by utilizing data from the national mandatory disease reporting system. In the EFS, the IR was significantly reduced in age-groups < 18 mo in 2008/09 and in age-groups < 24 mo in 2009/10–2010/11. In the WFS an IR-reduction was observed only in age-groups < 12 mo in 2008/09 and in age-groups < 18 mo in 2009/10–2010/11. Overall IR-reduction in age-groups < 24 mo comparing 2008–11 with 2004–06 was 36% and 25% in EFS and WFS, respectively. In addition, we computed IR-ratios (IRR) in the seasons after mid-2006 with negative binomial regression. The effect of vaccination was independent from the geographic region. Vaccination was associated with a significant reduction in RV-related hospitalizations in the age-groups 6–23 mo. Most prominently, vaccination of 50% of infants led to an estimated decrease in age group 6–11 mo by 42%. No significant reduction was observed in age-groups ≥ 24 mo. In conclusion, in the German setting with low to moderate vaccine uptake, RV-related hospitalization incidence decreased substantially depending on the achieved vaccination coverage, but only in the first two years of life.
COMMENTARIES
Business models and opportunities for cancer vaccine developers
Alex Kudrin
http://dx.doi.org/10.4161/hv.20629
Abstract:
Despite of growing oncology pipeline, cancer vaccines contribute only to a minor share of total oncology-attributed revenues. This is mainly because of a limited number of approved products and limited sales from products approved under compassionate or via early access entry in smaller and less developed markets. However revenue contribution from these products is extremely limited and it remains to be established whether developers are breaking even or achieving profitability with existing sales. Cancer vaccine field is well recognized for high development costs and risks, low historical rates of investment return and high probability of

failures arising in ventures, partnerships and alliances. The cost of reimbursement for new oncology agents is not universally acceptable to payers limiting the potential for a global expansion, market access and reducing probability of commercial success. In addition, the innovation in cancer immunotherapy is currently focused in small and mid-size biotech companies and academic institutions struggling for investment. Existing R&D innovation models are deemed unsustainable in current "value-for-money" oriented healthcare environment. New business models should be much more open to collaborative, networked and federated styles, which could help to outreach global, markets and increase cost-efficiencies across an entire value chain. Lessons learned from some developing countries and especially from South Korea illustrate that further growth of cancer vaccine industry will depends not only on new business models but also will heavily rely on regional support and initiatives from different bodies, such as governments, payers and regulatory bodies.

Tetanus toxoid vaccine: Elimination of neonatal tetanus in selected states of India

Ramesh Verma and Pardeep Khanna

Abstract:

Tetanus is caused by a neurotoxin produced by Clostridium tetani (C. tetani), a spore-forming bacterium. Infection begins when tetanus spores are introduced into damaged tissue. Tetanus is characterized by muscle rigidity and painful muscle spasms caused by tetanus toxin's blockade of inhibitory neurons that normally oppose and modulate the action of excitatory motor neurons. Maternal and neonatal tetanus (MNT) are caused by unhygienic methods of delivery, abortion, or umbilical-cord care. Maternal and neonatal tetanus are both forms of generalized tetanus and have similar clinical courses. About 90% of neonates with tetanus develop symptoms in the first 3–14 d of life, mostly on days 6–8, distinguishing neonatal tetanus from other causes of neonatal mortality which typically occur during the first two days of life. Overall case fatality rates for patients admitted to the hospital with neonatal tetanus in developing countries are 8–50%, while the fatality rate can be as high as 100% without hospital care. Tetanus toxoid (TT) vaccination of pregnant women to prevent neonatal tetanus was included in WHO's Expanded Program on Immunization (EPI) a few years after its inception in 1974. In 2000, WHO, UNICEF, and UNFPA formed a partnership to relaunch efforts toward this goal, adding the elimination of maternal tetanus as a program objective, and setting a new target date of 2005. By February 2007, 40 countries had implemented tetanus vaccination campaigns in high-risk areas, targeting more than 94 million women, and protecting more than 70 million subjects with at least two doses of TT. In 2011, 653 NT cases were reported in India compared with 9313 in 1990. As of February 2012, 25 countries and 15 States and Union Territories of India, all of Ethiopia except Somaliland, and almost 29 of 34 provinces in Indonesia have been validated to have eliminated MNT.

International Journal of Infectious Diseases
October 2012, Vol. 16, No. 10
http://www.ijidonline.com/
[Reviewed earlier; No relevant content]

JAMA
October 03, 2012, Vol 308, No. 13
http://jama.ama-assn.org/current.dtl
CDC Grand Rounds: the TB/HIV Syndemic

JAMA. 2012;308(13):1311-1317. doi:.
Extract [Free full-text]
Since Robert Koch's 1882 discovery of Mycobacterium tuberculosis, substantial progress has been made in tuberculosis (TB) control. Nevertheless, in the latter part of the 20th century, a long period of neglect of both quality program implementation and research led to persistently high TB incidence rates and failure to develop new tools to adequately address the problem. Today, most of the world continues to rely on the same diagnostic test invented by Koch approximately 125 years ago and on drugs developed 40 years ago. The world now faces a situation in which approximately 160 persons die of TB each hour (1.45 million died in 2009), in which a quarter of all deaths in persons with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) (PWHA) are caused by TB, and in which the evolution of the bacteria has outpaced the evolution of its treatment to such an extent that some forms of TB are now untreatable.1 More recently, renewed attention has been given to reducing the global burden of TB,2 but much remains to be done…

Journal of Health Organization and Management
Volume 26 issue 6 - Published: 2012
http://www.emeraldinsight.com/journals.htm?issn=1477-7266&show=latest
[Reviewed earlier; No relevant content]

Journal of Infectious Diseases
Volume 206 Issue 8 October 15, 2012
http://www.journals.uchicago.edu/toc/jid/current
[Reviewed earlier]

Journal of Global Infectious Diseases (JGID)
July-September 2012
Volume 4 | Issue 3 Page Nos. 139-186
http://www.jgid.org/currentissue.asp?sabs=n
[Reviewed earlier]

Journal of Medical Ethics
October 2012, Volume 38, Issue 10
http://jme.bmj.com/content/current
[Reviewed earlier]

Journal of Medical Microbiology
October 2012; 61 (Pt 10)
http://jmm.sgmjournals.org/content/current
[Reviewed earlier; No relevant content]

Journal of the Pediatric Infectious Diseases Society (JPIDS)

Volume 1 Issue 3 September 2012
http://jpids.oxfordjournals.org/content/current
[Reviewed earlier; No relevant content]

The Lancet
Oct 06, 2012 Volume 380 Number 9849 p1203 - 1280
http://www.thelancet.com/journals/lancet/issue/current
Health Policy
The quest for universal health coverage: achieving social protection for all in Mexico
Felicia Marie Knaul, Eduardo González-Pier, Octavio Gómez-Dantés, David García-Junco, Héctor Arreola-Ornelas, Mariana Barraza-Lloréns, Rosa Sandoval, Francisco Caballero, Mauricio Hernández-Avila, Mercedes Juan, David Kershenobich, Gustavo Nigenda, Enrique Ruelas, Jaime Sepúlveda, Roberto Tapia, Guillermo Soberón, Salomón Chertorivski, Julio Frenk
Summary
Mexico is reaching universal health coverage in 2012. A national health insurance programme called Seguro Popular, introduced in 2003, is providing access to a package of comprehensive health services with financial protection for more than 50 million Mexicans previously excluded from insurance. Universal coverage in Mexico is synonymous with social protection of health. This report analyses the road to universal coverage along three dimensions of protection: against health risks, for patients through quality assurance of health care, and against the financial consequences of disease and injury. We present a conceptual discussion of the transition from labour-based social security to social protection of health, which implies access to effective health care as a universal right based on citizenship, the ethical basis of the Mexican reform. We discuss the conditions that prompted the reform, as well as its design and inception, and we describe the 9-year, evidence-driven implementation process, including updates and improvements to the original programme. The core of the report concentrates on the effects and impacts of the reform, based on analysis of all published and publically available scientific literature and new data. Evidence indicates that Seguro Popular is improving access to health services and reducing the prevalence of catastrophic and impoverishing health expenditures, especially for the poor. Recent studies also show improvement in effective coverage. This research then addresses persistent challenges, including the need to translate financial resources into more effective, equitable and responsive health services. A next generation of reforms will be required and these include systemic measures to complete the reorganisation of the health system by functions. The paper concludes with a discussion of the implications of the Mexican quest to achieve universal health coverage and its relevance for other low-income and middle-income countries.

The Lancet Infectious Disease
Oct 2012 Volume 12 Number 10 p737 – 816 e1
http://www.thelancet.com/journals/laninf/issue/current
[Reviewed earlier]

Medical Decision Making (MDM)
September–October 2012; 32 (5)
http://mdm.sagepub.com/content/current

[Reviewed earlier]

The Milbank Quarterly
A Multidisciplinary Journal of Population Health and Health Policy
September 2012 Volume 90, Issue 3 Pages 417–629
http://onlinelibrary.wiley.com/doi/10.1111/milq.2012.90.issue-3/issuetoc
[Reviewed earlier; No relevant content]

Nature
Volume 490 Number 7418 pp5-136 4 October 2012
http://www.nature.com/nature/current_issue.html
[No relevant content]

Nature Immunology
October 2012, Volume 13 No 10 pp901-1019
http://www.nature.com/ni/journal/v13/n10/index.html
Focus issue:
Checks and Balances in the Immune System
[Reviewed earlier]

Nature Medicine
October 2012, Volume 18 No 10 pp1443-1592
http://www.nature.com/nm/journal/v18/n10/index.html
[No relevant content]

Nature Reviews Immunology
October 2012 Vol 12 No 10
http://www.nature.com/nri/journal/v12/n10/index.html
[No relevant content]

New England Journal of Medicine
October 4, 2012 Vol. 367 No. 14
http://content.nejm.org/current.shtml
[No relevant content]

OMICS: A Journal of Integrative Biology
September 2012, 16(9)
http://online.liebertpub.com/toc/omi/16/7-8
[No relevant content]

The Pediatric Infectious Disease Journal
October 2012 - Volume 31 - Issue 10 pp: 9-1105,e176-e188
http://journals.lww.com/pidj/pages/currenttoc.aspx
[Reviewed earlier]

Pediatrics
October 2012, VOLUME 130 / ISSUE 4
http://pediatrics.aappublications.org/current.shtml
[No relevant content]

Pharmacoeconomics
October 1, 2012 - Volume 30 - Issue 10 pp: 859-980
http://adisonline.com/pharmacoeconomics/pages/currenttoc.aspx
[Reviewed earlier]

PLoS One
[Accessed 6 October 2012]
http://www.plosone.org/article/browse.action;jsessionid=577FD8B9E1F322DAA533C413369CD6F3.ambra01?field=date
Background Rates of Adverse Pregnancy Outcomes for Assessing the Safety of Maternal Vaccine Trials in Sub-Saharan Africa
Lauren A. V. Orenstein, Evan W. Orenstein, Ibrahima Teguete, Mamoudou Kodio, Milagritos Tapia, Samba O. Sow, Myron M.
PLoS ONE: Research Article, published 04 Oct 2012 10.1371/journal.pone.0046638
Abstract
Background
Maternal immunization has gained traction as a strategy to diminish maternal and young infant mortality attributable to infectious diseases. Background rates of adverse pregnancy outcomes are crucial to interpret results of clinical trials in Sub-Saharan Africa.
Methods
We developed a mathematical model that calculates a clinical trial's expected number of neonatal and maternal deaths at an interim safety assessment based on the person-time observed during different risk windows. This model was compared to crude multiplication of the maternal mortality ratio and neonatal mortality rate by the number of live births. Systematic reviews of severe acute maternal morbidity (SAMM), low birth weight (LBW), prematurity, and major congenital malformations (MCM) in Sub-Saharan African countries were also performed.
Findings
Accounting for the person-time observed during different risk periods yields lower, more conservative estimates of expected maternal and neonatal deaths, particularly at an interim safety evaluation soon after a large number of deliveries. Median incidence of SAMM in 16 reports was 40.7 (IQR: 10.6–73.3) per 1,000 total births, and the most common causes were hemorrhage (34%), dystocia (22%), and severe hypertensive disorders of pregnancy (22%). Proportions of liveborn infants who were LBW (median 13.3%, IQR: 9.9–16.4) or premature (median 15.4%, IQR: 10.6–19.1) were similar across geographic region, study design, and

institutional setting. The median incidence of MCM per 1,000 live births was 14.4 (IQR: 5.5–17.6), with the musculoskeletal system comprising 30%.
Interpretation
Some clinical trials assessing whether maternal immunization can improve pregnancy and young infant outcomes in the developing world have made ethics-based decisions not to use a pure placebo control. Consequently, reliable background rates of adverse pregnancy outcomes are necessary to distinguish between vaccine benefits and safety concerns. Local studies that quantify population-based background rates of adverse pregnancy outcomes will improve safety assessment of interventions during pregnancy.

The Interplay of Public Intervention and Private Choices in Determining the Outcome of Vaccination Programmes

Alberto d'Onofrio, Piero Manfredi, Piero Poletti
PLoS ONE: Research Article, published 01 Oct 2012 10.1371/journal.pone.0045653
Abstract
After a long period of stagnation, traditionally explained by the voluntary nature of the programme, a considerable increase in routine measles vaccine uptake has been recently observed in Italy after a set of public interventions aiming to promote MMR immunization, whilst retaining its voluntary aspect. To account for this take-off in coverage we propose a simple SIR transmission model with vaccination choice, where, unlike similar works, vaccinating behaviour spreads not only through the diffusion of "private" information spontaneously circulating among parents of children to be vaccinated, which we call imitation, but also through public information communicated by the public health authorities. We show that public intervention has a stabilising role which is able to reduce the strength of imitation-induced oscillations, to allow disease elimination, and to even make the disease-free equilibrium where everyone is vaccinated globally attractive. The available Italian data are used to evaluate the main behavioural parameters, showing that the proposed model seems to provide a much more plausible behavioural explanation of the observed take-off of uptake of vaccine against measles than models based on pure imitation alone.

PLoS Medicine
(Accessed 6 October 2012)
http://www.plosmedicine.org/article/browse.action?field=date
[No new relevant content]

PLoS Neglected Tropical Diseases
September 2012
http://www.plosntds.org/article/browseIssue.action
[Reviewed earlier]

PNAS - Proceedings of the National Academy of Sciences of the United States of America
(Accessed 6 October 2012)
http://www.pnas.org/content/early/recent
[No new relevant content]

Public Health Ethics
Volume 5 Issue 2 July 2012
http://phe.oxfordjournals.org/content/current
[Reviewed earlier]

Trends in Molecular Medicine
Volume 18, Issue 10, Pages 575-626 (October 2012)
http://www.sciencedirect.com/science/journal/14714914
Reviews
Lipidated promiscuous peptides vaccine for tuberculosis-endemic regions
Review Article
Pages 607-614
Uthaman Gowthaman, Pradeep K. Rai, Nargis Khan, David C. Jackson, Javed N. Agrewala
Abstract
Despite nine decades of Bacillus Calmette–Guérin (BCG) vaccination, tuberculosis continues to be a major global health challenge. Clinical trials worldwide have proved the inadequacy of the BCG vaccine in preventing the manifestation of pulmonary tuberculosis in adults. Ironically, the efficacy of BCG is poorest in tuberculosis endemic areas. Factors such as nontuberculous or environmental mycobacteria and helminth infestation have been suggested to limit the efficacy of BCG. Hence, in high TB-burden countries, radically novel strategies of vaccination are urgently required. Here we showcase the properties of lipidated promiscuous peptide vaccines that target and activate cells of the innate and adaptive immune systems by employing a Toll-like receptor-2 agonist, S-[2,3-bis(palmitoyloxy)propyl]cysteine (Pam2Cys). Such a strategy elicits robust protection and enduring memory responses by type 1 T helper cells (Th1). Consequently, lipidated peptides may yield a better vaccine than BCG.

Science
5 October 2012 vol 338, issue 6103, pages 1-160
http://www.sciencemag.org/current.dtl
Perspective -
Epidemiology
Malaria in the Post-Genome Era
Brian Greenwood[1],
Seth Owusu-Agyei[2]
Summary
Ten years ago, the genome sequence of the mosquito *Anopheles gambiae*, the most important vector of malaria in Africa, and the genome sequence of *Plasmodium falciparum*, the most dangerous human malaria parasite, were published (*1*, *2*). It was anticipated that these remarkable pieces of research heralded a bright future for malaria control. Has this happened? The genome projects have made some contribution to the development of new malaria tools, such as new vaccine candidates, but a decade is probably too short a period for the research to be translated into success in the field. Knowledge gained from the genome projects may contribute more substantially in the coming decade as efforts to control infection increasingly focus on development of new drugs, insecticides, and vaccines.

Science Translational Medicine
3 October 2012 vol 4, issue 154
http://stm.sciencemag.org/content/current
[No relevant content]

Vaccine
Volume 30, Issue 46, Pages 6509-6608 (12 October 2012)
http://www.sciencedirect.com/science/journal/
[No relevant content]

Vaccine: Development and Therapy
(Accessed 6 October 2012)
http://www.dovepress.com/vaccine-development-and-therapy-journal
[No new relevant content]

Value in Health
Vol 15 | No. 6 | September-October 2012 | Pages 791-990
http://www.valueinhealthjournal.com/current
[No relevant content]

From Google Scholar: Dissertations, Theses, Selected Journal Articles

A tale of two vaccines: Lessons from polio that could inform the development of an HIV vaccine
J Esparza - AIDS, 2012
Abstract Two vaccine trials that were conducted 50 years apart are reviewed and compared: The 1954 field trial of the Salk inactivated polio vaccine and the RV144 HIV vaccine trial conducted in Thailand between 2003 and 2009. Despite the obvious differences in...

[PDF] Communicating with parents about vaccination: a framework for health professionals
J Leask, P Kinnersley, C Jackson, F Cheater… - BMC pediatrics, 2012

Human Papillomavirus (HPV) Vaccines as an Option for Preventing Cervical Malignancies:(How) Effective and Safe?
L Tomljenovic, CA Shaw, JP Spinosa - Current pharmaceutical design, 2012
... We carried out a systematic review of HPV vaccine pre- and post-licensure trials to assess the evidence of their effectiveness and safety. We find that HPV vaccine clinical trials design, and data interpretation of both efficacy and safety outcomes, were largely inadequate...

[PDF] Parents' Source of Vaccine Information and Impact on Vaccine Attitudes, Beliefs, and Nonmedical Exemptions
AM Jones, SB Omer, RA Bednarczyk, NA Halsey… - Advances in Preventive …, 2012

In recent years, use of the Internet to obtain vaccine information has increased. Historical data are necessary to evaluate current vaccine information seeking trends in context. Between 2002 and 2003, surveys were mailed to 1,630 parents of fully vaccinated...

Media Watch

Beginning in June 2012, *Vaccines: The Week in Review* expanded to alert readers to substantive news, analysis and opinion from the general media on vaccines, immunization, global; public health and related themes. *Media Watch* is not intended to be exhaustive, but indicative of themes and issues CVERP is actively tracking. This section will grow from an initial base of newspapers, magazines and blog sources, and is segregated from *Journal Watch* above which scans the peer-reviewed journal ecology.

We acknowledge the Western/Northern bias in this initial selection of titles and invite suggestions for expanded coverage. Most publications require either a registration or a fee-based subscription for access. We will provide full-text where content is published without restriction, but most publications require registration and some subscription level.

Economist

http://www.economist.com/

Accessed 6 October 2012

[No new unique, relevant content]

Financial Times

http://www.ft.com

Accessed 6 October 2012

India: calling the shots

October 2, 2012 3:58 am by Avantika Chilkoti

Extract

Fewer than half of India's babies are immunised against childhood diseases. For doctors, that's a nightmare. For vaccine makers, it's a dream opportunity.

A report from Global Business Intelligence Research (GBI) forecasts that the Indian vaccine market will grow 20 per cent a year for the next four years. Currently valued at $350m, it says, the industry will be worth $871m by 2016…

Forbes

http://www.forbes.com/

Accessed 6 October 2012

Leadership

10/04/2012 @ 1:21PM |

RahimKanani, Contributor

GAVI Alliance CEO: Leadership Is About Vision and Responsibility, Not Power

Extract

Recently, I interviewed Seth Berkley, CEO of the GAVI Alliance, a public-private global health partnership committed to saving children's lives and protecting people's health by increasing access to immunization in poor countries. We discussed the evolution and impact of the organization, their unique approach to development, their secret to successful collaborations, and much more….

Foreign Affairs
http://www.foreignaffairs.com/
September/October 2012 Volume 91, Number 5
Accessed 6 October 2012
[No new unique, relevant content]

Foreign Policy
http://www.foreignpolicy.com/
Accessed 6 October 2012]
[No new unique, relevant content]

The Guardian
http://www.guardiannews.com/
Accessed 6 October 2012
[No new unique, relevant content]

The Huffington Post
http://www.huffingtonpost.com/
Accessed 6 October 2012
The Blog
Dagfinn Høybråten
Vice President, Norwegian Parliament; Chair, GAVI Alliance Board
Vaccines and Ensuring the Health of Children No Matter Where They Live
Posted: 09/28/2012 10:15 am
http://www.huffingtonpost.com/dagfinn-hoybraten/post_3886_b_1922575.html

New Yorker
http://www.newyorker.com/
Accessed 6 October 2012
[No new unique, relevant content]

New York Times
http://www.nytimes.com/
Accessed 6 October 2012

Reuters
http://www.reuters.com/
China close to entering WHO-approved global vaccine market
Extract
A Chinese-made vaccine is on the verge of being approved for aid agency use by the World Health Organization, a move that would be a first for China and open the door to lucrative regional and global markets, a leading health alliance said on Thursday.

The vaccine is against Japanese encephalitis, a debilitating mosquito-borne disease prevalent in Southeast Asia and the Far East that can be fatal, especially in children.

Made by Chengdu Institute, part of China's top vaccine maker China National Biotech Group (CNBG), the vaccine is likely to win so-called prequalification status from the World Health

Organization (WHO), Seth Berkley, chief executive of the Global Alliance for Vaccines and Immunization (GAVI), said…
http://www.reuters.com/article/2012/10/04/us-vaccines-idUSBRE89313220121004

Wall Street Journal
http://online.wsj.com/home-page
Accessed 6 October 2012
[No new unique, relevant content]

Washington Post
http://www.washingtonpost.com/
Accessed 6 October 2012
[No new unique, relevant content]

Twitter Watch *[accessed 6 October 2012 17:46]*
Items of interest from a variety of twitter feeds associated with immunization, vaccines and global public health. This capture is highly selective and is by no means intended to be exhaustive.

HarvardPublicHealth @HarvardHSPH
RT @ForumHSPH: Health is a fundamental human right, and it can in no condition be delayed. - R. Akdag http://ht.ly/e1941
1:17 PM - 6 Oct 12

PAHO/WHO Equity @eqpaho
Sir Michael Marmot on Knowledge networks and Social Determinants of Health WHO commission #SDOH #healthequity #crics9 http://bit.ly/Su0ixP
Retweeted by PAHO/WHO
2:59 PM - 5 Oct 12

Kaiser Family Found @KaiserFamFound
What is the role of Dept. of Defense in global health? http://ow.ly/e8DR6 Report explores activities, strategy, policy & budget.
3:11 PM - 5 Oct 12

PAHO/WHO Equity @eqpaho
Global Conference on Health Promotion Helsinki, Finland, on June 10-14 2013 #SDOH http://bit.ly/K5p273
Retweeted by PAHO/WHO
11:45 AM - 5 Oct 12 ·

Seth Berkley @GAVISeth
Fun interview with me in Forbes on leadership and changes at GAVI
http://tinyurl.com/9hwb7af
4:21 AM - 5 Oct 12

PATH @PATHtweets
We promised we'd deliver a meningitis A vaccine. How're we doing? Our CEO reports from #CGI2012. http://ow.ly/eeqW0
2:31 PM - 4 Oct 12 ·

Jeff Raikes @jeffraikes
Pls read my latest annual letter and @gatesfoundation annual report-released today. "Building Better Lives Together" http://bit.ly/SwJO6l
Retweeted by Gates Foundation
11:10 AM - 4 Oct 12

Gates Health @gateshealth
Pasteur, Koch, Salk, Sabin, [You]. Be the next great vaccine pioneer. Grand Challenges wants your ideas to stop #TB: http://gates.ly/O2uLRc
Retweeted by GAVI Alliance
8:00 AM - 3 Oct 12

GAVI Alliance @GAVIAlliance
Good news! Efforts 2 eliminate meningitis takes big step fwd as 50M people receive vaccinations in 7 African countries! http://ht.ly/edMwc
8:46 AM - 4 Oct 12

VAC at JHSPH @IVACtweets
A New Chapter for IVAC - Blog post by Acting Director, Dr. Kate O'Brien http://bit.ly/OF4bil
6:08 AM - 4 Oct 12

* * * *

Vaccines: The Week in Review *is a service of the Center for Vaccines Ethics and Policy (CVEP) which is solely responsible for its content. Support for this service is provided by its governing institutions – Department of Medical Ethics, NYU Medical School; The Wistar Institute Vaccine Center and the Children's Hospital of Philadelphia Vaccine Education Center. Additional support is provided by PATH Vaccine Development Program and the International Vaccine Institute (IVI), and by vaccine industry leaders including GSK, Merck, Pfizer, and sanofi pasteur (list in formation), as well as the Developing Countries Vaccine Manufacturers Network (DCVMN). Support is also provided by a growing list of individuals who use this service to support their roles in public health, clinical practice, government, NGOs and other international institutions, academia and research organizations, and industry.*

* * * *