Vaccines and Global Health: The Week in Review
17 September 2016
Center for Vaccine Ethics & Policy (CVEP)

This weekly digest targets news, events, announcements, articles and research in the vaccine and global health 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 and Global Health: 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 8,000 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

***Request an email version:** Vaccines and Global Health: The Week in Review is published as a single email summary, scheduled for release each Saturday evening before midnight (EST/U.S.). If you would like to receive the email version, please send your request to david.r.curry@centerforvaccineethicsandpolicy.org.*

Contents *[click on link below to move to associated content]*

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Zika virus [to 17 September 2016]
Public Health Emergency of International Concern (PHEIC)
http://www.who.int/emergencies/zika-virus/en/

Zika situation report – 15 September 2016

Full report: http://apps.who.int/iris/bitstream/10665/250122/1/zikasitrep15Sep16-eng.pdf?ua=1

Key Updates
:: Countries and territories reporting mosquito-borne Zika virus infections for the first time in the past week:
…None
:: Countries in the Western Pacific Region have been reporting new cases as seen in Singapore, Philippines and Malaysia.
:: Countries and territories reporting microcephaly and other central nervous system (CNS) malformations potentially associated with Zika virus infection for the first time in the past week:
…None
:: Countries and territories reporting Guillain-Barré syndrome (GBS) cases associated with Zika virus infection for the first time in the past week:
…None
:: The 2016 Summer Paralympic Games continue in Rio de Janeiro, Brazil. WHO continues to provide technical support to the Ministry of Health to ensure the 2016 Summer Paralympic Games are as safe as possible for all athletes, volunteers, visitors and residents. There is a low, but not zero, risk of Zika transmission in this setting. All persons should continue to follow guidance on avoiding Zika infection.

Zika Open [to 17 September 2016]
[Bulletin of the World Health Organization]
:: All papers available here
No new papers identified.

African Development Bank Group [to 17 September 2016]
http://www.afdb.org/en/news-and-events/press-releases/
14/09/2016
AfDB approves a US $2-million grant to Cape Verde and Guinea Bissau to fight the Zika virus outbreak
The Board of Directors of the African Development Bank Group (AfDB) on September 8, 2016 in Abidjan, approved two grants of US $1 million each, to Cape Verde and Guinea Bissau as emergency assistance to support the implementation of National Preparedness and Response Plans to fight the Zika virus outbreak in the two countries.

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EBOLA/EVD [to 17 September 2016]
http://www.who.int/csr/disease/ebola/en/
"Threat to international peace and security" (UN Security Council)

[Editor's Note:
We note that the Ebola tab - which had been listed along with Zika, Yellow Fever, MERS CoV and other emergencies - has been removed from the WHO "home page. We deduce that WHO has suspended issuance of new Situation Reports after resuming them for several weekly

cycles. The most recent report posted is EBOLA VIRUS DISEASE – Situation Report - 10 JUNE 2016]

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POLIO [to 17 September 2016]
Public Health Emergency of International Concern (PHEIC)

Polio this week as of 13 September 2016
:: The regional polio outbreak response in Nigeria and the Lake Chad basin continues, within the broader humanitarian emergency response. Polio teams on the ground, at national, regional and global levels are closely coordinating with the humanitarian emergency response teams, other UN organizations and NGOs, to maximise the impact of all available resources and ensure that polio vaccine and broader health interventions can reach the most vulnerable and at-need populations in the region.

:: While much attention is given to the response, the risks of undetected circulation in the rest of Africa cannot be ignored. Efforts to strengthen subnational surveillance and immunity must continue across wide areas of west and central Africa, as well as in countries of the Horn of Africa. More

:: Selected Country Updates [excerpts]
Afghanistan
:: One new wild poliovirus type 1 (WPV1) case was reported in the past week, bringing the total number of WPV1 cases for 2016 to nine. It is the most recent case in the country, with onset of paralysis on 11 August, the second WPV1 case reported from the same district of Paktika province, close to the border with Pakistan.

Pakistan
:: Four new WPV1 environmental positive samples were reported in the past week, collected throughout August from Balochistan (Quetta and Pishin districts), and Punjab (Lahore and Rawalpindi districts).
:: Continued detection of environmental positive samples confirms that virus transmission continues to be geographically widespread across the country, despite strong improvements being achieved.
:: Efforts continue to further strengthen immunization and surveillance activities in all provinces of the country.

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Yellow Fever [to 17 September 2016]
http://www.who.int/emergencies/yellow-fever/en/

No new Situation Report posted.

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MERS-CoV [to 17 September 2016]
http://www.who.int/emergencies/mers-cov/en/

DONs
:: Middle East respiratory syndrome coronavirus (MERS-CoV) – Saudi Arabia 16 September 2016

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WHO & Regional Offices [to 17 September 2016]

Promoting health, promoting sustainable development: It's our health, our future, our choice

16 September 2016 – How can everyone on the planet, from people living in cities to remote communities, attain the highest level of health? All-of-government action, healthy environments and an empowered and informed public are essential. A healthy population is also key to advancing the 2030 Agenda for Sustainable Development. The 9th Global conference on health promotion, being held this November in Shanghai, will profile these and other innovative actions to promote health.

A global threat to prevention and treatment: Antimicrobial resistance

15 September 2016 – Antimicrobial resistance, also known as "drug resistance", threatens our ability to prevent and treat an ever-increasing range of deadly infections. Globally, 480 000 people develop multi-drug resistant tuberculosis each year, and antimicrobial resistance is complicating the fight against HIV and malaria. Without antibiotics, the major surgery and cancer chemotherapy are also compromised. Antimicrobial resistance is a serious threat.

Read the fact sheet

United Nations high-level meeting on antimicrobial resistance - 21 September 2016

Highlights

Poorest and most marginalised women continue to be most at risk of maternal death

September 2016 – The poorest and most marginalized women continue to face the highest risk of death from causes related to pregnancy and childbirth. Efforts must be drastically increased to safeguard the maternal health of all women everywhere, if the good health and well-being of all people are to be achieved.

Weekly Epidemiological Record, 9 September 2016, vol. 91, 36/37 (pp. 421–432)
Contents:

WHO-IVB:
15 September 2016
Vacancy notice: STI Vaccine Consultant pdf, 92kb
Deadline for application: 1 October 2016

14 September 2016
Call for Proposals on writing a "how-to" guide on implementing a post- vaccination campaign coverage survey pdf, 200kb
Deadline for application: 14 October 2016

12 September 2016
GIN July / August 2016 pdf, 2.70Mb

:: WHO Regional Offices
Selected Press Releases, Announcements
WHO African Region AFRO
No new announcements identified.

WHO Region of the Americas PAHO
:: PAHO calls for strengthening road safety legislation (09/13/2016)

WHO South-East Asia Region SEARO
:: WHO delivers emergency health supplies, funds to flood-hit DPR Korea
SEAR/PR/1639
Pyongyang, 15 September 2016 – World Health Organization is providing emergency health supplies and funds to DPR Korea where flash floods and landslides triggered by torrential rains have left hundreds of thousands of people in need of urgent humanitarian assistance in northern provinces.
"Many health facilities are damaged and some completely destroyed, severely hampering health services and availability of medicines for the affected population, now living in sub-optimal water and sanitation conditions and vulnerable to water borne and other diseases. Children, pregnant women, people with disabilities and the elderly are the most in need of support," Dr Poonam Khetrapal Singh, Regional Director WHO South-East Asia, said.
To meet immediate health needs of the affected population, WHO made available USD 175,000 from WHO South-East Asia Regional Emergency Fund (SEARHEF) within 24-hours of the request from the Ministry of Public Health. SEARHEF is WHO South-East Asia Region's emergency funding facility…

WHO European Region EURO
:: Day 4 highlights: Countries commit to strengthening the use of evidence and research in policy-making 15-09-2016
:: WHO/Europe launches new report on women's health and well-being in Europe 15-09-2016
:: Day 3 highlights: Agreement on women's health strategy and action plans for HIV and viral hepatitis 14-09-2016

:: Day 2 highlights: RC66 adopts European strategy and action plan for refugee and migrant health 13-09-2016
:: Day 1 highlights: RC66 opens – health central to the 2030 Agenda for Sustainable Development 12-09-2016

WHO Eastern Mediterranean Region EMRO
:: No major public health event reported during the pilgrimage: WHO concludes its mission to Saudi Arabia
14 September 2016, Mecca – The World Health Organization (WHO) has today concluded its mission to Saudi Arabia to support the Ministry of Health in ensuring a safe pilgrimage season (Hajj). So far there has been no major health threat or event of concern, with no major disease outbreak reported among the nearly two million pilgrims attending the holy sites.
In preparation for the Hajj, the Ministry of Health, together with WHO, conducted a strategic health risk assessment of the health hazards that might occur during the pilgrimage

WHO Western Pacific Region
:: Member States call for stronger tobacco control measures to end tobacco industry interference
MANILA, 16 September 2016 – Tobacco use kills approximately six million people every year worldwide. The Western Pacific Region has one third of the world's smokers and two people die every minute from tobacco-related diseases. It is estimated that in 2025, one fourth of the adult population would still be current smokers. As governments strive to put in place measures to reduce the rate of tobacco use, the tobacco industry continuously invents new tactics to interfere with such policies…

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CDC/ACIP [to 17 September 2016]
http://www.cdc.gov/media/index.html
https://www.cdc.gov/vaccines/acip/

MMWR Weekly September 16, 2016 / No. 36
:: Implementation of a National Semen Testing and Counseling Program for Male Ebola Survivors — Liberia, 2015–2016
:: Preliminary Findings from an Investigation of Zika Virus Infection in a Patient with No Known Risk Factors — Utah, 2016
:: Zika Virus Disease Cases — 50 States and the District of Columbia, January 1–July 31, 2016

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Announcements/Milestones/Perspectives

UNICEF [to 17 September 2016]
http://www.unicef.org/media/media_89711.html
World leaders must invest in better data on children - UNICEF
NEW YORK, 14 September 2016 - UNICEF is calling on world leaders to invest in better data on

children, warning in a new analysis that sufficient data is available only for half of the child-related Sustainable Development Goals indicators.

The UNICEF analysis shows that child-related data, including measures on poverty and violence that can be compared, are either too limited or of poor quality, leaving governments without the information they need to accurately address challenges facing millions of children, or to track progress towards achieving the Goals.

To shine a spotlight on the lack of data, United Nations Secretary General Ban Ki-moon and UNICEF today launched a "time machine" installation at the United Nations in New York. The Time Machine – a capsule structure that demonstrates data through art by translating childhood memories from data into sound - gives visitors and delegates attending the United Nations General Assembly from 14-30 September an opportunity to understand the data on children currently available and areas that fall short.

"The world is committed to eliminating extreme poverty among children by 2030 and to reaching those furthest behind first. If we are going to succeed in achieving these ambitious goals, we first need data that tells us who these children are, where they live and what they need," said Jeffrey O'Malley, UNICEF Director of the Division of Data, Research and Policy.

Examples of missing data:
:: Around one in three countries does not have comparable measures on child poverty.
:: Around 120 million girls under the age of 20 have been subjected to forced sexual intercourse or other forced sexual acts. Boys are also at risk, but almost no data is available.
:: There is a shortage of accurate and comparable data on the number of children with disabilities in almost all countries.
:: Universal access to safe drinking water is a fundamental need and human right. We have data about where drinking water comes from, but we often don't know how safe it is.
:: Nine out of 10 children are in primary school, yet crucial data about how many are learning is missing.
:: Every day 830 mothers die as a result of complications related to childbirth. Most of these deaths are preventable, yet there are critical data gaps about the quality of maternal care.
:: Stunting denies children a fair chance of survival, growth and development. Yet 105 out of 197 countries do not have recent data on stunting.
:: One in two countries around the world lack recent data on overweight children.

UNICEF has been actively supporting countries to collect, analyse and report data on progress for children for over 30 years. As part of these efforts UNICEF will continue to support direct collection of data through household surveys, and explore how new technological tools can help fill gaps in data.

UNICEF is calling for governments to invest in disaggregated, comparable and quality data for children, to adequately address issues including intergenerational cycles of poverty, preventable deaths, and violence against children.

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NIH/FDA [to 17 September 2016]

http://www.nih.gov/news-events/news-releases
September 16, 2016

HHS takes steps to provide more information about clinical trials to the public

In an effort to make information about clinical trials widely available to the public, the U.S. Department of Health and Human Services today issued a final rule that specifies requirements for registering certain clinical trials and submitting summary results information to ClinicalTrials.gov. The new rule expands the legal requirements for submitting registration and results information for clinical trials involving U.S. Food and Drug Administration-regulated drug, biological and device products. At the same time, the National Institutes of Health has issued a complementary policy for registering and submitting summary results information to ClinicalTrials.gov for all NIH-funded trials, including those not subject to the final rule.

"Access to more information about clinical trials is good for patients, the public and science," said NIH Director Francis S. Collins, M.D., Ph.D. "The final rule and NIH policy we have issued today will help maximize the value of clinical trials, whether publicly or privately supported, and help us honor our commitments to trial participants, who do so much to help society advance knowledge and improve health."

Clinical trials are vital to medical advances because they test new and existing health-related interventions, helping us understand whether they are safe and effective in humans when used as intended. Some clinical trials provide information about which medical treatments work best for certain illnesses or certain groups of people.

Expanding the registration information in ClinicalTrials.gov improves people's ability to find clinical trials in which they may be able to participate and access investigational therapies. More information about the scientific results of trials, whether positive or negative, may help inform healthcare providers and patients regarding medical decisions. Additional information will help researchers avoid unnecessary duplication of studies, focus on areas in need of study and improve study designs, ultimately advancing the development of clinical interventions.

Requirements under the final rule apply to most interventional studies of drug, biological and device products that are regulated by the FDA. The requirements do not apply to phase 1 trials of drug and biological products, or small feasibility studies of device products. The final rule specifies how and when information collected in a clinical trial must be submitted to ClinicalTrials.gov. It does not dictate how clinical trials should be designed or conducted, or what data must be collected.

"When people participate in clinical trials, they are volunteering to create generalizable knowledge to help others in the future and we want their participation honored by ensuring that the existence of trials and their results are available to all patients and their healthcare providers, as well as researchers," said FDA Commissioner Robert M. Califf, M.D. "The FDA will help ensure compliance with these new requirements so that patients and providers can have confidence in and access to significantly more clinical trial information, and researchers can improve clinical trial focus and design."

The final rule was informed by nearly 900 comments received during the public comment period on the Notice of Proposed Rulemaking and the National Library of Medicine's many years of

experience with managing and operating ClinicalTrials.gov. Important elements of the final rule include:

:: Providing a checklist for evaluating which clinical trials are subject to the regulations and who is responsible for submitting required information;

:: Expanding the scope of trials for which summary results information must be submitted to include trials involving FDA-regulated products that have not yet been approved, licensed, or cleared by the FDA;

:: Requiring additional registration and summary results information data elements to be submitted to ClinicalTrials.gov, including the race and ethnicity of trial participants, if collected, and the full protocol;

:: Requiring additional types of adverse event information; and

:: Providing a list of potential legal consequences for non-compliance.

Additional Information

:: Federal Register Notice: HHS Final Rule (link is external)

: Federal Register Notice: NIH Policy (link is external)

:: Summary of Changes: HHS Final Rule and NIH Policy

:: Summary Table: HHS Final Rule and NIH Policy

:: JAMA: Toward a New Era of Trust and Transparency in Clinical Trials (link is external)

: NEJM: The Final Rule for US Clinical Trial Registration and Results Information Submission (link is external)

: NIH Director's Blog: Clinical Trials – Sharing of Data and Living Up to Our End of the Bargain ClinicalTrials.gov

NIH Director's Blog

Clinical Trials: Sharing of Data and Living Up to Our End of the Bargain

Posted on September 16, 2016 by Drs. Kathy L. Hudson and Francis S. Collins

Today we took a huge step forward in our efforts to make sure that data from biomedical research is shared widely and rapidly. The NIH, in collaboration with our fine colleagues at the U.S. Food and Drug Administration (FDA), and with the valuable input from scientists, patients and other members of the public, has announced the HHS regulation and NIH policy to ensure that information about clinical trials is widely shared. In this blog I want to talk about what this will mean for patients, providers, and researchers. I also want to reflect a bit on how the new regulation and policy fit into our overall efforts to improve clinical trials and data sharing.

Clinical trials are essential for the translation of research advances to new approaches to prevention and treatment. Volunteers who take part in clinical trials often do so with no assurance of personal benefit, but with the expectation that their involvement will add to the growing body of knowledge about health and disease, and thus may help others someday. For that to be realized, all trial results information needs to be publicly reported in a timely fashion—and yet we know that doesn't always happen. Today's announcements aim to change that. The HHS regulation issued today, called a "final rule", describes requirements for registering certain clinical trials and submitting summary results information from these trials to ClinicalTrials.gov, a database managed by NIH's National Library of Medicine (NLM).

The rule implements the statutory requirements established by Congress for ClinicalTrials.gov to serve as a public source for information about clinical trials. The regulation applies to most interventional studies of drug, biological, and device products that are regulated by the FDA.

The requirements do not apply to phase 1 trials of drug and biological products, or small feasibility studies of device products. To help clinical researchers and research institutions understand their obligation under the regulation, NIH and FDA will be undertaking extensive outreach and education efforts over the coming weeks.

Because of our commitment to data sharing, especially for studies supported with public funds, NIH has issued a complementary policy today that applies to all NIH-funded trials, including those not subject to the regulation. That will also include clinical trials of behavioral interventions that don't involve an FDA-regulated product. We will be taking the implementation of the regulation and of the NIH policy very seriously and have put in place robust enforcement and compliance measures.

While data sharing is the right thing to do, it is not always easy. I learned this firsthand, when as part of a test of the new system some time ago, my senior team and I tried to enter sample data from a trial into ClinicalTrials.gov—it is not a trivial task. Registering a trial and submitting results information should not cause researchers to pull their hair out, nor should it take an inordinate amount of time away from valuable research. That is why we will be doing all we can to make submitting information to ClinicalTrials.gov as frictionless as possible for the regulated community. To this end, NIH's NLM, which operates and manages ClinicalTrials.gov, will be working hard over the coming weeks and months to improve the data entry portal for ClinicalTrials.gov, so that the process for submitting information to ClincialTrials.gov is significantly improved before the rule and NIH policy become effective early next year.

ClinicalTrials.gov contains a treasure trove of information, and the value of this information will continue to grow as more studies are added when investigators and institutions follow the new rules. We need to make this information easily accessible to patients and those who love and care for them. If your daughter, sister, or father is sick and out of options, it should be simple and intuitive to search for clinical trials that may be relevant. I am delighted to announce today that NLM will work with IT experts from the 18F group to help make ClincalTrials.gov a more user-friendly resource for finding information about clinical trials of interest to patients, family members, healthcare providers, and researchers. This partnership will build on lessons learned from the National Cancer Institute's collaboration with technical experts and Presidential Innovation Fellows to enhance access to information about cancer clinical trials at Cancer.gov as part of the Cancer Moonshot.

We have been encouraged in our efforts to make sure patients have the information they need by Vice President Biden, who has demonstrated an extraordinary interest and commitment to research and data sharing through the Cancer Moonshot. He is passionate about ensuring that patients and those who care for them have straightforward access to comprehensive and reliable information about clinical trials. And he has vigorously made the case that science can only contribute to progress if results information from clinical trials is shared rapidly and widely.

Rapid, broad sharing of research information is a core value of NIH and one that has been embraced and advanced by this Administration. Data sharing is also very close to my heart and has been a key priority throughout my career. In the early days of the Human Genome Project, we established data sharing policies for depositing genetic data into public databases within 24 hours. Today, we have set forth remarkable initiatives for sharing summary level clinical trials information. But we still have a long way to go. Sharing individual patient level data from trials

is still on the list. The NIH has evaluated various models for making the sharing of these data feasible and useful to researchers. We are also exploring ways to support large scale sharing of research data and other information through the development of a cloud-based data commons. The NIH is committed to doing our part in sharing research data, and I hope you will join us in this effort.

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FDA [to 17 September 2016]
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm
What's New for Biologics
:: Clinical Review - Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted (PDF - 845KB)
Posted: 9/15/2016
:: Statistical-Clinical Review - Addendum - Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted (PDF - 92KB)
Posted: 9/15/2016
:: Influenza Virus Vaccine for the 2016-2017 Season
Posted: 9/14/2016
:: September 13, 2016 Approval Letter - CUVITRU (PDF - 51KB)
Posted: 9/14/2016
:: The Voice of the Patient: A series of reports from the FDA's Patient-Focused Drug Development Initiative (PDF - 541KB)
Posted: 9/14/2016
:: September 9, 2016 Summary Basis of Regulatory Action - Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted (PDF - 119KB)
Posted: 9/13/2016
:: September 9, 2016 Approval Letter - Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted (PDF - 45KB)
Posted: 9/13/2016

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Global Fund [to 17 September 2016]
http://www.theglobalfund.org/en/news/?topic=&type=NEWS;&country=
16 September 2016
Private Donors Double Investments to the Global Fund
MONTREAL - The Global Fund to Fight AIDS, Tuberculosis and Malaria announced today that pledges from private donors and innovative financing initiatives reached US$250 million for the coming three years, more than twice as much as in the previous period.
The announcement was made at the launch of the Global Fund's Fifth Replenishment, hosted by the government of Canada, where leaders from all over the world gathered to show global commitment toward ending the epidemics of AIDS, tuberculosis and malaria for good.
Private sector companies play a pivotal role in the Global Fund partnership, contributing expertise that enhances the impact of programs supported by the Global Fund, in addition to contributing funding…

Qatar Pledges $10 Million to the Global Fund
16 September 2016

Germany Pledges €800 Million to Global Fund
15 September 2016

Benin Pledges $2 Million to Global Fund
14 September 2016

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European Vaccine Initiative [to 17 September 2016]
http://www.euvaccine.eu/news-events
News
VAC2VAC project website goes live
15 September 2016

VAC2VAC is a wide ranging collaborative research project funded by IMI2 which aims to develop and validate quality testing approaches for both human and veterinary vaccines using non animal methods.

The initiative that started on 1 March 2016 aims to provide the data to support the 'Consistency Approach' for quality control of established vaccines. More information on the project and on the participants can now be found under the following link: www.vac2vac.eu.

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Industry Watch [to 17 September 2016]
:: **Johnson & Johnson Announces World Health Organization will Review Ebola Vaccine Regimen for Emergency Use Assessment and Listing (EUAL)**
Preparations also underway to initiate first-in-human study for multivalent vaccine regimen to combat Ebola, Sudan and Marburg viruses

ANTWERP, Belgium, Sept. 12, 2016 /PRNewswire/ -- Johnson & Johnson announced today that Janssen Vaccines & Prevention B.V. (Janssen) has completed a submission to the World Health Organization (WHO) for Emergency Use Assessment and Listing (EUAL) for its investigational preventive Ebola prime-boost vaccine regimen. The EUAL is a special procedure that can be implemented when there is an outbreak of a disease with high rates of morbidity or mortality and a lack of treatment or prevention options.

"Over the past four decades, we have seen 25 Ebola outbreaks, with the most recent in West Africa killing seven times more people than all previous outbreaks combined," said Paul Stoffels, M.D., Chief Scientific Officer, Johnson & Johnson. "We must take action now so that a tragedy on the scale of West Africa never happens again. Having an Ebola vaccine available is critical for global preparedness. If the WHO grants an emergency use listing, this will accelerate the availability of Janssen's investigational vaccine regimen to the international community in the event another Ebola crisis occurs."

EUAL assists UN Member States and procurement agencies determine the acceptability for use of a specific vaccine in a public health emergency. The decision to grant EUAL to the investigational preventative vaccine regimen will be based on an evaluation of available data including quality, safety, and immunogenicity, as well as a risk/benefit analysis. While EUAL potentially allows for deployment of a vaccine in an emergency, the vaccine remains investigational pending formal regulatory agency review and approval.

The news coincides with the opening of the 8th International Symposium on Filoviruses in Antwerp, Belgium, hosted by the Antwerp Institute of Tropical Medicine, which is reviewing global progress against Ebola...

:: **Merck Joins DiViNe Consortium to Address Low Yields, High Costs of Vaccine Purification Processes**

- Five year project will create more cost-effective purification program
- Merck to provide chromatographic expertise

DARMSTADT, Germany, Sept. 14, 2016 /PRNewswire/ -- Merck, a leading science and technology company, has joined the DiViNe project, a European consortium of six companies to address the biggest challenges facing the development, manufacture and delivery of vaccines.

The objective of the DiViNe project is to create an integrated, cost-effective purification program specifically tailored for vaccines that achieves higher yields while preserving product integrity. Merck's specific focus will be on simplifying the process of vaccine purification that typically relies on affinity chromatography, a method of capturing antibodies. In support of this goal, Merck will be providing chromatographic materials and coupling technologies…

:: **DCVMN [Developing Country Vaccine Manufacturers Network] Annual General Meeting**

24 October 2016 to 27 October 2016
Buenos Aires / / Argentina

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GHIT Fund [to 17 September 2016]
https://www.ghitfund.org/
GHIT was set up in 2012 with the aim of developing new tools to tackle infectious diseases that devastate the world's poorest people. Other funders include six Japanese pharmaceutical companies, the Japanese Government and the Bill & Melinda Gates Foundation.
2016.09.13 *Events*
Event Report: GHIT Fund Side Event at TICAD IV

GHIT Fund hosted event on the sidelines of the 2016 Tokyo International Conference on African Development (TICAD), which took place in Nairobi, Kenya on August 26. TICAD is a major global economic policy forum initiated by Japan in the early 1990s with the United Nations Office of the Special Advisor on Africa, the United Nations Development Program (UNDP), and the World Bank. TICAD now plays a critical role in facilitating the implementation of African development initiatives under the dual principle of African ownership and international partnership

…The GHIT Fund, Japan's flagship global health R&D initiative, aligns with TICAD and the Noguchi prize to highlight the importance of global health R&D to broader Japan-Africa collaboration, and to further integrate global health R&D into Japan's internationally renowned global health activities…

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AERAS [to 17 September 2016]
http://www.aeras.org/pressreleases
No new digest content identified.

EDCTP [to 17 September 2016]

http://www.edctp.org/
The European & Developing Countries Clinical Trials Partnership (EDCTP) aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases in sub-Saharan Africa, with a focus on phase II and III clinical trials.
No new digest content identified.

European Medicines Agency [to 17 September 2016]
http://www.ema.europa.eu/
No new digest content identified

Fondation Merieux [to 17 September 2016]
Mission: Contribute to global health by strengthening local capacities of developing countries to reduce the impact of infectious diseases on vulnerable populations.
http://www.fondation-merieux.org/news
No new digest content identified.

Gavi [to 17 September 2016]
http://www.gavi.org/library/news/press-releases/
No new digest content identified

Hilleman Laboratories [to 17 September 2016]
http://www.hillemanlabs.org/
No new digest content identified

Human Vaccines Project [to 17 September 2016]
humanvaccinesproject.org
[Website in development]

IAVI – International AIDS Vaccine Initiative [to 17 September 2016]
https://www.iavi.org/
No new digest content identified

PATH [to 17 September 2016]
http://www.path.org/news/index.php
Website not responding at inquiry

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Reports/Research/Analysis/Commentary/Conferences/Meetings/Book Watch/Tenders

Vaccines and Global Health: 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

United Nations Secretary-General's High-Level Panel on Access to Medicines Calls For New Deal to Close the Health Innovation and Access Gap

Release Date: September 14, 2016
UN Secretary-General and Co-Chairs of the High-Level Panel
Pdf: http://www.unsgaccessmeds.org/s/UNSG-HLP-Report-FINAL-12-Sept-2016.pdf
…The UN Secretary-General established the High-Level Panel to propose solutions for addressing the incoherencies between international human rights, trade, intellectual property rights and public health objectives. The report recommendations come at the end of a ten-month process for the Panel under the leadership of Ruth Dreifuss and the former President of the Swiss Confederation and Festus Mogae, the former President of the Republic of Botswana.

"Policy incoherencies arise when legitimate economic, social and political interests and priorities are misaligned or in conflict with the right to health," said President Ruth Dreifuss. "On the one hand, governments seek the economic benefits of increased trade. On the other, the imperative to respect patents on health technologies could, in certain instances, create obstacles to the public health objectives and the right to health."

The Panel has formulated a set of concrete recommendations to help improve research and development of health technologies and people's access to vital therapies that are currently priced out-of-reach of patients and governments alike. The Panel's report points out that the cost of health technologies are putting a strain on both rich and poor countries.

"With no market incentives, there is an innovation gap in diseases that predominantly affect neglected populations, rare diseases and a crisis particularly with antimicrobial resistance, which poses a threat to humanity," said Malebona Precious Matsoso, Director General of the National Department of Health of South Africa. "Our report calls on governments to negotiate global agreements on the coordination, financing and development of health technologies to complement existing innovation models, including a binding R&D Convention that delinks the costs of R&D from end prices."

The Panel suggested that initially governments should form a working group to begin negotiating a Code of Principles for Biomedical R&D, and report annually on their progress in negotiating and implementing the Code in preparation for negotiating the Convention.

The Panel examined the way in which the application of the flexibilities found in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has facilitated access to health technologies, and how WTO Members can tailor national intellectual property law, competition law, government procurement and drug regulatory laws and regulations to fulfil public health obligations.

The new report noted with grave concern reports of governments being subjected to undue political and economic pressure to forgo the use of TRIPS flexibilities. The Panel felt strongly that this pressure undermines the efforts of governments to meet their human rights and public health obligations and violates the integrity and legitimacy of the Doha Declaration.

"WTO Members must make full use of TRIPS flexibilities as reaffirmed by the Doha Declaration on TRIPS and Public Health. This is essential to promote access to health technologies," said

Michael Kirby, member of the High-Level Panel and chair of the Expert Advisory Group. "In particular, governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. WTO Members must register complaints against undue political and economic pressure. They need to take strong, effective measures against offending Members."

Transparency was a recurring theme throughout the report of the High-Level Panel. The Panel repeatedly raised concerns regarding the negative impact of insufficient transparency on both health technology innovation and access. The Panel was also critical of the lack of transparency surrounding bilateral free trade and investment negotiations. The Panel views transparency as a core component of robust and effective accountability frameworks needed to hold all stakeholders responsible for the impact of their actions on innovation and access.

"A paradigm shift in transparency is needed to ensure that the costs of R&D, production, marketing, and distribution, as well as the end prices of health technologies are clear to consumers and governments," said President Festus Mogae. "Governments should require manufacturers and distributors of health technologies to disclose these costs and the details of any public funding received in the development of health technologies, including tax credits, subsidies, and grants."

The Panel also recommended the UN General Assembly convene a Special Session no later than 2018 on health technology innovation and access to agree on strategies and an accountability framework that will accelerate efforts towards promoting innovation and ensuring access in line with the 2030 Agenda for Sustainable Development.

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MSF/Médecins Sans Frontières [to 17 September 2016]
http://www.doctorswithoutborders.org/news-stories/press/press-releases
Press release
Doctors Without Borders Response to Report from UN Secretary-General's High-Level Panel on Access to Medicines
September 14, 2016
On September 14, The United Nations Secretary-General's High-Level Panel (UNHLP) on Access to Medicines will publish a landmark report on promoting innovation for and access to lifesaving medical tools.

Press release
MSF to UN General Assembly: Set Medical Priorities that Meet People's Health Needs
September 14, 2016
New report exposes pharmaceutical industry failings and highlights new ways of researching and developing medicines that address public health needs.
NEW YORK/GENEVA September 13, 2016—Governments must do more to promote the development of desperately-needed new medicines, vaccines, and diagnostics at affordable prices, said the international medical humanitarian organization Doctors Without Borders/Médecins Sans Frontières (MSF), in a new report released before the United Nations General Assembly this week.

R&D Report: Lives on the Edge

MSF Access Campaign
May 2016 :: 56 pages
PDF:
http://msfaccess.org/sites/default/files/MSF_assets/Access/Docs/R&D_report_LivesOnTheEdge_ENG_2016_0.pdf

Time to align medical research and development with people's health needs

Every day, MSF staff confront significant gaps in the availability of medical tools to address the health needs of the people we aim to care for, in crisis-affected communities in more than 60 countries. These gaps – which have persisted for as long as MSF has been in operation – contribute to preventable deaths and exacerbate ongoing humanitarian and medical crises. Filling these gaps with effective, affordable vaccines, diagnostics and treatments that can be used in a range of contexts, including underresourced and unstable places, could save innumerable lives.

In this report, MSF illustrates how our staff and patients around the world are impacted by the way biomedical research and development (R&D) is predominantly conducted today. The report also looks at a broad range of policies aimed at changing this dynamic by incentivising the development of medical tools that truly respond to patient and public health needs, and ensuring they are made broadly accessible.

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Biopharmaceutical industry calls the recommendations of UN High Level Panel on Access to Medicines a missed opportunity to genuinely address patients' needs

Geneva, 14 September 2016 – The biopharmaceutical industry believes the UN High Level Panel on Access to Medicines (HLP) lent an unprecedented opportunity to address critical issues affecting the ability of millions of people in receiving the medicines and vaccines they need. Many of the HLP recommendations ignore the most common issues that hamper access to medicines. As such, the report does not provide a sound basis for meaningful progress. The biopharmaceutical industry continues to support the existing platforms within the United Nations system that seek to improve access to medicines.

The environment into which new medicines are released is complex and solutions will be found in patient-centric and systemic approaches, political commitment, and good governance. Key issues to address are financing for health, improvements in health infrastructures, and enhancement of healthcare worker capacity and patients' literacy. The majority of the HLP recommendations fail to recognize these complexities as well as the many existing and innovative efforts already taking place to advance access to care in the last two decades. In addition, the report seems to take a reductive approach to the facts around the pharmaceutical research and development model, carrying the potential of unintended consequences on spurring future medical progress.

"Access to medicines is at the center of everything the innovative biopharmaceutical industry does. The report fails to address the genuine barriers to access that so many people around the world need to overcome every day" – says Eduardo Pisani, Director General of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). He adds: "The HLP took a very narrow focus and ignored the full range of variables influencing access to medicines. We need to build on what works, we need inclusive solutions that bring the global health community as a whole closer to patients, addressing what matters to them."…

PhRMA Statement on the United Nations High Level Panel Report on Access to Medicines
September 14, 2016

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Journal Watch

Vaccines and Global Health: 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 Infection Control
September 2016 Volume 44, Issue 9, p963-1082, e145-e166
http://www.ajicjournal.org/current
[Reviewed earlier]

American Journal of Preventive Medicine
September 2016 Volume 51, Issue 3, p281-410, e57-e90
http://www.ajpmonline.org/current
[Reviewed earlier]

American Journal of Public Health
Volume 106, Issue 9 (September 2016)
http://ajph.aphapublications.org/toc/ajph/current
[Reviewed earlier]

American Journal of Tropical Medicine and Hygiene
September 2016; 95 (3)
http://www.ajtmh.org/content/current
[Reviewed earlier]

Annals of Internal Medicine
6 September 2016, Vol. 165. No. 5
http://annals.org/issue.aspx
[Reviewed earlier]

BMC Cost Effectiveness and Resource Allocation
http://resource-allocation.biomedcentral.com/
(Accessed 17 September 2016)
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(Accessed 17 September 2016)
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http://www.biomedcentral.com/bmcinfectdis/content
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BMC Medical Ethics
http://www.biomedcentral.com/bmcmedethics/content
(Accessed 17 September 2016)
[No new content]

BMC Medicine
http://www.biomedcentral.com/bmcmed/content
(Accessed 17 September 2016)
Research article
The potential impact of BCG vaccine supply shortages on global paediatric tuberculosis mortality
Rebecca C. Harris, Peter J. Dodd and Richard G. White
BMC Medicine 2016 14:138
Published on: 15 September 2016
Abstract
Background
The Bacillus Calmette-Guérin (BCG) vaccine is provided to over 100 million neonates annually to protect against childhood tuberculosis (TB). Recent BCG manufacturing interruptions highlight global supply risks. We estimated the potential impact of BCG shortfalls on global paediatric (<15 years) TB mortality.
Methods
A static mathematical model was employed to estimate the number of paediatric TB deaths avoided by usual levels of BCG coverage, and potential additional TB deaths in the first 15 years of life due to 1-year BCG supply shortfalls of 6.3 % (as occurred in 2015) to 27.6 % (as anticipated without mitigating action in 2015) assuming no catch-up campaigns.
Results
BCG coverage without shortfalls, estimated at 90 % globally, was estimated to avoid 117,132 (95 % uncertainty range (UR): 5049–306,911) TB deaths globally per birth cohort in the first 15 years of life. An estimated 11,713 (UR: 505–30,691) additional TB deaths would occur in the

first 15 years of life per 10 % (26 million dose) annual supply shortfall. A 16.5 million dose (6.3 %) shortfall as reported at the close of 2015, reflecting 84 % global coverage, was estimated as associated with 7433 (95 % UR: 320–19,477) excess TB deaths in the affected cohort in the first 15 years. A possible 24,914 (UR: 1074–65,278) additional deaths were avoided due to prompt shortfall reduction measures in 2015.
Conclusions
BCG shortages could greatly increase paediatric TB mortality. Although rapid action in 2015 minimised BCG shortfalls, avoiding a large number of potential additional deaths, the possible public health impact of even relatively small shortfalls highlights the critical importance of ensuring secure future manufacturing capacity and global BCG supply continuity.

BMC Pregnancy and Childbirth
http://www.biomedcentral.com/bmcpregnancychildbirth/content
(Accessed 17 September 2016)
[No new relevant content identified]

BMC Public Health
http://bmcpublichealth.biomedcentral.com/articles
(Accessed 17 September 2016)
Research article
Predictors of incomplete immunization coverage among one to five years old children in Togo
Dadja Essoya Landoh, Farihétou Ouro-kavalah, Issifou Yaya, Anna-Lea Kahn, Peter Wasswa, Anani Lacle, Danladi Ibrahim Nassoury, Sheba Nakacubo Gitta and Abdramane Bassiahi Soura
BMC Public Health 2016 16:968
Published on: 13 September 2016
Abstract
Background
Incompleteness of vaccination coverage among children is a major public health concern because itcontinues to sustain a high prevalence of vaccine-preventable diseases in some countries. In Togo, very few data on the factors associated with incomplete vaccination coverage among children have been published. We determined the prevalence of incomplete immunization coverage in children aged one to five years in Togo and associated factors.
Methods
This was a cross-sectional study using secondary data from the 2010 Multiple Indicator Cluster Surveys (MICS4) conducted in 2010 among children aged 1 to 5 years in Togo. This survey was conducted over a period of two months from September to November, 2010.
Results
During Togo'sMICS4 survey, 2067 children met the inclusion criteria for our study. Female children accounted for 50.9 % (1051/2067) of the sample and 1372 (66.4 %) lived in rural areas. The majority of children (92.2 %; 1905/2067) lived with both parents and 30 % of the head of households interviewed were not schooled (620/2067). At the time of the survey, 36.2 % (750/2067) of the children had not received all vaccines recommended by Expanded Program on Immunization (EPI).
In multivariate analysis, factors associated with incompleteness of immunization at 1 year were: health region of residences (Maritime aOR=0.650; p=0.043; Savanes: aOR=0.324; p <0.001), non-schooled mother (aOR=1.725; p = 0.002),standard of living (poor: aOR=1.668; p=0.013;

medium: aOR=1.393; p=0.090) and the following characteristics of the household heads: sex (aOR=1.465; p=0.034), marital status (aOR=1.591; p=0.032), education level(non-educated: aOR=1.435; p=0.027.
Conclusion
The incomplete immunization coverage among children in Togo remains high. It is necessary to strengthen health promotion among the population in order to improve the use of immunization services that are essential to reduce morbidity and mortality among under five years old children.

Research article
Predictors of incompletion of immunization among children residing in the slums of Kathmandu valley, Nepal: a case-control study
Sumina Shrestha, Monika Shrestha, Rajendra Raj Wagle and Gita Bhandari
BMC Public Health 2016 16:970
Published on: 13 September 2016
Abstract
Background
Immunization is one of the most effective health interventions averting an estimated 2–3 million deaths every year. In Nepal, as in most low-income countries, infants are immunized with standard WHO recommended vaccines. However, 16.4 % of children did not receive complete immunization by 12 months of age in Nepal in 2011. Studies from different parts of the world showed that incomplete immunization is even higher in slums. The objective of this study was to identify the predictors of incompletion of immunization among children aged 12–23 months living in the slums of Kathmandu Valley, Nepal.
Methods
The unmatched case-control study was conducted in 22 randomly selected slums of Kathmandu Valley. The sampling frame was first identified by complete enumeration of entire households of the study area from which 59 incompletely immunized children as cases and 177 completely immunized children as controls were chosen randomly in 1:3 ratio. Data were collected from the primary caretakers of the children. Backward logistic regression with 95 % confidence interval and adjusted odds ratio (AOR) were applied to assess the factors independently associated with incomplete immunization.
Result
Twenty-six percent of the children were incompletely vaccinated. The coverage of BCG vaccine was 95.0 % while it was 80.5 % for measles vaccine. The significant predictors of incomplete immunization were the home delivery of a child, the family residing on rent, a primary caretaker with poor knowledge about the schedule of vaccination and negative perception towards vaccinating a sick child, conflicting priorities, and development of abscess following immunization.
Conclusion
Reduction of abscess formation rate can be a potential way to improve immunization rates. Community health volunteers should increase their follow-up on children born at home and those living in rent. Health institutions and volunteers should be influential in creating awareness about immunization, its schedule, and post-vaccination side effects.

BMC Research Notes
http://www.biomedcentral.com/bmcresnotes/content
(Accessed 17 September 2016)

[No new relevant content identified]

BMJ Open
2016, Volume 6, Issue 9
http://bmjopen.bmj.com/content/current
[Reviewed earlier]

Bulletin of the World Health Organization
Volume 94, Number 9, September 2016, 633-708
http://www.who.int/bulletin/volumes/94/9/en/
[Reviewed earlier]

Child Care, Health and Development
September 2016 Volume 42, Issue 5 Pages 603–773
http://onlinelibrary.wiley.com/doi/10.1111/cch.v42.5/issuetoc
[Reviewed earlier]

Clinical Therapeutics
August 2016 Volume 38, Issue 8, p1773-1922
http://www.clinicaltherapeutics.com/current
[Reviewed earlier]

Complexity
September/October 2016 Volume 21, Issue S1 Pages 1–632
http://onlinelibrary.wiley.com/doi/10.1002/cplx.v21.6/issuetoc
[New issue: No relevant content identified]

Conflict and Health
http://www.conflictandhealth.com/
[Accessed 17 September 2016]
[No new relevant content identified]

Contemporary Clinical Trials
Volume 50, In Progress (September 2016)
http://www.sciencedirect.com/science/journal/15517144/50
[New issue: No relevant content identified]

Current Opinion in Infectious Diseases
October 2016 - Volume 29 - Issue 5 pp: v-vi,433-537
http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx

[New issue: No relevant content identified]

Developing World Bioethics
August 2016 Volume 16, Issue 2 Pages 61–120
http://onlinelibrary.wiley.com/doi/10.1111/dewb.2016.16.issue-2/issuetoc
[Reviewed earlier]

Development in Practice
Volume 24, Number 8
http://www.developmentinpractice.org/journals/volume-24-number-8
[Reviewed earlier]

Disasters
October 2016 Volume 40, Issue 4 Pages 589–815
http://onlinelibrary.wiley.com/doi/10.1111/disa.2016.40.issue-4/issuetoc
Papers
The Indian Ocean tsunami and private donations to NGOs (pages 591–620)
Youngwan Kim, Peter Nunnenkamp and Chandreyee Bagchi
Version of Record online: 8 JAN 2016 | DOI: 10.1111/disa.12176
Abstract
Non-governmental organisations (NGOs) are widely believed to raise their flag in humanitarian hotspots with a strong media presence in order to attract higher private donations. We assess this hypothesis by comparing the changes in donations between US-based NGOs with and without aid operations in the four countries most affected by the tsunami in the Indian Ocean in 2004. Simple before-after comparisons tend to support the hypothesis that 'flying the flag' helps attract higher private donations. However, performing a difference-in-difference-in-differences (DDD) approach, we find only weak indications that private donors systematically and strongly preferred NGOs with operations in the region. Extended specifications of the baseline regressions reveal that our major findings are robust. NGO heterogeneity matters in some respects, but the DDD results hold when accounting for proxies of the NGOs' reputation and experience.

The Four Cs of disaster partnering: communication, cooperation, coordination and collaboration (pages 621–643)
Eric Martin, Isabelle Nolte and Emma Vitolo
Version of Record online: 8 JAN 2016 | DOI: 10.1111/disa.12173
Abstract
Public, nonprofit and private organisations respond to large-scale disasters domestically and overseas. Critics of these assistance efforts, as well as those involved, often cite poor interorganisational partnering as an obstacle to successful disaster response. Observers frequently call for 'more' and 'better' partnering. We found important qualitative distinctions existed within partnering behaviours. We identified four different types of interorganisational partnering activities often referred to interchangeably: communication, cooperation, coordination and collaboration—the Four Cs. We derived definitions of the Four Cs from the partnering literature. We then tested them in a case study of the response to the 2010 Haiti

earthquake. We suggest that the Four Cs are distinct activities, that organisations are typically strong or weak in one or more for various reasons, and that the four terms represent a continuum of increased interorganisational embeddedness in partnering activities.

Emerging Infectious Diseases
Volume 22, Number 9—September 2016
http://wwwnc.cdc.gov/eid/
[Reviewed earlier]

Epidemics
Volume 16, In Progress (September 2016)
http://www.sciencedirect.com/science/journal/17554365
[Reviewed earlier]

Epidemiology and Infection
Volume 144 - Issue 12 - September 2016
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[Reviewed earlier]

The European Journal of Public Health
Volume 26, Issue 4, 1 August 2016
http://eurpub.oxfordjournals.org/content/26/4
[Reviewed earlier]

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Volume 21, Issue 37, 15 September 2016
http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678
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Global Health: Science and Practice (GHSP)
June 2016 | Volume 4 | Issue 2
http://www.ghspjournal.org/content/current
[Reviewed earlier]

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Volume 11, Issue 9, 2016
http://www.tandfonline.com/toc/rgph20/current
[Reviewed earlier]

Globalization and Health

http://www.globalizationandhealth.com/
[Accessed 17 September 2016]
Commentary
ReRouting biomedical innovation: observations from a mapping of the alternative research and development (R&D) landscape
In recent years, the world has witnessed the tragic outcomes of multiple global health crises. From Ebola to high prices to antibiotic resistance, these events highlight the fundamental constraints of the curr...
Alexandra Greenberg and Rachel Kiddell-Monroe
Published on: 14 September 2016

Review
Understanding Ebola: the 2014 epidemic
Near the end of 2013, an outbreak of Zaire ebolavirus (EBOV) began in Guinea, subsequently spreading to neighboring Liberia and Sierra Leone. As this epidemic grew, important public health questions emerged about...
Jolie Kaner and Sarah Schaack
Published on: 13 September 2016

Health Affairs
September 2016; Volume 35, Issue 9
http://content.healthaffairs.org/content/current
Issue Focus: Payment Reforms, Prescription Drugs & More
[Reviewed earlier]

Health and Human Rights
Volume 18, Issue 1, June 2016
http://www.hhrjournal.org/
Special Section: Tuberculosis and the Right to Health
in collaboration with the International Human Rights Clinic, University of Chicago Law School
[Reviewed earlier]

Health Economics, Policy and Law
Volume 11 - Issue 03 - July 2016
http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue
[Reviewed earlier]

Health Policy and Planning
Volume 31 Issue 7 September 2016
http://heapol.oxfordjournals.org/content/current
[Reviewed earlier]

Health Research Policy and Systems

http://www.health-policy-systems.com/content
[Accessed 17 September 2016]
Research
Input analysis for two public consultations on the EU Clinical Trials Regulation
The European Union's (EU) Clinical Trials Directive was replaced by an EU-Regulation as of 2016. The policy revision process was subject to a formal impact assessment exercised by the European Commission (EC) from 2008 to 2014. Following the EU principles of Good Governance, deliberation with stakeholders was an integral part of this impact assessment and the policy formulation process. Hence, two public consultations (PCs) were held by the EC in 2009 and 2011, respectively. Various stakeholders contributed and submitted their written input to the EC. Though often cited in the further revision process, the input gathered in the PC was not communicated with full transparency and it is unclear how and to what extent the input has been processed and used in the policy formulation. The objective of this study was an analysis of submissions to both PCs in order to systematically present what topics have been discussed and which possible policy options have been raised by the stakeholders.
Holger Langhof, Jonas Lander and Daniel Strech
Published on: 17 September 2016

Humanitarian Exchange Magazine
Number 66 April 2016
http://odihpn.org/magazine/humanitarian-innovation/
Special Focus: Humanitarian Innovation
by Humanitarian Practice Network and Kim Scriven April 2016
[Reviewed earlier]

Infectious Agents and Cancer
http://www.infectagentscancer.com/content
[Accessed 17 September 2016]
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Infectious Diseases of Poverty
http://www.idpjournal.com/content
[Accessed 17 September 2016]
[No new content]

International Health
Volume 8 Issue 4 July 2016
http://inthealth.oxfordjournals.org/content/current
[Reviewed earlier]

International Journal of Epidemiology
Volume 45 Issue 3 June 2016
http://ije.oxfordjournals.org/content/current

[New issue: No relevant content identified]

International Journal of Infectious Diseases
August 2016 Volume 49, p1-210 Open Access
http://www.ijidonline.com/current
[Reviewed earlier]

JAMA
September 13, 2016, Vol 316, No. 10
http://jama.jamanetwork.com/issue.aspx
Viewpoint
Professing the Values of Medicine: The Modernized AMA *Code of Medical Ethics*
Stephen Brotherton, MD; Audiey Kao, MD, PhD; B. J. Crigger, PhD
Includes: Supplemental Content

Special Communication
Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine
Gillian D. Sanders, PhD; Peter J. Neumann, ScD; Anirban Basu, PhD; Dan W. Brock, PhD; David Feeny, PhD; Murray Krahn, MD, MSc; Karen M. Kuntz, ScD; David O. Meltzer, MD, PhD; Douglas K. Owens, MD, MS; Lisa A. Prosser, PhD; Joshua A. Salomon, PhD; Mark J. Sculpher, PhD; Thomas A. Trikalinos, MD; Louise B. Russell, PhD; Joanna E. Siegel, ScD; Theodore G. Ganiats, MD
Includes: CME, Supplemental Content
Editorial: The Next Chapter in Cost-effectiveness Analysis in Health and Medicine; Mark S. Roberts, MD, MPP
Abstract
Importance
Since publication of the report by the Panel on Cost-Effectiveness in Health and Medicine in 1996, researchers have advanced the methods of cost-effectiveness analysis, and policy makers have experimented with its application. The need to deliver health care efficiently and the importance of using analytic techniques to understand the clinical and economic consequences of strategies to improve health have increased in recent years.
Objective
To review the state of the field and provide recommendations to improve the quality of cost-effectiveness analyses. The intended audiences include researchers, government policy makers, public health officials, health care administrators, payers, businesses, clinicians, patients, and consumers.
Design
In 2012, the Second Panel on Cost-Effectiveness in Health and Medicine was formed and included 2 co-chairs, 13 members, and 3 additional members of a leadership group. These members were selected on the basis of their experience in the field to provide broad expertise in the design, conduct, and use of cost-effectiveness analyses. Over the next 3.5 years, the panel developed recommendations by consensus. These recommendations were then reviewed by invited external reviewers and through a public posting process.
Findings

The concept of a "reference case" and a set of standard methodological practices that all cost-effectiveness analyses should follow to improve quality and comparability are recommended. All cost-effectiveness analyses should report 2 reference case analyses: one based on a health care sector perspective and another based on a societal perspective. The use of an "impact inventory," which is a structured table that contains consequences (both inside and outside the formal health care sector), intended to clarify the scope and boundaries of the 2 reference case analyses is also recommended. This special communication reviews these recommendations and others concerning the estimation of the consequences of interventions, the valuation of health outcomes, and the reporting of cost-effectiveness analyses.
Conclusions and Relevance
The Second Panel reviewed the current status of the field of cost-effectiveness analysis and developed a new set of recommendations. Major changes include the recommendation to perform analyses from 2 reference case perspectives and to provide an impact inventory to clarify included consequences.

JAMA Pediatrics
September 2016, Vol 170, No. 9
http://archpedi.jamanetwork.com/issue.aspx
[Reviewed earlier]

Journal of Community Health
Volume 41, Issue 5, October 2016
http://link.springer.com/journal/10900/41/5/page/1
[Reviewed earlier]

Journal of Epidemiology & Community Health
October 2016, Volume 70, Issue 10
http://jech.bmj.com/content/current
[Reviewed earlier]

Journal of Global Ethics
Volume 12, Issue 2, 2016
http://www.tandfonline.com/toc/rjge20/current
[Reviewed earlier]

Journal of Global Infectious Diseases (JGID)
July-September 2016 Volume 8 | Issue 3 Page Nos. 95-126
http://www.jgid.org/currentissue.asp?sabs=n
[Reviewed earlier]

Journal of Health Care for the Poor and Underserved (JHCPU)
Volume 27, Number 3, August 2016

https://muse.jhu.edu/issue/33980
[Reviewed earlier]

Journal of Immigrant and Minority Health
Volume 18, Issue 5, October 2016
http://link.springer.com/journal/10903/18/5/page/1
[Reviewed earlier]

Journal of Immigrant & Refugee Studies
Volume 14, Issue 3, 2016
http://www.tandfonline.com/toc/wimm20/current
Special Issue: Social Mobilization and Political Participation in the Diaspora During the "Arab Spring"
[Reviewed earlier]

Journal of Infectious Diseases
Volume 214 Issue 6 September 15, 2016
http://jid.oxfordjournals.org/content/current
[Reviewed earlier]

The Journal of Law, Medicine & Ethics
Winter 2015 Volume 43, Issue 4 Pages 673–913
http://onlinelibrary.wiley.com/doi/10.1111/jlme.2015.43.issue-4/issuetoc
Special Issue: SYMPOSIUM: Harmonizing Privacy Laws to Enable International Biobank Research: Part I
[14 articles]
[Reviewed earlier]

Journal of Medical Ethics
September 2016, Volume 42, Issue 9
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[Reviewed earlier]

Journal of Medical Internet Research
Vol 18, No 7 (2016): July
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[Reviewed earlier]

Journal of Medical Microbiology
Volume 65, Issue 8, August 2016

http://jmm.microbiologyresearch.org/content/journal/jmm/65/8;jsessionid=8n8h02en4abqh.x-sgm-live-02
[New issue; No relevant digest content identified]

Journal of Patient-Centered Research and Reviews
Volume 3, Issue 3 (2016)
http://digitalrepository.aurorahealthcare.org/jpcrr/
[Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)
Volume 5 Issue 17 September 2016
http://jpids.oxfordjournals.org/content/current
[Reviewed earlier]

Journal of Pediatrics
September 2016 Volume 176, p1-228
http://www.jpeds.com/current
[New issue; No relevant digest content identified]

Journal of Public Health Policy
Volume 37, Issue 1 Supplement, September 2016
http://link.springer.com/journal/41271/37/1/suppl/page/1
[New issue; No relevant content identified]

Journal of the Royal Society – Interface
01 June 2016; volume 13, issue 119
http://rsif.royalsocietypublishing.org/content/current
[Reviewed earlier]

Journal of Virology
September 2016, volume 90, issue 18
http://jvi.asm.org/content/current
[New issue; No relevant digest content identified]

The Lancet
Sep 17, 2016 Volume 388 Number 10050 p1129-1248 e4-e5
http://www.thelancet.com/journals/lancet/issue/current
Editorial
Migrant and refugee children need our actions now
The Lancet

In a new report—released on Sept 7, UNICEF paints a grim picture. Worldwide, an estimated 50 million children are refugees or migrants, with the number of child migrants having doubled and the number of refugees having increased by 21% in the past 10 years. The most vulnerable of these children are unaccompanied, and have often fled war, insecurity, and poverty under harrowing circumstances. They might be alone or they might have lost or become separated from their family during their journey.

In one terrifying account, published on Sept 9 (Why are you keeping me here?) Human Rights Watch describes how unaccompanied migrant children are detained in police custody in Greece in unsanitary and degrading conditions. Germany's national investigative police agency, the Bundeskriminalamt, has admitted in new figures that by the end of August almost 9000 unaccompanied children who were registered entering the country are officially missing. And while some of these children may be safe with relatives somewhere, there is the very real danger of exploitation and abuse. The UK has only managed to extricate 50 of 220 unaccompanied children stranded in the camp in Calais and who have a legal right to be reunited with families in the UK. This delay and inaction is unexplained and shameful.
We agree with Zulfiqar Bhutta and colleagues' strong plea in a Correspondence letter, published online on Sept 5, that it is now time "to take the strongest action possible to protect children".

The UCL–Lancet Commission on Migration and Health, announced in this week's issue, promises to tackle key issues that affect the health and wellbeing of migrants, including unaccompanied children. Children not only need safe environments and access to health care, they need education and special psychosocial attention to mitigate the atrocities of war and persecution, including experiences of being uprooted into different cultural environments. Outrage about the plight of migrant and refugee children is not enough. Childhood is a precious and important time that strongly influences what happens in the future. We must act now.

Comment
Replenishment of the Global Fund: global solidarity needed
Peter A Singer

Series
HIV and related infections in prisoners
HIV, prisoners, and human rights
Leonard S Rubenstein, Joseph J Amon, Megan McLemore, Patrick Eba, Kate Dolan, Rick Lines, Chris Beyrer

HIV and related infections in prisoners
HIV and tuberculosis in prisons in sub-Saharan Africa
Lilanganee Telisinghe, Salome Charalambous, Stephanie M Topp, Michael E Herce, Christopher J Hoffmann, Peter Barron, Erik J Schouten, Andreas Jahn, Rony Zachariah, Anthony D Harries, Chris Beyrer, Joseph J Amon

HIV and related infections in prisoners
The perfect storm: incarceration and the high-risk environment perpetuating transmission of HIV, hepatitis C virus, and tuberculosis in Eastern Europe and Central Asia

Frederick L Altice, Lyuba Azbel, Jack Stone, Ellen Brooks-Pollock, Pavlo Smyrnov, Sergii Dvoriak, Faye S Taxman, Nabila El-Bassel, Natasha K Martin, Robert Booth, Heino Stöver, Kate Dolan, Peter Vickerman

Lancet Global Health
Sep 2016 Volume 4 Number 9 e579-e662
http://www.thelancet.com/journals/langlo/issue/current
[Reviewed earlier]

The Lancet Infectious Diseases
Sep 2016 Volume 16 Number 9 p981-1084 e178-e201
http://www.thelancet.com/journals/laninf/issue/current
[Reviewed earlier]

Maternal and Child Health Journal
Volume 20, Issue 9, September 2016
http://link.springer.com/journal/10995/20/9/page/1
[Reviewed earlier]

Medical Decision Making (MDM)
October 2016; 36 (7)
http://mdm.sagepub.com/content/current
Editorial
Cultural Diversity Calls for Culture-Sensitive Health Communication
Med Decis Making October 2016 36: 795-797, doi:10.1177/0272989X16663482
Cornelia Betsch and Robert Bohm

Review
Improving Medical Decision Making and Health Promotion through Culture-Sensitive Health Communication: An Agenda for Science and Practice
Cornelia Betsch, Robert Böhm, Collins O. Airhihenbuwa, Robb Butler, Gretchen B. Chapman, Niels Haase, Benedikt Herrmann, Tasuku Igarashi, Shinobu Kitayama, Lars Korn, Ülla-Karin Nurm, Bernd Rohrmann, Alexander J. Rothman, Sharon Shavitt, John A. Updegraff, and Ayse K. Uskul
Med Decis Making October 2016 36: 811-833, first published on August 21, 2015 doi:10.1177/0272989X15600434
Abstract
This review introduces the concept of culture-sensitive health communication. The basic premise is that congruency between the recipient's cultural characteristics and the respective message will increase the communication's effectiveness. Culture-sensitive health communication is therefore defined as the deliberate and evidence-informed adaptation of health communication to the recipients' cultural background in order to increase knowledge and improve preparation for medical decision making and to enhance the persuasiveness of messages in health promotion. To achieve effective health communication in varying cultural

contexts, an empirically and theoretically based understanding of culture will be indispensable. We therefore define culture, discuss which evolutionary and structural factors contribute to the development of cultural diversity, and examine how differences are conceptualized as scientific constructs in current models of cultural differences. In addition, we will explicate the implications of cultural differences for psychological theorizing, because common constructs of health behavior theories and decision making, such as attitudes or risk perception, are subject to cultural variation. In terms of communication, we will review both communication strategies and channels that are used to disseminate health messages, and we will discuss the implications of cultural differences for their effectiveness. Finally, we propose an agenda both for science and for practice to advance and apply the evidence base for culture-sensitive health communication. This calls for more interdisciplinary research between science and practice but also between scientific disciplines and between basic and applied research.

Original Articles

Cross-Cultural Household Influence on Vaccination Decisions

Eric Taylor, Katherine E. Atkins, Jan Medlock, Meng Li, Gretchen B. Chapman, and Alison P. Galvani

Med Decis Making October 2016 36: 844-853, first published on June 17, 2015
doi:10.1177/0272989X15591007

Abstract

Uptake of vaccination against seasonal influenza is suboptimal in most countries, and campaigns to promote vaccination may be weakened by clustering of opinions and decisions not to vaccinate. This clustering can occur at myriad interacting levels: within households, social circles, and schools. Given that influenza is more likely to be transmitted to a household contact than any other contact, clustering of vaccination decisions is arguably most problematic at the household level. We conducted an international survey study to determine whether household members across different cultures offered direct advice to each other regarding influenza vaccination and whether this advice was associated with vaccination decisions. The survey revealed that household members across the world advise one another to vaccinate, although to varying degrees, and that advice correlates with an increase in vaccination uptake. In addition, respondents in Japan, China, and the United States were less likely to offer advice to older adults than to the young, despite older adults' being the target age group for vaccination in both Far Eastern countries. Furthermore, advice was not primarily directed to household members within the age groups advised to vaccinate by national health policies. In Japan, advice was offered more to ages outside of the policy guidelines than inside. Harnessing the influence of household members may offer a novel strategy to improve vaccination coverage across cultures worldwide.

Inspecting the Mechanism: A Longitudinal Analysis of Socioeconomic Status Differences in Perceived Influenza Risks, Vaccination Intentions, and Vaccination Behaviors during the 2009–2010 Influenza Pandemic

Jürgen Maurer

Med Decis Making October 2016 36: 887-899, first published on September 28, 2015
doi:10.1177/0272989X15608379

Abstract

Background. Influenza vaccination is strongly associated with socioeconomic status, but there is only limited evidence on the respective roles of socioeconomic differences in vaccination intentions versus corresponding differences in follow-through on initial vaccination plans for

subsequent socioeconomic differences in vaccine uptake. Methods. Nonparametric mean smoothing, linear regression, and probit models were used to analyze longitudinal survey data on perceived influenza risks, behavioral vaccination intentions, and vaccination behavior of adults during the 2009–2010 influenza A/H1N1 ("swine flu") pandemic in the United States. Perceived influenza risks and behavioral vaccination intentions were elicited prior to the availability of H1N1 vaccine using a probability scale question format. H1N1 vaccine uptake was assessed at the end of the pandemic. Results. Education, income, and health insurance coverage displayed positive associations with behavioral intentions to get vaccinated for pandemic influenza while employment was negatively associated with stated H1N1 vaccination intentions. Education and health insurance coverage also displayed significant positive associations with pandemic vaccine uptake. Moreover, behavioral vaccination intentions showed a strong and statistically significant positive partial association with later H1N1 vaccination. Incorporating vaccination intentions in a statistical model for H1N1 vaccine uptake further highlighted higher levels of follow-through on initial vaccination plans among persons with higher education levels and health insurance. Limitations. Sampling bias, misreporting in self-reported data, and limited generalizability to nonpandemic influenza are potential limitations of the analysis. Conclusions. Closing the socioeconomic gap in influenza vaccination requires multipronged strategies that not only increase vaccination intentions by improving knowledge, attitudes, and beliefs but also facilitate follow-through on initial vaccination plans by improving behavioral control and access to vaccination for individuals with low education, employed persons, and the uninsured.

The Milbank Quarterly
A Multidisciplinary Journal of Population Health and Health Policy
June 2016 Volume 94, Issue 2 Pages 225–435
http://onlinelibrary.wiley.com/doi/10.1111/1468-0009.2016.94.issue-2/issuetoc
[Reviewed earlier]

Nature
Volume 537 Number 7620 pp279-442 15 September 2016
http://www.nature.com/nature/current_issue.html
[New issue; No relevant digest content identified]

Nature Medicine
September 2016, Volume 22 No 9 pp963-1061
http://www.nature.com/nm/journal/v22/n9/index.html
[Reviewed earlier]

Nature Reviews Immunology
September 2016 Vol 16 No 9
http://www.nature.com/nri/journal/v16/n9/index.html
[Reviewed earlier]

New England Journal of Medicine
September 15, 2016 Vol. 375 No. 11
http://www.nejm.org/toc/nejm/medical-journal
Perspective
History of Clinical Trials: Clinical Trials, Healthy Controls, and the Birth of the IRB
L. Stark and J.A. Greene

Original Article
Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older
Anthony L. Cunningham, M.B., B.S., M.D., Himal Lal, M.D., Martina Kovac, M.D., Roman Chlibek, M.D., Ph.D., Shinn-Jang Hwang, M.D., Javier Díez-Domingo, M.D., Ph.D., Olivier Godeaux, M.D., Myron J. Levin, M.D., Janet E. McElhaney, M.D., Joan Puig-Barberà, M.D., M.P.H., Ph.D., Carline Vanden Abeele, M.Sc., Timo Vesikari, M.D., Ph.D., Daisuke Watanabe, M.D., Ph.D., Toufik Zahaf, Ph.D., Anitta Ahonen, M.D., Eugene Athan, M.B., B.S., M.D., Jose F. Barba-Gomez, M.D., Laura Campora, M.D., Ferdinandus de Looze, M.B., B.S., H. Jackson Downey, M.D., Wayne Ghesquiere, M.D., Iris Gorfinkel, M.D., Tiina Korhonen, M.D., Edward Leung, M.B., B.S., Shelly A. McNeil, M.D., Lidia Oostvogels, M.D., Lars Rombo, M.D., Ph.D., Jan Smetana, M.D., Ph.D., Lily Weckx, M.D., Ph.D., Wilfred Yeo, M.B., Ch.B., M.D., and Thomas C. Heineman, M.D., Ph.D., for the ZOE-70 Study Group*
N Engl J Med 2016; 375:1019-1032 September 15, 2016 DOI: 10.1056/NEJMoa1603800
Abstract
Background
A trial involving adults 50 years of age or older (ZOE-50) showed that the herpes zoster subunit vaccine (HZ/su) containing recombinant varicella–zoster virus glycoprotein E and the AS01B adjuvant system was associated with a risk of herpes zoster that was 97.2% lower than that associated with placebo. A second trial was performed concurrently at the same sites and examined the safety and efficacy of HZ/su in adults 70 years of age or older (ZOE-70).
Methods
This randomized, placebo-controlled, phase 3 trial was conducted in 18 countries and involved adults 70 years of age or older. Participants received two doses of HZ/su or placebo (assigned in a 1:1 ratio) administered intramuscularly 2 months apart. Vaccine efficacy against herpes zoster and postherpetic neuralgia was assessed in participants from ZOE-70 and in participants pooled from ZOE-70 and ZOE-50.
Results
In ZOE-70, 13,900 participants who could be evaluated (mean age, 75.6 years) received either HZ/su (6950 participants) or placebo (6950 participants). During a mean follow-up period of 3.7 years, herpes zoster occurred in 23 HZ/su recipients and in 223 placebo recipients (0.9 vs. 9.2 per 1000 person-years). Vaccine efficacy against herpes zoster was 89.8% (95% confidence interval [CI], 84.2 to 93.7; P<0.001) and was similar in participants 70 to 79 years of age (90.0%) and participants 80 years of age or older (89.1%). In pooled analyses of data from participants 70 years of age or older in ZOE-50 and ZOE-70 (16,596 participants), vaccine efficacy against herpes zoster was 91.3% (95% CI, 86.8 to 94.5; P<0.001), and vaccine efficacy against postherpetic neuralgia was 88.8% (95% CI, 68.7 to 97.1; P<0.001). Solicited reports of injection-site and systemic reactions within 7 days after injection were more frequent among HZ/su recipients than among placebo recipients (79.0% vs. 29.5%). Serious adverse events, potential immune-mediated diseases, and deaths occurred with similar frequencies in the two study groups.
Conclusions

In our trial, HZ/su was found to reduce the risks of herpes zoster and postherpetic neuralgia among adults 70 years of age or older. (Funded by GlaxoSmithKline Biologicals; ZOE-50 and ZOE-70 ClinicalTrials.gov numbers, NCT01165177 and NCT01165229.)

Editorial
Preventing Shingles and Its Complications in Older Persons
K.M. Neuzil and M.R. Griffin
Free Full Text

Pediatrics
September 2016, VOLUME 138 / ISSUE 3
http://pediatrics.aappublications.org/content/138/2?current-issue=y
[Reviewed earlier]

Pharmaceutics
Volume 8, Issue 2 (June 2016)
http://www.mdpi.com/1999-4923/8/2
[Reviewed earlier]

PharmacoEconomics
Volume 34, Issue 9, September 2016
http://link.springer.com/journal/40273/34/9/page/1
[Reviewed earlier]

PLOS Currents: Disasters
http://currents.plos.org/disasters/
[Accessed 17 September 2016]
[No new relevant content identified]

PLoS Currents: Outbreaks
http://currents.plos.org/outbreaks/
(Accessed 17 September 2016)
[No new content]

PLoS Medicine
http://www.plosmedicine.org/
(Accessed 17 September 2016)
Research Article
Potential for Controlling Cholera Using a Ring Vaccination Strategy: Re-analysis of Data from a Cluster-Randomized Clinical Trial

Mohammad Ali, Amanda K. Debes, Francisco J. Luquero, Deok Ryun Kim, Je Yeon Park, Laura Digilio, Byomkesh Manna, Suman Kanungo, Shanta Dutta, Dipika Sur, Sujit K. Bhattacharya, David A. Sack
Research Article | published 13 Sep 2016 PLOS Medicine
http://dx.doi.org/10.1371/journal.pmed.1002120
Abstract

Introduction

Vaccinating a buffer of individuals around a case (ring vaccination) has the potential to target those who are at highest risk of infection, reducing the number of doses needed to control a disease. We explored the potential vaccine effectiveness (VE) of oral cholera vaccines (OCVs) for such a strategy.

Methods and Findings

This analysis uses existing data from a cluster-randomized clinical trial in which OCV or placebo was given to 71,900 participants in Kolkata, India, from 27 July to 10 September 2006. Cholera surveillance was then conducted on 144,106 individuals living in the study area, including trial participants, for 5 y following vaccination. First, we explored the risk of cholera among contacts of cholera patients, and, second, we measured VE among individuals living within 25 m of cholera cases between 8 and 28 d after onset of the index case. For the first analysis, individuals living around each index case identified during the 5-y period were assembled using a ring to define cohorts of individuals exposed to cholera index cases. An index control without cholera was randomly selected for each index case from the same population, matched by age group, and individuals living around each index control were assembled using a ring to define cohorts not exposed to cholera cases. Cholera attack rates among the exposed and non-exposed cohorts were compared using different distances from the index case/control to define the rings and different time frames to define the period at risk. For the VE analysis, the exposed cohorts were further stratified according to the level of vaccine coverage into high and low coverage strata. Overall VE was assessed by comparing the attack rates between high and low vaccine coverage strata irrespective of individuals' vaccination status, and indirect VE was assessed by comparing the attack rates among unvaccinated members between high and low vaccine coverage strata.

Cholera risk among the cohort exposed to cholera cases was 5–11 times higher than that among the cohort not exposed to cholera cases. The risk gradually diminished with an increase in distance and time. The overall and indirect VE measured between 8 and 28 d after exposure to a cholera index case during the first 2 y was 91% (95% CI 62%–98%) and 93% (95% CI 44%–99%), respectively. VE persisted for 5 y after vaccination and was similar whether the index case was a young child (<5 y) or was older. Of note, this study was a reanalysis of a cholera vaccine trial that used two doses; thus, a limitation of the study relates to the assumption that a single dose, if administered quickly, will induce a similar level of total and indirect protection over the short term as did two doses.

Conclusions

These findings suggest that high-level protection can be achieved if individuals living close to cholera cases are living in a high coverage ring. Since this was an observational study including participants who had received two doses of vaccine (or placebo) in the clinical trial, further studies are needed to determine whether a ring vaccination strategy, in which vaccine is given quickly to those living close to a case, is feasible and effective.

PLoS Neglected Tropical Diseases

http://www.plosntds.org/
[Accessed 17 September 2016]
[No new relevant content identified

PLoS One
http://www.plosone.org/
[Accessed 17 September 2016]
Research Article
Economic Evaluation of Screening Strategies Combined with HPV Vaccination of Preadolescent Girls for the Prevention of Cervical Cancer in Vientiane, Lao PDR
Phetsavanh Chanthavilay, Daniel Reinharz, Mayfong Mayxay, Keokedthong Phongsavan, Donald E. Marsden, Lynne Moore, Lisa J. White
Research Article | published 15 Sep 2016 PLOS ONE
http://dx.doi.org/10.1371/journal.pone.0162915

Research Article
Lay Health Worker Intervention Improved Compliance with Hepatitis B Vaccination in Asian Americans: Randomized Controlled Trial
Hee-Soon Juon, Carol Strong, Frederic Kim, Eunmi Park, Sunmin Lee
Research Article | published 12 Sep 2016 PLOS ONE
http://dx.doi.org/10.1371/journal.pone.0162683

PLoS Pathogens
http://journals.plos.org/plospathogens/
(Accessed 17 September 2016)
[No new relevant content identified]

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http://www.pnas.org/content/early/
(Accessed 17 September 2016)
[No new relevant content identified]

Prehospital & Disaster Medicine
Volume 31 - Issue 04 - August 2016
https://journals.cambridge.org/action/displayIssue?jid=PDM&tab=currentissue
[Reviewed earlier]

Preventive Medicine
Volume 89, Pages 1-348 (August 2016)
http://www.sciencedirect.com/science/journal/00917435/89
[Reviewed earlier]

Proceedings of the Royal Society B
10 February 2016; volume 283, issue 1824
http://rspb.royalsocietypublishing.org/content/283/1824?current-issue=y
[Reviewed earlier]

Public Health Ethics
Volume 9 Issue 17 September 2016
http://phe.oxfordjournals.org/content/current
[Reviewed earlier]

Public Health Reports
September/October 2016; 131 (5)
http://phr.sagepub.com/content/current
Surgeon General's Perspective
Food Insecurity: A Public Health Issue
Public Health Rep September/October 2016 131: 655-657, first published on August 24, 2016
doi:10.1177/0033354916664154

Law and the Public's Health
Human Papillomavirus and Mandatory Immunization Laws: What Can We Learn From Early Mandates?
Leila Barraza, Kim Weidenaar, Doug Campos-Outcalt, and Y. Tony Yang
Public Health Rep September/October 2016 131: 728-731, first published on August 24, 2016
doi:10.1177/003335491666318
[Excerpt]
…Public Health Implications
Coverage estimates for HPV vaccination are low despite evidence of the vaccine's effectiveness and safety. This large pool of unvaccinated adolescents in the United States means that considerable public health benefits are not being realized; many vaccine-preventable cancers caused by HPV will occur. Although numerous jurisdictions have faced difficulty passing an HPV vaccination mandate for school entry, now is an opportune time to move forward. Experts suggest that attempts to mandate the HPV vaccination failed because such attempts were made too closely after FDA approval and the ACIP recommendation. Ten years later, ample evidence supports the safety and effectiveness of HPV vaccines. Mandating HPV vaccination for school entry is a move that will protect the public's health by preventing HPV-related morbidity and mortality.

Qualitative Health Research
September 2016; 26 (11)
http://qhr.sagepub.com/content/current
Special Issue: HIV & Sexual Health [13 artticles]
[Reviewed earlier]

Reproductive Health
http://www.reproductive-health-journal.com/content
[Accessed 17 September 2016]
[No new relevant content identified]

Revista Panamericana de Salud Pública/Pan American Journal of Public Health (RPSP/PAJPH)
Recently Published Articles - July
http://www.paho.org/journal/index.php?option=com_content&view=featured&Itemid=101
[Reviewed earlier]

Risk Analysis
August 2016 Volume 36, Issue 8 Pages 1511–1681
http://onlinelibrary.wiley.com/doi/10.1111/risa.2016.36.issue-8/issuetoc
[Reviewed earlier]

Risk Management and Healthcare Policy
Volume 9, 2016
https://www.dovepress.com/risk-management-and-healthcare-policy-archive56
[Accessed 17 September 2016]
No new content identified]

Science
16 September 2016 Vol 353, Issue 6305
http://www.sciencemag.org/current.dtl
Perspective
VACCINES
Vaccine trust and the limits of information
Heidi J. Larson
Science 16 Sep 2016:
Vol. 353, Issue 6305, pp. 1207-1208
DOI: 10.1126/science.aah6190
Summary
Over the past decade, there has been growing recognition and increasing research around the phenomenon of vaccine reluctance and refusal (1, 2). More recently, there has been a flurry of articles on what is being referred to as "vaccine hesitancy," depolarizing the earlier characterization of individuals or groups as being outright pro- or antivaccine, and instead recognizing the liminal state between becoming aware of, and deciding whether or not to accept, vaccination. Episodes of waning public confidence around vaccines have become so global that the World Health Organization's Strategic Advisory Group of Experts on Immunization convened a working group (3) to better understand and recommend actions to address this growing challenge of vaccine hesitancy, which the group defined as "delay in acceptance or refusal of vaccination despite availability of vaccination services." Indeed, vaccine

hesitancy is complex and context specific (4). How can we better understand the circumstances that influence this state to ensure more effective uptake of vaccines and secure public health?

Science Translational Medicine
14 September 2016 Vol 8, Issue 356
http://stm.sciencemag.org/
[New issue: No relevant content identified]

Social Science & Medicine
Volume 160, Pages 1-130 (July 2016)
http://www.sciencedirect.com/science/journal/02779536/160
[Reviewed earlier]

Tropical Medicine & International Health
September 2016 Volume 21, Issue 9 Pages 1059–1196
http://onlinelibrary.wiley.com/doi/10.1111/tmi.2016.21.issue-9/issuetoc
[Reviewed earlier]

Vaccine
Volume 34, Issue 40, Pages 4763-4842 (14 September 2016)
http://www.sciencedirect.com/science/journal/0264410X/34/40
Original Research Article
Vaccination program in a resource-limited setting: A case study in the Philippines
Pages 4814-4819
Sarocha Chootipongchaivat, Varit Chantarastapornchit, Wantanee Kulpeng, Joyce Anne Ceria, Niña Isabelle Tolentino, Yot Teerawattananon
Abstract
Objective
Implementing national-level vaccination programs involves long-term investment, which can be a significant financial burden, particularly in resource-limited settings. Although many studies have assessed the economic impacts of providing vaccinations, evidence on the positive and negative implications of human resources for health (HRH) is still lacking. Therefore, this study aims to estimate the HRH impact of introducing pneumococcal conjugate vaccine (PCV) using a model-based economic evaluation.
Methods
This study adapted a Markov model from a prior study that was conducted in the Philippines for assessing the cost-effectiveness of 10-valent and 13-valent PCV compared to no vaccination. The Markov model was used for estimating the number of cases of pneumococcal-related diseases, categorized by policy options. HRH-related parameters were obtained from document reviews and interviews using the quantity, task, and productivity model (QTP model).
Results
The number of full-time equivalent (FTE) of general practitioners, nurses, and midwives increases significantly if the universal vaccine coverage policy is implemented. A universal coverage of PCV13 - which is considered to be the best value for money compared to other

vaccination strategies - requires an additional 380 FTEs for general practitioners, 602 FTEs for nurses, and 205 FTEs for midwives; it can reduce the number of FTEs for medical social workers, paediatricians, infectious disease specialists, neurologists, anaesthesiologists, radiologists, ultrasonologists, medical technologists, radiologic technologists, and pharmacists by 7, 17.9, 9.7, 0.4, 0.1, 0.7, 0.1, 12.3, 2, and 9.7, respectively, when compared to the no vaccination policy.
Conclusion
This is the first attempt to estimate the impact of HRH alongside a model-based economic evaluation study, which can be eventually applied to other vaccine studies, especially those which inform resource allocation in developing settings where not only financial resources but also HRH are constrained.

Original Research Article
A randomized non-inferiority clinical study to assess post-exposure prophylaxis by a new purified vero cell rabies vaccine (Rabivax-S) administered by intramuscular and intradermal routes
Pages 4820-4826
Anuradha Bose, Renuka Munshi, Radha Madhab Tripathy, Shampur N. Madhusudana, B.R. Harish, Saket Thaker, B.J. Mahendra, Bhagwat Gunale, Nithya J. Gogtay, Urmila M. Thatte, Reeta Subramaniam Mani, K. Manjunath, Kuryan George, Ashwin Belludi Yajaman, Ashish Sahai, Rajeev M. Dhere, Reginald G. Alex, Debasis Das Adhikari, Abhilash, Venkata Raghava, Dipti Kumbhar, et al.
Abstract
Background
Rabies is a 100% fatal disease but preventable with vaccines and immunoglobulins. We have developed a new purified vero cell rabies vaccine (Rabivax-S) and evaluated its safety and immunogenicity in post-exposure prophylaxis by intramuscular (IM) and intradermal (ID) routes.
Methods
This was a randomized active-controlled non-inferiority study in 180 individuals (age 5 years and above) with suspected rabies exposure (90 each with WHO Category II and Category III exposures). The participants received either Rabivax-S (1 mL IM; five doses), Rabivax-S (0.1 mL ID; eight doses) or purified chick embryo cell vaccine (PCEC, Rabipur®) (1 mL IM; five doses). The IM doses were given on Day 0, 3, 7, 14 and 28 while the ID doses were given on days 0, 3, 7 and 28. Category III patients also received a human rabies immunoglobulin (HRIG) on Day 0. Adverse events (AEs) were recorded with diary cards till day 42. Rabies neutralizing antibody levels were measured on day 0, 7, 14, 28 and 42.
Results
In both the category II and III patients, the geometric mean concentration (GMC) ratios of Rabivax-S IM and Rabivax-S ID groups to PCEC IM were more than 1, thus proving the non-inferiority. GMCs were similar or higher in Rabivax-S groups at all the time points. Seroresponse against rabies (RFFIT titre $\geqslant$ 0.5 IU/mL) was achieved in all participants. Mostly mild local and systemic adverse events were reported across the three groups and all resolved without sequelae.
Conclusions
Rabivax-S was well tolerated and showed immunogenicity comparable to a licensed rabies vaccine by both IM and ID routes in post-exposure prophylaxis.
Registry No.: CTRI/2012/11/003135

Vaccine: Development and Therapy
https://www.dovepress.com/vaccine-development-and-therapy-archive111
(Accessed 17 September 2016)
[No new content]

Vaccines — Open Access Journal
http://www.mdpi.com/journal/vaccines
(Accessed 17 September 2016)
[No new relevant content]

Value in Health
July 2016–August 2016 Volume 19, Issue 5, p511-698
http://www.valueinhealthjournal.com/current
[Reviewed earlier]

* * * *

From Google Scholar & other sources: Selected Journal Articles, Newsletters, Dissertations, Theses, Commentary

No new content identified.

* * * *

Media/Policy Watch

This section is intended 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 CVEP 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. We are conservative in our outlook in adding news sources which largely report on primary content we are already covering above. Many electronic media sources have tiered, fee-based subscription models for access. We will provide full-text where content is published without restriction, but most publications require registration and some subscription level.

The Atlantic
http://www.theatlantic.com/magazine/
Accessed 17 September 2016
[No new, unique, relevant content]

BBC
http://www.bbc.co.uk/
Accessed 17 September 2016
Vaccine brings new hope to India's largest leprosy colony
Published Date
12 Sep 2016
… But now, in what will hopefully become a watershed moment for leprosy, the government is rolling out the world's first leprosy vaccine in two of the worst affected states…

The Economist
http://www.economist.com/
Accessed 17 September 2016
[No new, unique, relevant content]

Financial Times
http://www.ft.com/home/uk
Accessed 17 September 2016
[No new, unique, relevant content]

Forbes
http://www.forbes.com/
Accessed 17 September 2016

Foreign Affairs
http://www.foreignaffairs.com/
Accessed 17 September 2016
[No new, unique, relevant content]

Foreign Policy
http://foreignpolicy.com/
Accessed 17 September 2016
[No new, unique, relevant content]

The Guardian
http://www.guardiannews.com/
Accessed 17 September 2016
[No new, unique, relevant content]

New Yorker
http://www.newyorker.com/
Accessed 17 September 2016
[No new, unique, relevant content]

New York Times
http://www.nytimes.com/
Accessed 17 September 2016
Florida Expands Zika Zone in Miami Beach After Five New Cases

"Every minute that passes that Congress doesn't approve funding means more time is lost from researching this virus to find a vaccine to help pregnant women and their developing babies," he said. (Reporting by Brendan O'Brien in
September 17, 2016 - By REUTERS - World - Print Headline: "Florida Expands Zika Zone in Miami Beach After Five New Cases"

Wall Street Journal
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Opinion
Saving Antibiotics So That Antibiotics Can Save Lives
By Jeremy Farrar, Seth Berkley
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Navigation: A. Ebola/EVD; Polio; MERS-Cov B. WHO; CDC C. Announcements/Milestones/Perspectives
D. Reports/Research/Analysis E. Journal Watch F. Media Watch