Vaccines and Global Health: The Week in Review
28 January 2017
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 https://centerforvaccineethicsandpolicy.net. This blog allows full-text searching of over 8,000 entries.*

Comments and suggestions should be directed to
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***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.*

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

A. Milestones :: Perspectives
B. Emergencies: Polio; Zika; Ebola/EVD; MERS-Cov; Yellow Fever
C. WHO; CDC
D. Announcements
E. Reports/Research/Analysis
E. Journal Watch
F. Media Watch

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Milestones :: Perspectives

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WHO Executive Board announces the names of the 3 nominees for the post of WHO Director-General

25 January 2017

The WHO Executive Board selected by vote the following 3 candidates to be presented to World Health Assembly as nominees for the post of Director-General of WHO.

Five candidates were interviewed by Member States today prior to the vote. The names of the 3 nominees were announced at a public meeting on Wednesday evening, 25 January 2017.

:: Dr Tedros Adhanom Ghebreyesus
:: Dr David Nabarro
:: Dr Sania Nishtar

All Member States will choose among the 3 nominees by vote at the World Health Assembly in May 2017. The new Director-General will take office on 1 July 2017.

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140th session of the Executive Board

23 January–1 February 2017, Geneva

FOLLOW LIVE: Executive Board

The Executive Board will open at 09:30 on Monday 23 January 2017 and can be watched live via webcast. The discussions will be translated into the six UN official languages: Arabic, Chinese, English, French, Russian and Spanish.

During the meeting, WHO's Executive Board will draw up a short list of 5 candidates on Tuesday 24 January. The following day the Executive Board members will then interview the five candidates and up to three of them to go forward to the World Health Assembly in May 2017.

Live web stream (begins 09:30 CET on Monday 23 January 2017)
Provisional agenda
Main Documents

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Global vaccine action plan

EB140/25
27 Jan 2017 - Webcast of Exec Board discussion
[Video: 1:15] http://www.who.int/mediacentre/events/2017/webstreaming/eb140/en/

Draft resolution proposed by Australia, Brazil and Colombia
Strengthening immunization to achieve the goals of the global vaccine action plan
EB140/CONF./2
[Not adopted; intersessional work to be undertaken to address proposed amendments]

Referenced Supporting Documents
SAGE assessment report 2016
WHO 2016 :: 26 pages
PDF [EN]:
http://www.who.int/entity/immunization/global_vaccine_action_plan/SAGE_GVAP_Assessment_Report_2016_EN.pdf?ua=1

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EXECUTIVE SUMMARY

At the midpoint of the Global Vaccine Action Plan, or GVAP (2012- 2020), the Strategic Advisory Group of Experts on Immunization (SAGE) remains gravely concerned that progress toward the goals to eradicate polio, eliminate measles and rubella, eliminate maternal and neonatal tetanus, and increase equitable access to lifesaving vaccines is too slow. Despite improvements in individual countries and a strong global rate of new vaccine introduction, global average immunization coverage has increased by only 1% since 2010.

In 2015, 68 countries fell short of the target to achieve at least 90% national coverage with the third dose of diphtheria-tetanus-pertussis vaccine. Not only that, 26 countries reported no change in coverage levels and 25 countries reported a net decrease in coverage since 2010. The 16 countries that have made measurable progress since 2010 are to be commended for reaching more people, especially vulnerable and marginalized members of society with immunization. Some of the countries with the highest numbers of unvaccinated people have made the most progress, including the Democratic Republic of the Congo, Ethiopia and India, and even though coverage targets have not been achieved in these countries, they are moving forward in the right direction.

The 111 countries that entered the decade with high immunization coverage and sustained it through 2015 are already setting their sights on more aggressive goals, additional vaccines, and more equitable coverage. Immunization programmes in these countries can lead the way by increasing access to other public health interventions and providing a platform for the delivery of preventive health services throughout the life course. Vaccine research and development is progressing rapidly, and an expanding pipeline of new vaccines underscores the need to build health systems that can reliably reach new target age groups.

The members of the SAGE are steadfast and passionate believers in the power of immunization to give individuals and their families a better start in life and to protect people from a growing array of debilitating illnesses. Immunization is one of the world's most effective and cost-effective tools against the threat of emerging diseases and has a powerful impact on social and economic development. Recognizing the role that immunization plays in ensuring good health and the role that good health plays in achieving sustainable development, the SAGE has supported the inclusion of immunization indicators to measure progress toward the Sustainable Development Goals.

The next four years present unprecedented opportunities for countries to leverage the attention and support that immunization receives and apply it for the benefit of people everywhere. Strident efforts on the part of all countries and immunization stakeholders are required to catch up and achieve GVAP goals by 2020.

The SAGE has made nine recommendations which are detailed at the end of this report:
:: Demonstrate stronger leadership and governance of national immunization systems
:: Prioritize immunization system strengthening
:: Secure necessary investments to sustain immunization during polio and Gavi transitions
:: Improve surveillance capacity and data quality and use
:: Enhance accountability mechanisms to monitor implementation of Global and Regional Vaccine Action Plans

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:: Achieve elimination targets for maternal and neonatal tetanus, measles, rubella and congenital rubella syndrome
:: Resolve barriers to timely supply of affordable vaccines in humanitarian crisis situations
:: Support vaccine R&D capacity in low- and middle-income countries
:: Accelerate the development and introduction of new vaccines and technologies

GVAP – Monitoring, Evaluation & Accountability - Secretariat report 2016
WHO, 2016 :: 288 pages
Table of Contents
I. Monitoring results: goals, strategic objectives and indicators
1. DISEASE ELIMINATION
2. IMMUNIZATION COVERAGE
3. MILLENNIUM DEVELOPMENT GOAL 4 AND INTEGRATION
4. COUNTRY OWNERSHIP
5. VACCINE HESITANCY
6. SURVEILLANCE
7. VACCINES STOCKOUTS AND USE OF VACCINES IN A CONTROLLED-TEMPERATURE CHAIN
8. SUSTAINABLE FINANCING AND SUPPLY FOR IMMUNIZATION
9. VACCINE SAFETY
10. RESEARCH AND DEVELOPMENT

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Emergencies

WHO Grade 3 Emergencies [to 28 January 2017]
Iraq –
:: Efforts ongoing to provide trauma care to people in need in Mosul, Iraq
Cairo, 25 January 2017 – As the conflict in Mosul intensifies and greater numbers of civilians are caught in the crossfire, WHO and partners have increased trauma care services to ensure that patients requiring medical care for injuries have a greater chance of survival. However, additional funds are needed in order to provide a full scale of health services to the 2.7 million people affected.

South Sudan -
:: WHO and partners scaling up measles vaccination to reach 2.3 million children in South Sudan
18 January 2017, Juba, South Sudan – WHO South Sudan in partnership with the MoH, UNICEF and other partners including state directors general for health and Expanded Program on Immunization (EPI) officers of all states, gathered from 17 to 21 January 2017 at Juba Grand Hotel to plan on how to reach 2.3 million persons with measles vaccines in the face of a difficult operating environment.

The Syrian Arab Republic - *No new announcements identified.*
Yemen - *No new announcements identified.*
Nigeria - *See measles immunization campaign announcement above.*

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UNICEF: 4.7 million children in vaccination campaign against measles in northeast Nigeria
26 January 2017 ABUJA, Nigeria,– In a major vaccination campaign concluding this week, 4.7 million children are being vaccinated in response to a measles outbreak in northeast Nigeria. The campaign is covering the three states most affected by the Boko Haram conflict – Adamawa, Borno and Yobe – where insecurity has limited vaccination efforts. In 2016, there were approximately 25,000 cases of measles among children in Nigeria; 97 per cent of the cases were in children under the age of ten and at least a hundred children died.

WHO Grade 2 Emergencies [to 28 January 2017]
:: Responding to forgotten crises - Together with the United Nations Central Emergency Response Fund
28 January 2017 -- With the number and scale of humanitarian crises around the world, some countries have fallen off the global radar. That is the case for countries like the Central African Republic, Libya and Sudan, where pressing needs don't seem to garner the world's attention. This can make it difficult to raise the funding necessary to carry out humanitarian response plans.

Cameroon - *No new announcements identified.*
Central African Republic - *No new announcements identified.*
Democratic Republic of the Congo - *No new announcements identified.*
Ethiopia - *No new announcements identified.*
Libya - *No new announcements identified.*
Myanmar - *No new announcements identified.*
Niger - *No new announcements identified.*
Ukraine - *No new announcements identified.*

UN OCHA – L3 Emergencies
The UN and its humanitarian partners are currently responding to three 'L3' emergencies. This is the global humanitarian system's classification for the response to the most severe, large-scale humanitarian crises.
Iraq
:: Iraq: Mosul Humanitarian Response Situation Report No. 17 (16 January - 22 January 2017) [EN/AR/KU]

Syria
:: Syria Arab Republic: Deir-ez-Zor Flash Update No. 2, 28 January 2017
:: 26 Jan 2017 Statement to the Security Council on Syria
:: 28 Jan 2017 Syria Arab Republic: Deir-ez-Zor Flash Update No. 2, 28 January 2017

Yemen
:: Under-Secretary-General for Humanitarian Affairs and Emergency Relief Coordinator, Stephen O'Brien Statement to the Security Council on Yemen, New York, 26 January 2017
:: 26 Jan 2017 Launch of the 2017-2018 Regional Refugee and Resilience Plan

Corporate Emergencies
Haiti

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:: Haiti: Hurricane Matthew - Situation Report No. 33 (25 January 2017)

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Zika virus [to 28 January 2017]
http://www.who.int/emergencies/zika-virus/en/

Latest Report: now bi-weekly
Zika situation report – 20 January 2017
Full report: http://apps.who.int/iris/bitstream/10665/253604/1/zikasitrep20Jan17-eng.pdf?ua=1
…A*nalysis*
Overall, the global risk assessment has not changed. Zika virus continues to spread geographically to areas where competent vectors are present. Although a decline in cases of Zika infection has been reported in some countries, or in some parts of countries, vigilance needs to remain high.

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POLIO [to 28 January 2017]
Public Health Emergency of International Concern (PHEIC)

Polio this week as of 26 January 2017
:: The Executive Board of the World Health Organization is meeting this week in Geneva, Switzerland. Ministries of Health will agree on the agenda for the May World Health Assembly (WHA), and will review various international public health topics. Ministers are expected to receive a comprehensive review and overview of the latest global poliovirus epidemiology.

Country Updates *[Selected Excerpts]*
Afghanistan
:: One new environmental WPV1 positive sample was reported in the past week, from Hilmand province, collected on 23 December 2016.

Pakistan
:: One new environmental WPV1 positive sample was reported in the past week, from Killa Abdullah, Balochistan, collected on 1 January 2017. It is the first WPV1-positive sample detected globally from this year.

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Editor's Note:
We will cluster these recent emergencies as below and continue to monitor the WHO pages for updates and key developments.

Yellow Fever [to 28 January 2017]
http://www.who.int/emergencies/yellow-fever/en/

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Disease Outbreak News [DONs]
:: Yellow fever – Brazil 28 January 2017

EBOLA/EVD [to 28 January 2017]
http://www.who.int/ebola/en/
"Threat to international peace and security" (UN Security Council)
No new digest content identified for this edition.

MERS-CoV [to 28 January 2017]
http://www.who.int/emergencies/mers-cov/en/
Disease Outbreak News [DONs]
:: Middle East respiratory syndrome coronavirus (MERS-CoV) – Saudi Arabia 26 January 2017

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WHO & Regional Offices [to 28 January 2017]

140th session of the Executive Board
23 January–1 February 2017, Geneva
[see selected main documents summary and live webcast information above]

Mahmoud Fikri appointed as Regional Director for the WHO Eastern Mediterranean Region
24 January 2017 -- WHO's Executive Board, currently holding its 140th session in Geneva, has appointed Dr Mahmoud Fikri, from United Arab Emirates (UAE) as WHO Regional Director for the Eastern Mediterranean Region (EMRO), following his nomination by the Regional Committee for EMRO in October last year.

Disease Outbreak News [DONs]
:: Yellow fever – Brazil 28 January 2017
:: Middle East respiratory syndrome coronavirus (MERS-CoV) – Saudi Arabia 26 January 2017 ::
:: Hepatitis E – Chad 24 January 2017

Weekly Epidemiological Record, 28 January 2017, vol. 92, 4 (pp. 37–44)
:: Detection of influenza virus subtype A by polymerase chain reaction: WHO external quality assessment programme summary analysis, 2016

WHO Immunization, Vaccines and Biologicals
24 January 2017 Call for Expressions of Interest for a Vaccine-Preventable Disease Surveillance Expertpdf, 254kb Application deadline: 17 February 2017

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

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WHO Region of the Americas PAHO
No new digest content identified.

WHO South-East Asia Region SEARO
:: Scale up efforts against leprosy; focus on preventing disabilities in children
28 January 2017

WHO European Region EURO
:: WHO calls for heightened vigilance as avian influenza continues to spread in Europe 26-01-2017
:: First meeting of the Health and SDGs Expert Working Group provides input to roadmap for health and sustainable development in the Region 25-01-2017

WHO Eastern Mediterranean Region EMRO
:: Mahmoud Fikri appointed as Regional Director for the WHO Eastern Mediterranean Region 24 January 2017
:: Trauma care now available in Bartalla 23 January 2017
:: Leishmaniasis continues to affect the lives of tens of thousands of Afghans 22 January 2017

WHO Western Pacific Region
No new digest content identified.

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CDC/ACIP [to 28 January 2017]
http://www.cdc.gov/media/index.html
https://www.cdc.gov/vaccines/acip/

MMWR Weekly January 27, 2017/No. 1
[Excerpts]
:: *Notes from the Field*: Impact of Increasing the Number of Ebola Surveillance Officers — Kambia District, Sierra Leone, September 2014–September 2015

Register for upcoming February ACIP meeting
February 22-23, 2017
Deadline for registration:
:: Non-US Citizens: February 1, 2017; US Citizens: February 13, 2017
Registration is NOT required to watch the live meeting webcast or to listen via telephone.

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Announcements

BMGF - Gates Foundation [to 28 January 2017]
http://www.gatesfoundation.org/Media-Center/Press-Releases
JANUARY 20, 2017

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Bill & Melinda Gates Foundation boosts vital work of the University of Washington's Institute for Health Metrics and Evaluation

SEATTLE (January 25, 2017) – The Bill & Melinda Gates Foundation and University of Washington's Institute for Health Metrics and Evaluation (IHME) announced today the foundation's commitment to invest $279 million in IHME to expand its work over the next decade.

The investment will allow IHME to build on its work providing independent health evidence to improve population health. The award complements other investments from the Gates Foundation to further the work of the University of Washington's Population Health Initiative, which was launched in May 2016 and is establishing a university wide, 25-year vision to advance the health and well-being of people around the world…

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Global Fund [to 28 January 2017]
http://www.theglobalfund.org/en/news/?topic=&type=NEWS;&country=
26 January 2017

New Global Fund Results Show Further Progress Against HIV, TB and Malaria

GENEVA – Latest results [Results Factsheet - Mid-2016] show that programs supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria have achieved significant increases in the number of people receiving treatment for HIV, diagnosis and treatment for TB and having an insecticide treated net to prevent malaria.

The new results, highlighting cumulative progress by programs supported by the Global Fund since 2002, show that the number of people currently on antiretroviral therapy increased 8.5 percent to 10 million. New smear-positive TB cases detected and treated rose by 9.4 percent to more than 16.6 million. Over 713 million insecticide treated nets were distributed to help families protect themselves from malaria, an increase of 8.1 percent. The results are based on data from the first half of 2016.

"These figures represent 15 years of impressive impact," said Mark Dybul, the Executive Director of the Global Fund. "Global investments in programs that free communities from the burden of these diseases are achieving results that have saved more than 20 million lives." Additional results include: 3.8 million HIV-positive women receiving services to prevent transmission of HIV to unborn children; 334,000 people treated for multidrug-resistant TB; 626 million cases of malaria treated…

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Hilleman Laboratories [to 28 January 2017]
http://www.hillemanlabs.org/
10/01/2017

Hilleman Laboratories awarded global patents for Oral Cholera Vaccine

New Delhi, 10 January, 2017: Hilleman Laboratories, a joint-venture partnership between MSD and Wellcome Trust, has announced that it has been awarded a set of global patents for its Oral Cholera Vaccine (OCV). The organisation has partnered with Gotovax AB, a Sweden based company as well as with Incepta Vaccine Ltd, Bangladesh, to develop OCV, with an aim to provide a safe and effective Cholera vaccine at a significantly lower cost than currently available in the market. The OCV patents, assigned to Hilleman Laboratories, have been

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granted at various patent offices including USA, European Union, Australia, China, Canada and South Africa…

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Gavi [to 28 January 2017]
http://www.gavi.org/library/news/press-releases/
28 January 2017
CAF and African football stars team-up to promote immunisation for children at 2017 Total Africa Cup of Nations
"Africa United" campaign highlights power of vaccination to save children's lives in Africa.

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IVI [to 28 January 2017]
http://www.ivi.int/
[Undated]
IVI as local host of U.S.-Japan Cooperative Medical Sciences Program's 19th International Conference on Emerging Infectious Diseases (EID), February 7-10, 2017

The U.S.-Japan Cooperative Medical Sciences Program's 19th International Conference on Emerging Infectious Diseases (EID) and associated Workshop on Cholera and Other Bacterial Enteric Infections will be on February 7-10, 2017 at the Novotel Seoul Ambassador Gangnam Hotel. Organized by the U.S. National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), the Japanese Ministries of Health, Labor and Welfare (MHLW) and Education, Culture, Sports, Science and Technology (MEXT), and the Japan Agency for Medical Research and Development (AMED), IVI is the local host of this year's conference.

Since 1996, the United States-Japan Cooperative Medical Sciences Program has been convening the EID conference annually in alternating countries. It serves as a venue for panel meetings and discussion of cross-cutting topics related to infectious disease research to promote international cooperation in research efforts in response to new, emerging infectious disease challenges of Asia and the greater Pacific region. Participants include researchers, government and public health officials, and representatives from academia and other public and private institutions from countries within the Pacific Rim region, including Korea, Japan, and the United States.

For more information about EID and the Workshop, please visit:
https://respond.niaid.nih.gov/conferences/USJapanCMSP2017/Pages/default.aspx

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Fondation Merieux [to 28 January 2017]
http://www.fondation-merieux.org/news
Mission: Contribute to global health by strengthening local capacities of developing countries to reduce the impact of infectious diseases on vulnerable populations.
25 January 2017, Erbil (Iraq)
Inauguration of a Mother and Child medical center in Erbil (Iraq) in partnership with Fondation Mérieux

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Fondation Mérieux helped to build a medical center in Erbil, in Iraqi Kurdistan. The Pauline-Marie Jaricot Mother and Child center was commissioned and opened on December 7, 2016. It provides comprehensive, quality medical care for displaced people, of whom there are many in the Iraqi Kurdistan region. These people now have access to diagnosis and targeted medical treatment.

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Wellcome Trust [to 28 January 2017]
https://wellcome.ac.uk/news
News / Published: 24 January 2017
New partnerships to tackle health and environmental issues
We've awarded four new research partnerships a total of £29m to tackle global environmental and health challenges.

The scientists – from Australia, South America and the UK – are receiving the funding as part of Wellcome's £75m commitment to population and planetary health.

Two of the partnerships will focus on the health challenges of diverse urban environments.
:: Professor Ana Diez Roux, at Drexel University in the USA, will study the links between health and the physical, natural and economic environments in highly urbanised Latin America.
:: Prof Rebekah Brown, at Monash University in Australia, will investigate how nature-based solutions can help to improve the sanitation and environment of people living in informal urban settlements in Fiji and Indonesia.

The other two partnerships will focus on food systems and choices.
:: Prof Charles Godfray, at Oxford University, will look at the environmental and health impacts of animal-sourced food, mainly in the UK, and what their future could look like.
:: Prof Alan Dangour, at the London School of Hygiene and Tropical Medicine, will build on work we've already funded to explore what factors form sustainable and healthy food systems in India and South Africa…

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FDA [to 28 January 2017]
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm
What's New for Biologics
:: **December 22, 2016 Summary of Safety and Effectiveness - Aptima HIV-1 Quaint assay (PDF - 527KB)**
Updated: 1/24/2017

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Industry Watch [to 28 January 2017]
:: **Pfizer Announces Positive Top-Line Results from Phase 2 Study of Investigational Clostridium difficile Vaccine for the Prevention of C. difficile Infection**

Pfizer's C. difficile Vaccine Candidate to Commence Phase 3 Study in First Half of 2017

C. difficile is an Increasing Worldwide Concern Associated with Approximately 29,000 Annual Deaths in the U.S. Alone
January 26, 2017

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NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that the Phase 2 study evaluating the Company's Clostridium difficile (C. difficile) vaccine candidate, PF-06425090, provided positive data, based on a pre-planned interim analysis. The randomized Phase 2 study (NCT02561195) examined the safety, tolerability, and immunogenicity of the vaccine in healthy adults 65 to 85 years of age. Pfizer's vaccine candidate is designed to help prevent C. difficile infection (CDI), which can include life-threatening diarrhea and pseudomembranous colitis,1 by inducing a functional antibody response capable of neutralizing the two main disease-causing toxins produced by C. difficile (toxins A and B).2 …

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PATH [to 28 January 2017]
http://www.path.org/news/index.php
Press release | January 23, 2017
Quansys Biosciences launches Q-Plex (TM) Micronutrient Array to combat malnutrition
Effective and affordable new tool can identify up to seven key nutrition markers and malaria infection with a single test.

…The Q-Plex™ Micronutrient Array responds. Developed through a collaboration between the global health nonprofit PATH and bioscience developer and manufacturer Quansys, the test can simultaneously measure up to seven nutrition-related biomarkers in a single sample of human serum. Using the test, countries and researchers can gather national data on micronutrient deficiency status and use it to implement and assess targeted interventions. Results also help leaders accurately establish the magnitude of the deficiency, identify subpopulations at greatest risk, and monitor the efficacy and progress of nutrition programs

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AERAS [to 28 January 2017]
http://www.aeras.org/pressreleases
No new digest content identified.

DCVMN [to 28 January 2017]
http://www.dcvmn.org/
No new digest content identified.

EDCTP [to 28 January 2017]
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 Vaccine Initiative [to 28 January 2017]
http://www.euvaccine.eu/news-events
No new digest content identified.

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GHIT Fund [to 28 January 2017]
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.
No new digest content identified.

Human Vaccines Project [to 28 January 2017]
http://www.humanvaccinesproject.org/media/press-releases/
No new digest content identified.

IAVI – International AIDS Vaccine Initiative [to 28 January 2017]
https://www.iavi.org/
No new digest content identified

IFPMA [to 28 January 2017]
http://www.ifpma.org/resources/news-releases/
No new digest content identified

NIH [to 28 January 2017]
http://www.nih.gov/news-events/news-releases
No new digest content identified.

The Vaccine Confidence Project [to 28 January 2017]
http://www.vaccineconfidence.org/
No new digest content identified

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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

22 CASE STUDIES WHERE PHASE 2 AND PHASE 3 TRIALS HAD DIVERGENT RESULTS

FDA
January 2017 :: 44 pages
Overview

Pre-market clinical testing usually progresses in phases, with increasingly rigorous methods at each phase. Product candidates that appear insufficiently safe or effective at one phase may not proceed to the next phase. Roughly 9 in 10 drugs/biologics that are tested in humans are never submitted to FDA for approval.[1] Typically, a candidate drug is submitted to the FDA for

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marketing approval after phase 3 testing. In recent years, there has been growing interest in exploring alternatives to requiring phase 3 testing before product approval, such as relying on different types of data and unvalidated surrogate endpoints.

To better understand the nature of the evidence obtained from many phase 2 trials and the contributions of phase 3 trials, we identified, based on publicly available information, 22 case studies of drugs, vaccines and medical devices since 1999 in which promising phase 2 clinical trial results were not confirmed in phase 3 clinical testing.* Phase 3 studies did not confirm phase 2 findings of effectiveness in 14 cases, safety in 1 case, and both safety and effectiveness in 7 cases. These unexpected results could occur even when the phase 2 study was relatively large and even when the phase 2 trials assessed clinical outcomes. In two cases, the phase 3 studies showed that the experimental product increased the frequency of the problem it was intended to prevent.

This paper is not intended to assess why each of these unexpected results occurred or why further product development was not pursued. Rather, these cases, chosen from a large pool of similar examples, illustrate the ways in which controlled trials of appropriate size and duration contribute to the scientific understanding of medical products.

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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
January 2017 Volume 45, Issue 1, p1-104, e1-e22
http://www.ajicjournal.org/current
[Reviewed earlier]

American Journal of Preventive Medicine
January 2017 Volume 52, Issue 1, p1-134, e1-e32
http://www.ajpmonline.org/current
[Reviewed earlier]

American Journal of Public Health
Volume 107, Issue 1 (January 2017)
http://ajph.aphapublications.org/toc/ajph/current
[Reviewed earlier]

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American Journal of Tropical Medicine and Hygiene
January 2017; 96 (1)
http://www.ajtmh.org/content/current
[Reviewed earlier]

Annals of Internal Medicine
17 January 2017 Vol: 166, Issue 2
http://annals.org/issue.aspx
[Reviewed earlier]

BMC Cost Effectiveness and Resource Allocation
http://resource-allocation.biomedcentral.com/
(Accessed 28 January 2017)
[No new content]

BMC Health Services Research
http://www.biomedcentral.com/bmchealthservres/content
(Accessed 28 January 2017)
[No new digest content identified]

BMC Infectious Diseases
http://www.biomedcentral.com/bmcinfectdis/content
(Accessed 28 January 2017)
[No new digest content identified]

BMC Medical Ethics
http://www.biomedcentral.com/bmcmedethics/content
(Accessed 28 January 2017)
Research article
Dynamic Consent: a potential solution to some of the challenges of modern biomedical research
Isabelle Budin-Ljøsne, Harriet J. A. Teare, Jane Kaye, Stephan Beck, Heidi Beate Bentzen, Luciana Caenazzo, Clive Collett, Flavio D'Abramo, Heike Felzmann, Teresa Finlay, Muhammad Kassim Javaid, Erica Jones, Višnja Katić, Amy Simpson and Deborah Mascalzoni
BMC Medical Ethics 2017 18:4
Published on: 25 January 2017
Abstract
Background
Innovations in technology have contributed to rapid changes in the way that modern biomedical research is carried out. Researchers are increasingly required to endorse adaptive and flexible approaches to accommodate these innovations and comply with ethical, legal and regulatory

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requirements. This paper explores how Dynamic Consent may provide solutions to address challenges encountered when researchers invite individuals to participate in research and follow them up over time in a continuously changing environment.
Methods
An interdisciplinary workshop jointly organised by the University of Oxford and the COST Action CHIP ME gathered clinicians, researchers, ethicists, lawyers, research participants and patient representatives to discuss experiences of using Dynamic Consent, and how such use may facilitate the conduct of specific research tasks. The data collected during the workshop were analysed using a content analysis approach.
Results
Dynamic Consent can provide practical, sustainable and future-proof solutions to challenges related to participant recruitment, the attainment of informed consent, participant retention and consent management, and may bring economic efficiencies.
Conclusions
Dynamic Consent offers opportunities for ongoing communication between researchers and research participants that can positively impact research. Dynamic Consent supports inter-sector, cross-border approaches and large scale data-sharing. Whilst it is relatively easy to set up and maintain, its implementation will require that researchers re-consider their relationship with research participants and adopt new procedures.

BMC Medicine
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Research article
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Sub-Saharan Africa is undergoing an epidemiological transition from a predominance of infectious diseases to non-communicable and lifestyle related conditions. However, the pace of this transition and the patt...
R. Zoleko Manego, G. Mombo-Ngoma, M. Witte, J. Held, M. Gmeiner, T. Gebru, B. Tazemda, J. Mischlinger, M. Groger, B. Lell, A. A. Adegnika, S. T. Agnandji, P. G. Kremsner, B. Mordmüller, M. Ramharter and P. B. Matsiegui
BMC Public Health 2017 17:130
Published on: 28 January 2017

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Research article
The impact of a vaccine scare on parental views, trust and information needs: a qualitative study in Sydney, Australia
Vaccine safety scares can undermine public confidence in vaccines and decrease immunisation rates. Understanding and addressing parental concerns arising during such scares can assist in lessening their impact...
Catherine King and Julie Leask
BMC Public Health 2017 17:106
Published on: 23 January 2017

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[Reviewed earlier]

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Volume 95, Number 1, January 2017, 1-84
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January 2017 Volume 43, Issue 1 Pages 1–159
http://onlinelibrary.wiley.com/doi/10.1111/cch.v43.1/issuetoc
[Reviewed earlier]

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January 2017 Volume 39, Issue 1, p1-230
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[New issue; No relevant content identified]

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November/December 2016 Volume 21, Issue S2 Pages 1–642
http://onlinelibrary.wiley.com/doi/10.1002/cplx.v21.S2/issuetoc
[Reviewed earlier]

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http://www.conflictandhealth.com/
[Accessed 28 January 2017]
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Volume 52, Pages 1-100 (January 2017)
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February 2017 - Volume 30 - Issue 1 pp: v-vi,1-142
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December 2016 Volume 16, Issue 3 Pages 121–180
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[Reviewed earlier]

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Volume 24, Number 8
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[Reviewed earlier]

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January 2017 Volume 41, Issue 1 Pages 1–208
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Volume 23, Number 1—January 2017
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Volume 17, In Progress (December 2016)
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[Reviewed earlier]

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Volume 145 - Issue 3 - February 2017
http://journals.cambridge.org/action/displayIssue?jid=HYG&tab=currentissue
REVIEW Poliovirus
Wild and vaccine-derived poliovirus circulation, and implications for polio eradication
P. L. LOPALCO
DOI: https://doi.org/10.1017/S0950268816002569
Published online: 21 November 2016, pp. 413-419
Abstract
Polio cases due to wild virus are reported by only three countries in the world. Poliovirus type 2 has been globally eradicated and the last detection of poliovirus type 3 dates to November 2012. Poliovirus type 1 remains the only circulating wild strain; between January and September 2016 it caused 26 cases (nine in Afghanistan, 14 in Pakistan, three in Nigeria). The use of oral polio vaccine (OPV) has been the key to success in the eradication effort. However, paradoxically, moving towards global polio eradication, the burden caused by vaccine-derived polioviruses (VDPVs) becomes increasingly important. In this paper circulation of both wild virus and VDPVs is reviewed and implications for the polio eradication endgame are discussed. Between April and May 2016 OPV2 cessation has been implemented globally, in a coordinated switch from trivalent OPV to bivalent OPV. In order to decrease the risk for cVDPV2 re-emergence inactivated polio vaccine (IPV) has been introduced in the routine vaccine schedule of all countries. The likelihood of re-emergence of cVDPVs should markedly decrease with time after OPV cessation, but silent circulation of polioviruses cannot be ruled out even a long time after cessation. For this reason, immunity levels against polioviruses should be kept as high as possible in the population by the use of IPV, and both clinical and environmental surveillance should be maintained at a high level.

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Volume 26, Issue 6, 1 December 2016
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[Reviewed earlier]

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December 2016 | Volume 4 | Issue 4
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[Reviewed earlier]

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Volume 12, 2017 Issue 2
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[Reviewed earlier]

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[Accessed 28 January 2017]
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January 2017; Volume 36, Issue 1
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[Reviewed earlier]

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Volume 18, Issue 2, December 2016
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[Reviewed earlier]

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Volume 12 - Issue 1 - January 2017
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Volume 31 Issue 28 January 2017
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Number 67 September 2016
http://odihpn.org/magazine/humanitarian-innovation/
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[Reviewed earlier]

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Volume 13, Issue 1, 2017
http://www.tandfonline.com/toc/khvi20/current

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Review

From discovery to licensure, the Adjuvant System story

Pages: 19-33

Nathalie Garçon & Alberta Di Pasquale

ABSTRACT

Adjuvants are substances added to vaccines to improve their immunogenicity. Used for more than 80 years, aluminum, the first adjuvant in human vaccines, proved insufficient to develop vaccines that could protect against new challenging pathogens such as HIV and malaria. New adjuvants and new combinations of adjuvants (Adjuvant Systems) have opened the door to the delivery of improved and new vaccines against re-emerging and difficult pathogens. Adjuvant Systems concept started through serendipity. The access to new developments in technology, microbiology and immunology have been instrumental for the dicephering of what they do and how they do it. This knowledge opens the door to more rational vaccine design with implications for developing new and better vaccines.

Reviews

Current prospects and future challenges for nasal vaccine delivery

Pages 34-45 | Received 07 Jul 2016, Accepted 18 Sep 2016, Published online: 09 Dec 2016

Helmy Yusuf & Vicky Kett

ABSTRACT

Nasal delivery offers many benefits over traditional approaches to vaccine administration. These include ease of administration without needles that reduces issues associated with needlestick injuries and disposal. Additionally, this route offers easy access to a key part of the immune system that can stimulate other mucosal sites throughout the body. Increased acceptance of nasal vaccine products in both adults and children has led to a burgeoning pipeline of nasal delivery technology. Key challenges and opportunities for the future will include translating in vivo data to clinical outcomes. Particular focus should be brought to designing delivery strategies that take into account the broad range of diseases, populations and healthcare delivery settings that stand to benefit from this unique mucosal route.

Article

Randomized clinical trial of the safety and immunogenicity of the Tdap vaccine in pregnant Mexican women

Pages: 128-135

Published online: 29 Sep 2016

Jesús Zacarías Villarreal Pérez, José Manuel Ramírez Aranda, Manuel de la O Cavazos, Michelle de J. Zamudio Osuna, José Perales Dávila, María Romelia Ballesteros Elizondo, Marco Vinicio Gómez Meza, Francisco Javier García Elizondo & Azucena M. Rodríguez González

ABSTRACT

Immunization with the tetanus, diphtheria, and pertussis (Tdap) vaccine raises controversies on immunogenicity and possible antibody interference. We performed an experimental, double-blind, parallel group controlled clinical trial to evaluate the safety and immunogenicity of the Tdap vaccine in 204 pregnant women and their children and to determine its interference in antibody production. Pregnant women 18 to 38 y of age with 12 to 24 weeks gestation, a low obstetric risk, and without serious disease were randomly selected. The experimental group received 0.5 mL IM of Tdap and the control group normal saline. Six blood samples were drawn before and after solution application, and from the umbilical cord of the infants and at 2, 4, and

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6 months of age. Pertactin and Pertussis toxin antibodies and possible interference of maternal antibodies with the vaccine were determined.
In the experimental group, antibodies against Bordetella pertussis pertactin (anti-PRN) (112 E/mL 95% CI 89.9–139.9) and antibodies against pertussis toxin (anti-PT) (24.0 E/mL, 95% CI 18.3–31.4) were elevated in the mother before vaccination. These were higher in the umbilical cord and descended in the infant at 2 months (71.4 (95% CI 56.8–89.7 and 10.9; 95% CI 8.7–13.7, respectively). Anti-PT showed a delay in production. Tdap safety was confirmed with only mild local pain at 24 and 48 hours.
Anti-PRN and anti-PT antibodies in the infant descend at 2 months of age. There is a delay in anti-PT in children of immunized mothers. Further studies are needed to elucidate its clinical significance.

Review
Ebola vaccines in clinical trial: The promising candidates
Pages: 153-168
Published online: 20 Oct 2016
Yuxiao Wang, Jingxin Li, Yuemei Hu, Qi Liang, Mingwei Wei & Fengcai Zhu
Abstract
Ebola virus disease (EVD) has become a great threat to humans across the world in recent years. The 2014 Ebola epidemic in West Africa caused numerous deaths and attracted worldwide attentions. Since no specific drugs and treatments against EVD was available, vaccination was considered as the most promising and effective method of controlling this epidemic. So far, 7 vaccine candidates had been developed and evaluated through clinical trials. Among them, the recombinant vesicular stomatitis virus-based vaccine (rVSV-EBOV) is the most promising candidate, which demonstrated a significant protection against EVD in phase III clinical trial. However, several concerns were still associated with the Ebola vaccine candidates, including the safety profile in some particular populations, the immunization schedule for emergency vaccination, and the persistence of the protection. We retrospectively reviewed the current development of Ebola vaccines and discussed issues and challenges remaining to be investigated in the future.

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Volume 9, Issue 1 1 January 2017
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[Reviewed earlier]

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International Journal of Community Medicine and Public Health
Vol 4, No 1 (2017) January 2017
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Volume 45 Issue 5 October 2016
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http://www.ijidonline.com/issue/S1201-9712(16)X0011-2
[Reviewed earlier]

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January 24, 2017, Vol 317, No. 4, Pages 333-450
http://jama.jamanetwork.com/issue.aspx
January NaN, 2017
Large HIV Vaccine Trial Launches in South Africa
JAMA. 2017;317(4):350. doi:10.1001/jama.2016.20743
Jennifer Abbasi
Full Text

A vaccine that prevents HIV infection may be a step closer to reality with the launch of the large HVTN 702 clinical trial in South Africa late last year. The trial will test the safety and efficacy of a new version of a candidate vaccine studied in the landmark RV144 clinical trial in Thailand.

In 2009, the RV144 vaccine regimen was found to be 31.2% effective at preventing HIV infection over the 3.5-year follow-up period. Now researchers hope a modified version of the vaccine will improve on the modest results of the Thai trial and provide a longer-lasting immune response against the virus that causes AIDS.

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January 1, 2017, Vol 171, No. 1, Pages 3-100
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Volume 42, Issue 1, February 2017
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January 2017, Volume 71, Issue 1
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Volume 12, Issue 3, 2016
http://www.tandfonline.com/toc/rjge20/current
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[Reviewed earlier]

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October-December 2016 Volume 8 | Issue 4 Page Nos. 127-162
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Volume 27, Number 4, November 2016
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Volume 18, Issue 6, December 2016
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Volume 215 Issue 1 January 1, 2017
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Winter 2015 Volume 43, Issue 4 Pages 673–913
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[14 articles]
[Reviewed earlier]

Journal of Medical Ethics
February 2017, Volume 43, Issue 2
http://jme.bmj.com/content/current
JME symposium 'The benefit/risk ratio challenge in clinical research, and the case of HIV cure.'
Paper
The benefit/risk ratio challenge in clinical research, and the case of HIV cure: an introduction
Nir Eyal, Professor Nir Eyal, Department of Global Health and Population, Harvard
[Full text; References at link above]
There is now hope to find a cure for HIV someday, or at least to accomplish long-term remission of the virus absent antiretroviral treatment (ART). Timothy Brown, the 'Berlin Patient', appears to have been completely cured of HIV. Six years after a curative intervention, Brown has no detectable level of the virus, and no need for ART. Patients undergoing a variety of other interventions in France, Boston, and Mississippi developed stable remission of the virus without taking antiretrovirals, typically until a final viral rebound.

While continued ART nearly eliminates morbidity and markedly prolongs life for people living with HIV, ART is treatment, not a cure. Under ART, the virus persists indefinitely in latent reservoirs in the patient's body; upon ART interruption, it rebounds. And even under ART, some co-morbidities, stigma, costs, and burdens continue to affect patients, and life-long treatment cost prevents adequate coverage for the 35 million people living with HIV.1 ,2

An emphasis area for the International AIDS Society and the US National Institutes of Health, work toward a cure and long-term sustainable remission of HIV is currently the focus of 19 completed studies and at least 35 ongoing or planned ones.3 Complementing old, recent, and planned treatment and prevention strategies to fight HIV, these clinical studies work toward the development of either:
:: A literal 'cure' (sometimes called a sterilising cure), namely, eradication of all replication-competent HIV in a patient's body, or:
:: 'Long-term remission', that is, the absence of viral rebound after ART cessation for a period of several years.1

But progress toward a cure and long-term remission comes with a serious ethical challenge.4–6 Many early-phase cure and remission studies would impose substantial risks, uncertainties, and invasive procedures on some participants. Some studies include interventions with high mortality, such as stem cell transplantation. Some include interventions never before tested in (immunocompromised) patients, which are therefore shrouded in complete uncertainty. Some necessitate a clinically-unnecessary interruption of ART in patients who are doing well on ART, potentially leading to morbidity or ART resistance. Some require invasive and clinically-unnecessary exams and biopsies, for example, ones to identify the internal tissue in which latent HIV reservoirs are hiding away from the impact of ART.

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In many areas of medicine, early-phase studies to characterise toxicity and pharmacokinetics involve risks and, very rarely, severe adverse events,[7] with only little hope for clinical effect. But the challenge in HIV cure studies is special. Many patients who consider joining risky early-phase studies for cancer, for instance, are doing poorly, arguably with sound reason to try just about anything. HIV patients tend nowadays to have good alternatives to study participation, namely, remaining on ART. While being cured without side effects would be even better than remaining on ART, severe side effects may accompany having been cured and even without side effects, being cured does not seem medically far superior to being stable on standard ART—to taking one pill a day with small expected morbidity; the superiority of mere durable remission to remaining stable on ART is even smaller.

Compare the use of stem cell transplantation in early-phase HIV cure studies to its occasional use in early-phase studies for chronic diseases with little short-term mortality, such as sickle cell disease,[8] Type I diabetes,[9] chronic granulomatous disease,[10] and thalassaemia.[11] Use of life-risking stem cell transplantation for these chronic diseases was often controversial. While untreated HIV clearly results in serious morbidity and mortality, these chronic diseases may well involve greater morbidity than HIV managed with ART. Since the use of stem cell transplantation for managing these chronic diseases was controversial, its use, and the use of other high-risk strategies, in HIV cure and remission studies pose a serious challenge. Differently put, a small chance of a slight improvement, accompanied by a greater chance of gaining nothing or being severely burdened or harmed, seems on the face of it like a bad 'gamble' for patients. It fails to maximise their medical prospects. A decision to join some early-phase HIV cure and remission trials may appear irrational for patients who are doing well on ART.

Hence, an ethical challenge. We want to identify and hone cure and remission strategies for HIV—we owe as much to patients. But to do so we need study participants, and we must treat these particular patients right too. Is there a way to make trial participation an advantageous 'gamble' for all cure study participants? If not, can these studies remain ethical?

This is not the sheer pragmatic challenge, of how to convince enough patients to join cure- and remission studies. In a recent survey of American HIV patients, a majority expressed willingness to participate in all 14 types of HIV cure study.[12] Though the per cent who would be willing and able to participate will be much smaller for any actual study, early-phase studies require only few participants. Nor is our challenge simply the ethical concern that, subjectively, patients might not fully comprehend the risks of study participation, or that they must be overestimating the medical benefits to them, so they are choosing a perfectly advantageous option non-autonomously.

The challenge is both ethical and objective. It is the concern that in many early-phase HIV cure and remission studies, a standard requirement in research ethics for a favourable benefit/risk ratio is transgressed.[13–15] Are we giving candidate participants a fair 'bargain'? Or are we inviting them to substitute what are objectively rather good medical prospects by worse ones? And if that is what we do when we conduct some early-phase cure and remission studies, are we acting wrongfully, or is this to some degree our prerogative given the vast global need for these interventions? Could we do things differently in these studies and in their administration, to keep them robustly ethical?

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Call this the benefit/risk ratio challenge in early-phase HIV cure- and remission studies.[5] Addressing this challenge is the business of contributions to this JME symposium, guest edited by ethicist Nir Eyal. Discussing a breadth of strategies for coping with this challenge turns out to cast light not only on the way forward in HIV research, but on the philosophical foundations of research ethics in general: What is an acceptable deal for the individuals who participate in our clinical studies? What is unacceptable, even in studies that advance science, healthcare, and human welfare?

The symposium starts with a descriptive background. Cure researcher Daniel Kuritzkes makes the fuller case for seeking a cure for HIV while laying out some of the serious risks to study participants in many early-phase HIV cure studies. HIV clinicians and investigators Paul Sax and Kenneth Freedberg provide greater detail on the likelihood of specific curative strategies, if found effective and safe, to become cost-effective and potentially scalable on a population level. A third piece, by the symposium editor, outlines the rest of the discussion. It catalogues candidate ethical solutions for the benefit/risk ratio challenge to early-phase HIV cure and remission studies. In so doing, it also presents the rest of the symposium. Consequent sections discuss some candidate solutions to the challenge. A short afterward notes wider implications for research ethics.

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Vol 19, No 1 (2017): January
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Volume 65, Issue 12, December 2016
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[Reviewed earlier]

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Volume 3, Issue 4 (2016)
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Journal of the Pediatric Infectious Diseases Society (JPIDS)
Volume 5 Issue 28 January 2017
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[Reviewed earlier]

Journal of Pediatrics
January 2017 Volume 180, p1-300
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Journal of Public Health Policy
Volume 37, Issue 2 Supplement, November 2016
http://link.springer.com/journal/41271/37/2/suppl/page/1
[Reviewed earlier]

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Volume 24, Issue 1, January 2017
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[Reviewed earlier]

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January 2017, volume 91, issue 2
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[Reviewed earlier]

The Lancet
Jan 28, 2017 Volume 389 Number 10067 p331-476
http://www.thelancet.com/journals/lancet/issue/current
Comment
Essential medicines for universal health coverage
Pamela Das, Richard Horton
Summary
Access to medicines has long been a potent flashpoint in global health, from antiretrovirals to drugs that cure hepatitis C. Indeed, as a new Lancet Commission report, Essential Medicines for Universal Health Coverage,1 asserts, essential medicines should be at the centre of our vision for global health, affecting, as they do, the lives and dignity of people worldwide. Led by Veronika Wirtz, Hans Hogerzeil, and Andy Gray, the Commission identifies lessons learned from 30 years of implementing essential medicines policies.

The Lancet Commissions
Essential medicines for universal health coverage
Veronika J Wirtz, Hans V Hogerzeil, Andrew L Gray, Maryam Bigdeli, Cornelis P de Joncheere, Margaret A Ewen, Martha Gyansa-Lutterodt, Sun Jing, Vera L Luiza, Regina M Mbindyo, Helene Möller, Corrina Moucheraud, Bernard Pécoul, Lembit Rägo, Arash Rashidian, Dennis Ross-Degnan, Peter N Stephens, Yot Teerawattananon, Ellen F M 't Hoen, Anita K Wagner, Prashant Yadav, Michael R Reich

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Summary
Essential medicines satisfy the priority health-care needs of the population. Essential medicines policies are crucial to promoting health and achieving sustainable development. Sustainable Development Goal 3.8 specifically mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a central component of Universal Health Coverage (UHC), and Sustainable Development Goal 3.b emphasises the need to develop medicines to address persistent treatment gaps.

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Jan 2017 Volume 5 Number 1 e1-e114
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[Reviewed earlier]

The Lancet Infectious Diseases
Jan 2017 Volume 17 Number 1 p1-116 e1-e29
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[Reviewed earlier]

Maternal and Child Health Journal
Volume 21, Issue 1, January 2017
http://link.springer.com/journal/10995/20/12/page/1
[Reviewed earlier]

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January 2017; 37 (1)
http://mdm.sagepub.com/content/current
[Reviewed earlier]

The Milbank Quarterly
A Multidisciplinary Journal of Population Health and Health Policy
December 2016 Volume 94, Issue 4 Pages 695–928
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[Reviewed earlier]

Nature
Volume 541 Number 7638 pp435-568 6 January 2017
http://www.nature.com/nature/current_issue.html
Editorials
Scientists must fight for the facts
President Trump's unconventional stances cannot go unchallenged.

Vaccine initiative marks bold resolution

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Preparation against future epidemic threats is a welcome and essential move.

Nature Medicine
January 2017, Volume 23 No 1 pp1-135
http://www.nature.com/nm/journal/v23/n1/index.html
[Reviewed earlier]

Nature Reviews Immunology
January 2017 Vol 17 No 1
http://www.nature.com/nri/journal/v16/n12/index.html
[Reviewed earlier]

New England Journal of Medicine
January 26, 2017 Vol. 376 No. 4
http://www.nejm.org/toc/nejm/medical-journal
Original Article
A Recombinant Vesicular Stomatitis Virus Ebola Vaccine
Jason A. Regules, M.D., John H. Beigel, M.D., Kristopher M. Paolino, M.D., Jocelyn Voell, R.N., M.S., Amy R. Castellano, L.P.N., Zonghui Hu, Ph.D., Paula Muñoz, B.S., James E. Moon, M.D., Richard C. Ruck, M.D., Jason W. Bennett, M.D., Patrick S. Twomey, M.D., Ramiro L. Gutiérrez, M.D., Shon A. Remich, M.D., Holly R. Hack, M.S., Meagan L. Wisniewski, Ph.D., Matthew D. Josleyn, M.S., Steven A. Kwilas, Ph.D., Nicole Van Deusen, B.S., Olivier Tshiani Mbaya, M.D., Yan Zhou, Ph.D., Daphne A. Stanley, M.S., Wang Jing, M.S., Kirsten S. Smith, Ph.D., Meng Shi, M.A., Julie E. Ledgerwood, D.O., Barney S. Graham, M.D., Nancy J. Sullivan, Ph.D., Linda L. Jagodzinski, Ph.D., Sheila A. Peel, M.S.P.H., Ph.D., Judie B. Alimonti, Ph.D., Jay W. Hooper, Ph.D., Peter M. Silvera, Ph.D., Brian K. Martin, Ph.D., Thomas P. Monath, M.D., W. Jay Ramsey, M.D., Ph.D., Charles J. Link, M.D., H. Clifford Lane, M.D., Nelson L. Michael, M.D., Ph.D., Richard T. Davey, Jr., M.D., and Stephen J. Thomas, M.D., for the rVSVΔG-ZEBOV-GP Study Group*
N Engl J Med 2017; 376:330-341January 26, 2017DOI: 10.1056/NEJMoa1414216
Abstrat
Background
The worst Ebola virus disease (EVD) outbreak in history has resulted in more than 28,000 cases and 11,000 deaths. We present the final results of two phase 1 trials of an attenuated, replication-competent, recombinant vesicular stomatitis virus (rVSV)–based vaccine candidate designed to prevent EVD.
Full Text of Background...
Methods
We conducted two phase 1, placebo-controlled, double-blind, dose-escalation trials of an rVSV-based vaccine candidate expressing the glycoprotein of a Zaire strain of Ebola virus (ZEBOV). A total of 39 adults at each site (78 participants in all) were consecutively enrolled into groups of 13. At each site, volunteers received one of three doses of the rVSV-ZEBOV vaccine (3 million plaque-forming units [PFU], 20 million PFU, or 100 million PFU) or placebo. Volunteers at one of the sites received a second dose at day 28. Safety and immunogenicity were assessed.
Full Text of Methods...

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Results
The most common adverse events were injection-site pain, fatigue, myalgia, and headache. Transient rVSV viremia was noted in all the vaccine recipients after dose 1. The rates of adverse events and viremia were lower after the second dose than after the first dose. By day 28, all the vaccine recipients had seroconversion as assessed by an enzyme-linked immunosorbent assay (ELISA) against the glycoprotein of the ZEBOV-Kikwit strain. At day 28, geometric mean titers of antibodies against ZEBOV glycoprotein were higher in the groups that received 20 million PFU or 100 million PFU than in the group that received 3 million PFU, as assessed by ELISA and by pseudovirion neutralization assay. A second dose at 28 days after dose 1 significantly increased antibody titers at day 56, but the effect was diminished at 6 months.
Full Text of Results...
Conclusions
This Ebola vaccine candidate elicited anti-Ebola antibody responses. After vaccination, rVSV viremia occurred frequently but was transient. These results support further evaluation of the vaccine dose of 20 million PFU for preexposure prophylaxis and suggest that a second dose may boost antibody responses. (Funded by the National Institutes of Health and others; rVSVΔG-ZEBOV-GP ClinicalTrials.gov numbers, NCT02269423 and NCT02280408.)

Pediatrics
January 2017, VOLUME 139 / ISSUE
http://pediatrics.aappublications.org/content/139/1?current-issue=y
[Reviewed earlier]

Pharmaceutics
Volume 9, Issue 1 (March 2017)
http://www.mdpi.com/1999-4923/9/1
[New issue; No new digest content identified]

PharmacoEconomics
Volume 35, Issue 1, January 2017
http://link.springer.com/journal/40273/35/1/page/1
[Reviewed earlier]

PLOS Currents: Disasters
http://currents.plos.org/disasters/
[Accessed 28 January 2017]
[No new content]

PLoS Currents: Outbreaks
http://currents.plos.org/outbreaks/
[Accessed 28 January 2017]
Research Article

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Rapid Molecular Detection of Zika Virus in Acute-Phase Urine Samples Using the Recombinase Polymerase Amplification Assay
January 25, 2017 ·
Background: Currently the detection of Zika virus (ZIKV) in patient samples is done by real-time RT-PCR. Samples collected from rural area are sent to highly equipped laboratories for screening. A rapid point-of-care test is needed to detect the virus, especially at low resource settings.
Methodology/Principal Findings: In this report, we describe the development of a reverse transcription isothermal recombinase polymerase amplification (RT-RPA) assay for the identification of ZIKV. RT-RPA assay was portable, sensitive (21 RNA molecules), and rapid (3-15 minutes). No cross-reactivity was detected to other flaviviruses, alphaviruses and arboviruses. Compared to real-time RT-PCR, the diagnostic sensitivity was 92%, while the specificity was 100%.
Conclusions/Significance: The developed assay is a promising platform for rapid point of need detection of ZIKV in low resource settings and elsewhere (e.g. during mass gathering).

PLoS Medicine
http://www.plosmedicine.org/
(Accessed 28 January 2017)
Health in Action
Bolstering Community Cooperation in Ebola Resurgence Protocols: Combining Field Blood Draw and Point-of-Care Diagnosis
Mosoka P. Fallah, Laura A. Skrip, Philomena Raftery, Miata Kullie, Watta Borbor, A. Scott Laney, David J. Blackley, Athalia Christie, Emily Kainne Dokubo, Terrence Q. Lo, Stewart Coulter, April Baller, Benjamin T. Vonhm, Philip Bemah, Sowillie Lomax, Adolphus Yeiah, Yatta Wapoe-Sackie, Jennifer Mann, Peter Clement, Gloria Davies-Wayne, Esther Hamblion, Caitlin Wolfe, Desmond Williams, Alex Gasasira, Francis Kateh, Tolbert G. Nyenswah, Alison P. Galvani
| published 24 Jan 2017 PLOS Medicine
http://dx.doi.org/10.1371/journal.pmed.1002227

PLoS Neglected Tropical Diseases
http://www.plosntds.org/
(Accessed 28 January 2017)
Research Article
A Comparison of the Quality of Informed Consent for Clinical Trials of an Experimental Hookworm Vaccine Conducted in Developed and Developing Countries
David J. Diemert, Lucas Lobato, Ashley Styczynski, Maria Zumer, Amanda Soares, Maria Flávia Gazzinelli
| published 23 Jan 2017 PLOS Neglected Tropical Diseases
http://dx.doi.org/10.1371/journal.pntd.0005327
[Uncorrected proof]
Abstract
Informed consent is one of the principal ethical requirements of conducting clinical research, regardless of the study setting. Breaches in the quality of the informed consent process are frequently described in reference to clinical trials conducted in developing countries, due to low levels of formal education, a lack of familiarity with biomedical research, and limited access to

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health services in these countries. However, few studies have directly compared the quality of the informed consent process in developed and developing countries using the same tool and in similar clinical trials. This study was conducted to compare the quality of the informed consent process of a series of clinical trials of an investigational hookworm vaccine that were performed in Brazil and the United States. A standardized questionnaire was used to assess the ethical quality of the informed consent process in a series of Phase 1 clinical trials of the Na-GST-1/Alhydrogel hookworm vaccine that were conducted in healthy adults in Brazil and the United States. In Brazil, the trial was conducted at two sites, one in the hookworm non-endemic urban area of Belo Horizonte, Minas, and one in the rural, resource-limited town of Americaninhas, both in the state of Minas Gerais; the American trial was conducted in Washington, DC. A 32-question survey was administered after the informed consent document was signed at each of the three trial sites; it assessed participants' understanding of information about the study presented in the document as well as the voluntariness of their decision to participate. 105 participants completed the questionnaire: 63 in Americaninhas, 18 in Belo Horizonte, and 24 in Washington, DC. Overall knowledge about the trial was suboptimal: the mean number of correct answers to questions about study objectives, methods, duration, rights, and potential risks and benefits, was 45.6% in Americaninhas, 65.2% in Belo Horizonte, and 59.1% in Washington, DC. Although there was no difference in the rate of correct answers between participants in Belo Horizonte and Washington, DC, there was a significant gap between participants at these two locations compared to Americaninhas ($p = 0.0002$ and $p = 0.0001$, respectively), which had a lower percentage of correct answers. Attitudes towards participating in the clinical trial also differed by site: while approximately 40% had doubts about participating in Washington, DC and Belo Horizonte, only 1.5% had concerns in Americaninhas. Finally, in Belo Horizonte and Washington, high percentages cited a desire to help others as motivation for participating, whereas in Americaninhas, the most common reason for participating was personal interest ($p = 0.001$). Understanding of information about a Phase 1 clinical trial of an experimental hookworm vaccine following informed consent was suboptimal, regardless of study site. Although overall there were no differences in knowledge between Brazil and the US, a lower level of understanding about the trial was seen in participants at the rural, resource-limited Brazilian site. These findings demonstrate the need for educational interventions directed at potential clinical trial participants, both in developing and developed countries, in order to improve understanding of the informed consent document.

Author Summary

Informed consent is an essential element of the ethical conduct of clinical trials of new vaccines, regardless of the study setting. However, the quality of informed consent is often suboptimal. Some research has suggested that the quality of the informed consent process may be reduced in resource-limited areas compared to developed country settings. To test this, we conducted a study of the quality of the informed consent process in two similar Phase 1 clinical trials of the Na-GST-1/Alhydrogel hookworm vaccine that were conducted in healthy adult volunteers in Brazil and in the United States. In Brazil, the trial was conducted at two sites, one a large urban area (Belo Horizonte), and the other a rural, resource-limited region of the state of Minas Gerais; in the United States, the trial was conducted in Washington, DC. A structured questionnaire was administered after the informed consent document was signed at each of the three clinical trial sites, which tested understanding about the information contained in the document and attitudes toward the volunteers' participation in the clinical trial. The results indicate that there were no substantial differences between the overall quality of the informed consent obtained from participants in the United States and in Brazil. However, a significant

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association was found between the particular site where the trial was conducted and the quality of the informed consent process, with residents of the site in rural Brazil having the lowest percentage of correct answers on the informed consent questionnaire. The informed consent process should therefore take into account the specific characteristics of the population in which the trial is being conducted.

PLoS One
http://www.plosone.org/
[Accessed 28 January 2017]
Research Article

Justice Is the Missing Link in One Health: Results of a Mixed Methods Study in an Urban City State

Tamra Lysaght, Benjamin Capps, Michele Bailey, David Bickford, Richard Coker, Zohar Lederman, Sangeetha Watson, Paul Anantharajah Tambyah
Research Article | published 27 Jan 2017 PLOS ONE

Abstract
Background
One Health (OH) is an interdisciplinary collaborative approach to human and animal health that aims to break down conventional research and policy 'silos'. OH has been used to develop strategies for zoonotic Emerging Infectious Diseases (EID). However, the ethical case for OH as an alternative to more traditional public health approaches is largely absent from the discourse. To study the ethics of OH, we examined perceptions of the human health and ecological priorities for the management of zoonotic EID in the Southeast Asia country of Singapore.
Methods
We conducted a mixed methods study using a modified Delphi technique with a panel of 32 opinion leaders and 11 semi-structured interviews with a sub-set of those experts in Singapore. Panellists rated concepts of OH and priorities for zoonotic EID preparedness planning using a series of scenarios developed through the study. Interview data were examined qualitatively using thematic analysis.
Findings
We found that panellists agreed that OH is a cross-disciplinary collaboration among the veterinary, medical, and ecological sciences, as well as relevant government agencies encompassing animal, human, and environmental health. Although human health was often framed as the most important priority in zoonotic EID planning, our qualitative analysis suggested that consideration of non-human animal health and welfare was also important for an effective and ethical response. The panellists also suggested that effective pandemic planning demands regional leadership and investment from wealthier countries to better enable international cooperation.
Conclusion
We argue that EID planning under an OH approach would benefit greatly from an ethical ecological framework that accounts for justice in human, animal, and environmental health.

Influenza Vaccination of Healthcare Workers Is an Important Approach for Reducing Transmission of Influenza from Staff to Vulnerable Patients

Andrew C. Hayward
Formal Comment | published 27 Jan 2017 PLOS ONE
http://dx.doi.org/10.1371/journal.pone.0169023

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Influenza Vaccination of Healthcare Workers: Critical Analysis of the Evidence for Patient Benefit Underpinning Policies of Enforcement
Gaston De Serres, Danuta M. Skowronski, Brian J. Ward, Michael Gardam, Camille Lemieux, Annalee Yassi, David M. Patrick, Mel Krajden, Mark Loeb, Peter Collignon, Fabrice Carrat
Research Article | published 27 Jan 2017 PLOS ONE
http://dx.doi.org/10.1371/journal.pone.0163586

Barriers of Influenza Vaccination Intention and Behavior – A Systematic Review of Influenza Vaccine Hesitancy, 2005 – 2016
Philipp Schmid, Dorothee Rauber, Cornelia Betsch, Gianni Lidolt, Marie-Luisa Denker
Research Article | published 26 Jan 2017 PLOS ONE
http://dx.doi.org/10.1371/journal.pone.0170550
Abstract
Background
Influenza vaccine hesitancy is a significant threat to global efforts to reduce the burden of seasonal and pandemic influenza. Potential barriers of influenza vaccination need to be identified to inform interventions to raise awareness, influenza vaccine acceptance and uptake.
Objective
This review aims to (1) identify relevant studies and extract individual barriers of seasonal and pandemic influenza vaccination for risk groups and the general public; and (2) map knowledge gaps in understanding influenza vaccine hesitancy to derive directions for further research and inform interventions in this area.
Methods
Thirteen databases covering the areas of Medicine, Bioscience, Psychology, Sociology and Public Health were searched for peer-reviewed articles published between the years 2005 and 2016. Following the PRISMA approach, 470 articles were selected and analyzed for significant barriers to influenza vaccine uptake or intention. The barriers for different risk groups and flu types were clustered according to a conceptual framework based on the Theory of Planned Behavior and discussed using the 4C model of reasons for non-vaccination.
Results
Most studies were conducted in the American and European region. Health care personnel (HCP) and the general public were the most studied populations, while parental decisions for children at high risk were under-represented. This study also identifies understudied concepts. A lack of confidence, inconvenience, calculation and complacency were identified to different extents as barriers to influenza vaccine uptake in risk groups.
Conclusion
Many different psychological, contextual, sociodemographic and physical barriers that are specific to certain risk groups were identified. While most sociodemographic and physical variables may be significantly related to influenza vaccine hesitancy, they cannot be used to explain its emergence or intensity. Psychological determinants were meaningfully related to uptake and should therefore be measured in a valid and comparable way. A compendium of measurements for future use is suggested as supporting information.

PLoS Pathogens
http://journals.plos.org/plospathogens/
[No new digest content identified]

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PNAS - Proceedings of the National Academy of Sciences of the United States of America
http://www.pnas.org/content/early/
[Accessed 28 January 2017]
[No new digest content identified]

Prehospital & Disaster Medicine
Volume 31 - Issue 6 - December 2016
https://www.cambridge.org/core/journals/prehospital-and-disaster-medicine/latest-issue
[Reviewed earlier]

Preventive Medicine
Volume 94, Pages 1-72 (January 2017)
http://www.sciencedirect.com/science/journal/00917435/94
[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
[No new digest content identified]

Public Health Ethics
Volume 9, Issue 3 November 2016
http://phe.oxfordjournals.org/content/current
[Reviewed earlier]

Public Health Reports
Volume 132, Issue 1, January/February 2017
http://phr.sagepub.com/content/current
[Reviewed earlier]

Qualitative Health Research
Volume 27, Issue 2, January 2017
http://qhr.sagepub.com/content/current
Special Issue: Violence
[Reviewed earlier]

Reproductive Health
http://www.reproductive-health-journal.com/content

:

[Accessed 28 January 2017]
[No relevant content identified]

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

Risk Analysis
December 2016 Volume 36, Issue 12 Pages 2187–2314
http://onlinelibrary.wiley.com/doi/10.1111/risa.2017.36.issue-12/issuetoc
[New issue; No new relevant content identified]

Risk Management and Healthcare Policy
Volume 9, 2016
https://www.dovepress.com/risk-management-and-healthcare-policy-archive56
[Reviewed earlier]

Science
28 January 2017 Vol 355, Issue 6323
http://www.sciencemag.org/current.dtl
[New issue; No new relevant content identified]

Science Translational Medicine
25 January 2017 Vol 9, Issue 374
http://stm.sciencemag.org/
[New issue; No new relevant content identified]

Social Science & Medicine
Volume 171, Pages 1-102 (December 2016)
http://www.sciencedirect.com/science/journal/02779536/170
[Reviewed earlier]

Travel Medicine and Infectious Diseases
November-December, 2016 Volume 14, Issue 6
http://www.travelmedicinejournal.com/
[Reviewed earlier]

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Tropical Medicine & International Health
January 2017 Volume 22, Issue 1 Pages 1–121
http://onlinelibrary.wiley.com/doi/10.1111/tmi.2017.22.issue-1/issuetoc
[Reviewed earlier]

Vaccine
Volume 35, Issue 5, Pages 713-850 (1 February 2017)
http://www.sciencedirect.com/science/journal/0264410X/35/5
Regular papers
Writing a scientific paper—A brief guide for new investigators
Original Research Article
Pages 722-728
Caroline L. Vitse, Gregory A. Poland
Abstract
When applying for funding, researchers must demonstrate their productivity. For most funding organizations, a key measure of productivity is the number of papers published. The road to publication is rarely straightforward; few journals provide practical guidance to researchers who are struggling to publish their data. Here, we outline the sections of a research paper and describe practical steps in each part of the publication process as an aid to newer authors.

Evaluating the first introduction of rotavirus vaccine in Thailand: Moving from evidence to policy
Original Research Article
Pages 796-801
Piyanit Tharmaphornpilas, Suchada Jiamsiri, Somchit Boonchaiya, Onwipa Rochanathimoke, Wiravan Thinyounyong, Sumana Tuntiwitayapun, Ratigorn Guntapong, Arthorn Riewpaiboon, Aim-on Rasdjarmrearnsook, Roger I. Glass
Abstract
Background
We assessed the effectiveness and possible impact of introducing rotavirus vaccine into the routine immunization program.
Methods
Two provinces were selected for an observational study, one where vaccine was introduced and another where vaccine was not available. In these areas, two sub-studies were linked. The prospective cohort study enrolled children 2 month old and followed them to the age of 18 months to detect all diarrhea episodes. The hospital surveillance study enrolled all children up to age 5 hospitalized with diarrhea whose fecal samples were tested for rotavirus. Rates of rotavirus hospitalizations in older children who had not been vaccinated in both settings provided data to determine whether immunization had an indirect herd effect. The key endpoints for the study were both vaccine effectiveness (VE) based upon hospitalized rotavirus diarrhea and herd protection.
Findings
From the cohort study, the overall VE for hospitalized rotavirus diarrhea was 88% (95%CI 76–94). Data from hospital surveillance indicated that for 2 consecutive years, the seasonal peak of rotavirus admissions was no longer present in the vaccinated area. Herd protection was observed among older children born before the rotavirus vaccine program was introduced, who experienced a 40–69% reduction in admission for rotavirus.

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Conclusions
Rotavirus vaccine was highly effective in preventing diarrheal hospitalizations and in conferring herd protection among older children who had not been vaccinated.

Associations of trust and healthcare provider advice with HPV vaccine acceptance among African American parents

Original Research Article
Pages 802-807
Linda Y. Fu, Gregory D. Zimet, Carl A. Latkin, Jill G. Joseph
Abstract
Objective
Healthcare providers (HCPs) are advised to give all parents a strong recommendation for HPV vaccination. However, it is possible that strong recommendations could be less effective at promoting vaccination among African Americans who on average have greater mistrust in the healthcare system. This study examines the associations of parental trust in HCPs and strength of HCP vaccination recommendation on HPV vaccine acceptance among African American parents.
Methods
Participants were recruited from an urban, academic medical center between July 2012 and July 2014. We surveyed 400 African American parents of children ages 10–12 years who were offered HPV vaccine by their HCPs to assess sociodemographic factors, vaccine beliefs, trust in HCPs, and the HPV vaccine recommendation received. Medical records were reviewed to determine vaccination receipt.
Results
In multivariable analysis, children whose parents were "very strongly" recommended the HPV vaccine had over four times higher odds of vaccine receipt compared with those whose parents were "not very strongly" recommended the vaccine. Having a parent with "a lot of" versus "none" or only "some" trust in HCPs was associated with over twice the odds of receiving HPV vaccine. Very strong HCP recommendations were associated with higher odds of vaccination among all subgroups, including those with more negative baseline attitudes toward HPV vaccine and those with lower levels of trust. Adding the variables strength of HCP recommendation and parental trust in HCPs to a multivariable model already adjusted for sociodemographic factors and parental vaccine beliefs improved the pseudo R2 from 0.52 to 0.55.
Conclusions
Among participants, receiving a strong vaccine recommendation and having a higher level of trust in HCPs were associated with higher odds of HPV vaccination, but did not add much to the predictive value of a model that already adjusted for baseline personal beliefs and sociodemographic factors.

Text messages for influenza vaccination among pregnant women: A randomized controlled trial

Original Research Article
Pages 842-848
Mark H. Yudin, Niraj Mistry, Leanne R. De Souza, Kate Besel, Vishal Patel, Sonia Blanco Mejia, Robyn Bernick, Victoria Ryan, Marcelo Urquia, Richard H. Beigi, Michelle H. Moniz, Michael Sgro
Abstract
Objective

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To evaluate if text message reminders increase the likelihood of receiving the influenza vaccine among pregnant women.
Methods
Pregnant women were randomized to either receive or not receive weekly text messages. Women were told the messages would be about health-related behavior in pregnancy. Those randomized to the intervention group received two messages weekly for four consecutive weeks reinforcing that the influenza vaccine is recommended for all pregnant women and safe during pregnancy and breastfeeding. Women were contacted six weeks postpartum to determine if they had received the vaccine. Sample size calculation determined that 108 women were required in both groups to see a 75% increase in vaccination rates over baseline in the text message group compared to the control group.
Results
Recruitment began November 4, 2013, and 317 women were randomized. The mean gestational age at recruitment was 22 weeks. There were 40/129 (31%) women in the text message group and 41/152 (27%) women in the control group who received the vaccine ($p = 0.51$). Significant predictors of vaccine acceptance were being married compared to single (95% vs. 67%, $p < 0.001$), having higher household income (55% vs. 39%, $p = 0.03$) and having received the vaccine before (77% vs. 36%, $p < 0.001$). Among women receiving text messages, the majority were satisfied, with only 15/129 (12%) reporting that they did not like receiving the messages, and 24/129 (19%) stating that the information in the messages was not helpful.
Conclusion
Weekly text messages reinforcing the recommendation for and safety of the influenza vaccine in pregnancy did not increase the likelihood of actually receiving the vaccine among pregnant women. Overall vaccination rates were low, highlighting the need for patient education and innovative techniques to improve vaccine acceptance.
Registered with ClinicalTrials.gov at http://www.clinicaltrials.gov, registration number NCT 02428738.

Vaccine: Development and Therapy
https://www.dovepress.com/vaccine-development-and-therapy-archive111
(Accessed 28 January 2017)
[No new content]

Vaccines — Open Access Journal
http://www.mdpi.com/journal/vaccines
(Accessed 28 January 2017)
[No new relevant content identified]

Value in Health
December 2016 Volume 19, Issue 8, p909-1074
http://www.valueinhealthjournal.com/current
[Reviewed earlier]

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

No new content identified.

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Media/Policy Watch

This watch section is intended to alert readers to substantive news, analysis and opinion from the general media and selected think tanks and similar organizations 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 28 January 2017

BBC
http://www.bbc.co.uk/
Accessed 28 January 2017
Brazil orders 11.5 million yellow fever vaccine doses
26 January 2017
Brazil's health ministry has ordered 11.5 million doses of yellow fever vaccine amid the largest outbreak of the disease in the country since 2000.
Seventy cases - including 40 deaths - are confirmed, mostly in rural areas of the state of Minas Gerais. More than 300 cases are under investigation.
Vaccinations are being recommended for people travelling to Minas and other areas with confirmed cases…

The Economist
http://www.economist.com/
Accessed 28 January 2017
[No new, unique, relevant content]

Financial Times
http://www.ft.com/home/uk
Accessed 28 January 2017
[No new, unique, relevant content]

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Forbes
http://www.forbes.com/
Accessed 28 January 2017
Letting Seriously Ill Patients Try Drugs Whose Safety, Efficacy Hasn't Been Proven Could Be Deadly
Rita Rubin, Contributor
Critics of the Food and Drug Administration, including at least one person under consideration to serve as its commissioner, accuse the agency of unnecessarily dragging out the drug approval process at a cost to both manufacturers and desperately ill patients.
But a new FDA report makes the point that the early promise of experimental treatments doesn't always pan out. The report includes examples of 16 drugs, five vaccines and one device, a heart stent, that appeared to be safe and effective in phase 2 trials, which usually involve a few hundred patients, but failed on one or both counts in much larger, more rigorous phase 3 trials…

Foreign Affairs
http://www.foreignaffairs.com/
Accessed 28 January 2017
[No new, unique, relevant content]

Foreign Policy
http://foreignpolicy.com/
Accessed 28 January 2017
Deadly Yellow Fever Outbreak in Brazil Sparks Fears of Zika-Like Epidemic
23 January 2017
By Robbie Gramer
… Brazil has recorded 25 deaths, 47 cases, and 160 suspected cases of yellow fever as of Monday. "The introduction of the virus in these areas could potentially trigger large epidemics of yellow fever," the World Health Organization (WHO) warned in a statement released on Jan. 13 as the outbreak first emerged.
The WHO is concerned yellow fever could quickly spread from the outbreak's ground zero to other states in the north and west because of the region's low rates of vaccinations and mosquito-friendly environments. The governor of Minas Gerais declared a state of emergency, while the Brazilian Ministry of Health deployed technical teams to respond to and surveil the outbreak. The WHO said the Zika virus "further complicated" Brazil's response to the yellow fever outbreak…

The Guardian
http://www.guardiannews.com/
Accessed 28 January 2017
[No new, unique, relevant content]

New Yorker
http://www.newyorker.com/
Accessed 28 January 2017
[No new, unique, relevant content]

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New York Times
http://www.nytimes.com/
Accessed 28 January 2017
China Jails Two Over Vaccine Scandal
January 24, 2017 - By REUTERS
BEIJING — A court in China on Tuesday jailed two people for selling vaccines without a license, state media said, after a scandal last year that sparked public anger.
The case, involving possibly as much as $90 million of illegal trades of vaccines through a black market drugs ring, underscored regulatory weaknesses in the world's second largest pharmaceuticals market.
The court in Jinan city sentenced Pang Hongwei to 15 years in prison for illegally purchasing vaccines, including rabies vaccines, which she stored in warehouses in Jinan and another city, before selling them around China, Xinhua news agency said.
Pang improperly stored the vaccines she bought, and earned nearly 75 million yuan ($10.93 million) from selling them, Xinhua added.
She was also given another six years for a previous accusation of illegally trading vaccines, and so will serve a total of 19 years, the news agency said.

Wall Street Journal
http://online.wsj.com/home-page?_wsjregion=na,us&_homepage=/home/us
Accessed 28 January 2017
Business
Latest Bout of Bird Flu Threatens U.S. Poultry Flocks
By Kelsey Gee
Jan. 26, 2017 10:24 pm ET
Avian influenza is spreading rapidly across Europe and Asia, roiling the global poultry industry as farmers destroy millions of infected birds…

Washington Post
http://www.washingtonpost.com/
Accessed 28 January 2017
[No new, unique, relevant content]

Think Tanks et al

Brookings
http://www.brookings.edu/
Accessed 28 January 2017
[No new relevant content]

Center for Global Development
http://www.cgdev.org/page/press-center
Accessed 28 January 2017
A Global Treaty to Reduce Antimicrobial Use in Livestock
1/25/17
Kimberly Ann Elliott , Charles Kenny and Janeen Madan

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While the misuse of antimicrobials in human health is a key factor accelerating the emergence of drug resistance, we should not overlook the role of agriculture. This paper makes the case for a global treaty to reduce antimicrobial use in livestock.

Council on Foreign Relations
http://www.cfr.org/
Accessed 28 January 2017
[No new relevant content]

CSIS
https://www.csis.org/
Accessed 28 January 2017
[No new relevant content]

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CVEP is a program of the GE2P2 Global Foundation – whose purpose and mission is to advance ethical and scientific rigor in research and evidence generation for governance, policy and practice in health, human rights action, humanitarian response, heritage stewardship, education and sustainable development – serving governments, international agencies, INGOs, civil society organizations (CSOs), commercial entities, consortia and alliances. CVEP maintains an academic affiliation with the Division of Medical Ethics, NYU School of Medicine, and an operating affiliation with the Vaccine Education Center of Children's Hospital of Philadelphia [CHOP].

Support for this service is provided by the Bill & Melinda Gates Foundation; Aeras; PATH; the International Vaccine Institute (IVI); and industry resource members Crucell/Janssen/J&J, Pfizer, PRA Health Sciences, Sanofi Pasteur U.S.,Takeda, Valera (list in formation), and the Developing Countries Vaccine Manufacturers Network (DCVMN).

Support is also provided by a growing list of individuals who use this membership service to support their roles in public health, clinical practice, government, NGOs and other international institutions, academia and research organizations, and industry.

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