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

This weekly digest targets news, events, announcements, articles and research in the vaccine and global health ethics and policy space and is aggregated from key governmental, NGO, international organization and industry sources, key peer-reviewed journals, and other media channels. This summary proceeds from the broad base of themes and issues monitored by the Center for Vaccine Ethics & Policy in its work: it is not intended to be exhaustive in its coverage.

*Vaccines and Global Health: The Week in Review is also **posted in pdf form** and as a set of blog posts at http://centerforvaccineethicsandpolicy.wordpress.com/. This blog allows full-text searching of over 8,000 entries.*

Comments and suggestions should be directed to
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Center for Vaccine Ethics & Policy
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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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Milestones

UNICEF - Supply of children's five-in-one vaccine secured at lowest-ever price
GENEVA, 19 October 2016 – Breakthrough prices have been achieved with six vaccine suppliers who offered to price pentavalent vaccine at 84 cents a dose average – half the price that the UN children's agency currently pays.

In the next three years, UNICEF will buy 450 million doses to send to 80 countries. Four hundred million doses will be allocated to Gavi-supported and transitioning countries. The vaccine will protect tens of millions of children from potentially deadly infections caused by diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae type b.

Since 2001, strong collaboration on market shaping across Gavi Alliance partners, including the Bill & Melinda Gates Foundation, WHO and UNICEF, has achieved an affordable and sustainable pentavalent vaccine supply for children in the world's poorest countries.

The new pricing can also be accessed by governments who self-finance procurement of this cost-effective vaccine. It will generate over $366 million in savings for donors and for governments.

"Ninety per cent of the world's children under five who die from vaccine-preventable diseases live in countries whose vaccine supply is no longer fully funded by donors," said Shanelle Hall, Director of UNICEF's supply and procurement headquarters. "For the most vulnerable children in the world, pricing can make a difference between life and death," Hall added.

"Gavi estimates that 5.7 million deaths will be averted thanks to pentavalent vaccination in Gavi-supported countries between 2011 and 2020," said Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance. "The market for five-in-one vaccines is now a lot healthier than it was just a few years ago thanks to our collective efforts to grow a base of vaccine suppliers. We remain committed to making vaccine markets work better for the world's poorest countries to ensure immunization investments and efforts are sustainable for all."

Achieving milestones in making vaccines more affordable illustrates how collaborative engagement, including with vaccine suppliers, can result in vaccine markets that put children's health first.

Careful monitoring of supply and demand in vaccine markets and consultations with vaccine manufacturers have helped determine the most effective actions to secure sufficient production levels and efficiencies of scale. Between 2001 and 2015, UNICEF's pentavalent vaccine procurement jumped from 14.5 million to more than 235 million doses, mainly driven by the increase in demand in countries supported by Gavi.

Broadening the supplier base reduces the risk of supply shortages and other serious market constraints that could negatively impact children. Collaboration between Gavi, the Gates Foundation and UNICEF leveraged the significant donor funding and through multi-year supplier contracts, improved demand forecasts and special contracting terms, helped grow the pentavalent vaccine supplier base from one in 2001 to six by 2016, and reduce prices.

As additional manufacturers become interested in supplying vaccines to UNICEF, competition between them intensifies. Since 2011, UNICEF publishes the prices of all vaccines it procures, giving manufacturers the advantage of seeing what their competitors charge – and this had led to better offers. By 2016, the price for donor-funded and government self-funded pentavalent vaccines was an average of $1.65 a dose.

In 2016, a competitive pentavalent vaccine market and excess supply capacity represented ideal conditions to launch a new phased approach to tendering.

In the first phase, UNICEF invited interested suppliers to submit a proposed price. After making awards to the most competitive bids, UNICEF published prices and launched a second request for proposals, which gave time for suppliers to sharpen their initial offers. The final awards achieved lowest ever pricing while sustaining a healthy supply market for the longer-term.

"Today's announcement demonstrates that partnerships can bring affordability and price sustainability to the table in supplier discussions, and this is transforming health outcomes for children," said Hall.

Gavi [to 22 October 2016]
http://www.gavi.org/library/news/press-releases/
19 October 2016
Millions more children to be protected from five diseases thanks to new vaccine supply agreement
5-in-1 pentavalent vaccine will come from a broad base of manufacturers at half the 2016 average price for the next three years.
Geneva, 19 October 2016 – Gavi, the Vaccine Alliance, welcomes the results of the UNICEF pentavalent vaccine tender that will secure sufficient supplies for the next three years to protect millions of children in Gavi-supported and transitioning countries. Moreover, pentavalent vaccine - a cornerstone of routine immunisation programmes – will be accessible from a broad base of manufacturers at less than US$1: half this year's average price…

Since Gavi's inception close to 300 million children have been reached with the vaccine and all 73 countries supported by the Alliance had introduced pentavalent vaccine by the end of 2014.

"Preventing illness through immunisation can have a huge impact on the social and economic well-being of individuals, families, communities and countries," added Dr Berkley. "The vaccine industry is a vital partner in ensuring that sufficient quantities of quality vaccines are available at affordable prices so that countries and donors implement sustainable immunisation programmes, increase coverage and promote equitable access to vaccines."…

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WHO seeks new mechanism for crisis vaccine supplies at low cost
Reuters
Oct 19, 2016
By Kate Kelland | LONDON

The World Health Organization, drugmakers and humanitarian groups are hammering out details of a new vaccine supply system aimed at getting vital shots to vulnerable people in crises such as wars or natural disasters.

The mechanism, which so far has British drugmaker GlaxoSmithKline signed up to provide its pneumonia vaccine at the lowest possible price, will ask other major pharmaceutical firms including Pfizer and Merck to make similar cut-price agreements for emergencies only.

"The idea is that this will set a model in place for other manufacturers to put their vaccines on the table," said Greg Elder, a medical coordinator with the international charity Medecins Sans Frontieres (MSF) which joined talks on the issue at the WHO's Geneva headquarters last week. A spokesman for the WHO said the humanitarian vaccine mechanism - which would only be used in crisis situations - could mean reaching millions of vulnerable people with protective shots against potential killers such as measles, yellow fever and pneumonia.

For now, GSK has pledged to make its PCV-10 vaccine for pneumococcal infection available at its lowest possible price, he said, and other manufacturers are considering which of their shots might also be included.

Signing up would mean drugmakers agreeing to supply the shots at a price equivalent to that paid by the United Nations children's fund UNICEF for vaccines supplied under the GAVI Vaccines Alliance to low and middle-income countries who can't afford to pay full price.

Yet unlike GAVI, the cheaper emergency vaccines would be accessible only to non-governmental organizations such as MSF and other charities and humanitarian groups - not to health ministries or national authorities.

This, said MSF's Elder, will ensure drugmakers are not exposed to having to supply large quantities of vaccines at rock-bottom prices that could dent their profits.

"We're talking about a very specific cohort - refugees, displaced populations, people who have gone through a lot of trauma and have had to flee their homes," Elder said.

"It's a small group of people who are caught in the middle of emergencies and can fall through the gaps. And it's a minute fraction of their (the drug companies') global market."

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Developing Countries Vaccine Manufacturers Network (DCVMN), who took part in the talks "expressed great interest" and said they would take the idea to their members, according to Noni MacDonald, an immunization specialist and professor of pediatrics at Canada's Dalhousie Medical School, who chaired the meeting.

Philippe Duclos, a senior WHO expert on immunization, said the hope is that the mechanism will ultimately cover some 23 shots against diseases ranging from cholera to rabies to polio to hepatitis to yellow fever.

"Of course some vaccines are more important in certain emergencies than in others," he said. "What we need is to rationalize, quickly, in each emergency, which ones are needed."

MacDonald said that while there is a way to go to agree prices and supplies, she is confident that starting with GSK's pneumococcal shot will show how the system can work for others. "It's rare to have such disparate groups come together so solidly to support the way forward," she told Reuters.

"It's going to take a lot of effort and education to make this process work, but we're all agreed it's important – and failure to deliver is not an option because lives depend upon getting this done right.

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European Medicines Agency [to 22 October 2016]
http://www.ema.europa.eu/
20/10/2016
Opening up clinical data on new medicines
EMA provides public access to clinical reports
As of today, the European Medicines Agency (EMA) gives open access to clinical reports for new medicines for human use authorised in the European Union (EU).

Vytenis Andriukaitis, European Commissioner for Health and Food Safety, said "Transparency is an essential component in clinical research. Its outcome – whether positive or negative – should be made publicly available. EMA's transparency initiative will make Europe a true front runner with respect to release of data concerning clinical trials. It will create a bridge from now until the new Clinical Trials Regulation - which foresees additional milestones towards transparency, becomes applicable."

For every new medicine, citizens, including researchers and academics, will be able to directly access thousands of pages from clinical reports submitted by pharmaceutical companies to EMA in the context of marketing-authorisation applications. Clinical reports give information on the methods used and results of clinical trials conducted on medicines. EMA is the first regulatory authority worldwide to provide such broad access to clinical data.

"Transparency on clinical data is a longstanding commitment from EMA and today, we are delivering on our promise to give access to the data on which our recommendations are based", explained EMA's Executive Director Guido Rasi. "Our initiative has shaped the global debate towards more transparency. It will benefit academic research and the practice of medicine as a whole."

With EMA's proactive approach to providing access to the data, patients and healthcare professionals will be able to find out more information about the data underpinning the approval of medicines they are taking or prescribing.

It will also facilitate the independent re-analysis of data by academics and researchers after a medicine has been approved. This will increase scientific knowledge, and potentially further inform regulatory decision making in the future.

Increased transparency will also benefit innovation. The shared knowledge about a medicine helps developers learn from the experience of others and can lead to more efficient medicine development programmes.

"Patients and clinicians have been waiting a long time for clinical trial data. This new approach will at last provide transparent information on all results of clinical trials, positive or negative, as submitted to the EMA", commented Yann Le Cam, Chief Executive Officer of EURORDIS-Rare Diseases Europe and member of the EMA's Management Board. "We expect this to enhance trust in the medicines approval system. Access to this new knowledge base can help to accelerate innovation by reducing duplication of research and de-risking some new developments."…

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Emergencies

WHO Grade 3 Emergencies [to 22 October 2016]
Iraq - *No new announcements identified.*
Nigeria
:: Early warnings on disease outbreaks guide response in Nigeria
20 October 2016 – WHO has rapidly expanded and strengthened disease detection and response in support of the Government of Nigeria's response to the humanitarian crisis in north eastern Nigeria, where 3.7 million people are in need of health assistance. Within two weeks of scaling up its emergency response in late August 2016, WHO rolled out its Early Warning Alert Response System in 56 health facilities in Borno state.
eastern Nigeria, where 3.7 million people are in need of health assistance.
South Sudan - *No new announcements identified.*
The Syrian Arab Republic - *No new announcements identified.*
Yemen
:: Yemen cholera outbreak: WHO and partners urgently require US$ 22.35 million to save lives and reduce suffering
18 October 2016 – The World Health Organization and health partners urgently require support from the international donor community to contain the spread of acute watery diarrhoea/cholera in Yemen. A total of US$ 22.35 million is required by the Health and Water, Sanitation and Hygiene clusters, of which US$ 16.6 million is immediately required.
[Editor's Note: No mention of OCV]

WHO Grade 2 Emergencies [to 22 October 2016]
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 - 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 –
:: Statement on Iraq [Mosul] - UN Humanitarian Chief 16 Oct 2016
Syria
- *No new announcements identified.*
Yemen
:: Yemen Humanitarian Bulletin Issue 16 | As of 30 September 2016 18 Oct 2016

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Mosul

UNOG- REGULAR PRESS BRIEFING BY THE INFORMATION SERVICE
21 October 2016
[Editor's text bolding]
Mosul
…Tarik Jasarevic, for the World Health Organization (WHO), said that WHO was planning for interventions in and around Mosul. WHO had just conducted a two-day planning exercise together with senior officials from the Federal Ministry of Health and humanitarian actors of national and international NGOs, to be able to map medical services and teams, identify gaps and put in place support arrangements. **Urgent health interventions would be required, among others the vaccination of the children of Mosul who had not received any vaccinations in two years**. Medical care was also required for an estimated more than 4,000 complicated deliveries. WHO was prepositioning medical supplies in various areas around Mosul. In the east and south of the city prepositioned supplies included interagency emergency health kits, reproductive health kits and mobile medical clinics. WHO and 31 partners had so far secured a stock of 33 mobile medical clinics, 17 mobile medical teams and 13 ambulances ready to operate in displacement locations Duhok, Erbil, and Bagdad in addition to 240 tons of medical supplies allocated to the same locations in those Governorates….

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Haiti

HURRICANE MATTHEW Situation Report No.18 Date: 17 October 2016 (18:00 EST)
This report is produced by PAHO/WHO
Haiti
:: UN's special advisor on sustainable development visited Jérémie today to meet with local authorities and population.
:: MSPP's main priority is cholera, due to the increase of suspected cases, mainly in Grand' Anse department.
:: PAHO, UNICEF, UNFPA and MSPP are compiling the results from joint evaluations of health facilities in Sud, Grand' Anse and Nippes Departments. The results will be shared shortly.

:: 23 organizations attended today's health group coordination meeting, with MSPP participation. Next meeting will be held on Wednesday 19 October at PAHO/WHO.
[Editor's Note: No mention in report of OCV status from stockpile deployment announced last week]

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Zika virus [to 22 October 2016]
Public Health Emergency of International Concern (PHEIC)
http://www.who.int/emergencies/zika-virus/en/

Zika situation report – 20 October 2016
Full report: http://apps.who.int/iris/bitstream/10665/250590/1/zikasitrep20Oct16-eng.pdf?ua=1
Key Updates
:: Countries and territories reporting mosquito-borne Zika virus infections for the first time in the past week:
… None
:: Countries and territories reporting microcephaly and other central nervous system (CNS) malformations potentially associated with Zika virus infection for the first time in the past week:
… Grenada
:: Countries and territories reporting Guillain-Barré syndrome (GBS) cases associated with Zika virus infection for the first time in the past week:
… None
:: The Ministry of Health of Viet Nam has reported a case of microcephaly, for which testing is underway to determine the cause.

Analysis
:: Overall, the global risk assessment has not changed.

CDC/ACIP [to 22 October 2016]
http://www.cdc.gov/media/index.html
https://www.cdc.gov/vaccines/acip/
Press Release FRIDAY, OCTOBER 21, 2016
CDC announces supplemental funding opportunity for continued Zika response in 2017
The Centers for Disease Control and Prevention (CDC) is announcing the availability of about $70 million in supplemental funding to states, cities, and territories to support continued efforts to protect...

Press Release WEDNESDAY, OCTOBER 19, 2016
CDC updates guidance related to local Zika transmission in Miami-Dade County, Florida
The Centers for Disease Control and Prevention (CDC) continues to work with Florida health officials to investigate new cases of locally transmitted Zika virus infection in Miami-Dade County, Florida.

Zika Open [to 22 October 2016]
[Bulletin of the World Health Organization]
:: All papers available here
No new papers identified.

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EBOLA/EVD [to 22 October 2016]
http://www.who.int/ebola/en/
"Threat to international peace and security" (UN Security Council)

[Editor's Note:
We note that the Ebola tab - which had been listed along with Zika, Yellow Fever, MERS CoV and other emergencies - has been removed from the WHO "home page". We deduce that WHO has suspended issuance of new Situation Reports after resuming them for several weekly cycles. The most recent report posted is EBOLA VIRUS DISEASE – Situation Report - 10 JUNE 2016. We have not encountered any UN Security Council action changing its 2014 designation of Ebola as a "threat to international peace and security." We will continue to highlight key articles and other developments around Ebola in this space.

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POLIO [to 22 October 2016]
Public Health Emergency of International Concern (PHEIC)

Polio this week as of 19 October 2016
:: On 24 October, World Polio Day provides an opportunity to celebrate progress towards a polio-free world and the tireless efforts of many towards our goal. Join Rotary and the Centres for Disease Control and Prevention for a live-streamed event, check polioeradication.org for the launch of a new series celebrating the innovations helping us reach the endgame and join in the conversation on Twitter and Facebook using the hashtags #WorldPolioDay and #EndPolio.

:: The Strategic Advisory Group of Experts on immunization (SAGE) is convening in Geneva this week (18-20 October). On polio eradication, the group is reviewing the latest global epidemiology, the global supply situation of inactivated polio vaccine (IPV) and discussing long-term polio immunization policy options. More

:: News from around the polio world:
Polio Programme Supports Anti-Fistula Efforts in Ethiopia
Containment: Shutting the Proverbial Door on Polioviruses

Formation of Containment Supporting Groups
WHO is establishing two new groups to support poliovirus containment activities:

:: the **Containment Working Group (CWG)** under the Global Commission for the Certification of Poliomyelitis Eradication (GCC), to review the national containment certification of poliovirus-essential facilities (PEFs) and make recommendations to GCC
Terms of Reference - Global Certification Commission Containment Working Group
Call for nomination - Global Certification Commission Containment Working Group
Declaration of interests for WHO experts

:: the **Containment Advisory Group (CAG)** to make recommendations on technical issues associated with GAPIII
Terms of Reference - Containment Advisory Group
Call for nomination - Containment Advisory Group
Declaration of interests for WHO experts - Containment Advisory Group

Pakistan to photograph parents who refuse polio drops for their children
The Express Tribune (Pakistan)/Associated Press of Pakistan
Published: October 21, 2016
RAWALPINDI:
Polio vaccinators will now take pictures of parents who refuse to have their children vaccinated against polio, District Coordination Officer (DCO) Talat Mehmood Gondal said on Thursday.
Chairing a meeting to review polio vaccination drive arrangements, he said vaccinators will be provided with android mobile phones to help make anti-polio campaign a success. Gondal said children who were missed in the last polio drive would be specifically targeted in the upcoming vaccination drive which is expected to start next week from October 24.
In addition to taking pictures of parents who refused vaccination, their phone numbers would also be collected. He said polio drops would be administered to unattended children within seven to 14 days in order to eliminate the crippling disease…

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Yellow Fever [to 22 October 2016]
http://www.who.int/emergencies/yellow-fever/en/

Yellow fever situation report
21 October 2016
Read the full situation report
Key updates
Angola epidemiological update (as of 22 September):
:: The last confirmed case had symptom onset on 23 June.
:: 45 probable cases were reported in the last 4 weeks
:: Phase II of the vaccination campaign is ongoing targeting more than 2 million people in 10 provinces.

Democratic Republic of the Congo epidemiological update (as of 18 September):
:: The last confirmed non-sylvatic case had symptom onset on 12 July.
:: A new confirmed, sylvatic case was reported from Lingomo Health Zone in Tshuapa province.

: 16 probable cases are under investigation (4 in Kinshasa, 8 in Kwango, and 1 case each in Bas Uele, Kwilu, Lualaba and Sud Ubangi provinces).
:: The reactive vaccination campaign in Feshi Health Zone in Kwango province concluded after 152 492 people were vaccinated. The reactive campaign in Mushenge Health Zone in Kasai province began on 20 October

Analysis
:: The continuing detection and investigation of suspected and laboratory-positive cases (including the 45 probable cases in Angola) demonstrate that active surveillance is ongoing. Nevertheless, it is important to note persistent difficulties in surveillance and laboratory confirmation capacities, which may delay case detection. A strong and sustained surveillance effort remains crucial.
:: The status of the probable cases in Angola will be reviewed by the Ministry of Health's Final Classification Committee once the investigations are completed as to their exposure history and yellow fever vaccination status.

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MERS-CoV [to 22 October 2016]
http://www.who.int/emergencies/mers-cov/en/

No new content identified.

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WHO & Regional Offices [to 22 October 2016]

WHO - Press Conference on Outcomes of SAGE Immunization Meeting (Geneva, 23 October 2015)
[Video: 59:16]
Briefing on outcomes and recommendations of the meeting of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization, held this week.
The WHO Strategic Advisory Group of Experts (SAGE) on Immunization, which was established to advise WHO on policies and strategies for immunization, met on 20-22 October 20-22 to review the best available scientific evidence on development and use of vaccines including those for use against Ebola virus, poliovirus and malaria. .
Speaker: Professor Jon S. Abramson – Chair of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization

Highlights
Community-based social innovations to support older people
October 2016 -- The WHO Kobe Centre has launched a large-scale research project on community-based social innovations for healthy ageing. This new research aims at improving health and well-being of older people at a community level, and to guide development and implementation of various models of community-based care and support services.

India's leprosy case detection campaign reaches 320 million people
October 2016 -- A recent door-to-door leprosy case detection campaign in India has screened a record 320 million people, revealing thousands of 'hidden' cases in some of the country's districts. The campaign by the National Leprosy Elimination Programme covered 149 districts across 19 states and mobilized almost 300 000 health workers.

Lead poisoning is entirely preventable
WHO
21 October 2016 – In 2013 lead exposure accounted for 853 000 deaths and 16.8 million life years lost due to its long-term effects on health, with the highest burden in developing countries. An important source of lead exposure, particularly in children, is paint containing high levels of lead. From 23 to 29 October 2016, the international lead poisoning prevention week of action will focus on eliminating lead paint.

Weekly Epidemiological Record, 21 October 2016, Vol. 91, No. 42, pp. 484-500
485 Zoonotic influenza viruses: antigenic and genetic characteristics and development of candidate vaccine viruses for pandemic preparedness
499 Monthly report on dracunculiasis cases, January–August 2016

:: WHO Regional Offices
Selected Press Releases, Announcements
WHO African Region AFRO
:: Thumbs up for the transformation process in the WHO African Region
October 2016 - The Regional Director's Independent Advisory Group (IAG) has unanimously commended the Regional Director, Dr Matshidiso Moeti, for progress made so far in the efforts to transform the Secretariat of the WHO African Region into an effective, efficient and transparent organization.
:: The heads of delegation of Members States of the World Health Organization (WHO) African Region adopt the Algiers's Call to Action for tobacco control - 19 October 2016
:: WHO hosts regional consultation to strengthen national school health programmes in the African Region - 18 October 2016

WHO Region of the Americas PAHO
:: Health leaders discuss action against mosquito-borne viruses such as Zika and dengue (10/21/2016)
:: The Americas celebrate 25 years without polio (10/21/2016)
:: USAID grants PAHO $31 million to improve health in Latin America and the Caribbean (10/17/2016)

WHO South-East Asia Region SEARO
No new content identified.

WHO European Region EURO
:: New WHO policy paper reviews opportunities to promote environmental sustainability in health systems 20-10-2016
:: World Statistics Day 2016 – be a data explorer 20-10-2016
:: Influenza vaccine: Protection for both health care workers and patients 17-10-2016

WHO Eastern Mediterranean Region EMRO
:: Cutting deaths caused by pollution 19 October 2016
:: Yemen cholera outbreak: WHO and partners urgently require US$ 22.35 million to save lives and reduce suffering 18 October 2016

WHO Western Pacific Region
No new content identified

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CDC/ACIP [to 22 October 2016]
http://www.cdc.gov/media/index.html
https://www.cdc.gov/vaccines/acip/
Press Release
FRIDAY, OCTOBER 21, 2016
CDC announces supplemental funding opportunity for continued Zika response in 2017
The Centers for Disease Control and Prevention (CDC) is announcing the availability of about $70 million in supplemental funding to states, cities, and territories to support continued efforts to protect...

Press Release
THURSDAY, OCTOBER 20, 2016
CDC recommends only two HPV shots for younger adolescents
CDC today recommended that 11- to 12-year-olds receive two doses of HPV vaccine at least six months apart rather than the previously recommended three doses to protect against cancers caused by human papillomavirus (HPV) infections. Teens and young adults who start the series later, at ages 15 through 26 years, will continue to need three doses of HPV vaccine to protect against cancer-causing HPV infection.

"Safe, effective, and long-lasting protection against HPV cancers with two visits instead of three means more Americans will be protected from cancer," said CDC Director Tom Frieden, M.D., M.P.H. "This recommendation will make it simpler for parents to get their children protected in time."

The Advisory Committee on Immunization Practices (ACIP) voted today to recommend a 2-dose HPV vaccine schedule for young adolescents. ACIP is a panel of experts that advises the CDC on vaccine recommendations in the United States. CDC Director Frieden approved the committee's recommendations shortly after the vote. ACIP recommendations approved by the CDC Director become agency guidelines on the date published in the Morbidity and Mortality Weekly Report (MMWR).

CDC and ACIP made this recommendation after a thorough review of studies over several meetings. CDC and ACIP reviewed data from clinical trials showing two doses of HPV vaccine in younger adolescents (aged 9-14 years) produced an immune response similar or higher than the response in young adults (aged 16-26 years) who received three doses.

Generally, preteens receive HPV vaccine at the same time as whooping cough and meningitis vaccines. Two doses of HPV vaccine given at least six months apart at ages 11 and 12 years will provide safe, effective, and long-lasting protection against HPV cancers. Adolescents ages 13-14 are also able to receive HPV vaccination on the new 2-dose schedule.

CDC will provide guidance to parents, healthcare professionals, and insurers on the change in recommendation. On October 7, 2016, the U.S. Food and Drug Administration (FDA) approved adding a 2-dose schedule for 9-valent HPV vaccine (Gardasil® 9) for adolescents ages 9 through 14 years. CDC encourages clinicians to begin implementing the 2-dose schedule in their practice to protect their preteen patients from HPV cancers.

ACIP, CDC, FDA and partners monitor vaccines in use in the U.S. year-round. These updated recommendations are an example of using the latest available evidence to provide the best possible protection against serious diseases.

Press Release
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CDC updates guidance related to local Zika transmission in Miami-Dade County, Florida
The Centers for Disease Control and Prevention (CDC) continues to work with Florida health officials to investigate new cases of locally transmitted Zika virus infection in Miami-Dade County, Florida.

MMWR Weekly October 21, 2016 / No. 41
:: National Progress Toward Hepatitis C Elimination — Georgia, 2015–2016
:: Status of New Vaccine Introduction — Worldwide, September 2016
[See Reports section below for full text]
:: Notes from the Field: Outbreak of Zika Virus Disease — American Samoa, 2016

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Announcements/Perspectives

Industry Watch [to 22 October 2016]
:: **CDC Advisory Committee on Immunization Practices Votes to Recommend New Dosing Schedule for Vaccination with TRUMENBA® (Meningococcal Group B Vaccine)**
October 19, 2016
NEW YORK--(BUSINESS WIRE)--Pfizer Inc. announced today that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend that:
:: For persons at increased risk for meningococcal disease and for use during serogroup B outbreaks, 3 doses of TRUMENBA should be administered at 0, 1-2, and 6 months
:: When given to healthy adolescents who are not at increased risk for meningococcal disease, 2 doses of TRUMENBA should be administered at 0 and 6 months

…If the second dose is given at an interval of less than 6 months, a third dose should be given at least 6 months after the first dose
"Today's ACIP recommendation is an important update that offers clear guidance to healthcare providers administering TRUMENBA to help prevent meningococcal group B disease, also known as MenB, in healthy adolescents and young adults, as well as those at increased risk for the disease," said Dr. Laura York, Global Medical Lead for Meningococcal Vaccines, Pfizer Vaccines. "This new recommendation enables flexible vaccination dosing intervals depending on one's risk of exposure to MenB, which makes it easier for healthcare providers to help protect individuals from this uncommon but life-threatening disease." …

:: **Pfizer Awarded Grant to Evaluate Vaccine to Protect Newborns Against Group B Streptococcus Infection**
October 19, 2016
Pfizer Inc. (NYSE:PFE) today announced an award of a grant from the Bill & Melinda Gates Foundation to conduct a Phase 1/2 clinical trial of Pfizer's vaccine candidate against group B Streptococcu...

:: **DCVMN Annual General Meeting** - 24 October 2016 to 27 October 2016 Buenos Aires, Argentina

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IVI [to 22 October 2016]
http://www.ivi.int/
IVI's 15th Scientific Advisory Group (SAG) meeting, October 17-18, 2016
IVI convened its 15th Scientific Advisory Group (SAG) meeting at the IVI headquarters from October 17-18. This is IVI's first SAG meeting after a three-year hiatus and the group consists of new members and a new chair. Chaired by Dr. Ralf Clemens, the SAG members include the world's leading scientific and global health experts…

IVI 2015 Annual Report
Titled IVI FORWARD: 2015 Annual Report, "forward" is the theme of the Report. The Report focuses on our progress in 2015 and highlights exciting changes taking place as we move forward to a new IVI. It describes preparations for our new strategy and also reports progress made in our major vaccine programs.
PDF: http://ivi.us11.list-manage.com/track/click?u=893db71dee13169582bd5f91e&id=e4f4bbfda2&e=1d53ab3167

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Global Fund [to 22 October 2016]
http://www.theglobalfund.org/en/news/?topic=&type=NEWS;&country=
Oct 18, 2016
UNDP and Global Fund sign a new $7 million grant to address human rights barriers to HIV services in eight Caribbean countries
United Nations Development Programme (UNDP) and the Global Fund have signed a new US$7 million grant to address human rights barriers to HIV services in eight Caribbean countries – Belize, Cuba, Dominican Republic, Guyana, Haiti, Jamaica, Suriname and Trinidad and

Tobago. The funds will focus on promoting and protecting human rights and access to HIV services for key populations such as men who have sex with men, transgender people, sex workers, marginalized young people and those using drugs, all of whom often bear the highest burden of HIV infection in the region.

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UNAIDS [to 22 October 2016]
http://www.unaids.org/en/resources/presscentre/
Press statement
BRICS countries underline the imperative of advancing cooperation and action on HIV and tuberculosis

GENEVA, 17 October 2016—At the close of the 2016 BRICS Summit in Goa, India, leaders of the BRICS countries (Brazil, the Russian Federation, India, China and South Africa) have underlined the imperative of advancing cooperation and action to respond to the epidemics of HIV and tuberculosis.

In their declaration, the leaders emphasized the importance of cooperation among BRICS countries in promoting the research and development of local pharmaceuticals and diagnostic tools in order to facilitate access to safe, effective, quality and affordable medicines.

The Goa Declaration, issued at the end of the two-day summit, also took note of efforts made by BRICS health ministers to achieve the 90–90–90 targets by 2020, whereby 90% of people living with HIV will know their HIV status, 90% of people who know their HIV-positive status will access treatment and 90% of people on treatment will have suppressed viral loads. The declaration also noted the United Nations High-Level Meeting on Ending AIDS, which took place in New York, United States of America, in June 2016, at which countries committed to following a Fast-Track response to ending the AIDS epidemic by 2030…

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NIH [to 22 October 2016]
http://www.nih.gov/news-events/news-releases
October 19, 2016
Large increases in HIV suppression needed to reduce new infections in critical population
— NIH-funded study aims to identify and treat HIV-infected men who have sex with men.

NIH contributes to global effort to prevent and manage lung diseases
October 19, 2016 — NIH-funded trial will measure health benefits of clean cookstoves.

Women report vaginal ring for preventing HIV had little effect on sexual intercourse
October 18, 2016 — Violence and social harm were associated with low adherence.

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FDA [to 22 October 2016]
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm
FDA News Release
October 17, 2016

FDA awards 21 grants to stimulate product development for rare diseases

The U.S. Food and Drug Administration today announced that it has awarded 21 new clinical trial research grants totaling more than $23 million over the next four years to boost the development of products for patients with rare diseases. These new grants were awarded to principal investigators from academia and industry with research spanning domestic and international clinical sites.

"We are proud of our 30-year track record of fostering and encouraging the development of safe and effective therapies for rare diseases through our clinical trials grant program," said Gayatri R. Rao, M.D., J.D., director of FDA's Office of Orphan Product Development, within the Office of Special Medical Programs. "The grants awarded this year will support much-needed research in 21 different rare diseases, many of which have little, or no, available treatment options."

The FDA awards the grants through the Orphan Products Clinical Trials Grants Program to encourage clinical development of drugs, biologics, medical devices, or medical foods for use in rare diseases. The grants are intended for clinical studies evaluating the safety and effectiveness of products that could either result in, or substantially contribute to, the FDA approval of products…

What's New for Biologics

:: October 19, 2016 Approval Order - ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay (PDF - 87KB)
Posted: 10/20/2016
:: Information on CBER Restructuring
Posted: 10/19/2016

The Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) recently conducted a thorough review of its review functions and organizational structure. Senior Center leadership evaluated a variety of alternatives that would allow the Center to more efficiently accomplish its regulatory mission.

Based on this review, and in consultation with FDA leadership, CBER has undergone an internal restructuring. The new CBER structure includes the Office of Blood Research and Review (OBRR), the Office of Vaccines Research and Review (OVRR), and the Office of Tissues and Advanced Therapies (OTAT, formerly known as the Office of Cellular, Tissue and Gene Therapies, or OCTGT). The formation of OTAT involves the transfer of OBRR's Division of Hematology Clinical Review and Division of Hematology Research and Review, along with appropriate support staff, to OCTGT to constitute the new office. The products now regulated by OTAT include all purified and recombinant versions of therapeutic proteins for hematology. Antivenins have also been transferred to OTAT.

This new organizational structure became effective on October 16, 2016. This restructuring should not have a significant impact on the review of pending applications, and CBER anticipates meeting its user fee obligations, including performance goals, during this transition.

:: Clinical Review - GARDASIL 9 (PDF - 395KB)
Posted: 10/19/2016
:: Statistical Review - GARDASIL 9 (PDF - 409KB)
Posted: 10/19/2016
:: Influenza Virus Vaccine for the 2016-2017 Season
Updated: 10/18/2016
:: October 7, 2016 Summary Basis for Regulatory Action - Flublok Quadrivalent (PDF - 172KB)
Posted: 10/17/2016

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Coalition for Epidemic Preparedness Innovations (CEPI) [to 22 October 2016]
http://cepi.net/
Request for Proposals: Permanent CEPI Secretariat
CEPI invites all interested organizations (not-for-profit or public) and/or countries (or a network/group of organizations/countries) who are interested in hosting CEPI to apply for hosting the permanent CEPI Secretariat.
The application should contain the following:
: Proposal, up to 10 pages, 10-point text, not including appendices
:: Budget for 5 years, 2018-2022 on spreadsheet provided
:: Appendices to include recommendation letters from hosting country government (relevant ministry/-ies) as well as potential recommendation letters from other actors.
Facts:
:: Deadline for applications: 14 November 2016
:: Application Package - ZIP FORMAT - 627KB - Download

::::::

AERAS [to 22 October 2016]
http://www.aeras.org/pressreleases
Aeras released its **Annual Report** for 2015.

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BMGF - Gates Foundation [to 22 October 2016]
http://www.gatesfoundation.org/Media-Center/Press-Releases
No new digest content identified.

EDCTP [to 22 October 2016]
http://www.edctp.org/
The European & Developing Countries Clinical Trials Partnership (EDCTP) aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases in sub-Saharan Africa, with a focus on phase II and III clinical trials.
No new digest content identified.

European Vaccine Initiative [to 22 October 2016]
http://www.euvaccine.eu/news-events
No new digest content identified.

Fondation Merieux [to 22 October 2016]
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.
No new digest content identified.

GHIT Fund [to 22 October 2016]
https://www.ghitfund.org/
GHIT was set up in 2012 with the aim of developing new tools to tackle infectious diseases that devastate the world's poorest people. Other funders include six Japanese pharmaceutical companies, the Japanese Government and the Bill & Melinda Gates Foundation.
No new digest content identified.

Hilleman Laboratories [to 22 October 2016]
http://www.hillemanlabs.org/
No new digest content identified

Human Vaccines Project [to 22 October 2016]
http://www.humanvaccinesproject.org/media/press-releases/
No new digest content identified

IAVI – International AIDS Vaccine Initiative [to 22 October 2016]
https://www.iavi.org/
No new digest content identified

PATH [to 22 October 2016]
http://www.path.org/news/index.php
No new digest content identified

* * * *

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

Guidance for managing ethical issues in infectious disease outbreaks

World Health Organization
2016 :: 68 pages ISBN: 9789241549837
PDF: http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf
Overview
Infectious disease outbreaks are frequently characterized by scientific uncertainty, social and institutional disruption, and an overall climate of fear and distrust. Invariably, the countries most affected by outbreaks have limited resources, under-developed legal and regulatory structures, and health systems that lack the resilience to deal with crisis situations. Policy-makers and public health professionals may be forced to weigh and prioritize potentially competing ethical values in the face of severe time and resource constraints . This document seeks to assist policy-makers, health care providers, researchers, and others prepare for outbreak situations by anticipating and preparing for the critical ethical issues likely to arise. In

addition to setting forth ethical principles applicable to infectious disease outbreaks generally, it shows how these principles can be adapted to different epidemiological and social circumstances.

Status of New Vaccine Introduction — Worldwide, September 2016

CDC - MMWR Weekly / October 21, 2016 / 65(41);1136–1140

Since the global Expanded Program on Immunization (EPI) was launched in 1974, vaccination against six diseases (tuberculosis, polio, diphtheria, tetanus, pertussis, and measles) has prevented millions of deaths and disabilities (1). Significant advances have been made in the development and introduction of vaccines, and licensed vaccines are now available to prevent 25 diseases (2,3). Historically, new vaccines only became available in low-income and middle-income countries decades after being introduced in high-income countries. However, with the support of global partners, including the World Health Organization (WHO) and the United Nations Children's Fund, which assist with vaccine prequalification and procurement, as well as Gavi, the Vaccine Alliance (Gavi) (4), which provides funding and shapes vaccine markets through forecasting and assurances of demand in low-income countries in exchange for lower vaccine prices, vaccines are now introduced more rapidly.

Based on data compiled in the WHO Immunization Vaccines and Biologicals Database* (5), this report describes the current status of introduction of Haemophilus influenzae type b (Hib), hepatitis B, pneumococcal conjugate, rotavirus, human papillomavirus, and rubella vaccines, and the second dose of measles vaccine. As of September 2016, a total of 191 (99%) of 194 WHO member countries had introduced Hib vaccine, 190 (98%) had introduced hepatitis B vaccine, 132 (68%) had introduced pneumococcal conjugate vaccine (PCV), and 86 (44%) had introduced rotavirus vaccine into infant vaccination schedules. Human papillomavirus vaccine (HPV) had been introduced in 67 (35%) countries, primarily targeted for routine use in adolescent girls. A second dose of measles-containing vaccine (MCV2) had been introduced in 161 (83%) countries, and rubella vaccine had been introduced in 149 (77%). These efforts support the commitment outlined in the Global Vaccine Action Plan (GVAP), 2011–2020 (2), endorsed by the World Health Assembly in 2012, to extend the full benefits of immunization to all persons.

Data on the status of vaccine introduction into the country's routine immunization program, as of September 2016, were obtained from the WHO Immunization Vaccines and Biologicals Database, which receives vaccine introduction reports from 194 WHO countries. Vaccine introduction status is also presented by the 73 countries that were eligible† for support from Gavi for new vaccine introduction at any time since 2000 (5).

In 1992, WHO recommended hepatitis B vaccine as the first new vaccine in the childhood immunization schedule beyond the original EPI vaccines.§ Hepatitis B vaccine is now included in childhood immunization schedules in 190 (98%) countries, including 119 (61%) countries that have implemented a birth dose to prevent perinatal transmission of hepatitis B virus, as recommended by WHO in 2009 (6).

In 2000, Hib vaccine was only in widespread use in the WHO Region of the Americas and European Region. By 2006, when WHO recommended Hib vaccine in all routine infant immunization schedules, 108 countries, accounting for >55% of the world's children, had

introduced routine Hib vaccination (7). During the last decade, with continued WHO and Gavi support, expansion has continued and, as of September 2016, a total of 191 (98%) countries had incorporated Hib vaccine in national immunization schedules, including all 73 Gavi-eligible countries. Hib vaccine has not yet been introduced in China, the Russian Federation, and Thailand (5) (supplemental map 1, at https://stacks.cdc.gov/view/cdc/41681).

In 2007, WHO recommended use of PCV in all countries, prioritizing its introduction in countries with high pneumonia prevalence and high mortality rates among children aged <5 years. By 2008, although 24 high-income and two middle-income countries had initiated routine PCV vaccination, no countries in Africa or Asia, regions with high rates of pneumonia mortality among children aged <5 years, had yet introduced PCV (8). However, by September 2016, PCV had been introduced in national immunization schedules in 132 (68%) countries, and six more are planning introduction by the end of 2016. Among the 73 Gavi-eligible countries, 56 (77%) had introduced PCV, and three are planning introduction by the end of 2016 (5) (Figure 1).

Rotavirus vaccination has been recommended by WHO for inclusion in all national immunization schedules since 2009, particularly in countries with high rotavirus gastroenteritis–associated mortality, including South and Southeast Asia and sub-Saharan Africa. By September 2016, rotavirus vaccine had been introduced in 86 (44%) countries, including 38 (52%) Gavi-eligible countries. Five more countries plan to introduce rotavirus vaccine by the end of 2016 (5) (Figure 2).

Before 2012, HPV was not widely used outside North America, Australia, and Europe. In 2009, WHO recommended HPV for adolescent girls in all countries where cervical cancer prevention is a public health priority and introduction is feasible and sustainable. By September 2016, HPV had been introduced in 67 (35%) countries (5) (Figure 3). Among Gavi-eligible countries, 23 (32%) had conducted HPV pilot demonstration projects, and three had introduced HPV nationally.

Since 2009, WHO recommended 2 doses of MCV as the standard for all national immunization schedules (9). Routine MCV2 is usually administered during the second year of life, although in some countries it is scheduled around the age of school entry. As of September 2016, MCV2 had been introduced in 161 (83%) countries, and two countries have planned introduction in 2016 (5) (supplemental map 2, at https://stacks.cdc.gov/view/cdc/41682). Forty-six (63%) Gavi-eligible countries had introduced MCV2.

Rubella vaccine was first licensed in 1969 and initially was used primarily in high-income and middle-income countries. By 1996, only 85 countries included rubella vaccine in national immunization schedules. Since a 2011 Gavi commitment to support rubella vaccine introduction using combined measles-rubella vaccine, more countries have introduced rubella-containing vaccines, and, as of September 2016, rubella vaccine was included in national immunization schedules in 149 (77%) countries (5) (supplemental map 3, at https://stacks.cdc.gov/view/cdc/41683). Thirty-five (48%) Gavi-eligible countries had introduced rubella-containing vaccine in national immunization schedules.

Discussion

With the recognition of immunization as a core component of the human right to health, the availability of innovative funding mechanisms, and stronger international partnerships, vaccines

are increasingly being introduced into national immunization schedules (2). Nearly all countries have introduced hepatitis B vaccine, more than three fourths have introduced rubella, MCV2 and Hib vaccines, and two thirds have introduced PCV. However, fewer than half have introduced rotavirus vaccine or HPV. In addition, market analyses indicate that recently introduced vaccines are reaching low-income countries faster than in the past. For example, Hib vaccine, introduced in 1989, took 20 years to reach 70% of low-income countries; PCV, introduced in 2000, is anticipated to reach 70% of low-income countries 5 years sooner (10). Although uneven, the overall success in extending vaccine introduction reflects both global commitment to achieving the GVAP goals and growing technical and resource capacities in low-income and middle-income countries.

Despite available resources from donors to introduce vaccines in countries, countries might choose not to introduce a particular vaccine because of national policies; financial constraints on implementation; lack of disease burden data; or vaccine hesitancy by the community, health system, or policy-makers. Establishing and strengthening independent advisory mechanisms at the national level (e.g., National Immunization Technical Advisory Groups) is critical for improving leadership in making informed and evidence-based recommendations about the introduction and financial sustainability of vaccines.

In countries where vaccines have been recently introduced into the national schedule, incomplete coverage might result in many children not receiving these vaccines. Immunization programs must closely review vaccine implementation and coverage to identify actions necessary to ensure equity and optimize impact. Continued progress in vaccine introduction will require national commitment and funding, ensuring vaccine supply and procurement, creating and maintaining new age and target population delivery platforms, and addressing competing demands on health care systems and resources. This is particularly critical for lower–middle-income countries and countries transitioning from eligibility for Gavi support, based on the World Bank data for gross national income.

Strategies that can help provide vaccine supply security include innovative pricing and procurement mechanisms, especially for lower–middle-income countries, as well as supply-side interventions and support for the manufacture of affordable vaccines in middle-income countries (1). Recent supply shortages of rotavirus, PCV, and other vaccines demonstrate the need to work with manufacturers at the global level to prevent stockouts (i.e., situations in which local vaccine providers run out of stock) or missed opportunities. Global and regional training initiatives targeting national programs have contributed to considerable improvements in vaccine stock management and cold-chain capacity; sustaining these infrastructure efforts will be important, particularly for vaccines that involve delivery and monitoring in new settings (e.g., school-based or outreach vaccination).

Vaccine introduction provides opportunities for strengthening a country's immunization program and overall health system. Although vaccine introductions might require additional resources and innovative delivery strategies (e.g., school-based delivery of HPV, delivery of the hepatitis B birth dose as part of neonatal care), platforms for providing immunization to new age groups offer opportunities to improve access to health care and facilitate vaccination throughout the life course. Scheduled immunization visits provide a platform for integrating other public health interventions (e.g., vitamin A supplementation, deworming, bed nets for malaria prevention, and growth monitoring) to improve overall health. Delivering vaccination services beyond

infancy (e.g., MCV2 in the second year of life) also offers an opportunity to provide vaccines missed during infancy to protect the child and improve vaccination coverage in the community. New partnerships established for vaccine introduction can enhance the delivery and efficiency of health services in new settings (e.g., ministries of education for school-based HPV vaccination) and strengthen traditional sites of service delivery. These partnerships also can support social and operational research and new communication strategies needed to increase acceptance of new vaccines by the target populations and among persons involved in the delivery of vaccines.

Sustaining the health gains made through vaccine introduction requires continued support for implementation, as well as support for surveillance to monitor disease burden, vaccine effectiveness, and vaccine safety. New or improved vaccines for diseases such as meningitis, cholera, typhoid, malaria, and dengue will be available in the near future, bringing with them additional delivery and financing challenges along with the promise of decreased morbidity and mortality and the opportunity to further strengthen health systems.

* * * *

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
October 2016 Volume 44, Issue 10, p1083-1196, e167-e182
http://www.ajicjournal.org/current
[Reviewed earlier]

American Journal of Preventive Medicine
October 2016 Volume 51, Issue 4, p411-636, e91-e118
http://www.ajpmonline.org/current
[Reviewed earlier]

American Journal of Public Health
Volume 106, Issue 10 (October 2016)
http://ajph.aphapublications.org/toc/ajph/current
[Reviewed earlier]

American Journal of Tropical Medicine and Hygiene
October 2016; 95 (4)
http://www.ajtmh.org/content/current
[Reviewed earlier]

Annals of Internal Medicine
18 October 2016 Vol: 165, Issue 8
http://annals.org/issue.aspx
[New issue; No relevant content identified]

BMC Cost Effectiveness and Resource Allocation
http://resource-allocation.biomedcentral.com/
(Accessed 22 October 2016)
[No new content]

BMC Health Services Research
http://www.biomedcentral.com/bmchealthservres/content
(Accessed 22 October 2016)
[No new relevant content]

BMC Infectious Diseases
http://www.biomedcentral.com/bmcinfectdis/content
(Accessed 22 October 2016)
Research article
A DNA vaccine targeting TcdA and TcdB induces protective immunity against Clostridium difficile
Clostridium difficile-associated disease (CDAD) constitutes a great majority of hospital diarrhea cases in industrialized countries and is induced by two types of large toxin molecules...
Bao-Zhong Zhang, Jianpiao Cai, Bin Yu, Yanhong Hua, Candy Choiyi Lau, Richard Yi-Tsun Tsun Kao, Kong-Hung Sze, Kwok-Yung Yuen and Jian-Dong Huang
BMC Infectious Diseases 2016 16:596
Published on: 22 October 2016

Research article
School closure policies at municipality level for mitigating influenza spread: a model-based evaluation
Nearly every year Influenza affects most countries worldwide and the risk of a new pandemic is always present. Therefore, influenza is a major concern for public health. School-age individuals are often the mo...
Constanze Ciavarella, Laura Fumanelli, Stefano Merler, Ciro Cattuto and Marco Ajelli
BMC Infectious Diseases 2016 16:576
Published on: 18 October 2016

Research article

An outbreak of pneumococcal meningitis among older children (≥5 years) and adults after the implementation of an infant vaccination programme with the 13-valent pneumococcal conjugate vaccine in Ghana

An outbreak of pneumococcal meningitis among non-infant children and adults occurred in the Brong-Ahafo region of Ghana between December 2015 and April 2016 despite the recent nationwide implementation of a va...

Brenda Anna Kwambana-Adams, Franklin Asiedu-Bekoe, Badu Sarkodie, Osei Kuffour Afreh, George Khumalo Kuma, Godfred Owusu-Okyere, Ebenezer Foster-Nyarko, Sally-Ann Ohene, Charles Okot, Archibald Kwame Worwui, Catherine Okoi, Madikay Senghore, Jacob Kweku Otu, Chinelo Ebruke, Richard Bannerman, Kwame Amponsa-Achiano…

BMC Infectious Diseases 2016 16:575

Published on: 18 October 2016

BMC Medical Ethics

http://www.biomedcentral.com/bmcmedethics/content

(Accessed 22 October 2016)

Research article

Seeking consent for research with indigenous communities: a systematic review

Emily F. M. Fitzpatrick, Alexandra L. C. Martiniuk, Heather D'Antoine, June Oscar, Maureen Carter and Elizabeth J. Elliott

BMC Medical Ethics 2016 17:65

Published on: 22 October 2016

Abstract

Background

When conducting research with Indigenous populations consent should be sought from both individual participants and the local community. We aimed to search and summarise the literature about methods for seeking consent for research with Indigenous populations.

Methods

A systematic literature search was conducted for articles that describe or evaluate the process of seeking informed consent for research with Indigenous participants. Guidelines for ethical research and for seeking consent with Indigenous people are also included in our review.

Results

Of 1447 articles found 1391 were excluded (duplicates, irrelevant, not in English); 56 were relevant and included. Articles were categorised into original research that evaluated the consent process (n = 5) or publications detailing the process of seeking consent (n = 13) and guidelines for ethical research (n = 38). Guidelines were categorised into international (n = 8); national (n = 20) and state/regional/local guidelines (n = 10). In five studies based in Australia, Canada and The United States of America the consent process with Indigenous people was objectively evaluated. In 13 other studies interpreters, voice recording, videos, pictures, flipcharts and "plain language" forms were used to assist in seeking consent but these processes were not evaluated. Some Indigenous organisations provide examples of community-designed resources for seeking consent and describe methods of community engagement, but none are evaluated. International, national and local ethical guidelines stress the importance of upholding Indigenous values but fail to specify methods for engaging communities or obtaining individual consent. In the 'Grey literature' concerns about the consent process are identified but no solutions are offered.

Conclusion

Consultation with Indigenous communities is needed to determine how consent should be sought from the community and the individual, and how to evaluate this process.

Research article

National ethics guidance in Sub-Saharan Africa on the collection and use of human biological specimens: a systematic review

Francis Barchi and Madison T. Little
BMC Medical Ethics 2016 17:64
Published on: 22 October 2016\

Abstract

Background

Ethical and regulatory guidance on the collection and use of human biospecimens (HBS) for research forms an essential component of national health systems in Sub-Saharan Africa (SSA), where rapid advances in genetic- and genomic-based technologies are fueling clinical trials involving HBS and the establishment of large-scale biobanks.

Methods

An extensive multi-level search for publicly available ethics regulatory guidance was conducted for each SSA country. A second review documented active trials listed in the WHO International Clinical Trials Registry Platform as of January 2015 in which HBS collection was specified in the protocol. Findings were combined to determine the extent to which countries that are study sites for HBS-related research are supported by regulatory guidance language on the collection, use, ownership and storage of biospecimens.

Results

Of the 49 SSA countries, 29 had some form of national ethics guidance, yet only 17 provided language relating to HBS-related research, with specific guidance on consent (14), ownership (6), reuse (10), storage (9), and export/import/transfer (13). Ten countries accounted for 84 % of the active clinical trials involving the collection of HBS in SSA. All except one of these countries were found to have some national guidance in the form of regulations, codes of ethics, and/or standard operating procedures; however, only seven of the ten offered any language specific to HBS.

Conclusions

Despite the fact that the bulk of registered clinical trials in SSA involving HBS, as well as existing and proposed sites for biorepositories under the H3Africa Initiative, are currently situated in countries with the most complete ethics and regulatory guidance, variability in the regulations themselves may create challenges for planned and future pan-African collaborations and may require legislative action at the national level to revise. Countries in SSA that still lack regulatory guidance on HBS will require extensive health system strengthening in ethics governance before they can be full participants in the modern research enterprise.

Research article

Research in disaster settings: a systematic qualitative review of ethical guidelines

Signe Mezinska, Péter Kakuk, Goran Mijaljica, Marcin Waligóra and Dónal P. O'Mathúna
BMC Medical Ethics 2016 17:62
Published on: 21 October 2016

Abstract

Background

Conducting research during or in the aftermath of disasters poses many specific practical and ethical challenges. This is particularly the case with research involving human subjects. The

extraordinary circumstances of research conducted in disaster settings require appropriate regulations to ensure the protection of human participants. The goal of this study is to systematically and qualitatively review the existing ethical guidelines for disaster research by using the constant comparative method (CCM).
Methods
We performed a systematic qualitative review of disaster research ethics guidelines to collect and compare existing regulations. Guidelines were identified by a three-tiered search strategy: 1) searching databases (PubMed and Google Scholar), 2) an Internet search (Google), and 3) a search of the references in the included documents from the first two searches. We used the constant comparative method (CCM) for analysis of included guidelines.
Results
Fourteen full text guidelines were included for analysis. The included guidelines covered the period 2000-2014. Qualitative analysis of the included guidelines revealed two core themes: vulnerability and research ethics committee review. Within each of the two core themes, various categories and subcategories were identified.
Conclusions
Some concepts and terms identified in analyzed guidelines are used in an inconsistent manner and applied in different contexts. Conceptual clarity is needed in this area as well as empirical evidence to support the statements and requirements included in analyzed guidelines.

Debate

An analysis of common ethical justifications for compassionate use programs for experimental drugs

Kasper Raus
BMC Medical Ethics 2016 17:60
Published on: 18 October 2016

Abstract

Background
When a new intervention or drug is developed, this has to pass through various phases of clinical testing before it achieves market approval, which can take many years. This raises an issue for drugs which could benefit terminally ill patients. These patients might set their hopes on the experimental drug but are unable to wait since they are likely to pass away before the drug is available. As a means of nevertheless getting access to experimental drug, many seriously ill and terminally ill patients are therefore very willing to participate in randomised controlled trials. However, only very few terminally ill patients are able to actually participate, and those that do participate are at risk of participating solely as a way of getting experimental drugs. Currently, there are, however, ways of getting access to drugs that have not (yet) gained market approval. One such mean is via expanded access or compassionate use programs where terminally ill patients receive experimental new drugs that are not yet market approved. In this paper, I examine some of the common justifications for such programs.
Main body
The most frequently voiced justifications for compassionate use or expanded access programs could be put in one of three categories. First, there are justifications of justice, where compassionate use programs could be seen as a just or fair way to distribute experimental new drugs to patients who are denied access to RCT's through no fault of their own. Second, such programs could be justified by reference to the ethical principle of beneficence where it could be claimed that terminally ill patients stand to benefit greatly at very little risk (as they are already dying). Third, there are considerations of autonomy where, it is claimed, patients should

be able to exercise their autonomy and have access to such drugs if that is there free choice and they are fully aware of the risks associated with that choice.
Short conclusion
In this paper, I argue currently all justifications are potentially problematic. If they truly form the basis for justification, compassionate use programs should be designed to maximize justice, beneficence and autonomy.

BMC Medicine
http://www.biomedcentral.com/bmcmed/content
(Accessed 22 October 2016)
[No new relevant content]

BMC Pregnancy and Childbirth
http://www.biomedcentral.com/bmcpregnancychildbirth/content
(Accessed 22 October 2016)
[No new relevant content]

BMC Public Health
http://bmcpublichealth.biomedcentral.com/articles
(Accessed 22 October 2016)
Research article
Coverage, efficacy or dosing interval: which factor predominantly influences the impact of routine childhood vaccination for the prevention of varicella? A model-based study for Italy
Varicella is a highly infectious disease with a significant public health and economic burden, which can be prevented with childhood routine varicella vaccination. Vaccination strategies differ by country. Som...
Katsiaryna Holl, Christophe Sauboin, Emanuele Amodio, Paolo Bonanni and Giovanni Gabutti
BMC Public Health 2016 16:1103
Published on: 21 October 2016

BMC Research Notes
http://www.biomedcentral.com/bmcresnotes/content
(Accessed 22 October 2016)
[No new relevant content]

BMJ Open
2016, Volume 6, Issue 10
http://bmjopen.bmj.com/content/current
[Reviewed earlier]

Bulletin of the World Health Organization

Volume 94, Number 10, October 2016, 709-784
http://www.who.int/bulletin/volumes/94/10/en/
[Reviewed earlier]

Child Care, Health and Development
November 2016 Volume 42, Issue 6 Pages 775–955
http://onlinelibrary.wiley.com/doi/10.1111/cch.v42.6/issuetoc
Original Articles
Questioning assent: how are children's views included as families make decisions about clinical trials? (pages 900–908)
L. Madden, V. Shilling, K. Woolfall, E. Sowden, R. L. Smyth, P. R. Williamson and B. Young
Version of Record online: 2 MAY 2016 | DOI: 10.1111/cch.12347
Abstract
Background
Assent is used to take children's wishes into account when they are invited into clinical trials, but the concept has attracted considerable criticism. We investigated children's accounts of decision-making with the aim of informing practice in supporting children when invited to join a clinical trial.
Methods
We audio-recorded qualitative, semi-structured interviews with 22 children aged 8–16 years about being invited to take part in a clinical trial. Most children were interviewed with their parents. Analysis of the transcribed interviews examined the content of participants' accounts thematically, whilst also drawing on principles of discourse analysis, which examines how individuals use talk to achieve certain effects or social practices.
Results
It was not possible to separate children's knowledge of the clinical trial, or their decision-making processes from that of their parents, with parents taking a substantial mediating role in producing their children's decisions. Decision-making gradually unfolded across time and events and was interwoven within the family context, rather than happening in one moment or in the clinical setting. Whilst children valued their parents' role, a case study of child–parent disagreement indicated how children can struggle to be heard.
Conclusions
Decisions happen within a process of family dynamics, in contrast to ideas of assent that isolate it from this context. Parents have a substantial role in children's decisions, and thus how families come to provide consent. Reflecting this we argue that assent practices need to focus on supporting parents to support their children in learning and deliberating about trials. However, this needs to be accompanied by practitioners being alert to the possibility of divergence in child and parent views and enabling children's perspectives to be heard.

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[Reviewed earlier]

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Virginie Gosselin, Mélissa Généreux, Arnaud Gagneur & Geneviève Petit

review
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Catherine Yen, Kelly Healy, Jacqueline E. Tate, Umesh D. Parashar, Julie Bines, Kathleen Neuzil, Mathuram Santosham & A. Duncan Steele PhD

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Promotion of flu vaccination among healthcare workers in an Italian academic hospital: An experience with tailored web tools
Pages: 2628-2633
Alessandro Conte, Rosanna Quattrin, Elisa Filiputti, Roberto Cocconi, Luca Arnoldo, Pierfrancesco Tricarico, Mauro Delendi & Silvio Brusaferro

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Can mobile technologies improve on-time vaccination? A study piloting maternal use of ImmunizeCA, a Pan-Canadian immunization app
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Volume 45 Issue 4 August 2016
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October 2016 Volume 51, p1-140
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Editorial

A Global Antimicrobial Conservation Fund for Low- and Middle-Income Countries
Marc Mendelson, Osman A. Dar, Steven J. Hoffman, Ramanan Laxminarayan, Mirfin M. Mpundu, John-Arne Røttingen
p70–72
Published online: September 16, 2016

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Association between timely initiation of hepatitis B vaccine and completion of the hepatitis B vaccine and national immunization program vaccine series
Jiang-nan Wu, Da-jin Li, Yong Zhou
p62–65
Published online: August 31, 2016

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Volume 27, Number 3, August 2016
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Volume 18, Issue 5, October 2016
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Volume 14, Issue 3, 2016
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October 2016, Volume 42, Issue 10
http://jme.bmj.com/content/current
Published: 21 October 2016
Research in disaster settings: a systematic qualitative review of ethical guidelines
Authors: Mezinska Signe, Kakuk Péter, Mijaljica Goran, Waligóra Marcin, O'Mathúna Dónal,
Journal: BMC Medical Ethics.2016, 17:62
DOI: 10.1186/s12910-016-0148-7
URL: http://www.biomedcentral.com/1472-6939/17/62
Abstract
Background

Conducting research during or in the aftermath of disasters poses many specific practical and ethical challenges. This is particularly the case with research involving human subjects. The extraordinary circumstances of research conducted in disaster settings require appropriate regulations to ensure the protection of human participants. The goal of this study is to systematically and qualitatively review the existing ethical guidelines for disaster research by using the constant comparative method (CCM).
Methods
We performed a systematic qualitative review of disaster research ethics guidelines to collect and compare existing regulations. Guidelines were identified by a three-tiered search strategy: 1) searching databases (PubMed and Google Scholar), 2) an Internet search (Google), and 3) a search of the references in the included documents from the first two searches. We used the constant comparative method (CCM) for analysis of included guidelines.
Results
Fourteen full text guidelines were included for analysis. The included guidelines covered the period 2000-2014. Qualitative analysis of the included guidelines revealed two core themes: vulnerability and research ethics committee review. Within each of the two core themes, various categories and subcategories were identified.
Conclusions
Some concepts and terms identified in analyzed guidelines are used in an inconsistent manner and applied in different contexts. Conceptual clarity is needed in this area as well as empirical evidence to support the statements and requirements included in analyzed guidelines.

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Volume 65, Issue 9, September 2016
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Oct 2016 Volume 16 Number 10 p1085-1202 e202-e240
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October 20, 2016 Vol. 375 No. 16
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Original Articles
Guillain–Barré Syndrome Associated with Zika Virus Infection in Colombia
Beatriz Parra, Ph.D., Jairo Lizarazo, M.D., Jorge A. Jiménez-Arango, M.D., Andrés F. Zea-Vera, M.D., Ph.D., Guillermo González-Manrique, M.D., José Vargas, M.D., Jorge A. Angarita, M.D., Gonzalo Zuñiga, M.D., Reydmar Lopez-Gonzalez, M.D., Cindy L. Beltran, M.D., Karen H. Rizcala, M.D., Maria T. Morales, M.D., Oscar Pacheco, M.D., Martha L. Ospina, M.D., Anupama Kumar, M.B., B.S., David R. Cornblath, M.D., Laura S. Muñoz, M.D., Lyda Osorio, M.D., Ph.D., Paula Barreras, M.D., and Carlos A. Pardo, M.D.
N Engl J Med 2016; 375:1513-1523 October 20, 2016 DOI: 10.1056/NEJMoa1605564

Editorials
Zika Getting on Your Nerves? The Association with the Guillain–Barré Syndrome
J.A. Frontera and I.R.F. da Silva

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October 2016, VOLUME 138 / ISSUE 4
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Education and Training of Emergency Medical Teams: Recommendations for a Global Operational Learning Framework
October 21, 2016 · *Discussion*
An increasing number of international emergency medical teams are deployed to assist disaster-affected populations worldwide. Since Haiti earthquake those teams have been criticised for ill adapted care, lack of preparedness in addition to not coordinating with the affected country healthcare system. The Emergency Medical Teams (EMTs) initiative, as part of the Word Health Organization's Global Health Emergency Workforce program, aims to address these shortcomings by improved EMT coordination, and mechanisms to ensure quality and accountability of national and international EMTs. An essential component to reach this goal is appropriate education and training. Multiple disaster education and training programs are available. However, most are centred on individuals' professional development rather than on the EMTs operational performance. Moreover, no common overarching or standardised training frameworks exist. In this report, an expert panel review and discuss the current approaches to disaster education and training and propose a three-step operational learning framework that could be used for EMTs globally. The proposed framework includes the following steps: 1) ensure professional competence and license to practice, 2) support adaptation of technical and non-technical professional capacities into the low-resource and emergency context and 3) prepare for an effective team performance in the field. A combination of training methodologies is also recommended, including individual theory based education, immersive simulations and team training. Agreed curriculum and open access training materials for EMTs need to be further developed, ideally through collaborative efforts between WHO, operational EMT organizations, universities, professional bodies and training agencies.

Laboratory Diagnosis for Outbreak-Prone Infectious Diseases after Typhoon Yolanda (Haiyan), Philippines

October 21, 2016 · *Research Article*
Introduction: Typhoon Yolanda (Haiyan) hit the central part of the Philippines on November 8, 2013. To identify possible outbreaks of communicable diseases after the typhoon, nasopharyngeal swabs, stool and blood samples were collected from patients who visited the Eastern Visayas Regional Medical Center due to acute respiratory infection (ARI), acute gastroenteritis (AGE) or other febrile illness (OFI) including suspected dengue fever, between November 28, 2013 and February 5, 2014.
Methods: Samples were tested on-site for selected pathogens using rapid diagnostic tests. Confirmation and further analysis were conducted at the Research Institute for Tropical Medicine (RITM) in Manila using polymerase chain reaction (PCR) and sequencing. Residues of the rapid diagnostic tests and samples collected in the filter papers (FTATM card) were transported to Manila under suboptimal conditions. PCR results were compared between the kit residues and the filter papers.
Results: A total of 185 samples were collected. Of these, 128 cases were ARI, 17 cases were AGE and 40 cases were OFI. For nasopharyngeal swab samples, detection rates for enterovirus and rhinovirus residues were higher than the filter papers. For stool samples, rotavirus positive rate for the filter paper was higher than the kit residues. We also managed to obtain the sequence data from some of the kit residues and filter papers.
Discussion: Our results confirmed the importance of PCR for the laboratory diagnosis of infectious diseases in post-disaster situations when diagnostic options are limited.

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Volume 31 - Issue 5 - October 2016
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12 October 2016; volume 283, issue 1840
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Volume 9 Issue 22 October 2016
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October 2016; 26 (12)
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Childbirth in Brazil **Volume 13 Supplement 3**
Research
Publication of this supplement was funded by the Oswaldo Cruz Foundation. The articles have been through the journal's standard peer review process for supplements. The Supplement Editor declares that he has no competing interests.

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Addressing public health vulnerabilities and promoting sustainable adaptation
[Reviewed earlier]

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September 2016 Volume 36, Issue 9 Pages 1683–1812
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[Reviewed earlier]

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Volume 9, 2016
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19 October 2016 Vol 8, Issue 361
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Volume 160, Pages 1-130 (July 2016)
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October 2016 Volume 21, Issue 10 Pages 1197–1345
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Volume 34, Issue 46, Pages 5463-5696 (4 November 2016)
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Conference reports
Equity in disease prevention: Vaccines for the older adults – a national workshop, Australia 2014
Pages 5463-5469
C. Raina MacIntyre, Robert Menzies, Elizabeth Kpozehouen, Michael Chapman, Joanne Travaglia, Michael Woodward, Lisa Jackson Pulver, Christopher J. Poulos, David Gronow, Timothy Adair
Abstract
On the 20th June, 2014 the National Health and Medical Research Council's Centre for Research Excellence in Population Health "Immunisation in under Studied and Special Risk Populations", in collaboration with the Public Health Association of Australia, hosted a workshop "Equity in disease prevention: vaccines for the older adults". The workshop featured international and national speakers on ageing and vaccinology. The workshop was attended by health service providers, stakeholders in immunisation, ageing, primary care, researchers, government and non-government organisations, community representatives, and advocacy groups. The aims of the workshop were to: provide an update on the latest evidence around immunisation for the older adults; address barriers for prevention of infection in the older adults; and identify immunisation needs of these groups and provide recommendations to inform policy.
There is a gap in immunisation coverage of funded vaccines between adults and infants. The workshop reviewed provider misconceptions, lack of Randomised Control Trials (RCT) and cost-effectiveness data in the frail elderly, loss of autonomy, value judgements and ageism in health care and the need for an adult vaccination register. Workshop recommendations included recognising the right of elderly people to prevention, the need for promotion in the community and amongst healthcare workers of the high burden of vaccine preventable diseases and the need to achieve high levels of vaccination coverage, in older adults and in health workers involved in their care. Research into new vaccine strategies for older adults which address poor coverage, provider attitudes and immunosenescence is a priority. A well designed national register for tracking vaccinations in older adults is a vital and basic requirement for a successful adult immunisation program. Eliminating financial barriers, by addressing inequities in the mechanisms for funding and subsidising vaccines for the older adults compared to those for children, is important to improve equity of access and vaccination coverage. Vaccination coverage rates should be included in quality indicators of care in residential aged care for older adults. Vaccination is key to healthy ageing, and there is a need to focus on reducing the immunisation gap between adults and children

Review

Assessing strategies for increasing urban routine immunization coverage of childhood vaccines in low and middle-income countries: A systematic review of peer-reviewed literature

Review Article
Pages 5495-5503
Kristin N. Nelson, Aaron S. Wallace, Samir V. Sodha, Danni Daniels, Vance Dietz
Abstract
Introduction
Immunization programs in developing countries increasingly face challenges to ensure equitable delivery of services within cities where rapid urban growth can result in informal settlements, poor living conditions, and heterogeneous populations. A number of strategies have been utilized in developing countries to ensure high community demand and equitable availability of urban immunization services; however, a synthesis of the literature on these strategies has not previously been undertaken.
Methods
We reviewed articles published in English in peer-reviewed journals between 1990 and 2013 that assessed interventions for improving routine immunization coverage in urban areas in low- and middle-income countries. We categorized the intervention in each study into one of three groups: (1) interventions aiming to increase utilization of immunization services; (2) interventions aiming to improve availability of immunization services by healthcare providers, or (3) combined availability and utilization interventions. We summarized the main quantitative outcomes from each study and effective practices from each intervention category.
Results
Fifteen studies were identified; 87% from the African, Eastern Mediterranean and Southeast Asian regions of the World Health Organization (WHO). Six studies were randomized controlled trials, eight were pre- and post-intervention evaluations, and one was a cross-sectional study. Four described interventions designed to improve availability of routine immunization services, six studies described interventions that aimed to increase utilization, and five studies aiming to improve both availability and utilization of services. All studies reported positive change in their primary outcome indicator, although seven different primary outcomes indicators were used across studies. Studies varied considerably with respect to the type of intervention assessed, study design, and length of intervention assessment.
Conclusion
Few studies have assessed interventions designed explicitly for the unique challenges facing immunization programs in urban areas. Further research on sustainability, scalability, and cost-effectiveness of interventions is needed to fill this gap.

The Roma vaccination gap: Evidence from twelve countries in Central and South-East Europe

Original Research Article
Pages 5524-5530
Laetitia Duval, François-Charles Wolff, Martin McKee, Bayard Roberts
Abstract
Aim
To investigate differences in vaccination coverage between Roma and otherwise comparable non-Roma children, including factors associated with the vaccination gap, health care access and discrimination faced by Roma.
Methods

We analyse data from the Roma Regional Survey 2011 implemented in twelve countries of Central and South-East Europe. Our sample comprises 8233 children aged up to 6 with 7072 Roma children and 1161 non-Roma children. Estimates of the Roma vaccination gap are estimated using Logit regressions.
Results
We find that the Roma children have a lower probability of being vaccinated compared to non-Roma (odds ratio = 0.325). The odds of being vaccinated for a Roma child is 33.9% that of a non-Roma child for DPT, 34.4% for Polio, 38.6% for MMR and 45.7% for BCG. These differences do not appear to be explained entirely by their worse socio-economic status. The ethnic gap narrows by about 50% once individual characteristics are controlled for, with odds ratios of 0.548 for DPT, 0.559 for Polio, 0.598 for MMR and 0.704 for BCG. The probability of being vaccinated increases with access to health care, especially when Roma have a doctor to approach when needed.
Conclusions
Our findings point out a large difference in vaccination coverage between Roma and non-Roma and support the need for better understanding of factors influencing vaccination among Roma as well as policies that might improve services for Roma in Central and South-East Europe.

Immunisation practices in centres caring for children with perinatally acquired HIV: A call for harmonisation
Original Research Article
Pages 5587-5594
Alasdair Bamford, Emma C. Manno, Maria Jose Mellado, Vana Spoulou, Laura Marques, Henriette J. Scherpbier, Tim Niehues, Agnieszka Oldakowska, Paolo Rossi, Paolo Palma, On behalf of PENTA-vac Group
Abstract
Background
Current national immunisation schedules differ between countries in terms of vaccine formulation, timing of vaccinations and immunisation programme funding and co-ordination. As a result, some HIV infected paediatric population may be left susceptible to vaccine preventable infections. Vaccines used in healthy population should be subjected to high quality ethical research and be explicitly validated for use in children with special vaccination needs such as those infected with HIV. This survey was completed to assess current vaccination practices and attitudes toward vaccination among pediatricians who care for vertically HIV infected children.
Methods
An online questionnaire was completed by 46 experts in paediatric HIV-infection from the Paediatric European Network for Treatment of AIDS (PENTA). Data were collected between November 2013 and March 2014.
Results
46 units looking after 2465 patients completed the questionnaire. The majority of units (67%) reported that common childhood immunisation were administered by the family doctor or local health services rather than in the HIV specialist centre. Vaccination histories were mostly incomplete and difficult to obtain for 40% of the studied population. Concerns were reported regarding the use of live attenuated vaccines, such as varicella and rotavirus, and these were less frequently recommended (61% and 28% of the units respectively). Monitoring of vaccine responses was employed in a minority of centres (41%). A range of different assays were used resulting in diverse units of measurement and proposed correlates of protection.
Conclusion

Vaccination practices for perinatally HIV-infected children vary a great deal between countries. Efforts should be made to improve communication and documentation of vaccinations in healthcare settings and to harmonise recommendations relating to additional vaccines for HIV infected children and the use of laboratory assays to guide immunisation. This will ultimately improve coverage and vaccine induced immunity in this vulnerable patient group.

Adolescent confidence in immunisation: Assessing and comparing attitudes of adolescents and adults

Original Research Article

Pages 5595-5603

Bing Wang, Lynne Giles, Hossein Haji Ali Afzali, Michelle Clarke, Julie Ratcliffe, Gang Chen, Helen Marshall

Abstract

Introduction

There is limited knowledge of adolescent views and attitudes towards immunisation. Our study investigated adolescent attitudes to immunisation and compared differences in vaccination attitudes between adolescents and adults.

Methods

This study was a cross-sectional, national online survey. Recruitment was stratified by state and gender to ensure findings were nationally representative. Regression analyses were performed to assess and compare adolescent and adult views on vaccine benefits, community protection, risks, side effects, sources of information, and decision-making preference.

Results

In 2013, 502 adolescents and 2003 adults completed the online survey. Lower levels of vaccine confidence were observed in adolescents with adolescents less likely to believe vaccines are beneficial and/or safe compared to adults ($p = 0.043$). Compared to females, males were less confident of vaccine benefits ($p < 0.05$) but less concern about vaccine side effects ($p < 0.05$). Adolescents were more concerned about vaccine side effects than adults for pain ($p < 0.001$), redness or swelling ($p < 0.001$), and fever ($p = 0.006$). Adolescents were less likely than adults to consider health professionals ($p < 0.001$) and the media (e.g. internet) ($p = 0.010$) as important sources of information, and were more likely to seek information from social networks ($p < 0.001$) including families and schools. Although 62.0% of adolescents agreed that parents should make the decision about vaccination for them, adolescents were more likely to prefer a joint decision with parents ($p < 0.001$) or by themselves ($p = 0.007$) compared with adults.

Conclusion

Adolescents have a lesser understanding of vaccine safety and benefits than adults and have higher concerns about potential vaccine reactions. Improving adolescent awareness and knowledge of the benefits and risks of vaccination through school-based educational programs may improve confidence in and uptake of vaccines for adolescents and increase vaccine confidence in the next generation of parents.

Trends in compliance with two-dose influenza vaccine recommendations in children aged 6 months through 8 years, 2010–2015

Original Research Article

Pages 5623-5628

Xia Lin, Amy Parker Fiebelkorn, Laura J. Pabst

Abstract

Background
Children aged 6 months through 8 years may require two doses of influenza vaccine for adequate immune response against the disease. However, poor two-dose compliance has been reported in the literature.
Methods
We analyzed data for >2.6 million children from six immunization information system (IIS) sentinel sites, and assessed full vaccination coverage and two-dose compliance in the 2010–2015 influenza vaccination seasons. Full vaccination was defined as having received at least the recommended number of influenza vaccine doses (one or two), based on recommendations from the Advisory Committee on Immunization Practices. Two-dose compliance was defined as the percentage of children during each season who received at least two doses of influenza vaccine among those who required two doses and initiated the series.
Results
Across seasons, ⩾1-dose influenza vaccination coverage was mainly unchanged among 6–23 month olds (range: 60.9–66.6%), 2–4 year olds (range: 44.8–47.4%), and 5–8 year olds (range: 34.5–38.9%). However, full vaccination coverage showed increasing trends from 2010–11 season to 2014–15 season (6–23 months: 43.0–46.5%; 2–4 year olds: 26.3–39.7%; 5–8 year olds, 18.5–33.9%). Across seasons, two-dose compliance remained modest in children 6–23 months (range: 63.3–67.6%) and very low in older children (range: 11.6–18.7% in children 2–4 years and 6.8–13.3% in children 5–8 years). In the 2014–15 season, among children who required and received 2 doses, only half completed the two-dose series before influenza activity peaked.
Conclusions
Improved messaging of the two-dose influenza vaccine recommendations is needed for providers and parents. Providers are encouraged to determine a child's eligibility for two doses of influenza vaccine using the child's vaccination history, and to vaccinate children early in the season so that two-dose series are completed before influenza peaks.

Changes in childhood immunization decisions in the United States: Results from 2012 & 2014 National Parental Surveys

Original Research Article
Pages 5689-5696
Paula M. Frew, Allison Kennedy Fisher, Michelle M. Basket, Yunmi Chung, Jay Schamel, Judith L. Weiner, Jennifer Mullen, Saad B. Omer, Walter A. Orenstein
Abstract
Objective
Understanding the current status of parents' vaccine decision making is crucial to inform public policy. We sought to assess changes in vaccine decisions among parents of young children.
Methods
We conducted a web-based national poll of parents of children <7 years in 2012 and 2014. Participants reported vaccine decisions for their youngest child. We calculated survey-weighted population estimates of overall immunizations decisions, and delay/refusal rates for specific vaccines.
Results
In 2012, 89.2% (95% CI, 87.3–90.8%) reported accepting or planning to accept all recommended non-influenza childhood vaccines, 5.5% (4.5–6.6%) reported intentionally delaying one or more, and 5.4% (4.1–6.9%) reported refusing one or more vaccines. In 2014, the acceptance, delay, and refusal rates were 90.8% (89.3–92.1%), 5.6% (4.6–6.9%), and

3.6% (2.8–4.5%), respectively. Between 2012 and 2014, intentional vaccine refusal decreased slightly among parents of older children (2–6 years) but not younger children (0–1 years). The proportion of parents working to catch up on all vaccines increased while those refusing some but not all vaccines decreased. The South experienced a significant increase in estimated acceptance (90.1–94.1%) and a significant decrease in intentional ongoing refusal (5.0–2.1%). Vaccine delay increased in the Northeast (3.2–8.8%).

Vaccine: Development and Therapy
https://www.dovepress.com/vaccine-development-and-therapy-archive111
(Accessed 22 October 2016)
Review
The new first-line defense: the potential of nasopharyngeal colonization in vaccine strategies
Chan WY, Cohen JM, Brown JS
Vaccine: Development and Therapy 2016, 6:47-57
Published Date: 17 October 2016

Vaccines — Open Access Journal
http://www.mdpi.com/journal/vaccines
(Accessed 22 October 2016)
[No new relevant content]

Value in Health
September 2016–October 2016 Volume 19, Issue 6, p699-908
http://www.valueinhealthjournal.com/current
Themed Section: Incorporating Patient Preferences into Regulatory Decision Making
[Reviewed earlier]

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

Journal of Health Psychology
Published online before print October 17, 2016, doi: 10.1177/1359105316672924
Human papillomavirus vaccine information, motivation, and behavioral skills among young adult US women
EL Thompson, CA Vamos, DM Straub, WM Sappenfield…
Abstract
This study elicited the information needs, motivations, and behavioral skills related to human papillomavirus vaccine decision-making among young adult women. Interviews were conducted with college women, aged 18–26 years, and stratified by recently vaccinated (N = 25) and unvaccinated (N = 25). Comparative thematic analysis using the Information, Motivation, and

Behavioral Skills Model was conducted. Healthcare providers were identified as the most trusted sources for information. While unvaccinated women did not have experience receiving the vaccine, they reported the same procedural knowledge for vaccination. These findings suggest that young adult women have the information and procedural knowledge for human papillomavirus vaccination, but motivations may influence their decision-making.

Lancet Global Health
2016; 4: e856–63
Effectiveness of one dose of oral cholera vaccine in response to an outbreak: a case-cohort study
Andrew S Azman, Lucy A Parker, John Rumunu, Fisseha Tadesse, Francesco Grandesso, Lul L Deng, Richard Laku Lino, Bior K Bior, Michael Lasuba, Anne-Laure Page, Lameck Ontweka, Augusto E Llosa, Sandra Cohuet, Lorenzo Pezzoli, Dossou Vincent Sodjinou, Abdinasir Abubakar, Amanda K Debes, Allan M Mpairwe, Joseph F Wamala, Christine Jamet, Justin Lessler, David A Sack, Marie-Laure Quilici, Iza Ciglenecki, Francisco J Luquero

Summary
Background
Oral cholera vaccines represent a new effective tool to fight cholera and are licensed as two-dose regimens with 2–4 weeks between doses. Evidence from previous studies suggests that a single dose of oral cholera vaccine might provide substantial direct protection against cholera. During a cholera outbreak in May, 2015, in Juba, South Sudan, the Ministry of Health, Médecins Sans Frontières, and partners engaged in the first field deployment of a single dose of oral cholera vaccine to enhance the outbreak response. We did a vaccine effectiveness study in conjunction with this large public health intervention.
Methods
We did a case-cohort study, combining information on the vaccination status and disease outcomes from a random cohort recruited from throughout the city of Juba with that from all the cases detected. Eligible cases were those aged 1 year or older on the fi rst day of the vaccination campaign who sought care for diarrhoea at all three cholera treatment centres and seven rehydration posts throughout Juba. Confirmed cases were suspected cases who tested positive to PCR for Vibrio cholerae O1. We estimated the short-term protection (direct and indirect) conferred by one dose of cholera vaccine (Shanchol, Shantha Biotechnics, Hyderabad, India).
Findings
Between Aug 9, 2015, and Sept 29, 2015, we enrolled 87 individuals with suspected cholera, and an 898-person cohort from throughout Juba. Of the 87 individuals with suspected cholera, 34 were classified as cholera positive, 52 as cholera negative, and one had indeterminate results. Of the 858 cohort members who completed a follow-up visit, none developed clinical cholera during follow-up. The unadjusted single-dose vaccine effectiveness was 80·2% (95% CI 61·5–100·0) and after adjusting for potential confounders was 87·3% (70·2–100·0).
Interpretation
One dose of Shanchol was effective in preventing medically attended cholera in this study. These results support the use of a single-dose strategy in outbreaks in similar epidemiological settings.
Funding
Médecins Sans Frontières.

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Media/Policy Watch

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

We acknowledge the Western/Northern bias in this initial selection of titles and invite suggestions for expanded coverage. We are conservative in our outlook in adding news sources which largely report on primary content we are already covering above. Many electronic media sources have tiered, fee-based subscription models for access. We will provide full-text where content is published without restriction, but most publications require registration and some subscription level.

The Atlantic
http://www.theatlantic.com/magazine/
Accessed 22 October 2016
Why Doctors Without Borders Refused a Million Free Vaccines
The climax of a standoff with the pharmaceutical industry over high prices
James Hamblin
Oct 14, 2016

BBC
http://www.bbc.co.uk/
Accessed 22 October 2016
[No new, unique, relevant content]

The Economist
http://www.economist.com/
Accessed 22 October 2016
[No new, unique, relevant content]

Financial Times
http://www.ft.com/home/uk
Accessed 22 October 2016
[No new, unique, relevant content]

Forbes
http://www.forbes.com/
Accessed 22 October 2016
The Lives Of Your Children Are In Your Hands
Peter Lipson, Contributor
15 October 2016

…Babies are another matter. About half of kids under a year old who get whooping cough end up in the hospital. About 1/100 die of it. And you and I are to blame. (This link will take you to a video of a baby with whooping cough. It's hard to watch, but do it anyway.)

We're to blame in two ways: first, we fail to vaccinate our babies against pertussis, even though it couldn't be easier. Second, we fail to vaccinate ourselves. Immunity from the vaccine doesn't last very long, but it lasts long enough to get a baby through that critical first year. By the time we're adults, though, our protection has often worn off, unless we get a booster shot…

Foreign Affairs
http://www.foreignaffairs.com/
Accessed 22 October 2016
[No new, unique, relevant content]

Foreign Policy
http://foreignpolicy.com/
Accessed 22 October 2016
[No new, unique, relevant content]

The Guardian
http://www.guardiannews.com/
Accessed 22 October 2016
[No new, unique, relevant content]

New Yorker
http://www.newyorker.com/
Accessed 22 October 2016
[No new, unique, relevant content]

New York Times
http://www.nytimes.com/
Accessed 22 October 2016
Polio Vaccine Makers Failing to Make Enough Doses-WHO Experts
October 21, 2016 - By REUTERS
GENEVA — Two companies making vaccines to help the world eradicate polio are failing to produce enough, so many countries should prepare to give lower doses to make stocks last, a group of experts has advised the World Health Organization.

With polio on the brink of eradication globally, the WHO wants to see a worldwide switch from the traditional "live" oral polio vaccine, which runs the risk of spreading the disease, to an inactivated vaccine that needs to be injected.

But WHO's Strategic Advisory Group of Experts (SAGE), which meets twice a year, said a severe shortage of inactivated vaccine means many countries should use a fractional dose, via an intra-dermal rather than intra-muscular injection, allowing each dose to go twice as far.

"There are only two manufacturers of the vaccine and they are having some problems with production of the vaccine, and getting enough raw material of the polio virus," SAGE Chairman Jon Abramson told reporters on a conference call on Friday.

Polio is a contagious viral disease which invades the nervous system and can cause irreversible paralysis within hours.

"Each time we hear that there's a further reduction in the amount that can be anticipated, we have to make further adjustments," Abramson said. "My hope is this problem can be solved by 2018. But I can't promise that, obviously. It's not something we can control."

The two manufacturers are French drugmaker Sanofi Pasteur and Asia's largest vaccine maker, Serum Institute of India Ltd, owned by the billionaire Cyrus Poonawalla. No comment was available from the companies on Friday evening.

"It's a serious inconvenience," said Philippe Duclos, senior health adviser at WHO. "By and large the two manufacturers... underestimated the challenges of scaling up their production when they made the pledge to WHO."..

Wall Street Journal
http://online.wsj.com/home-page?_wsjregion=na,us&_homepage=/home/us
Accessed 22 October 2016
New Approach to Promoting HPV Vaccinations
17 October 2016
By Betsy McKay
Updated Oct. 17, 2016 2:07 p.m. ET
Health experts have a new strategy to get more young people vaccinated against HPV—don't talk about sex…

Washington Post
http://www.washingtonpost.com/
Accessed 22 October 2016
[No new, unique, relevant content]

Think Tanks et al

Brookings
http://www.brookings.edu/
Accessed 22 October 2016
[No new relevant content]

Center for Global Development [to 22 October 2016]
http://www.cgdev.org/page/press-center
Accessed 22 October 2016
[No new relevant content]

Council on Foreign Relations
http://www.cfr.org/
Accessed 22 October 2016
Global Polio Eradication Initiative's Response to Polio outbreak in the Lake Chad Basin
Council on Foreign Relations |
18 October 2016

The public reappearance of polio in northeast Nigeria is a disappointment. Nigeria had been thought to be free of polio for two years. The recent cases of paralysis caused by polio are likely the result of ongoing, undetected transmission rather than a new introduction of the disease from elsewhere. The small numbers of paralysis probably masks the extent of the presence of the disease. Only about one in two hundred polio cases results in paralysis…

CSIS

https://www.csis.org/
Accessed 22 October 2016
[No new relevant content]

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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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