

Vaccines and Global Health: The Week in Review 6 May 2017 Center for Vaccine Ethics & Policy (CVEP)

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

Vaccines and Global Health: The Week in Review is also **posted in pdf form** and as a set of blog posts at https://centerforvaccineethicsandpolicy.net. This blog allows full-text searching of over 8,000 entries. Comments and suggestions should be directed to

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Milestones :: Perspectives

Julius Youngner, Polio Vaccine Pioneer, Dies at 96

New York Times, May 04, 2017 - By SAM ROBERTS

Julius Youngner, an inventive virologist whose nearly fatal childhood illness destined him to become a medical researcher and a core member of the team that developed the Salk <u>polio vaccine</u> in 1955, died on April 27 at his home in Pittsburgh. He was 96.

His death was confirmed by his son, Dr. Stuart Youngner.

Dr. Youngner was the last surviving member of the original three-man research team assembled by Dr. Jonas Salk at the <u>University of Pittsburgh</u> to address the <u>polio</u> scourge, which peaked in the United States in the early 1950s when more than 50,000 children were struck by it in one year. Three other assistants later joined the group.

Dr. Salk credited his six aides with major roles in developing the polio vaccine, a landmark advance in modern medicine, which he announced on April 12, 1955.

The announcement — that the vaccine had proved up to 90 percent effective in tests on 440,000 youngsters in 44 states — was greeted with ringing churchbells and openings of public swimming pools, which had been drained for fear of contagion. Within six years, annual cases of the paralyzing disease had declined from 14,000 to fewer than 1,000.

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Populism, Politics and Measles

New York Times, The Opinion Pages - Editorial 1 May 2017

One of the tragedies of these post-truth times is that the lies, conspiracy theories and illusions spread by social media and populist politicians can be downright dangerous. The denial of human responsibility for climate change is one obvious example; another is opposition to vaccination. A serious outbreak of <u>measles</u> in Italy and in some other European countries could well be the result of a drop-off in <u>vaccinations</u> caused by utterly misguided and discredited claims about their dangers.

Vaccines are among the greatest achievements of medical science, an easily and safely administered defense against once common and often deadly diseases like measles, <u>polio</u>, <u>smallpox</u>, <u>whooping cough</u> and <u>cervical cancer</u>. Yet fear of vaccines has spread over the past two decades, fueled in part by an infamous study published in the medical journal Lancet in 1998 and later retracted and completely discredited.

More recently, President Trump has added his voice to vaccine skepticism, like this utterly unfounded and irresponsible tweet: "Healthy young child goes to doctor, gets pumped with massive shot of many vaccines, doesn't feel good and changes - <u>AUTISM</u>. Many such cases!" In Italy, the populist Five Star Movement (M5S) led by the comedian Beppe Grillo has campaigned actively on an anti-vaccination platform, likewise repeating the false ties between vaccinations and autism.

To these and other skeptics, the measles outbreak in Italy should sound a piercing alarm. As of April 26, the Italian Ministry of Health had reported 1,739 cases of the disease, compared with

840 in all of 2016 and only 250 in 2015. Of those stricken, 88 percent had not been vaccinated. The danger was not only to them: 159 of the cases were health care workers infected by patients. Yet studies show that 97 percent of people who receive the recommended two doses of MMR (measles, <u>mumps</u> and <u>rubella</u>) vaccine are fully protected. Most people today would not remember a time when measles — or mumps, or polio — were commonplace.

M5S may not be responsible for the entire outbreak, since vaccine skepticism predates the party's rise. Yet the percentage of 2-year-olds given vaccinations has steadily fallen in recent years, from 88 percent in 2013 to 86 percent in 2014 and 85.3 percent in 2015. The World Health Organization regards 95 percent as the level to achieve "herd immunity," at which point the disease poses no threat to the entire community.

Combating vaccine skepticism is not easy, because even the countless studies by innumerable health groups affirming that there is no link between vaccines and autism have failed to penetrate the fog spread by Mr. Grillo and his ilk. The Italian measles outbreak, unfortunate as it is, does give health authorities an opportunity to strengthen their case by pointing to concrete evidence of what inevitably follows when vaccinations drop off.

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Regional Director commits continuing support to Romania to stop measles outbreak and improve immunization performance

WHO Europe, 03-05-2017

...The ongoing outbreak in Romania has spread across the country since January 2016, affecting people of all ages and causing over 4800 cases, including 23 deaths as of 28 April 2017. The highest burden has fallen on children, including 888 infants too young to be vaccinated. Of all cases, 96.6% were not vaccinated. Today, Romania is facing critical vaccine shortages or delays, including of the measles, mumps and rubella (MMR) vaccine, along with a substantial drop in immunization coverage.

At the policy dialogue event, Prime Minister Sorin Grindeanu, spoke of the government's commitment to resolve the current vaccine supply shortage and ensure predictability, flexibility and continuity of supply in the future: "It's a situation that can no longer be tolerated or accepted. It's inadmissible for multiple vaccine shortage crises to occur in Romania each year.

This situation has caused suffering to those families whose children died of measles. There are no excuses for these tragedies, nor for the fact that for certain vaccines only 1 in 2 children are immunized".

Minister of Health, Dr Florian Bodog, outlined the government's plans to accelerate the response to the current measles outbreak through a far-reaching countrywide vaccination campaign. In the longer term the minister committed to:

- :: establish an effective vaccine management system;
- :: amend legislation regarding the purchasing of vaccines to keep the process transparent and predictable;
- :: develop a multi-year plan for assessing the need for vaccines;
- :: simplify pricing mechanisms;

:: build a national stock of vaccines for exceptional situations.

In early April 2017, the Ministry of Health introduced a new law on vaccination for public debate, which would make vaccination mandatory for kindergarten or school enrollment.

"We are open to dialogue and determined to work together to adopt the necessary legislative changes, adapting our legislation to the problems and conditions of our society," stressed Dr Laszlo Attila, head of the Public Health Committee of the Senate of Romania during the policy dialogue on immunization...

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Emergencies

Public Health Emergencies of International Concern (PHEIC) [to 6 May 2017]

POLIO

Public Health Emergency of International Concern (PHEIC)
Polio this week as of 25 April 2017

- :: The Strategic Advisory Group of Experts on immunization (SAGE) convened last week in Geneva. On polio eradication, the group noted the progress achieved in the remaining endemic countries. Recognizing an ongoing global supply constraint of inactivated polio vaccine (IPV), the group urged countries to adopt a fractional-dose approach (1/5th of a full dose), noting that several countries which had implemented this approach are able to meet their national vaccine requirements for its populations, and to prioritize supply to routine immunization rather than to outbreak response. SAGE also reviewed long-term immunization policy options for the post-certification world and put forward key recommendations for this period. A summary report from the meeting is available <a href="https://example.com/hereal/nee/block-nee/b
- :: The report from the 13th Meeting of the International Health Regulations Emergency Committee on the international spread of poliovirus and available on www.polioeradication.org. The Committee concluded that the current epidemiological situation continued to remain a Public Health Emergency of International Concern, and recommended the extension of the Temporary Recommendations for a further three months.[see below]

Country Updates [Selected Excerpts]

New cases or environmental samples reported across the monitored country/region settings: Afghanistan, Pakistan, Nigeria, Lake Chad Basin. Guinea and West Africa, and Lao People's Democratic Republic have been removed from the monitored geographies list.

Pakistan

:: Seven new WPV1 positive environmental samples were reported in the past week, all collected in April, from Islamabad, Pishin (Balochistan), Peshawar (Khyber Pakhtunkhwa), and Sindh (three from greater Karachi and one from Sukkur in northern Sindh).

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<u>Statement of the 13th IHR Emergency Committee regarding the international spread of poliovirus</u>

WHO statement 2 May 2017

[Excerpts; text bolding by Editor]

The thirteenth meeting of the Emergency Committee under the International Health Regulations (2005) (IHR) regarding the international spread of poliovirus was convened via teleconference by the Director General on 24 April 2017.

The Emergency Committee reviewed the data on wild poliovirus (WPV1) and circulating vaccinederived polioviruses (cVDPV). The Secretariat presented a report of progress for affected IHR States Parties subject to Temporary Recommendations. The following IHR States Parties presented an update on the implementation of the WHO Temporary Recommendations since the Committee last met on 7 February 2017: Afghanistan, Pakistan, Nigeria, and Equatorial Guinea. The committee also invited the Russian Federation and the Netherlands to provide information about polio events in their respective territories.

Wild polio

Overall the Committee was encouraged by continued steady progress in all three WPV1 infected countries, Pakistan, Afghanistan, and Nigeria, and the fall in the number of cases globally. While falling transmission in these three countries decreased the risk of international spread, the consequences should spread occur would represent a significant set-back to eradication and a risk to public health....

Vaccine derived poliovirus

The committee noted that there were no new outbreaks of cVDPV, and no new cases in the three current cVDPV2 outbreaks (Borno and Sokoto in northern Nigeria, and in Quetta Pakistan). However, these outbreaks highlighted the presence of vulnerable under immunized populations in countries with endemic transmission. The committee noted the comprehensive response to these outbreaks.

The Russian Federation provided an update on the actions taken following the detection of VDPV2s in two children from the Chechen Republic and Moscow, but the committee noted there were still some important gaps in the information and the final classification of the case is therefore pending. However, the surveillance and immunization activities taken in response to this event were welcomed, and there appears to be very little risk of international spread. In Lao PDR, the most recent case of cVDPV had onset in January 2016, and based on the most recent outbreak response assessment and the criteria of the committee, the country is no longer considered as infected, but remains vulnerable.

Conclusion

The Committee unanimously agreed that the risk of international spread of poliovirus remains a Public Health Emergency of International Concern (PHEIC), and recommended the extension of revised Temporary Recommendations for a further three months...

...Based on the advice concerning WPV1 and cVDPV, and the reports made by Afghanistan, Pakistan, Nigeria, and Equatorial Guinea, the Director General accepted the Committee's

assessment and on 2 May 2017 determined that the events relating to poliovirus continue to constitute a PHEIC, with respect to WPV1 and cVDPV. The Director General endorsed the Committee's recommendations for countries falling into the definition for 'States infected with WPV1, cVDPV1 or cVDPV3 with potential risk for international spread', 'States infected with cVDPV2' and for 'States no longer infected by WPV1 or cVDPV, but which remain vulnerable to re-infection by WPV or cVDPV' and extended the Temporary Recommendations as revised by the Committee under the IHR to reduce the risk of international spread of poliovirus, effective 2 May 2017.

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WHO Grade 3 Emergencies [to 6 May 2017]

<u>Iraq</u> - No new announcements identified

<u>Yemen</u> – *No new announcements identified*

Nigeria - No new announcements identified

South Sudan - No new announcements identified

The Syrian Arab Republic - No new announcements identified

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WHO Grade 2 Emergencies [to 6 May 2017]

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.

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UN OCHA – L3 Emergencies

The UN and its humanitarian partners are currently responding to three 'L3' emergencies. This is the global humanitarian system's classification for the response to the most severe, large-scale humanitarian crises.

Iraa

:: <u>Iraq: Mosul Humanitarian Response Situation Report No. 31 (24 April to 30 April 2017)</u> [EN/AR/KU]

:: <u>Support provided to Yazidi survivors of kidnapping and sexual violence [EN/AR/KU]</u> Report Published on 30 Apr 2017

Syrian Arab Republic

:: 5 May 2017 Leo Messi Foundation helps UNICEF get Syrian children back into the classroom

Yemen - No new announcements identified.

UN OCHA – Corporate Emergencies

When the USG/ERC declares a Corporate Emergency Response, all OCHA offices, branches and sections provide their full support to response activities both at HQ and in the field.

Somalia

- :: Somalia: Drought Response Situation Report No. 6 (as of 30 April 2017)
- :: <u>Humanitarian Bulletin Somalia April 2017 | Issued on 4 May 2017</u>

Ethiopia

:: 2 May 2017 Ethiopia Weekly Humanitarian Bulletin, 01 May 2017

Nigeria – No new announcements identified.

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Editor's Note:

We will cluster these recent emergencies as below and continue to monitor the WHO webpages for updates and key developments.

EBOLA/EVD [to 6 May 2017]

http://www.who.int/ebola/en/

4 May 2017

Leaders gather in Guinea to celebrate Ebola vaccine successes

"The world is far better prepared for another Ebola outbreak," said Dr Margaret Chan, Director-General of the World Health Organization, today at a celebratory event to recognize the Governments and people of the three most-affected countries for their contribution to the control of the Ebola outbreak in 2014-15.

Dr Chan joined the President of the Republic of Guinea, HE Professor Alpha Conde, His Excellency Minister of Health, Dr Abdourahmane Diallo, and representatives from the Governments of Liberia and Sierra Leone, in celebrating the successful development of the world's first vaccine against Ebola. Dr Matshidiso Moeti, Regional Director of WHO's Office of the African Region, was also present at this celebration.

"This truly remarkable achievement is thanks to collaborative efforts of the Government of Guinea, health workers, local and international scientists, public and private entities, international donors and, above all, the thousands of people who consented to be vaccinated in this vaccine trial," she said.

In December 2016, The Lancet published results of the WHO-led Guinea ring vaccination trial, showing that the world's first Ebola vaccine provides substantial protection. Among more than 11 000 people who were vaccinated in the trial, no cases of Ebola virus disease occurred. Building on the work done to fast-track the development and testing of this vaccine, WHO established the R&D Blueprint to help cut the time in future for the development of new vaccines and treatments against new and emerging infectious diseases including Lassa Fever and MERS Coronavirus.

Dr Chan presented certificates to selected individuals for their remarkable contribution to the vaccine trial as well as the control of the Ebola outbreak in Guinea, Liberia and Sierra Leone.

:: <u>Opening remarks by WHO Director-General at the Ebola vaccines for Guinea and the world</u> event

MERS-CoV [to 6 May 2017]

http://www.who.int/emergencies/mers-cov/en/
[No new digest content identified]

Yellow Fever [to 6 May 2017] http://www.who.int/emergencies/yellow-fever/en/ [No new digest content identified]

Zika virus [to 6 May 2017] http://www.who.int/emergencies/zika-virus/en/ [No new digest content identified]

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WHO & Regional Offices [to 6 May 2017]

Somalia launches second cholera vaccination campaign in Baidoa

3 May 2017 – WHO and the Federal Ministry of Health of Somalia launched the first round of a preventative oral cholera vaccination campaign (OCV) today in Baidoa at the Baidoa Regional Hospital, targeting 224 000 persons aged 1 year and older.

The launch was attended by the President of South West State H.E. Sharif Hassan Sheikh Adan, Somalia's Minister of Health and Social Services H.E. Dr Fawziya Abikar, WHO Representative for Somalia Dr Ghulam Popal and state Minister of Health Issak Ali Subag along with the community, local leaders and representative of UN and NGO partners.

The vaccination campaign is in response to a major cholera outbreak in Somalia that began in January 2017. Since the beginning of the year, a total of 31 674 cases and 618 deaths have been reported in Somalia. Of these, 18 608 cases and 415 deaths have been reported in the South West State, which is nearly 60% of all AWD/ cholera cases reported in the country.

The start of the rainy season has brought some respite to the community where clean water sources are scare, however, the effects of the drought in Somalia have had its harsh impact. Lack of access to clean water and hygiene, food insecurity and malnutrition caused by drought have increased cases of cholera in the area.

The vaccination campaign is conducted in 2 rounds and will conclude before the start of Ramadan. The cholera vaccine does not replace traditional preventative measures such as access to clean water and safe hygiene practises. Supplementing the cholera vaccine, water treatment tablets were distributed to the community during the campaign by the WASH cluster. H.E. Dr Fawziya Abikar thanked WHO for supporting the Ministry of Health in introducing oral cholera vaccines in the country. "This is an important step to prevent the further spread of

cholera and we are thankful to WHO and partners for their continued support in containing this outbreak," she said.

The OCV campaign in Baidoa follows a successful vaccination campaign that was implemented in 7 high-risk districts in Banadir, Hiraan and Lower Jubba regions. A concurrent vaccination campaign has also started in Jowhar in Middle Shebelle region this week, targeting 239000 vulnerable persons aged 1 year and above.

Dr Ghulam Popal reiterated WHO's commitment to support cholera response efforts across the country. "We are working with health authorities at all levels and humanitarian partners to limit this outbreak," he said.

The vaccination campaigns are supported by the Global Task Force on Cholera Control, GAVI the Vaccine Alliance, UNICEF, Sweden and health partners in its various stages of planning and implementation. WHO is also engaged in planning, organization and monitoring of the campaigns.

Disease outbreak news [DONs]

- :: <u>Unexplained cluster of deaths Liberia</u> 5 May 2017
- :: Hepatitis E Niger 5 May 2017
- :: Human infection with avian influenza A(H7N9) virus China 1 May 2017

Highlights

Noncommunicable diseases: the slow motion disaster

May 2017 -- Of all the major health threats to emerge, none has challenged the very foundations of public health so profoundly as the rise of chronic noncommunicable diseases. Heart disease, cancer, diabetes, and chronic respiratory diseases, once linked only to affluent societies, are now global, and the poor suffer the most.

"Fight antibiotic resistance... it's in your hands"

May 2017 – World Hand Hygiene Day, marked globally on 5 May, highlights the importance of hand hygiene in health care. The slogan of this year's campaign illustrates the important relationship between good infection prevention and control practices like washing your hands and preventing antibiotic resistance.

Drowning: confronting the silent killer in the Philippines

May 2017 – In the Philippines, an average of 3276 deaths per year from accidental drowning and submersion were recorded in 2006–2013. To address this, WHO, the Philippine Department of Health, local government units, and Bloomberg Philanthropies undertook a drowning prevention project.

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Weekly Epidemiological Record, 5 May 2017, vol. 92, 18 (pp. 229–240)

- :: Progress towards measles elimination African Region, 2013–2016
- :: Monthly report on dracunculiasis cases, January- March 2017

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WHO Regional Offices

Selected Press Releases, Announcements

WHO African Region AFRO

- :: <u>High-level meeting on Ebola Vaccines gets underway in Conakry, Guinea</u> [undated] WHO Regional Director for Africa Dr Matshidiso Moeti and the Director-General of WHO, Dr Margaret Chan are in Conakry, Guinea to participate in the high-level meeting on Ebola Vaccines for Guinea and the World
- :: In Kenya, the path to elimination of malaria is lined with good preventions 02 May 2017

WHO Region of the Americas PAHO

- :: Traffic speed management key to saving lives, making cities more livable (05/04/2017)
- :: Hand hygiene is key to safe care and prevention of antibiotic resistance (05/04/2017)

WHO South-East Asia Region SEARO

No new announcements identified.

WHO European Region EURO

- :: Hand hygiene a key defence in Europe's fight against antibiotic resistance 04-05-2017
- :: <u>Highlighting nurses and midwives' commitment to delivering the highest quality care</u> 04-05-2017
- :: <u>Regional Director commits continuing support to Romania to stop measles outbreak and</u> improve immunization performance 03-05-2017
- :: WHO Regional Director for Europe highlights key health aspects for SDG implementation at the first Regional Forum on Sustainable Development 03-05-2017
- :: <u>Georgia hosts meeting on improving antenatal care in eastern Europe and central Asia</u> 02-05-2017

WHO Eastern Mediterranean Region EMRO

:: Antimicrobial resistance: now a political priority May 2017

WHO Western Pacific Region

:: Slow down to save lives 5 May 2017

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CDC/ACIP [to 6 May 2017]

http://www.cdc.gov/media/index.html

Press Release

Friday, May 05, 2017

CDC updates guidance on interpretation of Zika testing results for pregnant women

Recommendations focus on women who live in or frequently travel to areas with a CDC Zika travel notice

The Centers for Disease Control and Prevention (CDC) today issued a <u>Health Alert Notice</u> with updated guidance for healthcare professionals to interpret Zika test results for women who live in, or frequently travel (daily or weekly) to areas with a CDC Zika travel notice.

This change is being made because CDC's Zika testing guidance for pregnant women relies, in part, on a test [Zika virus Immunoglobulin M (IgM) ELISA] to detect Zika antibodies or proteins that the body makes to fight Zika infections. New data suggest that Zika virus infection, similar to some other flavivirus infections, may result in Zika antibodies staying in the body for months after infection for some individuals. As a result, results of these tests may not be able to determine whether women were infected before or after they became pregnant.

Specifically, CDC recommends the following guidance for healthcare professionals evaluating women without symptoms who had potential Zika exposure—particularly women who live in or frequently travel (daily or weekly) to areas with CDC Zika travel notices. Use of these tests may be helpful, but may not always be conclusive, in distinguishing how recent the infection is.

- :: Screen pregnant women for risk of Zika exposure and symptoms of Zika. Test pregnant women promptly, using nucleic acid testing (NAT), if they develop symptoms at any point during pregnancy or if their sexual partner tests positive for Zika virus infection;
- :: Consider NAT testing at least once during each trimester of pregnancy to detect evidence of Zika virus, unless a previous test has been positive;
- :: Consider testing specimens obtained during amniocentesis to detect evidence of Zika virus if amniocentesis is performed for other reasons;
 - :: Counsel all pregnant women each trimester about the limitations of Zika testing."...

MMWR News Synopsis for May 4, 2017

Progress Toward Measles Elimination — African Region, 2013–2016 CDC Media Relations (404) 639-3286

To eliminate measles by 2020, countries in the region and partners need to 1) achieve ≥95% two-dose measles vaccine coverage through improved immunization services, including introducing a second vaccine dose of measles into routine immunization schedules; 2) improve vaccine campaign quality by preparing 12-15 months in advance, and using related preparation and assessment tools; 3) fully perform necessary disease surveillance for elimination purposes; 4) conduct annual district-level risk assessments; and 5) establish commissions to verify measles elimination. Countries in the World Health Organization African Region show progress and setbacks toward a regional goal of measles elimination by 2020. The number of new cases annually in the region has decreased by 63% from 2013 to 2016. However, not enough children are receiving the recommended two doses of vaccine to provide full protection against measles. The majority of children in the region not being fully protected against measles reside in four countries: Nigeria, Ethiopia, the Democratic Republic of the Congo, and Angola; these countries also account for the majority of the region's measles cases each year. Only half of all African Region countries have introduced a second vaccine dose against measles. For the region to eliminate measles by 2020, efforts are needed for countries to achieve ≥95% two-dose coverage.

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Announcements

PATH [to 6 May 2017]

http://www.path.org/news/index.php

Press release | May 01, 2017

Biovac and PATH announce partnership to develop novel vaccine against newborn infection

South African manufacturer will be the first in a low-resource country to develop a vaccine against Group B Streptococcus vaccine, a leading cause of severe infection in infants

Durban, South Africa, 2 May 2017—The South Africa—based Biovac Institute (Biovac) and PATH, an international health organization, are pleased to announce the launch of a collaborative partnership to develop a novel vaccine against Group B Streptococcus (GBS), supported by a grant from the Bill & Melinda Gates Foundation. The partnership was announced today at the Innovation Effect Africa symposium held alongside the World Economic Forum event in Durban.

Biovac, a public-private partnership based in Cape Town, will be one of only three companies in the world and the only developing-country vaccine manufacturer to develop a novel conjugate vaccine against GBS....

Announcement | May 01, 2017

PATH Statement on the US Fiscal Year 2017 Appropriations Bill

PATH Applauds Congress for Protecting Vital Health Programs

Press release | May 01, 2017

Powering African innovation for health and economic growth

Leaders convene ahead of the World Economic Forum on Africa to accelerate investment in African-led innovation

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Human Vaccines Project [to 6 May 2017]

http://www.humanvaccinesproject.org/media/press-releases/03 May, 2017

Jose-Maria Fernandez Joins The Human Vaccines Project Board Of Directors

NEW YORK, May 3, 2017 /PRNewswire-USNewswire/ -- The Human Vaccines Project, a nonprofit public-private partnership focused on decoding the immune system to improve human health, today announced the board appointment of Jose-Maria Fernandez, managing partner at Altamar Credit, Altamar Capital Partners LLC. Fernandez brings extensive experience in economics, finance and capital markets to the post. He formerly served as Director General of the Spanish Treasury.

"Jose-Maria brings deep expertise in financial markets in the US and Europe. Engaging him as part of our team will strengthen our current board as we continue to expand our project and reach," said Wayne C. Koff, president and CEO of the Human Vaccines Project. "Along with his background in business leadership and finance, he brings a strong personal commitment to seeing biomedical research expand and improve to advance global public health."...

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Global Fund [to 6 May 2017]

http://www.theglobalfund.org/en/news/?topic=&type=NEWS;&country= News

Global Fund Accelerates Efforts To End Epidemics

04 May 2017

KIGALI, Rwanda – At its 37th Meeting, the Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria took significant steps toward increasing impact and maximizing effectiveness in its goal of ending epidemics, which will achieve greater health security and long-term prosperity.

Taking on serious challenges like expanding impact in public health as more countries transition toward domestic funding, the Board addressed numerous issues on how to continue to expand prevention, treatment and care for people affected by HIV, TB and malaria in the coming years.

The Global Fund is embedding into its work the principles and practices of a new policy on sustainability, transition and co-financing. It aims to leverage additional sources of funding, strengthen domestic investment and co-financing of core interventions, while planning for long-term transition.

In his final address to the Board, outgoing Executive Director Mark Dybul weaved together global dynamics as he pointed to a clear direction for the Global Fund: working together collaboratively, optimizing portfolio management, improving program quality and efficiency, and constantly looking for ways to maximize the impact of funds in countries where we invest. Dr. Dybul completes a four-year term on 31 May 2017. Marijke Wijnroks, currently Chief of Staff, will serve as Interim Executive Director until the Board selects a replacement for Dr. Dybul.

The Board confirmed an Executive Director Nomination Committee with nine members to oversee the search for the Global Fund's next Executive Director. The Global Fund anticipates soliciting applications for the position beginning in early June, and intends to select a new Executive Director at the Board's next meeting in November 2017...

News

Global Fund Board Selects New Chair and Vice-Chair

03 May 2017

KIGALI, Rwanda – The Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria selected Aida Kurtović as its new Chair, after serving as Vice-Chair for the past two years. The Board also selected Ambassador John Simon as incoming Vice-Chair.

Kurtović, who is from Bosnia and Herzegovina, was selected for a two-year term during a Board meeting that is being hosted by the government of Rwanda...

As Chair of the Board, Kurtović succeeds Norbert Hauser of Germany, whose term began in April 2015.

Ambassador John Simon, selected as Vice-Chair of the Board, is a distinguished government official with special expertise in innovative finance, and is currently founder and managing partner of Total Impact Capital, an impact investing firm. He has served as United States Ambassador to the African Union, and as Executive Vice President of the Overseas Private Investment Corporation (OPIC)...

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UNAIDS [to 6 May 2017]

http://www.unaids.org/

Selected Press Releases & Updates

Update

PEPFAR is on track to deliver yet more results

04 May 2017

Since its establishment in 2003, the United States President's Emergency Plan for AIDS Relief (PEPFAR) has saved millions of lives. In 2016, around 11.5 million people living with HIV had access to antiretroviral treatment through PEPFAR-funded programmes, including 1.1 million children. Nearly 2 million babies born to women living with HIV were born HIV-free, and 6.2 million orphans and other vulnerable children received care and support.

In addition, PEPFAR funding supported more than 11.7 million voluntary medical male circumcision procedures to help prevent HIV acquisition and one million adolescent girls and young women were reached through the DREAMS initiative in 10 countries in sub-Saharan Africa.

And PEPFAR is on track to continue to deliver yet more results. Through a series of consultations over the past three months, PEPFAR has completed planning for its 2017 funding cycle to support more than 30 countries through Country Operational Plans...

Update

Generating evidence to ensure HIV is part of social protection

04 May 2017

Widely used in developed countries to maintain living standards and address transient poverty, social protection has now become an essential element of modern development efforts. Social protection in developing countries encompasses a range of programmes designed to help lift people out of poverty and prevent, manage and overcome situations that adversely affect their well-being.

To ensure that HIV is considered and integrated appropriately into social protection programmes, UNAIDS and partners have developed an <u>HIV and social protection assessment tool</u>. The tool has been designed to analyse social protection schemes and establish whether they take into account the needs of people at higher risk of contracting HIV and people living with and affected by the virus...

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IVI [to 6 May 2017]

http://www.ivi.int/

IVI Annual Report 2015

May 2017

[Excerpt from introductory letter from IVI Director General Jerome H. Kim, MD]

...IVI is the first international organization hosted by the Republic of Korea, which has since seen the establishment of several international organizations and UN offices. We are pleased to South Korea's partner in international cooperation efforts, particularly in global health. We also appreciate the long-standing support and trust of our other key funders, Sweden and the Bill & Melinda Gates Foundation.

Shortly after my appointment, it was universally agreed that IVI was in need of revitalization so we underwent a strategic refresh in 2015. With support from the Boston Consulting Group (BCG), we reviewed and reevaluated our core capabilities and redefined our direction. The

eight-month long process resulted in major organizational and strategic changes for the organization:

- :: Revised mission statement to reflect our expanded focus on new and emerging diseases of global health importance such as MERS.
- :: Articulation of a more clear direction that builds on our best-in-class product development and translational capabilities.
- :: Renewed focus on diseases where we have exceptional expertise and experience, such as cholera, typhoid, dengue, hepatitis E, and MERS.
- :: Reorganized scientific structure designed to facilitate cross-departmental communication and to focus talent against highest priority activities.
- :: Streamlined core cost structure that ensures financial sustainability and operational efficiency.
- :: Renewed focus on strengthening relationships with key funders and stakeholders to ensure IVI will be at the forefront of efforts to develop affordable vaccines for global health...

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Wellcome Trust [to 6 May 2017]

https://wellcome.ac.uk/news Opinion / Published: 3 May 2017

Is public mistrust of expertise damaging research?

What does the world think about 'experts' – and how does that make you feel? We're exploring the role of expertise in research, policy making and wider society in our four-week #ExpertDebate.

Over the past couple of years, there seems to have been a pushback in society on 'experts', whether it's politicians saying that people have had enough of experts, or a rejection of scientific consensus on issues such as climate change, vaccination, or evidence-based decision-making.

We think this could be hindering the environment for research to thrive. So we're holding a four-week debate on <u>Facebook (opens in a new tab)</u> and <u>Twitter (opens in a new tab)</u> to explore the role of expertise, find out what the issues are and see what, if anything, Wellcome as an organisation might be able to do to help...

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European Medicines Agency [to 6 May 2017]

http://www.ema.europa.eu/ema/05/05/2017

New guide on biosimilar medicines for healthcare professionals

Increasing understanding of biosimilar medicines

The European Medicines Agency (EMA) and the <u>European Commission</u> have published an <u>information guide for healthcare professionals</u> on biosimilar medicines. Biosimilars are biological medicines that are highly similar in all essential aspects to a biological medicine that has already been authorised.

The objective of the guide is to provide <u>healthcare professionals</u> with reference information on both the science and regulation underpinning the use of biosimilars.

"Today, biosimilars are an integral part of the effective biological therapies available in the EU," said Professor Guido Rasi, EMA's <u>Executive Director</u>. "Given the role of healthcare

professionals on the front line of patient care, it is vital that they have access to reliable information on these medicines: what they are and how they are developed, approved and monitored."...

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AERAS [to 6 May 2017]

http://www.aeras.org/pressreleases
No new digest content identified.

BIO [to 6 May 2017] https://www.bio.org/insights
No new digest content identified.

BMGF - Gates Foundation [to 6 May 2017]

http://www.gatesfoundation.org/Media-Center/Press-Releases No new digest content identified.

CEPI – Coalition for Epidemic Preparedness Innovations [to 6 May 2017]

http://cepi.net/

No new digest content identified.

DCVMN – Developing Country Vaccine Manufacturers Network [to 6 May 2017]

http://www.dcvmn.org/

No new digest content identified

EDCTP [to 6 May 2017]

http://www.edctp.org/

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

European Vaccine Initiative [to 6 May 2017]

http://www.euvaccine.eu/news-events No new digest content identified.

FDA [to 6 May 2017]

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm No new digest content identified.

Fondation Merieux [to 6 May 2017]

http://www.fondation-merieux.org/news

Mission: Contribute to global health by strengthening local capacities of developing countries to reduce the impact of infectious diseases on vulnerable populations.

No new digest content identified.

Gavi [to 6 May 2017]

http://www.gavi.org/library/news/press-releases/

No new digest content identified.

GHIT Fund [to 6 May 2017]

https://www.ghitfund.org/

GHIT was set up in 2012 with the aim of developing new tools to tackle infectious diseases that devastate the world's poorest people. Other funders include six Japanese pharmaceutical companies, the Japanese Government and the Bill & Melinda Gates Foundation. No new digest content identified.

Hilleman Laboratories [to 6 May 2017]

http://www.hillemanlabs.org/

No new digest content identified.

IAVI – International AIDS Vaccine Initiative [to 6 May 2017]

https://www.iavi.org/

No new digest content identified.

IFPMA [to 6 May 2017]

http://www.ifpma.org/resources/news-releases/

No new digest content identified.

NIH [to 6 May 2017]

http://www.nih.gov/news-events/news-releases

No new digest content identified.

PhRMA [to 6 May 2017]

http://www.phrma.org/press-room

No new digest content identified.

Sabin Vaccine Institute [to 6 May 2017]

http://www.sabin.org/updates/pressreleases

No new digest content identified.

UNICEF [to 6 May 2017]

https://www.unicef.org/media/media_94367.html

No new digest content identified.

* * * *

<u>Reports/Research/Analysis/Commentary/Conferences/Meetings/Book</u> 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

No new digest content identified.

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Journal Watch

Vaccines and Global Health: The Week in Review continues its weekly scanning of key peer-reviewed journals to identify and cite articles, commentary and editorials, books reviews and other content supporting our focus on vaccine ethics and policy. Journal Watch is not intended to be exhaustive, but indicative of themes and issues the Center is actively tracking. We selectively provide full text of some editorial and comment articles that are specifically relevant to our work. Successful access to some of the links provided may require subscription or other access arrangement unique to the publisher.

If you would like to suggest other journal titles to include in this service, please contact David Curry at: david.r.curry@centerforvaccineethicsandpolicy.org

American Journal of Infection Control

May 01, 2017 Volume 45, Issue 5, p463-582, e45-e52 http://www.ajicjournal.org/current *Brief Reports*

Seasonal influenza vaccination among Chinese health care workers

Paul H. Lee, Benjamin J. Cowling, Lin Yang p575–578

Published online: September 21, 2016

Hiahliahts

- :: 13% of Chinese healthcare workers (HCWs) received influenza vaccination in 2014-2015.
- :: 98% of doctors and 99% of nurses maintained their vaccination practice over 4 seasons.
- :: Doctors aged ≥45 and worked in surgical departments were more likely to be vaccinated.
- :: Nurses who received influenza training and recommended high-risk patients to be vaccinated were more likely to be vaccinated.

We conducted a study to examine the knowledge, attitudes, and opinions of health care workers (HCWs) and the factors associated with receipt of influenza vaccination in HCWs during August 2015 in 3 hospitals in Jiangsu Province, China. Among the 173 doctors and 220 nurses included in this study, the proportions who received vaccination for the 2014-2015 season were 14% and 13%, respectively. Ninety-eight percent of doctors and 99% of nurses maintained their vaccination practice over 4 seasons.

American Journal of Preventive Medicine

May 2017 Volume 52, Issue 5, p557-690, e123-e156 http://www.ajpmonline.org/current [New issue; No digest content identified]

American Journal of Public Health

Volume 107, Issue 5 (May 2017)

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

AJPH POLICY - REFUGEES

Evaluation of Measles-Mumps-Rubella Vaccination Among Newly Arrived Refugees

American Journal of Public Health: May 2017, Vol. 107, No. 5: 684–686.

<u>Deborah Lee</u>, <u>Michelle Weinberg</u>, <u>Stephen Benoit</u>

Abstract

Objectives. To assess US availability and use of measles-mumps-rubella (MMR) vaccination documentation for refugees vaccinated overseas.

Methods. We selected 1500 refugee records from 14 states from March 2013 through July 2015 to determine whether overseas vaccination records were available at the US postarrival health assessment and integrated into the Advisory Committee on Immunization Practices schedule. We assessed number of doses, dosing interval, and contraindications.

Results. Twelve of 14 (85.7%) states provided data on 1118 (74.5%) refugees. Overseas records for 972 (86.9%) refugees were available, most from the Centers for Disease Control and Prevention's Electronic Disease Notification system (66.9%). Most refugees (829; 85.3%) were assessed appropriately for MMR vaccination; 37 (3.8%) should have received MMR vaccine but did not; 106 (10.9%) did not need the MMR vaccine but were vaccinated. Conclusions. Overseas documentation was available at most clinics, and MMR vaccinations typically were given when needed. Further collaboration between refugee health clinics and state immunization information systems would improve accessibility of vaccination documentation.

American Journal of Tropical Medicine and Hygiene

Volume 96, Issue 5, 2017

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

Perspective Pieces

<u>Motorcycles, Cell Phones, and Electricity Can Dramatically Change the Epidemiology of Infectious Disease in Africa</u>

Authors: Jean-Christophe Lagier, Cheikh Sokhna and Didier Raoult

https://doi.org/10.4269/ajtmh.16-0290

Abstract

Some observations and recent publications demonstrated, particularly in Africa, the potential influence that low-cost motorcycles, cell phones, and even widespread electrification could have on the evolution of infectious diseases, particularly zoonoses. Our reflections support the conclusion that we should focus on the real-time surveillance systems including alerting systems leading to a rapid and flexible response rather than the strongly limited modeling of infectious diseases because of the continuous evolution of microorganisms, as well as changes in the environment and human habits that are unpredictable.

Annals of Internal Medicine

2 May 2017 Vol: 166, Issue 9 http://annals.org/aim/issue

BMC Cost Effectiveness and Resource Allocation

http://resource-allocation.biomedcentral.com/ (Accessed 6 May 2017)

Review

Economic evaluations of vaccines in Canada: a scoping review

Ellen R. S. Rafferty, Heather L. Gagnon, Marwa Farag and Cheryl L. Waldner

Published on: 5 May 2017

Abstract Background

This study aims to summarise and describe the evolution of published economic evaluations of vaccines in Canada, thereby outlining the current state of this expanding and meaningful research.

Methods

Using Arksey and O'Malley's scoping review framework we assembled relevant research from both academic and grey literature. Following abstract and full-text review we identified 60 articles to be included in the final analysis.

Results

We found that since 1988 there has been a steady increase in the number of economic evaluations on vaccines in Canada. Many of these studies focus on the more recently licensed vaccines, such as influenza (16.7%), human papillomavirus (15.0%) and pneumococcal disease (15.0%). Since 2010 economic evaluations of vaccines have shown increased adherence to economic evaluation guidelines (OR = 4.6, CI = 1.33, IR = 1.33, IR = 1.33), suggesting there has been improvement in the consistency and transparency of these studies. However, there remains room for improvement, for instance, we found evidence that studies who stated a conflict of interest are more likely to assert the vaccine of interest was cost-effective (IR = 1.4), IR = 1.04, IR = 1

Researchers should examine identified research gaps and continue to improve standardization and transparency when reporting to ensure economic evaluations of vaccines best meet the needs of policy-makers, other researchers and the public.

BMJ Global Health

January 2017; volume 2, issue 1 http://gh.bmj.com/content/2/1?current-issue=y [Reviewed earlier]

BMC Health Services Research

http://www.biomedcentral.com/bmchealthservres/content (Accessed 6 May 2017)
[No new digest content identified]

BMC Infectious Diseases

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

(Accessed 6 May 2017)

Research article

Assessing real-time Zika risk in the United States

Confirmed local transmission of Zika Virus (ZIKV) in Texas and Florida have heightened the need for early and accurate indicators of self-sustaining transmission in high risk areas across the southern United S...

Lauren A. Castro, Spencer J. Fox, Xi Chen, Kai Liu, Steven E. Bellan, Nedialko B. Dimitrov, Alison P. Galvani and Lauren Ancel Meyers

BMC Infectious Diseases 2017 17:284

Published on: 4 May 2017

BMC Medical Ethics

http://www.biomedcentral.com/bmcmedethics/content (Accessed 6 May 2017) [No new digest content identified]

BMC Medicine

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

(Accessed 6 May 2017)

Research article

Application of real-time global media monitoring and 'derived questions' for enhancing communication by regulatory bodies: the case of human papillomavirus vaccines

Priya Bahri, Julianna Fogd, Daniel Morales and Xavier Kurz

BMC Medicine 2017 15:91 Published on: 2 May 2017

Abstract Background

The benefit-risk balance of vaccines is regularly debated by the public, but the utility of media monitoring for regulatory bodies is unclear. A media monitoring study was conducted at the European Medicines Agency (EMA) concerning human papillomavirus (HPV) vaccines during a European Union (EU) referral procedure assessing the potential causality of complex regional pain syndrome (CRPS) and postural orthostatic tachycardia syndrome (POTS) reported to the authorities as suspected adverse reactions.

Methods

To evaluate the utility of media monitoring in real life, prospective real-time monitoring of worldwide online news was conducted from September to December 2015 with inductive content analysis, generating 'derived questions'. The evaluation was performed through the validation of the predictive capacity of these questions against journalists' queries, review of the EMA's public statement and feedback from EU regulators.

Results

A total of 4230 news items were identified, containing personal stories, scientific and policy/process-related topics. Explicit and implicit concerns were identified, including those raised due to lack of knowledge or anticipated once more information would be published. Fifty

derived questions were generated and categorised into 12 themes. The evaluation demonstrated that providing the media monitoring findings to assessors and communicators resulted in (1) confirming that public concerns regarding CRPS and POTS would be covered by the assessment; (2) meeting specific information needs proactively in the public statement; (3) predicting all queries from journalists; and (4) altering the tone of the public statement with respectful acknowledgement of the health status of patients with CRSP or POTS. Conclusions

The study demonstrated the potential utility of media monitoring for regulatory bodies to support communication proactivity and preparedness, intended to support trusted safe and effective vaccine use. Derived questions seem to be a familiar and effective format for presenting media monitoring results in the scientific-regulatory environment. It is suggested that media monitoring could form part of regular surveillance for medicines of high public interest. Future work is recommended to develop efficient monitoring strategies for that purpose.

BMC Pregnancy and Childbirth

http://www.biomedcentral.com/bmcpregnancychildbirth/content (Accessed 6 May 2017) [No new digest content identified]

BMC Public Health

http://bmcpublichealth.biomedcentral.com/articles (Accessed 6 May 2017) [No new digest content identified]

BMC Research Notes

http://www.biomedcentral.com/bmcresnotes/content (Accessed 6 May 2017) [No new digest content identified]

BMJ Open

April 2017 - Volume 7 - 4 http://bmjopen.bmj.com/content/current [Reviewed earlier]

Bulletin of the World Health Organization

Volume 95, Number 5, May 2017, 313-388 http://www.who.int/bulletin/volumes/95/5/en/ E*DITORIALS*

<u>Tuberculosis and antimicrobial resistance – new models of research and development needed</u>

Grania Brigden, José Luis Castro, Lucica Ditiu, Glenda Gray, Debra Hanna, Marcus Low, Malebona Precious Matsoso, Greg Perry, Melvin Spigelman, Souyma Swaminathan, Els Torreele

& Sidney Wong

http://dx.doi.org/10.2471/BLT.17.194837

Tuberculosis is a disease that needs more investment in research and development. More people - 1.4 million in 2015 - die from tuberculosis every year than from human immunodeficiency virus (1.1 million deaths; 400 000 die from combinations of these infections) and malaria (429 000 deaths). Despite a current global caseload of 580 000 people infected with drug-resistant tuberculosis, 1 current levels of investment - 620 million United States dollars - in research and development are at their lowest since 2008. Over the past decade, only two new drugs have been licensed; bedaquiline and delamanid. Tuberculosis cannot be cured by a single drug, but requires at least three different classes of antibiotic for treatment. Drug-resistant tuberculosis - bacilli resistant to two or more of the available antibiotics - is a persistent problem and is projected to account for 25% of deaths from all drug-resistant pathogens in the future.

In 2010, the World Health Organization's (WHO's) Consultative Expert Working Group on Research and Development was established to examine current financing and incentives for research and development and to propose new approaches addressing unmet medical needs. Delegates at this month's World Health Assembly will continue discussions to implement the recommendations from the group's 2012 report on global financing and coordination of research and development.4

A United Nations (UN) General Assembly session on antimicrobial resistance and the UN High Level panel on Access to Medicines, 5 as well as reports from the United Kingdom of Great Britain and Northern Ireland 3 and the German government 6 have all looked at new research and development models to incentivize research for drug-resistant infections.

Several nongovernmental organizations, medical research councils, civil society representatives and the South African government have recently developed a new funding framework to support research and development of tuberculosis treatments – the 3P Project (pull, pool and push). This initiative (i) uses a pull incentive, by rewarding research through prizes; (ii) pools intellectual property and data; and (iii) uses push incentives through research grants. The 3P project is a collaborative research initiative that aims to support the discovery and development of a one-month treatment regimen that can be used to cure all cases of tuberculosis. The project's funding model will ensure that a new regimen is affordable and accessible to all those in need. The 3P Project incentivizes researchers by providing cash prizes for compounds that meet predefined product characteristics and are ready to enter phase I clinical trials. Coupling this financial reward with an obligation to pool the compounds data and intellectual property, the 3P Project will then fund the development of treatment combinations. The project will thus de-link the costs of research and development from the final cost of the treatment and sales as defined by the UN Political declaration of the high-level meeting of the General Assembly on antimicrobial resistance; ensuring treatment affordability.

We suggest that new models of research and development for tuberculosis, like the 3P Project, should be included in inter-governmental discussions on antimicrobial resistance priority setting. We encourage member states to support this initiative as a proactive response to address the priority pathogen for antimicrobial resistance.

Equity trends in ownership of insecticide-treated nets in 19 sub-Saharan African countries

Cameron Taylor, Lia Florey & Yazoume Ye http://dx.doi.org/10.2471/BLT.16.172924

Evaluation of a social franchising and telemedicine programme and the care provided for childhood diarrhoea and pneumonia, Bihar, India

Manoj Mohanan, Soledad Giardili, Veena Das, Tracy L Rabin, Sunil S Raj, Jeremy I Schwartz, Aparna Seth, Jeremy D Goldhaber-Fiebert, Grant Miller & Marcos Vera-Hernández http://dx.doi.org/10.2471/BLT.16.179556

PERSPECTIVES

National drug policy reform for noncommunicable diseases in low-resource countries: an example from Bangladesh

Sheikh Mohammed Shariful Islam, Md Tauhidul Islam, Anwar Islam, Anthony Rodgers, Clara K Chow & Aliya Naheed http://dx.doi.org/10.2471/BLT.15.161117

Child Care, Health and Development

May 2017 Volume 43, Issue 3 Pages 323–461 http://onlinelibrary.wiley.com/doi/10.1111/cch.v43.3/issuetoc [Reviewed earlier]

Clinical and Experimental Vaccine Research

2017 Jan;6(1):31-37. English. http://ecevr.org/
[Reviewed earlier]

Clinical Therapeutics

April 2017 Volume 39, Issue 4, p665-872 http://www.clinicaltherapeutics.com/issue/S0149-2918(17)X0004-0 [Reviewed earlier]

Complexity

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

Conflict and Health

http://www.conflictandhealth.com/ [Accessed 6 May 2017] [No new digest content identified]

Contemporary Clinical Trials

Volume 56, Pages 1-52 (May 2017)

http://www.sciencedirect.com/science/journal/15517144/56

[New issue; No digest content identified]

Current Opinion in Infectious Diseases

June 2017 - Volume 30 - Issue 3

http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx

PAEDIATRIC AND NEONATAL INFECTIONS

Placental transfer of antibody and its relationship to vaccination in pregnancy

Calvert, Anna; Jones, Christine E.

Current Opinion in Infectious Diseases . 30(3):268-273, June 2017.

Abstract:

Purpose of review: Vaccination in pregnancy boosts maternal vaccine-specific antibody concentration and therefore increases transplacental transfer of antibody to optimize protection of the infant. The purpose of this review is to describe what is known about placental transfer of antibody in the context of vaccination in pregnancy, focussing on the recent literature and areas of debate, particularly about the timing of vaccination.

Recent findings: There is a debate about the timing of pertussis vaccination in pregnancy with some studies reporting that vaccination in the third trimester results in higher pertussis antigenspecific IgG concentrations in cord blood and others finding that the concentration is higher following vaccination in the second trimester. The impact of timing of vaccination on antibody avidity in cord blood has also been investigated and one study suggests that avidity may be increased following vaccination at 27–30+6 gestational weeks compared with later vaccination. Summary: Understanding placental transfer of antibody is vital in informing maternal vaccination strategy. There has been recent research about the timing of pertussis vaccination in pregnancy that has implications for the timing of both current and future vaccines to be used in pregnancy.

Developing World Bioethics

April 2017 Volume 17, Issue 1 Pages 1–60 http://onlinelibrary.wiley.com/doi/10.1111/dewb.2017.17.issue-1/issuetoc [Reviewed earlier]

Development in Practice

Volume 27, Issue 3 http://www.tandfonline.com/toc/cdip20/current [Reviewed earlier]

Disasters

April 2017 Volume 41, Issue 2 Pages 209–426 http://onlinelibrary.wiley.com/doi/10.1111/disa.2017.41.issue-2/issuetoc [Reviewed earlier]

EMBO Reports

Volume 18, Issue 3, 2017 http://embor.embopress.org/front.current-issue [Reviewed earlier]

Emerging Infectious Diseases

Volume 23, Number 4—April 2017 http://wwwnc.cdc.gov/eid/ [Reviewed earlier]

Epidemics

Volume 18, Pages 1-112 (March 2017)
http://www.sciencedirect.com/science/journal/17554365

Multi-model comparisons for neglected tropical diseases - validation and projection Edited by Déirdre Hollingsworth and Graham Medley [Reviewed earlier]

Epidemiology and Infection

Volume 145 - Issue 5 - April 2017 https://www.cambridge.org/core/journals/epidemiology-and-infection/latest-issue [Reviewed earlier]

The European Journal of Public Health

Volume 27, Issue 2, 6 May 2017 https://academic.oup.com/eurpub/issue/27/2 [Reviewed earlier]

Global Health Action

Volume 10, 2017 - Issue 1 http://www.tandfonline.com/toc/zgha20/10/1?nav=tocList [Reviewed earlier]

Global Health: Science and Practice (GHSP)

March 24, 2017, 5 (1) http://www.ghspjournal.org/content/current [Reviewed earlier]

Global Public Health

Volume 12, 2017 Issue 6

http://www.tandfonline.com/toc/rgph20/current

Special Issue: Maternal and Child Health in Africa for Sustainable Development Goals (SDGs) Beyond 2015

[Reviewed earlier]

Globalization and Health

http://www.globalizationandhealth.com/ [Accessed 6 May 2017] [No new digest content identified]

Health Affairs

April 2017; Volume 36, Issue 4 http://content.healthaffairs.org/content/current

Issue Focus: Maternity Coverage, Children, Disability & More

[Reviewed earlier]

Health and Human Rights

Volume 18, Issue 2, December 2016
http://www.hhrjournal.org/

Special Section: Universal Health Coverage and Human Rights

[Reviewed earlier]

Health Economics, Policy and Law

Volume 12 - Issue 2 - April 2017 https://www.cambridge.org/core/journals/health-economics-policy-and-law/latest-issue **Special Issue: Towards a Global Framework for Health Financing** [Reviewed earlier]

Health Policy and Planning

Volume 32 Issue 3 April 2017 http://heapol.oxfordjournals.org/content/current [Reviewed earlier]

Health Research Policy and Systems

http://www.health-policy-systems.com/content [Accessed 6 May 2017] [Reviewed earlier]

Humanitarian Exchange Magazine

Number 68 January 2017 http://odihpn.org/magazine/the-crisis-in-south-sudan/

The crisis in South Sudan

[Reviewed earlier]

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)

Volume 13, Issue 4, 2017 http://www.tandfonline.com/toc/khvi20/current [Reviewed earlier]

Infectious Agents and Cancer

http://www.infectagentscancer.com/content [Accessed 6 May 2017] [No new digest content identified]

Infection

2017, vol. 45, no2, pp. 157-164 [Reviewed earlier]

Infectious Diseases of Poverty

http://www.idpjournal.com/content [Accessed 6 May 2017] Commentary

<u>Commentary: restarting NTD programme activities after the Ebola outbreak in</u> Liberia

Brent C. Thomas, Karsor Kollie, Benjamin Koudou and Charles Mackenzie Infectious Diseases of Poverty 2017 6:52

Published on: 1 May 2017

Abstract

It is widely known that the recent Ebola Virus Disease (EVD) in West Africa caused a serious disruption to the national health system, with many of ongoing disease focused programmes, such as mass drug administration (MDA) for onchocerciasis (ONC), lymphatic filariasis (LF) and schistosomiasis (SCH), being suspended or scaled-down. As these MDA programmes attempt to restart post-EVD it is important to understand the challenges that may be encountered. This commentary addresses the opinions of the major health sectors involved, as well as those of community members, regarding logistic needs and challenges faced as these important public health programmes consider restarting. There appears to be a strong desire by the communities to resume NTD programme activities, although it is clear that some important challenges remain, the most prominent being those resulting from the severe loss of trained staff.

International Health

Volume 9, Issue 2 March 2017 http://inthealth.oxfordjournals.org/content/current [Reviewed earlier]

International Journal of Community Medicine and Public Health

Vol 4, No 4 (2017) April 2017 http://www.ijcmph.com/index.php/ijcmph/issue/view/22 [Reviewed earlier]

International Journal of Epidemiology

Volume 46, Issue 1 February 2017 http://ije.oxfordjournals.org/content/current [Reviewed earlier]

International Journal of Infectious Diseases

April 2017 Volume 57, p1-150 http://www.ijidonline.com/issue/S1201-9712(17)X0002-7 [Reviewed earlier]

JAMA

May 2, 2017, Vol 317, No. 17, Pages 1707-1812 http://jama.jamanetwork.com/issue.aspx **Special Issue on COI**

Viewpoint

Conflict of InterestWhy Does It Matter?

Harvey V. Fineberg, MD, PhD

In this Viewpoint, the former president of the Institute of Medicine discusses the importance of conflicts of interest to the integrity of the medical profession, and the importance of policies to manage conflicts of interest that are specific, clear, public, comprehensible, and fair.

Editorials

The Complex and Multifaceted Aspects of Conflicts of Interest

William W. Stead, MD

Conflict of Interest and Medical Journals

Phil Fontanarosa, MD, MBA; Howard Bauchner, MD

Why There Are No "Potential" Conflicts of Interest

Matthew S. McCoy, PhD; Ezekiel J. Emanuel, MD, PhD

This Viewpoint argues that "potential" conflicts of interest (COIs) are actual COIs that are effectively managed, and calls for clear terminology to describe the severity of COIs and how they are identified and managed.

Addressing Bias and Conflict of Interest Among Biomedical Researchers

Lisa Bero, PhD

JAMA. 2017;317(17):1723-1724. doi:10.1001/jama.2017.3854

This Viewpoint explores the differences between financial and nonfinancial conflicts of interest, the effects of both on research bias, and the importance of managing each in ways that reduce bias.

Role of Leaders in Fostering Meaningful Collaborations Between Academic Medical Centers and Industry While Also Managing Individual and Institutional Conflicts of Interest

Philip A. Pizzo, MD; Thomas J. Lawley, MD; Arthur H. Rubenstein, MBBCH JAMA. 2017;317(17):1729-1730. doi:10.1001/jama.2017.2573

This Viewpoint discusses the important role that leaders of academic medical centers (AMCs) play in fostering collaborations with industry while managing individual and institutional conflicts of interest (COI).

Managing Conflicts of Interest in Industry-Sponsored Clinical ResearchMore Physician Engagement Is Required

Joanne Waldstreicher, MD; Michael E. Johns, MD

JAMA. 2017;317(17):1751-1752. doi:10.1001/jama.2017.4160

This Viewpoint discusses the conflicts of interest that arise from industry's dual obligations to patients and shareholders and outlines progress academic medical centers and others have made managing conflicts of interest in industry-sponsored clinical research.

Conflict of Interest and Legal Issues for Investigators and Authors

Joseph P. Thornton, JD

JAMA. 2017;317(17):1761-1762. doi:10.1001/jama.2017.4235

This Viewpoint discusses the duty of authors to report potential conflicts of interest, the legal and professional consequences of omissions, and processes for investigating allegations of failure to disclose conflicts of interest.

JAMA Pediatrics

May 2017, Vol 171, No. 5, Pages 407-500 http://archpedi.jamanetwork.com/issue.aspx Viewpoint

Preparing for Emerging Infectious Diseases

Lisa Saiman, MD, MPH; Amy S. Arrington, MD, PhD; Michael Bell, MD JAMA Pediatr. 2017;171(5):411-412. doi:10.1001/jamapediatrics.2016.4947

This Viewpoint argues for increased preparedness in the pediatric community for emerging infectious diseases

JBI Database of Systematic Review and Implementation Reports

April 2017 - Volume 15 - Issue 4 http://journals.lww.com/jbisrir/Pages/currenttoc.aspx [Reviewed earlier]

Journal of Community Health

Volume 42, Issue 3, June 2017

http://link.springer.com/journal/10900/42/3/page/1

Original Paper

<u>Variation in Human Papillomavirus Vaccine Uptake and Acceptability Between</u> Female and Male Adolescents and Their Caregivers

Kristin L. Johnson, Meng-Yun Lin, Howard Cabral...

Original Paper

<u>Community BMI Surveillance Using an Existing Immunization Registry in San Diego,</u>
<u>California</u>

Amanda R. Ratigan, Suzanne Lindsay, Hector Lemus...

Original Paper

<u>Factors Related to Pertussis and Tetanus Vaccination Status Among Foreign-Born</u>
Adults Living in the United States

Liliana Sánchez-González, Alfonso Rodriguez-Lainz...

Journal of Epidemiology & Community Health

May 2017 - Volume 71 - 5 http://jech.bmj.com/content/current [New issue; No digest content identified]

Journal of Global Ethics

Volume 12, Issue 3, 2016

http://www.tandfonline.com/toc/rjge20/current

Theme Issue: Refugee Crisis: The Borders of Human Mobility

[Reviewed earlier]

Journal of Global Infectious Diseases (JGID)

January – March 2017 Vol 9 Issue 1 Pages 1-37 http://www.jgid.org/currentissue.asp?sabs=n [Reviewed earlier]

Journal of Health Care for the Poor and Underserved (JHCPU)

Volume 28, Number 2 Supplement, May 2017

https://muse.jhu.edu/issue/36192

The Power of Prevention: Reaching At-Risk Emerging Adults to Reduce Substance Abuse and HIV

Guest Editors: Lorece Edwards, DrPH, MHS, Morgan State University and Ronald L. Braithwaite, PhD, Morehouse School of Medicine [Reviewed earlier]

Journal of Immigrant and Minority Health

Volume 19, Issue 3, June 2017

http://link.springer.com/journal/10903/19/3/page/1

[New issue; No digest content identified]

Journal of Immigrant & Refugee Studies

Volume 15, Issue 1, 2017 http://www.tandfonline.com/toc/wimm20/current [Reviewed earlier]

Journal of Infectious Diseases

Volume 215, Issue suppl_3 15 March 2017 http://jid.oxfordjournals.org/content/current [New issue; No digest content identified]

Journal of Medical Ethics

May 2017 - Volume 43 - 5 http://jme.bmj.com/content/current [New issue; No digest content identified]

Journal of Medical Internet Research

Vol 19, No 4 (2017): April http://www.jmir.org/2017/4 [Reviewed earlier]

Journal of Medical Microbiology

Volume 66, Issue 4, April 2017 http://jmm.microbiologyresearch.org/content/journal/jmm/66/4 [New issue; No digest content identified]

Journal of Patient-Centered Research and Reviews

Volume 4, Issue 2 (2017) http://digitalrepository.aurorahealthcare.org/jpcrr/ [Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)

Volume 6 Issue 1, March 2017 http://jpids.oxfordjournals.org/content/current [Reviewed earlier]

Journal of Pediatrics

May 2017 Volume 184, p1-246

http://www.jpeds.com/current

The Editors' Perspectives

Pediatric clinical trials—number needed to recruit

Denise M. Goodman

p1-2

Published in issue: May 2017

Abstract

As pediatricians we often extrapolate findings from adult clinical trials to comparable pediatric populations, acknowledging that this is an imperfect approach while bemoaning the lack of adequately powered pediatric trials. There are many reasons for the difficulties in completing clinical trials in children. For instance, the prevalence of certain conditions may be lower, and outcomes different, than for adults. By way of example, mortality is not infrequently used as an end point for adult studies of intensive care unit patients, but mortality in the pediatric intensive care unit is low and thus, an insensitive marker by which to assess the success of many interventions. In addition, there are special considerations in advancing studies in the vulnerable population of children, including a more complex informed consent process and potential reluctance on the part of parents as surrogate decision makers.

In this context, any empiric data regarding the execution of clinical trials in children is helpful. In this volume of The Journal, Schandelmaier et al report on premature discontinuation of clinical trials in children. They drew from studies approved by 6 research ethics committees in 3 countries. By using this approach they minimized issues with incomplete registration and reporting bias that might be present using trial registries or publications as the basis for examining trials. They also waited for as long as 10 years or more to ensure that recruitment and publication could be accomplished. These investigators found that 40% of pediatric trials, compared with 29% ofadult clinical trials, are prematurely discontinued, with slow recruitment the most common reason across the board. After controlling for other trial characteristics, such as source of funding, they found, however, that being a pediatric trial was not in andof itself an independent risk factor for discontinuation. This suggests that other features of trial implementation, such as planned recruitment targets and adequate funding, may be more important.

These findings underscore the importance of robust clinical trial design, including a realistic recruitment strategy, an adequately sized pool of potential enrollees, and sufficient support for patient screening and consenting. The evidence needed to support good clinical decision making rests on rigorous science and a disciplined approach to trial implementation. We owe both the patients we treat and those who generously participate in clinical trials no less.

Original Articles

Racial and Ethnic Disparities in Parental Refusal of Consent in a Large, Multisite Pediatric Critical Care Clinical Trial

Joanne E. Natale, Ruth Lebet, Jill G. Joseph, Christine Ulysse, Judith Ascenzi, David Wypij, Martha A.Q. Curley for the Randomized Evaluation of Sedation Titration for Respiratory Failure (RESTORE) Study Investigators

p204-208.e1

Published online: March 3, 2017

Abstract
Objective

To evaluate whether race or ethnicity was independently associated with parental refusal of consent for their child's participation in a multisite pediatric critical care clinical trial. Study design

We performed a secondary analyses of data from Randomized Evaluation of Sedation Titration for Respiratory Failure (RESTORE), a 31-center cluster randomized trial of sedation management in critically ill children with acute respiratory failure supported on mechanical ventilation. Multivariable logistic regression modeling estimated associations between patient race and ethnicity and parental refusal of study consent.

Among the 3438 children meeting enrollment criteria and approached for consent, 2954 had documented race/ethnicity of non-Hispanic White (White), non-Hispanic Black (Black), or Hispanic of any race. Inability to approach for consent was more common for parents of Black (19.5%) compared with White (11.7%) or Hispanic children (13.2%). Among those offered consent, parents of Black (29.5%) and Hispanic children (25.9%) more frequently refused consent than parents of White children (18.2%, P < .0167 for each). Compared with parents of White children, parents of Black (OR 2.15, 95% CI 1.56-2.95, P < .001) and Hispanic (OR 1.44, 95% CI 1.10-1.88, P = .01) children were more likely to refuse consent. Parents of children offered participation in the intervention arm were more likely to refuse consent than parents in the control arm (OR 2.15, 95% CI 1.37-3.36, P < .001).

Conclusions

Result

Parents of Black and Hispanic children were less likely to be approached for, and more frequently declined consent for, their child's participation in a multisite critical care clinical trial. Ameliorating this racial disparity may improve the validity and generalizability of study findings. Trial registration

ClinicalTrials.gov: NCT00814099.

Original Articles

<u>Premature Discontinuation of Pediatric Randomized Controlled Trials: A Retrospective Cohort Study</u>

Stefan Schandelmaier, Yuki Tomonaga, Dirk Bassler, Joerg J. Meerpohl, Erik von Elm, John J. You, Anette Bluemle, Francois Lamontagne, Ramon Saccilotto, Alain Amstutz, Theresa Bengough, Mihaela Stegert, Kelechi K. Olu, Kari A.O. Tikkinen, Ignacio Neumann, Alonso Carrasco-Labra, Markus Faulhaber, Sohail M. Mulla, Dominik Mertz, Elie A. Akl, Xin Sun, Jason W. Busse, Ignacio Ferreira-González, Alain Nordmann, Viktoria Gloy, Heike Raatz, Lorenzo Moja, Rachel Rosenthal, Shanil Ebrahim, Per O. Vandvik, Bradley C. Johnston, Martin A. Walter, Bernard Burnand, Matthias Schwenkglenks, Lars G. Hemkens, Gordon Guyatt, Heiner C. Bucher, Benjamin Kasenda, Matthias Briel

p209-214.e1

Published online: March 4, 2017

Abstract
Objectives

To determine the proportion of pediatric randomized controlled trials (RCTs) that are prematurely discontinued, examine the reasons for discontinuation, and compare the risk for recruitment failure in pediatric and adult RCTs.

Study design

A retrospective cohort study of RCTs approved by 1 of 6 Research Ethics Committees (RECs) in Switzerland, Germany, and Canada between 2000 and 2003. We recorded trial characteristics,

trial discontinuation, and reasons for discontinuation from protocols, corresponding publications, REC files, and a survey of trialists.

Results

We included 894 RCTs, of which 86 enrolled children and 808 enrolled adults. Forty percent of the pediatric RCTs and 29% of the adult RCTs were discontinued. Slow recruitment accounted for 56% of pediatric RCT discontinuations and 43% of adult RCT discontinuations. Multivariable logistic regression analyses suggested that pediatric RCT was not an independent risk factor for recruitment failure after adjustment for other potential risk factors (aOR, 1.22; 95% CI, 0.57-2.63). Independent risk factors were acute care setting (aOR, 4.00; 95% CI, 1.72-9.31), nonindustry sponsorship (aOR, 4.45; 95% CI, 2.59-7.65), and smaller planned sample size (aOR, 1.05; 95% CI 1.01-1.09, in decrements of 100 participants). Conclusion

Forty percent of pediatric RCTs were discontinued prematurely, owing predominately to slow recruitment. Enrollment of children was not an independent risk factor for recruitment failure.

Journal of Public Health Policy

Volume 38, Issue 1, February 2017 http://link.springer.com/journal/41271/38/1/page/1 [Reviewed earlier]

Journal of the Royal Society – Interface

01 April 2017; volume 14, issue 129 http://rsif.royalsocietypublishing.org/content/current Life Sciences-Mathematics interface [Reviewed earlier]

Journal of Travel Medicine

Volume 24, Issue 2, March/April 2017 https://academic.oup.com/jtm/issue/24/2 [Reviewed earlier]

Journal of Virology

May 2017, volume 91, issue 10 http://jvi.asm.org/content/current [New issue; No digest content identified]

The Lancet

May 06, 2017 Volume 389 Number 10081 p1771-1858 http://www.thelancet.com/journals/lancet/issue/current Editorial

Research integrity—have we made progress?

The Lancet

Published: 06 May 2017

DOI: http://dx.doi.org/10.1016/S0140-6736(17)31201-1

This month there will be two important anniversaries related to research integrity. The first is the 20 year anniversary of the Committee on Publication Ethics (COPE), celebrated at COPE's European annual meeting in London, UK, on May 25. The second marks 10 years since the first World Conference on Research Integrity (WCRI) in Lisbon, Portugal, in 2007—to be held at the fifth WCRI in Amsterdam, Netherlands, May 28–31. More than 600 delegates will gather and present research on research integrity and debate current policies and initiatives, progress, and difficulties. The conference theme is transparency and accountability. So what have these initiatives and organisations achieved and what is the current state of research integrity?

Compared with 20 years ago there is undoubtedly more discussion and awareness of research misconduct. There is more research into research integrity and inappropriate research practice. And there is more guidance and support for those researchers, funders, institutions, and journals that want to have good policies, practices, and processes in place. However, there are depressingly familiar examples that show we still have a long way to go to strengthen research integrity and publication ethics. Every day, dubious new journals and conference organisers solicit papers and presentations for a fee. The rise of such predatory journals and conferences is a disappointingly unsavoury by-product of the open access business model.

On April 20, the publisher Springer retracted a record 107 papers from one journal (Tumor Biology) because they had been accepted after fake peer review. These papers were discovered after additional screening as a consequence of an earlier round of retractions, but clearly stronger editorial practices could have detected these fatal flaws before publication. And last week, the investigators of the Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist (TOPCAT) trial, originally published in the New England Journal of Medicine in 2014, concluded in a correspondence letter in the journal that after further experiments the findings "arouse concerns regarding study conduct in Russia, and by implication, Georgia"—an example of a multicountry collaboration gone wrong.

Additionally, there are worrying signs that the research environment, which was highlighted at the last WCRI conference in Rio de Janeiro, Brazil, in 2015, as an important factor to promote and ensure responsible research, is becoming more competitive and less resilient. The uncertainty over long-term National Institute of Health funding in the USA sent shock waves through the scientific community. Similar concerns by Canadian scientists have emerged over the past few months where research funding is stagnating and increasingly linked to political priorities. And many researchers in the UK are concerned about European Union funding after Brexit.

So what can be done? A <u>new report</u> by the US National Academies of Sciences, Engineering, and Medicine—Fostering Integrity in Research, released on April 11—produced best practice checklists and issued 11 recommendations. Most of these are obvious and do not cover new ground, such as whistleblower protection and improved education. What the report does add beyond summarising the state of integrity and best practice recommendations is clearer and stronger language. It terms what has previously been called questionable or inappropriate research practices "detrimental practices", recognising these to be detrimental to the research enterprise. Similarly, the World Association of Medical Editors earlier this year argued that a better name for predatory journals would be pseudo-journals to clearly identify them as

destinations that researchers should avoid. And when there are outcries about the so-called reproducibility crisis, it should be understood that reproducibility is used in many different ways, which leads to confusion and disagreement. Steven Goodman concluded in Science
Translational Medicine in June, 2016, that "we need to move toward a better understanding of the relationship between reproducibility, cumulative evidence, and the truth of scientific claims".

The Amsterdam conference theme is a good one. Transparency and accountability are the fundamental principles for research integrity. Transparency in describing all aspects of the research process, from planning, proposing, performing, and reporting, goes a long way towards allowing better selection, scrutiny, and use of research. Such quality assessment needs to be at the heart of academic reward. What we do need also, however, is transparency of policies for all involved in research —institutions, funders, and journals alike—to allow a similar level of assessment and scrutiny by others. Accountability needs to be shared by all.

Editorial

The next chapter in malaria eradication

The Lancet

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The narrative around combating malaria has long been equal parts optimism and pessimism. Remarkably, it was only a decade ago that Bill and Melinda Gates made the game-changing call for the eradication of malaria. Previous control efforts to reduce the burden, particularly in low-resource, malaria-endemic countries in sub-Saharan Africa, were limited by poor access to tools such as insecticide-treated nets, and faced rapidly drug-resistant strains of the highly lethal Plasmodium falciparum parasite requiring treatment with costly artemisinin-combination therapies. The proclamation that eradicating malaria was an achievable goal met with stern criticism at the time, but nevertheless spurred massive increases in international funding commitments and served as a lever to shift the then overarching malaria policy towards a common goal of eradication. It also resulted in the introduction of RTS,S, the first candidate malaria vaccine to yield promising safety and efficacy results and to be recommended by both the Strategic Advisory Group of Experts on Immunization and the Malaria Policy Advisory Committee.

Turning a page in the story of malaria, on April 24, 2017, the WHO Regional Office for Africa (WHO/AFRO) announced a pilot implementation programme beginning in 2018. The RTS,S vaccine will be available in three African countries—Ghana, Kenya, and Malawi—chosen for having mature existing immunisation programmes and high coverage of insecticide-treated nets, yet with persistently high malaria burdens. Although the availability and roll out of the RTS,S vaccine is a remarkable achievement, the decision to implement the pilot programme at this stage is not without controversy. Critics have pointed out several serious shortcomings, including the intensive regimen (three injected doses at months 0, 1, and 2, and a booster dose at month 20), which could be unfeasible outside of rigorously controlled clinical trials, as well as waning efficacy over time.

Cautious optimism is understandable, but it must be emphasised that the vaccine is but one additional tool in the current limited armamentarium for making progress against malaria. Adequate support and scrupulous monitoring will determine whether the pilot programme is a success or a cautionary tale.

Lancet Global Health

May 2017 Volume 5 Number 5 e467-e555 http://www.thelancet.com/journals/langlo/issue/current

<u>Introducing The Lancet Global Health Commission on High-Quality Health Systems</u> in the SDG Era

Margaret E Kruk, Muhammad Pate, Zoë Mullan

The Millennium Development Goals on health have expanded access to basic health interventions to millions of people in low-income and middle-income countries (LMICs). However, access alone will not be sufficient to meet the Sustainable Development Goals (SDGs) if health systems cannot provide high quality care—ie, care that improves health outcomes and provides value to people. Emerging data show that many LMIC health systems struggle to consistently provide good quality of care.1, 2 Yet change is possible. Primary health-care facilities, which tend to reach the poorest segment of populations, are an important plank in the drive towards achieving the SDGs. In Nigeria, supporting primary health-care centres in rural areas with quality assessment, an action plan, and technical assistance in management resulted in significant improvements in adoption of quality practices.3

Health system quality in lower-income countries has been under-defined and under-researched. There is no agreed upon single definition of a high-quality health system or its aims and there is no consensus on metrics. Instead, many countries face a proliferation of definitions and measures across disease areas. The emphasis in quality measurement has been on inputs: equipment, medicines, staff. Yet, this does not paint the full picture of quality—a well-equipped facility may still provide poor care. And patients' experience of care and patient-reported outcomes, which influence people's decisions to use or avoid services and provide valuable insights on performance, are rarely measured. There is little information on national and regional levels of quality and its distribution, weak evidence on the factors that drive quality variations, and low effectiveness of current quality improvement approaches. Finally, there is an urgent need to expand the solution space for quality improvement: to move beyond in-service training and other clinic-focused approaches to consider structural solutions, such as service regionalisation, updating medical and nursing education, technological innovation, and strengthening professional and community oversight of care.

To galvanise research and action on quality of care in LMIC health systems, The Lancet Global Health has commissioned a major report: The Lancet Global Health Commission on High-Quality Health Systems in the SDG Era (HQSS Commission). This will be a piece of science-led, multidisciplinary, actionable work with wide-reaching goals and measurable indicators, and will embody the journal's commitment to "the best science for better lives". The HQSS Commission will be chaired by Margaret Kruk and Muhammad Pate and brings together 30 academics, policymakers, and health system experts from 18 countries. Guided by the values of originality, rigour, relevance, and respect for local context and actors, the Commission will review current and improving quality in pursuit of the SDGs. It will produce a single conceptual framework of high-quality health systems to increase the salience of the concept to policymakers, providers, and people. It will build on and inform the work of other ongoing efforts including Countdown to 2030; the Health Data Collaborative; the Quality, Equity, and Dignity Network; and the Primary Health Care Performance Initiative.

The Commission's specific aims are to (1) define health system quality, (2) describe quality of care and its distribution across tracer SDG conditions, (3) propose practical measures of quality, and (4) identify structural approaches to improve quality. The work will be underpinned by an exploration of the ethical dimensions of quality, including the right to quality health-care and equity. The analysis will be done by four Commission working groups, shown in the <u>panel</u>. The HQSS Commission will hold its first meeting on March 13–15, 2017, in Boston, USA, convening the commissioners and an Advisory Council of experts and global partners.

Articles

<u>Pathways between childhood trauma, intimate partner violence, and harsh</u> <u>parenting: findings from the UN Multi-country Study on Men and Violence in Asia</u> and the Pacific

Emma Fulu, Stephanie Miedema, Tim Roselli, Sarah McCook, Ko Ling Chan, Regine Haardörfer, Rachel Jewkes on behalf of the UN Multi-country Study on Men and Violence study team

Articles

Measuring Iran's success in achieving Millennium Development Goal 4: a systematic analysis of under-5 mortality at national and subnational levels from 1990 to 2015

Younes Mohammadi, Mahboubeh Parsaeian, Parinaz Mehdipour, Ardeshir Khosravi, Bagher Larijani, Ali Sheidaei, Anita Mansouri, Amir Kasaeian, Kamran Yazdani, Maziar Moradi-Lake, Elaheh Kazemi, Saeideh Aghamohammadi, Nazila Rezaei, Maryam Chegini, Rosa Haghshenas, Hamidreza Jamshidi, Farnaz Delavari, Mohsen Asadi-Lari, Farshad Farzadfar

Articles

<u>Progress and inequities in maternal mortality in Afghanistan (RAMOS-II): a retrospective observational study</u>

Linda Bartlett, Amnesty LeFevre, Linnea Zimmerman, Sayed Ataullah Saeedzai, Sabera Torkamani, Weeda Zabih, Hannah Tappis, Stan Becker, Peter Winch, Marge Koblinsky, Ahmed Javed Rahmanzai

Lancet Infectious Diseases

May 2017 Volume 17 Number 5 p461-562 e128-e165 http://www.thelancet.com/journals/laninf/issue/current Editorial

Is malaria elimination within reach?

The Lancet Infectious Diseases

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Released on March 24, in ample time for World Malaria Day on April 25, WHO's *A Framework for Malaria Elimination* is the first time <u>WHO returns to this significant topic since 2007</u>. Given the launch of this update to the framework it is fitting that the theme for World Malaria Day will ambitiously be "End Malaria for Good". Within the theme of ending malaria for good there will be particular focus on prevention through the use of insecticide-treated nets and indoor spraying. Prevention has been a significant factor in the reduction of infections and deaths over the past 17 years.

Crucially, WHO has avoided a rigid approach to its framework, acknowledging the need for ongoing revision should new tools and strategies emerge. Pedro Alonso, Director of the Global Malaria Programme, emphasises that the framework does not offer a one size fits all approach; each country is to tailor the interventions to suit local needs. This flexibility is refreshingly pragmatic and stands a greater chance of success.

One tangible gap in the framework is its focus on only two species of the human malaria parasite: Plasmodium falciparum and Plasmodium vivax. The other species (Plasmodium malariae, Plasmodium ovale, and the zoonotic Plasmodium knowlesi) get scant mention. When some species are not factored into the equation it becomes difficult to understand how the ultimate aim of elimination can be achieved. However, taking such a critical view might allow the best to become the enemy of the good. The opening paragraph of the framework lays out why the focus is on P falciparum and P vivax: they pose the greatest threat. And the inclusion of P vivax is a notable advance given this was once considered a <u>neglected parasite</u>. Nonetheless, the promotion of a strategy that is not comprehensive does risk saving up problems for the future.

<u>To reach the milestones of WHO's</u> Global Technical Strategy 2016–2030, the pace of progress must be rapidly accelerated. Progress has been particularly difficult in low-income countries. It does not take an inspired leap of imagination to grasp that funding is a limiting factor—in 2015, requirements to support malaria programmes were forecast at US\$6·4 billion by 2020, \$7·7 billion by 2025, and \$8·7 billion by 2030. Thankfully, as noted in the <u>January Editorial</u> in this journal, despite early concerns about the incoming US administration, crucial investment from the USA is likely to be forthcoming, which sends a powerful signal to other partners.

In 2015, when the <u>millennium development goal for malaria</u> was declared met, many stakeholders were at pains to express that this achievement was only the end of the beginning and too soon for any sort of victory celebration. That the framework still focuses on the low-hanging fruit of "areas of low transmission that are progressing to zero" highlights how much there is still to do. Adding to the complexity of the task ahead is the emergence of antimalarial resistance. In this issue, <u>Mallika Imwong and colleagues</u> chronicle the spread of artemisinin-resistant P falciparum in the Greater Mekong subregion. Their worrying conclusion is that elimination of P falciparum malaria from this region should be accelerated while available antimalarial drugs still remain effective. Although not part of the new framework, WHO did release a strategy specific to this region in November, 2016.

A section on innovation and research rounds out the framework, providing a very brief outline of ongoing work. Substantial advances have been made. For example, in this issue <u>Mahamadou Sissoko, Sara Healy, and colleagues</u> report for the first time on the safety and efficacy of a P falciparum sporozoite vaccine in the field. Also, progress is being made in the development of new treatments. Recently online in The Lancet Infectious Diseases, <u>James McCarthy and colleagues and Mihály Sulyok and colleagues</u> reported early trials of a new, long-lasting antimalarial, DSM265. Although clearly at an early stage of development, a new treatment offers some hope that it might be possible to keep pace with the emergence of antimalarial resistance.

A notable addition to the framework is the outlining of the requirements for achieving and maintaining malaria elimination. Included among these requirements is a greater emphasis on

health systems. If applied with care, this focus on health systems could have broader benefits than on malaria alone. As with any document aimed at policymakers, the aims (ie, elimination) can seem very ambitious; however, as evident from progress so far, ambition is a strategy that has served the malaria community well.

Comment

Cholera vaccination: pregnant women excluded no more

Pedro L Moro, Lakshmi Sukumaran

Summary

Cholera is a serious dehydrating diarrhoeal disease caused by toxigenic serogroups (O1 and O139) of Vibrio cholerae, which is spread by faecal contamination of water and food. It is a disease of poverty and is closely linked to poor sanitation and lack of clean water.1 Cholera affects up to 2·8 million people and kills approximately 91 000 each year.2 Children aged younger than 5 years have the greatest incidence of disease in endemic areas. Among pregnant women, cholera can cause serious complications—namely, fetal loss, with rates varying from 2% to 36%.

Articles

The spread of artemisinin-resistant Plasmodium falciparum in the Greater Mekong subregion: a molecular epidemiology observational study

Mallika Imwong, Kanokon Suwannasin, Chanon Kunasol, Kreepol Sutawong, Mayfong Mayxay, Huy Rekol, Frank M Smithuis, Tin Maung Hlaing, Kyaw M Tun, Rob W van der Pluijm, Rupam Tripura, Olivo Miotto, Didier Menard, Mehul Dhorda, Nicholas P J Day, Nicholas J White, Arjen M Dondorp

Open Access

<u>Safety and efficacy of PfSPZ Vaccine against Plasmodium falciparum via direct venous inoculation in healthy malaria-exposed adults in Mali: a randomised, double-blind phase 1 trial</u>

Mahamadou S Sissoko, Sara A Healy, Abdoulaye Katile, Freda Omaswa, Irfan Zaidi, Erin E Gabriel, Bourama Kamate, Yacouba Samake, Merepen A Guindo, Amagana Dolo, Amadou Niangaly, Karamoko Niaré, Amatigue Zeguime, Kourane Sissoko, Hama Diallo, Ismaila Thera, Kelly Ding, Michael P Fay, Elise M O'Connell, Thomas B Nutman, Sharon Wong-Madden, Tooba Murshedkar, Adam J Ruben, Minglin Li, Yonas Abebe, Anita Manoj, Anusha Gunasekera, Sumana Chakravarty, B Kim Lee Sim, Peter F Billingsley, Eric R James, Michael Walther, Thomas L Richie, Stephen L Hoffman, Ogobara Doumbo, Patrick E Duffy

Safety, immunogenicity, and preliminary clinical efficacy of a vaccine against extraintestinal pathogenic Escherichia coli in women with a history of recurrent urinary tract infection: a randomised, single-blind, placebo-controlled phase 1b trial Angela Huttner, Christoph Hatz, Germie van den Dobbelsteen, Darren Abbanat, Alena Hornacek, Rahel Frölich, Anita M Dreyer, Patricia Martin, Todd Davies, Kellen Fae, Ingrid van den Nieuwenhof, Stefan Thoelen, Serge de Vallière, Anette Kuhn, Enos Bernasconi, Volker Viereck, Tilemachos Kavvadias, Kerstin Kling, Gloria Ryu, Tanja Hülder, Sabine Gröger, David Scheiner, Cristina Alaimo, Stephan Harbarth, Jan Poolman, Veronica Gambillara Fonck

<u>Safety of a killed oral cholera vaccine (Shanchol) in pregnant women in Malawi: an observational cohort study</u>

Mohammad Ali, Allyson Nelson, Francisco J Luquero, Andrew S Azman, Amanda K Debes, Maurice Mwesawina M'bang'ombe, Linly Seyama, Evans Kachale, Kingsley Zuze, Desire Malichi, Fatima Zulu, Kelias Phiri Msyamboza, Storn Kabuluzi, David A Sack Summary

Background

Pregnancy increases the risk of harmful effects from cholera for both mothers and their fetuses. A killed oral cholera vaccine, Shanchol (Shantha Biotechnics, Hydrabad, India), can protect against the disease for up to 5 years. However, cholera vaccination campaigns have often excluded pregnant women because of insufficient safety data for use during pregnancy. We did an observational cohort study to assess the safety of Shanchol during pregnancy. Methods

This observational cohort study was done in two adjacent districts (Nsanje and Chikwawa) in Malawi. Individuals older than 1 year in Nsanje were offered oral cholera vaccine during a mass vaccination campaign between March 30 and April 30, 2015, but no vaccines were administered in Chikwawa. We enrolled women who were exposed to oral cholera vaccine during pregnancy in Nsanje district, and women who were pregnant in Chikwawa district (and thus not exposed to oral cholera vaccine) during the same period. The primary endpoint of our analysis was pregnancy loss (spontaneous miscarriage or stillbirth), and the secondary endpoints were neonatal deaths and malformations. We evaluated these endpoints using log-binomial regression, adjusting for the imbalanced baseline characteristics between the groups. This study is registered with ClinicalTrials.gov, number NCT02499172. Findings

We recruited 900 women exposed to oral cholera vaccine and 899 women not exposed to the vaccine between June 16 and Oct 10, 2015, and analysed 835 in each group. 361 women exposed to the vaccine and 327 not exposed to the vaccine were recruited after their pregnancies had ended. The incidence of pregnancy loss was 27.54 (95% CI 18.41-41.23) per 1000 pregnancies among those exposed to the vaccine and 21.56 (13.65-34.04) per 1000 among those not exposed. The adjusted relative risk for pregnancy loss among those exposed to oral cholera vaccine was 1.24 (95% CI 0.64-2.43; p=0.52) compared with those not exposed to the vaccine. The neonatal mortality rate was 11.78 (95% CI 5.92-23.46) per 1000 livebirths for infants whose mothers were exposed to oral cholera vaccine versus 8.91 (4.02-19.77) per 1000 livebirths for infants whose mothers were not exposed to the vaccine (crude relative risk 1.32, 95% CI 0.46-3.84; p=0.60). Only three newborn babies had malformations, two in the vaccine exposure group and one in the no-exposure group, yielding a relative risk of 2.00 (95% CI 0.18-22.04; p=0.57), although this estimate is unreliable because of the small number of outcomes.

Interpretation

Our study provides evidence that fetal exposure to oral cholera vaccine confers no significantly increased risk of pregnancy loss, neonatal mortality, or malformation. These data, along with findings from two retrospective studies, support use of oral cholera vaccine in pregnant women in cholera-affected regions.

Funding

Bill & Melinda Gates Foundation.

Lancet Public Health

May 2017 Volume 2 Number 5 e202-e246 http://thelancet.com/journals/lanpub/issue/current

Articles

<u>Progress and prospects for the control of HIV and tuberculosis in South Africa: a dynamical modelling study</u>

Brian G Williams, Somya Gupta, Matthew Wollmers, Reuben Granich *Summary*

Background

In September, 2016, South Africa adopted a policy of providing antiretroviral treatment to everyone infected with HIV irrespective of their CD4 cell count. Studies of universal treatment and expanded prevention of HIV differ widely in their projections of effects and the associated costs, so we did this analysis to attempt to find a consensus.

Methods

We used data on HIV from the Joint UN Programme on HIV and AIDS (UNAIDS) from 1988 to 2013 and from data from WHO on tuberculosis from 1980 to to 2013 to fit a dynamical model to time trends in HIV prevalence, antiretroviral therapy (ART) coverage, and tuberculosis notification rates in South Africa. We then used the model to estimate current trends and project future patterns in HIV prevalence and incidence, AIDS-related mortality, and tuberculosis notification rates, and we used data from the South African National AIDS Council to assess current and future costs under different combinations of treatment and prevention approaches. We considered two treatment strategies: the Constant Effort strategy, in which people infected with HIV continue to start treatment at the rate in 2016, and the Expanded Treatment and Prevention (ETP) strategy, in which testing rates are increased, treatment is started immediately after HIV is detected, and prevention programmes are expanded. Findings

Our estimates show that HIV incidence among adults aged 15 years or older fell from 2·3% per year in 1996 to 0·65% per year in 2016, AIDS-related mortality decreased from 1·4% per year in 2006 to 0·37% per year in 2016, and both continue to fall at a relative rate of 17% per year. Our model shows that maintenance of Constant Effort will have a substantial effect on HIV but will not end AIDS, whereas ETP could end AIDS by 2030, with incidence of HIV and AIDs-related mortality rates both at less than one event per 1000 adults per year. Under ETP the annual cost of health care and prevention will increase from US\$2·3 billion in 2016 to \$2·9 billion in 2018, then decrease to \$1·7 billion in 2030 and \$0·9 billion in 2050. Over the next 35 years, the expansion of treatment will avert an additional 3·8 million new infections, save 1·1 million lives, and save \$3·2 billion compared with continuing Constant Effort up to 2050. Expansion of prevention, including provision of pre-exposure prophylaxis, condom distribution, and male circumcision, could avert a further 150 000 new infections, save 5000 lives, and cost an additional \$5·7 billion compared with Constant Effort.

Interpretation

Our results suggest that South Africa is on track to reduce HIV incidence and AIDS-related mortality substantially by 2030, saving both lives and money. Success will depend on high rates of HIV testing, ART delivery and adherence, good patient monitoring and support, and data to monitor progress.

Funding

None.

Lancet Respiratory Medicine

May 2017 Volume 5 Number 5 p361-456 e16-e19 http://www.thelancet.com/journals/lanres/issue/current [New issue: No digest content identified]

Maternal and Child Health Journal

Volume 21, Issue 5, May 2017

http://link.springer.com/journal/10995/21/5/page/1

From the Field

Knowledge, Attitudes and Perceptions About Routine Childhood Vaccinations Among Jewish Ultra-Orthodox Mothers Residing in Communities with Low Vaccination Coverage in the Jerusalem District

Chen Stein Zamir, Avi Israeli

Abstract

Background and aims

Childhood vaccinations are an important component of primary prevention. Maternal and Child Health (MCH) clinics in Israel provide routine vaccinations without charge. Several vaccine-preventable-diseases outbreaks (measles, mumps) emerged in Jerusalem in the past decade. We aimed to study attitudes and knowledge on vaccinations among mothers, in communities with low immunization coverage.

Methods

A qualitative study including focus groups and semi-structured interviews. Results Low immunization coverage was defined below the district's mean (age 2 years, 2013) for measles-mumps-rubella-varicella 1st dose (MMR1\MMRV1) and diphtheria-tetanus-pertussis 4th dose (DTaP4), 96 and 89%, respectively. Five communities re included, all were Jewish ultra-orthodox. The mothers' (n=87) median age was 30 years and median number of children 4. Most mothers (94%) rated vaccinations as the main activity in the MCH clinics with overall positive attitudes. Knowledge about vaccines and vaccination schedule was inadequate. Of vaccines scheduled at ages 0–2 years (n=13), the mean number mentioned was 3.9 ± 2.8 (median 4, range 0–9). Vaccines mentioned more often were outbreak-related (measles, mumps, polio) and HBV (given to newborns). Concerns about vaccines were obvious, trust issues and religious beliefs were not. Vaccination delay was very common and timeliness was considered insignificant. Practical difficulties in adhering to the recommended schedule prevailed. The vaccinations visits were associated with pain and stress. Overall, there was a sense of self-responsibility accompanied by inability to influence others.

Conclusion

Investigating maternal knowledge and attitudes on childhood vaccinations provides insights that may assist in planning tailored intervention programs aimed to increase both vaccination coverage and timeliness.

Original Paper

<u>Vaccination Coverage and Timelines Among Children 0–6 Months in Kinshasa, the Democratic Republic of Congo: A Prospective Cohort Study</u>
Paul N. Zivich, Landry Kiketa, Bienvenu Kawende...

Medical Decision Making (MDM)

Volume 37, Issue 3, April 2017 http://mdm.sagepub.com/content/current [Reviewed earlier]

The Milbank Quarterly

A Multidisciplinary Journal of Population Health and Health Policy
March 2017 Volume 95, Issue 1 Pages 1–209
http://onlinelibrary.wiley.com/doi/10.1111/milq.2017.95.issue-1/issuetoc
[Reviewed earlier]

Nature

Volume 545 Number 7652 pp5-128 4 May 2017 http://www.nature.com/nature/current_issue.html

[New issue: No digest content identified]

Nature Medicine

May 2017, Volume 23 No 5 pp527-643 http://www.nature.com/nm/journal/v23/n5/index.html Editorial

The curse of uncertainty

doi:10.1038/nm.4342

Proposed US budget cuts and the impending exit of the UK from the European Union have the potential to destabilize the global biomedical-research enterprise. In the meantime, the uncertainty of not knowing just how bad the effects will be will inflict its own damage.

Nature Reviews Immunology

May 2017 Vol 17 No 5

http://www.nature.com/nri/journal/v17/n4/index.html

[New issue: No digest content identified]

New England Journal of Medicine

May 4, 2017 Vol. 376 No. 18

http://www.nejm.org/toc/nejm/medical-journal

Review Article

The Changing Face of Clinical Trials

Jeffrey M. Drazen, M.D., David P. Harrington, Ph.D., John J.V. McMurray, M.D., James H. Ware, Ph.D., Janet Woodcock, M.D., Editors

Academic, Foundation, and Industry Collaboration in Finding New Therapies

Bonnie W. Ramsey, M.D., Gerald T. Nepom, M.D., Ph.D., and Sagar Lonial, M.D. N Engl J Med 2017; 376:1762-1769 May 4, 2017 DOI: 10.1056/NEJMra1612575

Breakthroughs in the ability to probe and better understand biologic systems during the past 30 years 1-3 have enabled the medical community to develop new therapeutic agents and change the course of many life-shortening diseases. 4,5 Despite this success, bridging the gap between promising laboratory observations and the development of effective therapies remains risky and expensive, with fewer than 1 in 10,000 early translational programs successfully achieving Food and Drug Administration (FDA) approval, at a cost of nearly \$1 billion. 6 Most

therapeutic development fails in the preclinical phase, which is sometimes described as the "valley of death."

For this reason and because therapies for some conditions will have a limited eventual market value, the pharmaceutical industry has been hesitant to initiate early-stage programs to treat so-called orphan diseases. In recognition of a critical need, federal agencies have developed programs to catalyze innovation and reduce barriers to early development of new therapies. In the past two decades, disease-focused foundations also have developed a new approach to bridging this preclinical gap. In a process known as venture philanthropy, such foundations have formed partnerships with industry and federal agencies to share the financial risk of therapeutic development, shorten the early translational pipeline, and advance research with "a focus on human, not financial, return." In addition, foundations and their academic partners have accelerated early development by providing access to patient populations for clinical trials and assistance from disease-specific experts in study design, which has helped in bridging the gap in therapeutic development.

In this review, we will focus on three diseases — cystic fibrosis, multiple myeloma, and type 1 diabetes mellitus — to illustrate how collaborations among academic institutions, foundations, and industry partners have evolved to address the therapeutic challenges of these conditions.

Pediatrics

May 2017, VOLUME 139 / ISSUE 5

http://pediatrics.aappublications.org/content/139/5?current-issue=y

Influenza Vaccine Effectiveness Against Pediatric Deaths: 2010-2014

Brendan Flannery, Sue B. Reynolds, Lenee Blanton, Tammy A. Santibanez, Alissa O'Halloran, Peng-Jun Lu, Jufu Chen, Ivo M. Foppa, Paul Gargiullo, Joseph Bresee, James A. Singleton, Alicia M. Fry

Pediatrics May 2017, 139 (5) e20164244; DOI: 10.1542/peds.2016-4244

Articles

Effectiveness of Vaccination During Pregnancy to Prevent Infant Pertussis

Roger Baxter, Joan Bartlett, Bruce Fireman, Edwin Lewis, Nicola P. Klein Pediatrics May 2017, 139 (5) e20164091; DOI: 10.1542/peds.2016-4091

Articles

The Concordance of Parent and Child Immunization

Steve G. Robison, Andrew W. Osborn

Pediatrics May 2017, 139 (5) e20162883; DOI: 10.1542/peds.2016-2883

State-of-the-Art Review Articles

Ethical Conduct of Research in Children: Pediatricians and Their IRB (Part 1 of 2)

Carlos D. Rose

Pediatrics May 2017, 139 (5) e20163648; DOI: 10.1542/peds.2016-3648 *Abstract*

As human experimentation continues to grow into an ever more complex and sophisticated endeavor, the relevant ethical and regulatory structures become more intricate. When pediatricians and general practitioners are invited by pharmaceutical companies to enroll their offices in a clinical trial or a multicenter observational study or when they develop their own

research questions, they frequently find themselves at a loss in the human research environment. The legal and regulatory complexity may have an unintended deterring effect at a time when office-based high quality pediatric research is urgently needed to support evidence-based medicine. Unfortunately, in many instances, unaware practitioners become involved in low-risk research activities without knowing it and become entangled in legal, auditing, and compliance procedures. This paper, written in 2 parts, aims at providing a general guidance on the principles that regulate human research with a focus on pediatrics. Part 1 discusses the history, the legal framework, and the consent process and highlights some practical aspects of initial protocol submission, continued review, and institutional review board determinations with the main focus on multicenter clinical trials (industry-sponsored research). Part 2 focuses on pediatric research regulation, also known as subpart-D, and minimal risk research, which encompasses many research activities aimed at addressing questions that may emerge in pediatricians' practices (investigator-initiated research).

Special Articles

The Next 7 Great Achievements in Pediatric Research

Tina L. Cheng, Clifford W. Bogue, George J. Dover Pediatrics May 2017, 139 (5) e20163803; DOI: 10.1542/peds.2016-3803 *Abstract*

The "7 Great Achievements in Pediatric Research" campaign noted discoveries in the past 40 years that have improved child and adult health in the United States and around the globe. This article predicts the next 7 great pediatric research advancements, including new immunizations, cancer immunotherapy, genomic discoveries, identification of early antecedents of adult health, impact of specific social—environmental influences on biology and health, quality improvement science, and implementation and dissemination research to reduce global poverty. It is an extraordinary time of new research tools that include electronic health records, technological ability to manage big data and measure "omics," and new functional and structural imaging modalities. These tools will discern mechanisms leading to health and disease with new prevention targets and cures. This article further discusses the challenges and opportunities to accelerate these exciting pediatric research discoveries to improve the lives of children and the adults they will become.

Improving Recruitment and Retention Rates in a Randomized Controlled Trial

Hadley S. Sauers-Ford, Jennifer M. Gold, Angela M. Statile, Heather L. Tubbs-Cooley, Jeffrey M. Simmons, Samir S. Shah, Kathleen Bell, Cory Pfefferman, Margo J. Moore, Katherine A. Auger, on behalf of the H2O Study Group

Pediatrics May 2017, 139 (5) e20162770; DOI: 10.1542/peds.2016-2770 Abstract

High recruitment and retention rates in randomized controlled trials are essential to ensure validity and broad generalizability. We used quality improvement methods, including run charts and intervention cycles, to achieve and sustain high recruitment and retention rates during the Hospital-To-Home Outcomes randomized controlled trial. This study is examining the effects of a single nurse–led home health care visit after discharge for an acute pediatric hospitalization. A total of 1500 participants were enrolled in the 15-month study period. For study recruitment, we assessed the percentage of patients who enrolled in the study among those randomly selected to approach (goal \geq 50%) and the percentage of patients who refused to enroll from those randomly selected to approach (goal \leq 30%). For intervention completion, we examined the percentage of patients who completed the home visit intervention among those randomized

to receive the intervention (goal ≥95%) were examined. Follow-up rates were tracked as the percentage of patients who completed the 14-day follow-up telephone survey (goal ≥95%). The study goals for 2 of the 4 metrics were met and sustained, with statistically significant improvements over time in 3 metrics. The median enrollment rate increased from 50% to 59%, and the median refusal rate decreased from 37% to 32%. The median intervention completion rate remained unchanged at 88%. The 14-day follow-up completion median rate increased from 94% to 96%. These results indicate that quality improvement methods can be used within the scope of a large research study to achieve and sustain high recruitment and retention rates.

Pharmaceutics

Volume 9, Issue 1 (March 2017) http://www.mdpi.com/1999-4923/9/1 [Reviewed earlier]

PharmacoEconomics

Volume 35, Issue 5, May 2017 http://link.springer.com/journal/40273/35/5/page/1 Original Research Article

The Potential Cost Effectiveness of Different Dengue Vaccination Programmes in Malaysia: A Value-Based Pricing Assessment Using Dynamic Transmission **Mathematical Modelling**

Asrul Akmal Shafie, Hui Yee Yeo, Laurent Coudeville, Lucas Steinberg...

Abstract

Background

Dengue disease poses a great economic burden in Malaysia.

Methods

This study evaluated the cost effectiveness and impact of dengue vaccination in Malaysia from both provider and societal perspectives using a dynamic transmission mathematical model. The model incorporated sensitivity analyses, Malaysia-specific data, evidence from recent phase III studies and pooled efficacy and long-term safety data to refine the estimates from previous published studies. Unit costs were valued in \$US, year 2013 values. Results

Six vaccination programmes employing a three-dose schedule were identified as the most likely programmes to be implemented. In all programmes, vaccination produced positive benefits expressed as reductions in dengue cases, dengue-related deaths, life-years lost, disabilityadjusted life-years and dengue treatment costs. Instead of incremental cost-effectiveness ratios (ICERs), we evaluated the cost effectiveness of the programmes by calculating the threshold prices for a highly cost-effective strategy [ICER $<1 \times$ gross domestic product (GDP) per capita] and a cost-effective strategy (ICER between 1 and 3 × GDP per capita). We found that vaccination may be cost effective up to a price of \$US32.39 for programme 6 (highly cost effective up to \$US14.15) and up to a price of \$US100.59 for programme 1 (highly cost effective up to \$US47.96) from the provider perspective. The cost-effectiveness analysis is sensitive to under-reporting, vaccine protection duration and model time horizon.

Conclusion

Routine vaccination for a population aged 13 years with a catch-up cohort aged 14-30 years in targeted hotspot areas appears to be the best-value strategy among those investigated.

Dengue vaccination is a potentially good investment if the purchaser can negotiate a price at or below the cost-effective threshold price.

PLOS Currents: Disasters

http://currents.plos.org/disasters/

[Accessed 6 May 2017]

Risk Criteria in Hospital Site Selection: A Systematic Review

May 1, 2017 · Review

Introduction: Hospitals should be safe and remain functional in emergencies and disasters as it is mentioned in the Sendai Framework. Proper selection of a hospital location has a direct effect on survival of affected population in disasters as well as cost and benefit of the hospital in non-emergency situation. Different studies applied different criteria for Hospital Site Selection (HSS). The present study through a systematic review aimed to find out a categorized criteria list that have been used for (HSS) in the literature.

Methods: In accordance with the PRISMA statement, "PubMed", "ScienceDirect", "Google Scholar", and "Scopus" were searched up to end of 2015. All English Articles that were published in peer-reviewed journals and had discussed site selection criteria for hospitals were included. Out of 41 articles, 15 met the inclusion criteria in which 39 general criteria for HSS were applied. These criteria were categorized in six main groups including cost, demand, environmental, administrative, disaster risk, and "other" concerns through a focus group discussion.

Results: Accordingly, the application percentage of cost, demand, environmental, administrative, disaster risk, and "other" concerns in the articles was 100, 93.3, 53.3, 33.3, 20.0, and 13.3 respectively. The least devoted attention was to disaster risk issues. Discussion: Few researchers applied risk related criteria for HSS. Further consideration of "risk of hazards" and "burden of diseases" in comprehensive studies, is recommended for HSS to guide the decision makers for building more resilient hospitals.

PLoS Currents: Outbreaks

http://currents.plos.org/outbreaks/

[Accessed 6 May 2017]

No Evidence of On-farm Circulation of Avian Influenza H5 Subtype in Ca Mau Province, Southern Vietnam, March 2016 – January 2017

May 5, 2017 · Research Article

Background: Subtype H5N1 avian influenza viruses, both high pathogenicity and low pathogenicity, have been enzootic in Vietnam since 2001. The viruses are readily identified at live bird markets, but virus prevalence on smallholder poultry is typically zero or very low. If the true direction of the viral transmission chain is farm to market, it is unknown why farm prevalence should be low when market prevalence is moderate to high.

Methods: We established a cohort of 50 smallholder poultry farms in Ca Mau province in the Mekong Delta regions of Vietnam. From March 2016 to January 2017, we collected nasopharyngeal and cloacal samples from 156 ducks and 96 chickens. In addition, 126 environmental samples were collected. Samples were assayed for H5 subtype influenza by real-time RT-PCR.

Results/Discussion: None of the 378 collected samples were positive for H5 influenza. This is likely to mean that circulation of subtype H5 influenza viruses was low in Ca Mau in

2016. Detection of avian influenza on smallholder poultry farms is necessary to determine the directionality and association between farm prevalence and market prevalence of avian influenza viruses. Larger farm-level studies should be planned as these will be critical for determining the presence and strength of this association.

Rapid Assessment Zika Virus Knowledge Among Clinical Specialists in Singapore: A Cross-sectional Survey

May 3, 2017 · Research Article

Introduction: We report the results of a rapid assessment of Zika virus awareness among key clinical specialties in Singapore.

Methods: Between June 6 and June 19, 2016 we conducted an online survey of doctors working in obstetrics and gynaecology, neonatology and paediatrics in Singapore. The survey included 15 multiple choice questions to measure respondents' knowledge of Zika virus in four domains covering clinical and public health.

Results: A total of 110 survey responses (15% response rate) were obtained, 82% of respondents worked in the public sector. Overall, the median respondent score was 9.4 (Max score=15), with substantial variation (range: 3.5 – 14.7). Microcephaly and Guillain-Barré syndrome were recognised as causal complications of Zika virus infection by 99% and 50% of respondents respectively. Clinical features which could help differentiate Zika from Dengue were less well understood with 50% and 68% correctly identifying conjunctivitis and low grade fever respectively. Worryingly, 14% favoured non-steroidal anti-inflammatory drugs as part of treatment, without first excluding dengue as a diagnosis. Also, only 36% of respondents were aware of the current recommendation for preventing sexual transmission of Zika virus. Fewer than 50% were aware of the need for ophthalmological evaluation as part of congenital Zika virus infection.

Discussion: Our assessment demonstrates that there is good awareness of the clinical manifestation of Zika virus disease among key specialty doctors, but confusion with Dengue disease remains. It also highlights knowledge gaps in the prevention of sexually-transmitted Zika virus infection and the clinical management of congenital Zika virus infection in newborns. Our study identified strategic areas to improve communication to front-line doctors during public health response to the Zika epidemic.

PLoS Medicine

http://www.plosmedicine.org/ (Accessed 6 May 2017) Perspective

<u>Towards control of the global HIV epidemic: Addressing the middle-90 challenge in the UNAIDS 90–90–90 target</u>

Collins Iwuji, Marie-Louise Newell | published 02 May 2017 PLOS Medicine

https://doi.org/10.1371/journal.pmed.1002293

n 2016, just over 2 million people worldwide acquired HIV infection, mostly via heterosexual transmission and mostly in sub-Saharan Africa [1]. Antiretroviral treatment (ART) aims to suppress viral load to very low, or undetectable, levels, delaying HIV disease progression [2,3] and reducing the risk of onward transmission [4]. Following the 2015 WHO guidelines recommending ART for all HIV-positive people regardless of CD4 count, WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) issued the 90–90–90 target, aiming by 2020

to have 90% of infected people knowing their HIV status, 90% of HIV-positive people initiated on ART, and 90% of people treated with ART virally suppressed [5], so as to achieve containment of the HIV epidemic.

We commend Richard Hayes and colleagues for their success in navigating the complex logistic challenges in implementing a large-scale universal testing and treatment (UTT) intervention in sub-Saharan Africa, as described in their accompanying research article in PLOS Medicine [6]. They report how close they were able to come to reaching the first two stages of the 90–90–90 target in four communities in Zambia after one year of implementing their PopART intervention (comprising home-based HIV testing by Community HIV care Providers [CHiPs] with support for linkage to care, adherence, and retention). Among those consenting to the intervention, 6,197 HIV-positive individuals not on ART (most of whom had never been in care) were referred to care, 42% of whom initiated ART within six months and 53% by 12 months. Extrapolating to the entire population, the estimated percentage of HIV-positive adults who knew their status increased from 52% to 78% (men) and from 56% to 87% (women); percentages of known HIV-positive people on ART increased from 54% to 74% (men) and from 53% to 73% (women). The overall estimated percentage of HIV-positive adults on ART was 61% after 1 y of intervention implementation, compared to the WHO/UNAIDS target of 81% (90% of 90%). We note that many process indicators in the study were based on self-report and, apparently, data from the CHiPs electronic capture system were not verified with clinic data. Further, in this setting, in which nearly 50% of all HIV-positive individuals were ART-naive because they were newly diagnosed, it is likely that most of the 20% of people who migrated out of the area never linked to care or commenced ART. This 20% of people, no longer resident in the PopART communities, was not included in the denominator for the post-CHiPs evaluation at 12 months on linkage to care and ART initiation, which could have resulted in an overestimate of the change observed following the CHiPs intervention.

Hayes and colleagues' findings thus confirm the high acceptability of home-based HIV testing, and a less-than-optimal linkage to care, with initiation of ART rates suggesting that those who do link to care are willing to start ART; there is a substantial proportion of people identified as HIV positive who do not (yet) link to care, can therefore not be initiated on ART, and who may continue to transmit HIV. The Agence Nationale de Recherche sur le Sida et les hépatites virales (ANRS) 12249 Treatment as Prevention (TasP) trial, also evaluating a UTT intervention in rural South Africa, recently reported that 92% of HIV-positive individuals knew their status, 49% of those people initiated ART, and 93% achieved virological suppression on ART [7]. Higher rates of ART initiation were reported from Uganda and Kenya in the Sustainable East Africa Research in Community Health (SEARCH) trial, another UTT intervention study, with 97% of HIV-positive individuals knowing their status, 93% on ART, and 90% virologically suppressed at the end of year two [8]. Similarly, estimates from the Botswana Combination Prevention Project (BCPP) trial, a UTT intervention implemented in Botswana, reported that, overall, 70% of all HIVpositive individuals were virologically suppressed, close to the UNAIDS target of 73% (90% of 90% of 90%), with 83% of HIV-positive individuals diagnosed and 87% on ART, of whom 97% achieved virological suppression [9]. The different approaches to the estimation of percentages in the HIV care cascade in these trials hinder direct comparison of results; hence, we agree with Hayes and colleagues that approaches for estimating proportions of people at different stages in the HIV cascade need to be harmonised.

Hayes and colleagues report that it was challenging to find young men at home, again in line with experience elsewhere [10]. Slow linkage to care suggests that people will only attend

facilities once they prioritise doing so, and this is especially pertinent before they are driven to do so by the development of HIV symptoms and signs. An earlier study in rural KwaZulu-Natal highlighted that linkage to care was significantly less likely in those who had never been in HIV care, students in education, and those further away from the clinic, while those who had positive experience of ART in friends or family were more likely to access the trial clinic [11]. Hayes and colleagues will address progress towards the third 90% target later in their trial, but evidence from other studies suggests that once people engage with ART care, they are likely to adhere, at least in the short term [7], and that early linkage to ART care is the main hurdle in the HIV care cascade.

The big question remains whether, in the global heterosexually-driven HIV epidemic, UTT will ultimately reduce HIV incidence to levels sufficient for containment. Findings from the ANRS 12249 TasP trial in South Africa showed little impact on HIV incidence [7], likely due to the slow linkage to care. Hayes and colleagues, although suggesting success of UTT in the first round of trial implementation, do not provide information about sustainability of either HIV test offer uptake or ART adherence, issues which may be especially important in settings with high migration movements.

Overall, these results would suggest that it is unlikely that the rather optimistic forecasts, based on statistical modelling [12], of an imminent end to the global HIV epidemic will be fulfilled. The current gloomy political environment, with uncertainty about the global will to continue to support the large-scale implementation of HIV treatment and care programmes worldwide [13], further adds to the already considerable challenges faced by public health programmes in many settings with a high HIV burden. Health care system requirements for a successful UTT programme are not negligible, even if a UTT approach is found to be cost-effective [14]. Substantial resources are needed to further scale up ART for all HIV-positive adults, and allocation of limited resources will need to be optimised on the basis of evidence of efficacy. Given extensive resource constraints, there may come a time to consider whether public programmes will need to focus on providing optimal health care and support for those people who engage with care at public facilities and who have thus indicated that they have prioritised access to health care in their lives.

PLoS Neglected Tropical Diseases

http://www.plosntds.org/ (Accessed 6 May 2017) Research Article

<u>Safety and immunogenicity of the Na-GST-1 hookworm vaccine in Brazilian and American adults</u>

David J. Diemert, Janaína Freire, Vanderson Valente, Carlos Geraldo Fraga, Frederico Talles, Shannon Grahek, Doreen Campbell, Amar Jariwala, Maria Victoria Periago, Martin Enk, Maria Flávia Gazzinelli, Maria Elena Bottazzi, Robert Hamilton, Jill Brelsford, Anna Yakovleva, Guangzhao Li, Jin Peng, Rodrigo Correa-Oliveira, Peter Hotez, Jeffrey Bethony Research Article | published 02 May 2017 PLOS Neglected Tropical Diseases https://doi.org/10.1371/journal.pntd.0005574

<u>External quality assessment study for ebolavirus PCR-diagnostic promotes</u> <u>international preparedness during the 2014 – 2016 Ebola outbreak in West Africa</u> Heinz Ellerbrok, Sonja Jacobsen, Pranav Patel, Toni Rieger, Markus Eickmann, Stephan Becker, Stephan Günther, Dhamari Naidoo, Livia Schrick, Kathrin Keeren, Angelina Targosz, Anette Teichmann, Pierre Formenty, Matthias Niedrig Research Article | published 01 May 2017 PLOS Neglected Tropical Diseases https://doi.org/10.1371/journal.pntd.0005570

PLoS One

http://www.plosone.org/ [Accessed 6 May 2017] Research Article

Neutralizing misinformation through inoculation: Exposing misleading argumentation techniques reduces their influence

John Cook, Stephan Lewandowsky, Ullrich K. H. Ecker Research Article | published 05 May 2017 PLOS ONE https://doi.org/10.1371/journal.pone.0175799

Abstract

Misinformation can undermine a well-functioning democracy. For example, public misconceptions about climate change can lead to lowered acceptance of the reality of climate change and lowered support for mitigation policies. This study experimentally explored the impact of misinformation about climate change and tested several pre-emptive interventions designed to reduce the influence of misinformation. We found that false-balance media coverage (giving contrarian views equal voice with climate scientists) lowered perceived consensus overall, although the effect was greater among free-market supporters. Likewise, misinformation that confuses people about the level of scientific agreement regarding anthropogenic global warming (AGW) had a polarizing effect, with free-market supporters reducing their acceptance of AGW and those with low free-market support increasing their acceptance of AGW. However, we found that inoculating messages that (1) explain the flawed argumentation technique used in the misinformation or that (2) highlight the scientific consensus on climate change were effective in neutralizing those adverse effects of misinformation. We recommend that climate communication messages should take into account ways in which scientific content can be distorted, and include pre-emptive inoculation messages.

<u>Cost-effectiveness of alternate strategies for childhood immunization against</u> <u>meningococcal disease with monovalent and quadrivalent conjugate vaccines in</u> <u>Canada</u>

Thomas E. Delea, Derek Weycker, Mark Atwood, Dion Neame, Fabián P. Alvarez, Evelyn Forget, Joanne M. Langley, Ayman Chit Research Article | published 04 May 2017 PLOS ONE https://doi.org/10.1371/journal.pone.0175721

PLoS Pathogens

http://journals.plos.org/plospathogens/
[Accessed 6 May 2017]
[No new digest content identified]

PNAS - Proceedings of the National Academy of Sciences of the United States of America

http://www.pnas.org/content/early/ [Accessed 6 May 2017] [No new digest content identified]

Prehospital & Disaster Medicine

Volume 32 - Issue 2 - April 2017 https://www.cambridge.org/core/journals/prehospital-and-disaster-medicine/latest-issue [Reviewed earlier]

Preventive Medicine

Volume 98, Pages 1-44 (May 2017)

http://www.sciencedirect.com/science/journal/00917435/98

Special Issue: Emerging Paradigms in Cervical Cancer Screening

Edited by Mark Schiffman

<u>Cervical cancer screening in women vaccinated against human papillomavirus infection: Recommendations from a consensus conference</u>

Original Research Article

Pages 21-30

Paolo Giorgi Rossi, Francesca Carozzi, Antonio Federici, Guglielmo Ronco, Marco Zappa, Silvia Franceschi, The Italian Screening in HPV vaccinated girls Consensus Conference group Abstract

In Italy, the cohorts of women who were offered Human papillomavirus (HPV) vaccination in 2007/08 will reach the age (25 years) for cervical cancer (CC) screening from 2017. The simultaneous shift from cytology-based screening to HPV test-based screening gives the opportunity for unprecedented reorganisation of CC prevention. The ONS (National Screening Monitoring Centre) Directive and the GISCi (Italian Group for Cervical Screening) identified the consensus conference as the most suitable method for addressing this topic. A summary of consensus recommendations is reported here. The main objective was to define the best screening methods in girls vaccinated against HPV and the knowledge required for defining evidence-based screening strategies. A Jury made recommendations about questions and proposals formulated by a panel of experts representative of Italian scientific societies involved in CC prevention and based on systematic reviews of literature and evidence. The Jury considered changing the screening protocols for girls vaccinated in their twelfth year as appropriate. Tailored screening protocols based on vaccination status could be replaced by "one size fits all" protocols only when a herd immunity effect has been reached. Vaccinated women should start screening at age 30, instead of 25, with HPV test. Furthermore, there is a strong rationale for applying longer intervals for re-screening HPV negative women than the currently recommended 5 years, but research is needed to determine the optimal screening time points. For non-vaccinated women and for women vaccinated in their fifteenth year or later, the current protocol should be kept.

<u>Considerations for HPV primary screening in lower-middle income countries</u>
Original Research Article

Pages 39-41 Mauricio Maza, Julia C. Gage *Abstract*

The accumulated scientific evidence now provides ample support for HPV primary screening as a superior method for detecting cervical precancer and preventing cervical cancer. Approximately half of the global burden of cervical cancer could be reduced in lower-middle income countries where attempts to implement traditional cytology-based programs have not experienced successes. In these countries screening programs have struggled with poor screening and diagnostic test sensitivity, difficulties maintaining quality control and adequate population coverage. HPV testing is not only more accurate and reliable, but also requires less training, quality assurance and expensive personnel. Because these countries are especially vulnerable to economic, political and societal instabilities, HPV tests must become more affordable and accessible in order to enable Ministries of Health to make long-term resource commitments.

The time is now to implement HPV testing for primary screening in low resource settings

Original Research Article Pages 42-44 Louise Kuhn, Lynette Denny *Abstract*

Unacceptable disparities in cervical cancer between richer and poorer countries persist and serve as reminders of gross disparities in access to and quality of screening services. HPV testing is well-suited to address some of the barriers to implementing adequate screening programs in low resource settings. HPV testing has considerably better sensitivity than cytology providing the same extent of safety with fewer rounds of screening. New robust HPV testing platforms require little to no skill by laboratory workers and some can be used at the point-ofcare. This allows for a round of screening to be accomplished in one or two visits, reducing costs and the inevitable attrition that occurs when women need to be recalled to obtain their results. HPV testing is ideal for incorporating into the new "screen-and-treat" approaches designed to overcome limitations of conventional, multi-visit, colposcopy-based approaches to screening. Visual inspection with acetic acid (VIA) is the screening test that has been used most widely in screen-and-treat programs to date but the performance characteristics of this test are poor. HPV-based screen-and-treat is more effective in reducing disease in the population and reduces over-treatment intrinsic to this approach. HPV testing can be adapted or combined with other molecular tests to improve treatment algorithms. Infrastructure established to support VIA-based screen-and-treat can effectively incorporate HPV testing. We are poised at a critical juncture in public health history to implement HPV testing as part of primary screening and thereby improve women's health in low resource settings.

Proceedings of the Royal Society B

12 April 2017; volume 284, issue 1852 http://rspb.royalsocietypublishing.org/content/284/1852?current-issue=y [Reviewed earlier]

Public Health Ethics

Volume 10, Issue 1 April 2017

http://phe.oxfordjournals.org/content/current

Original Articles

Research Ethics Governance in Times of Ebola

<u>Doris Schopper</u>; <u>Raffaella Ravinetto</u>; <u>Lisa Schwartz</u>; <u>Eunice Kamaara</u>; <u>Sunita Sheel</u> ... *Abstract*

The Médecins Sans Frontières (MSF) ethics review board (ERB) has been solicited in an unprecedented way to provide advice and review research protocols in an 'emergency' mode during the recent Ebola epidemic. Twenty-seven Ebola-related study protocols were reviewed between March 2014 and August 2015, ranging from epidemiological research, to behavioural research, infectivity studies and clinical trials with investigational products at (very) early development stages. This article examines the MSF ERB's experience addressing issues related to both the process of review and substantive ethical issues in this context. These topics include lack of policies regarding blood sample collection and use, and engaging communities regarding their storage and future use; exclusion of pregnant women from clinical and vaccine trials; and the difficulty of implementing timely and high-quality qualitative/anthropological research to consider potential upfront harms. Having noticed different standards across ethics committees (ECs), we propose that when multiple ethics reviews of clinical and vaccine trials are carried out during a public health emergency they should be accompanied by transparent communication between the ECs involved. The MSF ERB experience should trigger a broader discussion on the 'optimal' ethics review in an emergency outbreak and what enduring structural changes are needed to improve the ethics review process.

Public Health Reports

Volume 132, Issue 3, May/June 2017 http://phr.sagepub.com/content/current Reports and Recommendations

Overcoming Barriers and Identifying Opportunities for Developing Maternal
Immunizations: Recommendations From the National Vaccine Advisory Committee
Approved by the National Vaccine Advisory Committee on September 20, 2016
First Published April 5, 2017; pp. 271–284

Research

<u>Voluntarily Reported Immunization Registry Data: Reliability and Feasibility to Predict Immunization Rates, San Diego, California, 2013</u>

Zachary J. Madewell, Robert B. Wester, Wendy W. Wang, Tyler C. Smith, K. Michael Peddecord, Jessica Morris, Heidi DeGuzman, Mark H. Sawyer, Eric C. McDonald First Published April 5, 2017; pp. 357–365

Qualitative Health Research

Volume 27, Issue 6, May 2017 http://qhr.sagepub.com/content/current

Special Issue: Phenomenology/Qualitative Evaluation

[No new digest content identified]

Reproductive Health

http://www.reproductive-health-journal.com/content [Accessed 6 May 2017] [No new digest content identified]

Revista Panamericana de Salud Pública/Pan American Journal of Public Health (RPSP/PAJPH)

http://www.paho.org/journal/index.php?option=com_content&view=featured&Itemid=101 Recently Published Articles -[No new digest content identified]

Risk Analysis

March 2017 Volume 37, Issue 3 Pages 399–597 http://onlinelibrary.wiley.com/doi/10.1111/risa.2017.37.issue-3/issuetoc [Reviewed earlier]

Risk Management and Healthcare Policy

Volume 10, 2017 https://www.dovepress.com/risk-management-and-healthcare-policy-archive56 [No new digest content identified]

Science

05 May 2017 Vol 356, Issue 6337 http://www.sciencemag.org/current.dtl Editorial

Moving forward after the march

Rush D. Holt

Science 05 May 2017:

Vol. 356, Issue 6337, pp. 467 DOI: 10.1126/science.aan5596

Summary

On 22 April, many thousands of people took part in demonstrations, teach-ins, museum open houses, and science festivals in hundreds of places around the world—an unparalleled show of support for science. Some journalists have tried to portray the march as yet another political demonstration against President Trump and Congress. Yet, neither appeared to be the target for most marchers—not in the United States and even less so around the world. That the March for Science saw the scientific community and the wider public come together in unprecedented numbers signaled that the day was not just a protest by scientists with concerns about their funding or job security. The multitude of T-shirt slogans, placards, and impassioned remarks by marchers and speakers of all ages, backgrounds, and professions spoke volumes—something serious was going on.

In Depth

Congress trumps president in backing science

By Jeffrey Mervis, Science News Staff

Science05 May 2017: 470-471 Restricted Access

Legislators ignore Trump's call for cuts and give NIH, NASA research big increases Summary

A new U.S. budget deal makes it clear that scientists have enough friends in Congress to counter the chill from the White House—at least for now. This week, lawmakers were expected to approve a spending plan for the 2017 fiscal year, which ends on 30 September. The deal they voted on contains a lot more good news than the two budget requests that President Donald Trump so far has sent to Congress. The National Institutes of Health (NIH) and NASA's science programs are the biggest winners in a 1665-page document that closes a tumultuous budget year and staves off a government shutdown. NIH was in line for a 6.2% boost, to \$34 billion, whereas NASA's science missions received a hike of 3.1%, to \$5.76 billion. The rest of the big four federal research programs—the Office of Science at the Department of Energy and the National Science Foundation—trail those leaders but still grow modestly.

Science Translational Medicine

03 May 2017 Vol 9, Issue 388 http://stm.sciencemag.org/ Research Articles

A highly potent extended half-life antibody as a potential RSV vaccine surrogate for all infants

By Qing Zhu, Jason S. McLellan, Nicole L. Kallewaard, Nancy D. Ulbrandt, Susan Palaszynski, Jing Zhang, Brian Moldt, Anis Khan, Catherine Svabek, Josephine M. McAuliffe, Daniel Wrapp, Nita K. Patel, Kimberly E. Cook, Bettina W. M. Richter, Patricia C. Ryan, Andy Q. Yuan, JoAnn A. Suzich

Science Translational Medicine03 May 2017 Full Access

Development of a highly potent anti-RSV monoclonal antibody with extended half-life intended to be used as RSV prophylaxis for all infants.

Pan-RSV prophylaxis

The common respiratory syncytial virus (RSV) can progress to a very dangerous lower respiratory infection in some infants. A protective monoclonal antibody is available but is not recommended for general use. Zhu et al. describe the selection and optimization of a human monoclonal antibody able to neutralize a wide array of RSV A and B viruses and protect cotton rats at lower doses than the currently approved antibody. The antibody was optimized to persist in circulation, and data indicate that infants could be given a single dose and be protected for the entirety of the RSV season. If administered widely, this antibody could potentially prevent the hospitalization of thousands of children each year.

Social Science & Medicine

Volume 179, Pages 1-218 (April 2017) http://www.sciencedirect.com/science/journal/02779536/179 [New issue; No new digest content identified]

Travel Medicine and Infectious Diseases

March-April, 2017 - Volume 16

http://www.travelmedicinejournal.com/
[Reviewed earlier]

Tropical Medicine & International Health

May 2017 Volume 22, Issue 5 Pages 513–654 http://onlinelibrary.wiley.com/doi/10.1111/tmi.2017.22.issue-5/issuetoc http://onlinelibrary.wiley.com/doi/10.1111/tmi.2017.22.issue-5/issuetoc

<u>Can infant vaccination prevent pneumococcal meningitis outbreaks in sub-Saharan</u>
<u>Africa? (pages 514–515)</u>

James M. Stuart

Version of Record online: 29 MAR 2017 | DOI: 10.1111/tmi.12860

The WHO Strategic Advisory Group of Experts is reviewing the technical evidence to inform policy on optimal use of infant pneumococcal conjugate vaccines (PCV) [$\underline{1}$]. Since 2010, multivalent vaccines (PCV-10, PCV-13) have been successfully introduced with the support of Gavi, the Vaccine Alliance into infant immunisation programmes across the developing world [$\underline{2}$]. One recommended schedule consists of three doses under the age of 6 months (3 + 0), with the aim of providing maximum protection to infants, the age group at highest risk of pneumococcal disease [$\underline{3}$]. An alternative schedule consists of two vaccine doses under the age of 6 months with a booster at 9–15 months (2 + 1). This schedule may have more impact on reducing carriage and transmission of vaccine serotypes to unvaccinated individuals, leading to indirect or herd protection. The question around the most cost-effective policy to achieve both direct and indirect protection has particular importance for the meningitis belt of sub-Saharan Africa.

The launch of mass campaigns with a serogroup A conjugate vaccine (MenAfriVacR) across the meningitis belt in 2010 saw a dramatic fall in the incidence of meningitis due to serogroup A, while meningitis due to other meningococcal serogroups and Streptococcus pneumoniae has become more prominent [4]. Recent publications from the meningitis belt emphasise the continuing burden of pneumococcal meningitis among older children and adults in this region. In Ghana, a large outbreak occurred in 2016 with close to 900 suspected cases and 104 cases confirmed as due to S. pneumoniae, mainly serotype 1, with a median age of 20 years, in part of the country adjoining the meningitis belt [5]. In Burkina Faso from 2011 to 13, 1528 (53%) of 2858 cases of laboratory confirmed bacterial meningitis was due to S. pneumoniae, also mainly serotype 1 [6]. The proportion of cases aged over 5 years was 95% in Ghana and 69% in Burkina Faso. PCV programmes that started in 2013 in Ghana likely protected young children in the 2016 outbreak, whereas the Burkina Faso data were taken from the years preceding PCV vaccination.

Bacterial meningitis due to S. pneumoniae has a remarkably high case fatality ratios in sub-Saharan Africa [7] and causes much disability in survivors [8]. A systematic review of paediatric meningitis in children in Africa found among cases of confirmed pneumococcal meningitis that the median in-hospital case fatality ratio was 35% and that 25% of survivors had in-hospital sequelae, these figures being $9 \times$ and $4 \times$ higher respectively than those for meningococcal meningitis [8]. Incidence of pneumococcal meningitis is particularly high in the meningitis belt, with a similar seasonality to meningococcal meningitis, consistent with similar predisposing environmental factors [7,9]. Reducing the burden of pneumococcal meningitis in these countries should be given high public health priority.

For outbreak control, pneumococcal vaccines could potentially be given to children and adults in reactive mass campaigns, a similar strategy to that using meningococcal vaccines for controlling outbreaks of meningococcal meningitis [$\underline{10}$]. However, reactive vaccination for meningococcal meningitis is resource intensive and relatively ineffective unless undertaken promptly [$\underline{11}$, $\underline{12}$], and effectiveness of such a policy in controlling outbreaks of pneumococcal meningitis is not known [$\underline{13}$]. Preventive vaccination offers more hope. Even though serotype 1 is rarely found in carriage isolates, evidence of indirect protection against serotype 1 was found in South Africa after introduction of a 2 + 1 PCV-13 infant vaccination schedule [$\underline{14}$].

How best can we achieve indirect protection of older age groups at high risk of pneumococcal meningitis in the meningitis belt? Inclusion of a booster dose may be more important for some serotypes, including serotype 1 [15], and extended vaccination among children up to the age of 5 years, in whom carriage prevalence is highest in sub-Saharan Africa [16], may increase effectiveness [2, 17]. A 3 + 0 schedule supplemented by a catch-up campaign to the age of 5 years in Kenya reduced carriage of vaccine serotypes in vaccinated and unvaccinated age groups [18]. In contrast, a study from the Gambia showed no evidence as yet of a reduction in serotype 1 disease in persons aged >5 years after introducing a 3 + 0 PCV-13 schedule without catch-up in 2011 [19], and the pneumococcal meningitis outbreak this year in Ghana occurred despite the prior introduction of a 3 + 0 schedule with high coverage in the two previous years. Most countries of the meningitis belt have introduced a 3 + 0 schedule. Switching to a 2 + 1 schedule with a single dose catch-up in children up to 5 years of age could extend individual protection, lead to a higher level of indirect protection and lower the risk of outbreaks from this devastating disease.

Vaccine

Volume 35, Issue 22, Pages 2871-3006 (19 May 2017) http://www.sciencedirect.com/science/journal/0264410X/35/22 Reviews

<u>Coverage and determinants of childhood immunization in Nigeria: A systematic review and meta-analysis</u>

Review Article Pages 2871-2881

Davies Adeloye, Wura Jacobs, Ann O. Amuta, Oluwatomisin Ogundipe, Oluwaseun Mosaku, Muktar A. Gadanya, Gbolahan Oni

Abstract

Introduction

The proportion of fully immunized children in Nigeria is reportedly low. There are concerns over national immunization data quality, with this possibly limiting country-wide response. We reviewed publicly available evidence on routine immunization across Nigeria to estimate national and zonal coverage of childhood immunization and associated determinants.

Methods

A systematic search of Medline, EMBASE, Global Health and African Journals Online (AJOL) was conducted. We included population-based studies on childhood immunization in Nigeria. A random effects meta-analysis was conducted on extracted crude rates to arrive at national and zonal pooled estimates for the country.

Results

Our search returned 646 hits. 21 studies covering 25 sites and 26,960 children were selected. The estimated proportion of fully immunized children in Nigeria was 34.4% (95% confidence interval [CI]: 27.0-41.9), with South-south zone having the highest at 51.5% (95% CI: 20.5-82.6), and North-west the lowest at 9.5% (95% CI: 4.6-14.4). Mother's social engagements (OR = 4.0, 95% CI: 1.9-8.1) and vaccines unavailability (OR = 3.9, 95% CI: 1.2-12.3) were mostly reported for low coverage. Other leading determinants were vaccine safety concerns (OR = 3.0, 95% CI: 0.9-9.4), mother's low education (OR = 2.5, 95% CI: 1.8-3.6) and poor information (OR = 2.0, 95% CI: 0.8-4.7).

Conclusion

Our study suggests a low coverage of childhood immunization in Nigeria. Due to the paucity of data in the Northern states, we are still uncertain of the quality of evidence presented. It is hoped that this study will prompt the needed research, public health and policy changes toward increased evenly-spread coverage of childhood immunization in the country.

Review Article

<u>Indirect (herd) protection, following pneumococcal conjugated vaccines introduction: A systematic review of the literature</u>

Pages 2882-2891

Gal Tsaban, Shalom Ben-Shimol

Abstract

Background

Pneumococcal diseases are major causes of morbidity among adults, especially those over 50 years of age. While pneumococcal conjugated vaccines (PCV's) impact on pneumococcal disease rates among children is well established, the extent of its impact on adult pneumococcal related illness remains unclear. The aim of this systematic literature review was to describe the impact of PCV introduction to childhood national immunization programs worldwide on PCV-naive adult population.

Methods

A systematic literature search was performed using the PubMed database. The search was limited to articles written in English and published between January 2000 and February 2016. Studies evaluating pneumococcal disease rates in individuals over 5 years of age were included. Independent extraction of articles was performed by the two authors. Search terms included: Pneumococcal conjugated vaccine, herd, indirect, adults, and pneumonia.

Results

Forty-nine articles meeting the selection criteria were identified, 39 regarding invasive pneumococcal disease (IPD, one on meningitis only), 8 regarding pneumonia, and 2 on both IPD and pneumonia. The majority of reports were from the US, UK and Canada. Considerable variability in the data sources, quality and completeness was observed. While most studies reported either statistically significant reduction or insignificant changes in IPD and pneumonia disease rates in adults following PCV nationwide implementation, few studies reported statistically significant increase in pneumococcal disease rates, these were mainly from countries with low PCV coverage rates and/or inadequate surveillance.

Conclusion

Invasive pneumococcal diseases and pneumonia rates among the adult population decreased in most countries following PCV introduction into the NIP. This indirect effect on older population seems to be dependent on PCV coverage rates and time from PCV nationwide implementation. Adults >65 years old seem to benefit the most from PCV introduction.

<u>Two-dose schedules for human papillomavirus vaccine: Systematic review and meta-analysis</u>

Review Article Pages 2892-2901

Maddalena D'Addario, Shelagh Redmond, Pippa Scott, Dianne Egli-Gany, A. Ximena Riveros-Balta, Ana Maria Henao Restrepo, Nicola Low

Abstract

Simpler schedules for human papillomavirus (HPV) vaccine delivery could improve vaccine coverage and the effectiveness of cervical cancer prevention. The objective of this study was to systematically review evidence about the effects of two-dose compared with three-dose schedules for human papillomavirus (HPV) vaccine and to describe the uptake of two-dose HPV vaccination schedules globally. We searched PubMed, the Cochrane Central Registry of Controlled Trials, trials registers, and manufacturers' databases from their earliest date to February 2016. We selected randomised controlled trials and controlled clinical trials that directly compared HPV vaccine schedules with two or three doses. We extracted data on immunological and clinical outcomes and used meta-analysis where appropriate. We also described the use of two-dose HPV vaccine schedules globally. We screened 1464 items and included seven eligible noninferiority trials in 11 countries. In randomised comparisons amongst adolescent girls (three trials), geometric mean concentrations (GMC) of antibodies against HPV16 and HPV18 were non-inferior or inconclusive, up to 24 months after a two-dose compared with a three-dose schedule. One trial with a clinical outcome found no persistent HPV infections occurred after either two or three doses. In non-randomised comparisons, GMC were non-inferior or superior in adolescent girls receiving the two-dose schedule compared with women receiving the three-dose schedule for at least 21 months after vaccination. By February 2017, 23 low and middle income and 25 high income countries had adopted a two-dose HPV vaccination schedule. A two-dose HPV vaccine schedule provides satisfactory immunological outcomes in adolescent girls, but uptake globally is limited, particularly in countries with the highest burden of cervical cancer.

Original papers

Repeat pneumococcal polysaccharide vaccine in Indigenous Australian adults is associated with decreased immune responsiveness

Original Research Article

Pages 2908-2915

Sarah Moberley, Paul V. Licciardi, Anne Balloch, Ross Andrews, Amanda J. Leach, Marie Kirkwood, Paula Binks, Kim Mulholland, Jonathan Carapetis, Mimi L.K. Tang, Sue Skull *Abstract*

Background

Indigenous adults residing in the Northern Territory of Australia experience elevated rates of invasive pneumococcal disease despite the routine use of 23-valent pneumococcal polysaccharide vaccine (23vPPV). We hypothesised that the limited protection from 23vPPV may be due to hyporesponsiveness as a result of vaccine failure from repeated vaccination. To explore this possibility, we evaluated the immune response to a first and second dose of 23vPPV in Indigenous adults and a first dose of 23vPPV in non-Indigenous adults. Methods

Serotype-specific IgG was measured by ELISA for all 23 vaccine serotypes at baseline and at one month post-vaccination. Individuals were considered to have an adequate immune response if paired sera demonstrated either: a four-fold rise in antibody concentration; a two-

fold rise if the post vaccination antibody was >1.3 µg/ml but <4.0 µg/ml; or a post-vaccination antibody concentration >4.0 µg/ml for at least half of the serotypes tested (12/23). Our perprotocol analysis included the comparison of outcomes for three groups: Indigenous adults receiving a second 23vPPV dose (N=20) and Indigenous (N=60) and non-Indigenous adults (N=25) receiving their first 23vPPV dose.

All non-Indigenous adults receiving a first dose of 23vPPV mounted an adequate immune response (25/25). There was no significant difference in the proportion of individuals with an adequate response using our definition (primary endpoint), with 88% of Indigenous adults mounted an adequate response following first dose 23vPPV (53/60) compared to 70% having an adequate response following a second dose of 23vPPV (14/20; p=0.05). The risk difference between Indigenous participants receiving first dose compared to non-Indigenous participants receiving first dose was significant when comparing a response threshold of at least 70% (-27%, 95% CI: -43% to -11%; p=0.01) and 90% (-38%, 95% CI: -60% to -16%; p=0.006) of serotypes with a positive response.

Conclusion

Indigenous participants demonstrated a poorer response to a first dose 23vPPV compared to their non-Indigenous counterparts, with lower IgG following a second 23vPPV dose. These findings highlight the critical need to evaluate the efficacy of future pneumococcal vaccine programs in the Australian Indigenous populations that recommend repeated doses of 23vPPV.

<u>Health workers' attitudes, perceptions and knowledge of influenza immunization in Lima, Peru: A mixed methods study</u>

Original Research Article

Pages 2930-2936

Magdalena Bazán, Erika Villacorta, Gisella Barbagelatta, M. Michelle Jimenez, Cecilia Goya, Rosario M. Bartolini, Mary E. Penny

Abstract

Background

Vaccination against seasonal influenza in health workers is recommended but coverage is variable. This study aimed to determine coverage of influenza vaccination among health workers in Lima, Peru in 2010; explore barriers and enabling elements for vaccination; and suggest strategies to improve coverage.

Methods

Qualitative interviews informed the development of a survey instrument that consisted of open and close-ended questions. Sub-analyses were done by occupational group and results were calculated as percentages for each possible response with confidence intervals of 95%. Results

Coverage of the influenza vaccination was 77.2%. Vaccinated staff were less likely to have permanent contracts (p=0.0150) and vaccination coverage was lower in physicians (p=0.0001). Over 90% cited protection of themselves, families and patients as reasons for vaccination and 48% mentioned peer encouragement. Fear of adverse events (47%) and organizational barriers (>30%) were reasons for non-vaccination. To improve coverage, highest priority was given to strategies providing more information.

Conclusions

Key factors in driving health worker vaccination include desire for protection and peer encouragement. Perceptual barriers based on a misunderstanding of the epidemiology of influenza and vaccination could be overcome by targeted education and information. Organizational barriers require attention to how vaccination is implemented within health facilities.

Vaccine hesitancy among parents in a multi-ethnic country, Malaysia

Original Research Article

Pages 2955-2961

Fatin Shaheera Mohd Azizi, Yueting Kew, Foong Ming Moy

Abstract

Background

Vaccine hesitancy is a threat in combating vaccine-preventable diseases. It has been studied extensively in the Western countries but not so among Asian countries.

Objectives

To assess the test-retest reliability of the Parent Attitudes about Childhood Vaccines (PACV) questionnaire in Malay language; to determine the prevalence of vaccine hesitancy among parents and its associations with parents' socio-demographic characteristics.

Methods

Forward and backward translation of PACV in Malay language was carried out. The reliability of the Malay-PACV questionnaire was tested among parents with children. The same questionnaire was used to study vaccine hesitancy among parents in a tertiary hospital in Kuala Lumpur. Information pertaining to socio-demographic characteristics, sources of information regarding vaccination and vaccine hesitancy were collected. Associations between vaccine hesitancy with socio-demographic factors were tested using Multivariable Logistic Regression. Results

The Spearman correlation coefficient and Cronbach alpha for total PACV was 0.79 (p < 0.001) and 0.79 respectively. The intra-class correlation coefficients of the subscales ranged from 0.54 to 0.90 demonstrating fair to excellent reliability. A total of 63 (11.6%) parents were noted to be vaccine hesitant. In the univariate analyses, vaccine hesitancy was associated with unemployed parents, parents who were younger, had fewer children and non-Muslim. In the multivariate model, pregnant mothers expecting their first child were four times more likely to be vaccine hesitant compared to those who already had one or more children (aOR: 3.91, 95% CI: 1.74-8.79) and unemployed parents were also more likely to be vaccine hesitant (aOR: 1.97, 95% CI: 1.08-3.59). The internet (65.6%) was the main source of information on vaccination followed by brochures (56.9%).

Conclusion

The Malay-PACV questionnaire is reliable to be used. The prevalence of vaccine hesitancy among the multi-ethnic Malaysians was comparable with other populations. Pregnant mothers expecting their first child and unemployed parents were found to be more vaccine hesitant.

<u>Immunogenicity to poliovirus type 2 following two doses of fractional intradermal inactivated poliovirus vaccine: A novel dose sparing immunization schedule</u>

Original Research Article

Pages 2993-2998

Abhijeet Anand, Natalie A. Molodecky, Mark A. Pallansch, Roland W. Sutter Abstract

Introduction

The polio eradication endgame strategic plan calls for the sequential removal of Sabin poliovirus serotypes from the trivalent oral poliovirus vaccine (tOPV), starting with type 2, and the introduction of ≥ 1 dose of inactivated poliovirus vaccine (IPV), to maintain an immunity base

against poliovirus type 2. The global removal of oral poliovirus type 2 was successfully implemented in May 2016. However, IPV supply constraints has prevented introduction in 21 countries and led to complete stock-out in >20 countries.

Methods

We conducted a literature review and contacted corresponding authors of recent studies with fractional-dose IPV (fIPV), one-fifth of intramuscular dose administered intradermally, to conduct additional type 2 immunogenicity analyses of two fIPV doses compared with one full-dose IPV.

Results

Four studies were identified that assessed immunogenicity of two fIPV doses compared to one full-dose IPV. Two fractional doses are more immunogenic than 1 full-dose, with type 2 seroconversion rates improving between absolute 19–42% (median: 37%, p < 0.001) and relative increase of 53–125% (median: 82%), and antibody titer to type 2 increasing by 2–32-fold (median: 10-fold). Early age of administration and shorter intervals between doses were associated with lower immunogenicity.

Discussion

Overall, two fIPV doses are more immunogenic than a single full-dose, associated with significantly increased seroconversion rates and antibody titers. Two fIPV doses together use two-fifth of the vaccine compared to one full-dose IPV. In response to the current IPV shortage, a schedule of two fIPV doses at ages 6 and 14 weeks has been endorsed by technical oversight committees and has been introduced in some affected countries.

Vaccine: Development and Therapy

https://www.dovepress.com/vaccine-development-and-therapy-archive111 (Accessed 6 May 2017)
[No new content]

Vaccines — Open Access Journal

http://www.mdpi.com/journal/vaccines (Accessed 6 May 2017) [No new digest content identified]

Value in Health

April 2017 Volume 20, Issue 4, p519-726 http://www.valueinhealthjournal.com/current [Reviewed earlier]

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<u>From Google Scholar & other sources: Selected Journal Articles, Newsletters, Dissertations, Theses, Commentary</u>

International Journal of Health Policy and Management

ePublished: 8 April 2017

Original Article

How Are New Vaccines Prioritized in Low-Income Countries? A Case Study of Human Papilloma Virus Vaccine and Pneumococcal Conjugate Vaccine in Uganda Lauren Wallace1, Lydia Kapiriri2*

Abstract

Background: To date, research on priority-setting for new vaccines has not adequately explored the influence of the global, national and sub-national levels of decision-making or contextual issues such as political pressure and stakeholder influence and power. Using Kapiriri and Martin's conceptual framework, this paper evaluates priority setting for new vaccines in Uganda at national and sub-national levels, and considers how global priorities can influence country priorities. This study focuses on 2 specific vaccines, the human papilloma virus (HPV) vaccine and the pneumococcal conjugate vaccine (PCV).

Methods: This was a qualitative study that involved reviewing relevant Ugandan policy documents and media reports, as well as 54 key informant interviews at the global level and national and sub-national levels in Uganda. Kapiriri and Martin's conceptual framework was used to evaluate the prioritization process.

Results: Priority setting for PCV and HPV was conducted by the Ministry of Health (MoH), which is considered to be a legitimate institution. While respondents described the priority setting process for PCV process as transparent, participatory, and guided by explicit relevant criteria and evidence, the prioritization of HPV was thought to have been less transparent and less participatory. Respondents reported that neither process was based on an explicit priority setting framework nor did it involve adequate representation from the districts (program implementers) or publicity. The priority setting process for both PCV and HPV was negatively affected by the larger political and economic context, which contributed to weak institutional capacity as well as power imbalances between development assistance partners and the MoH. Conclusion: Priority setting in Uganda would be improved by strengthening institutional capacity and leadership and ensuring a transparent and participatory processes in which key stakeholders such as program implementers (the districts) and beneficiaries (the public) are involved. Kapiriri and Martin's framework has the potential to guide priority setting evaluation efforts, however, evaluation should be built into the priority setting process a priori such that information on priority setting is gathered throughout the implementation cycle.

Journal of Health Communication

Published online: 27 Apr 2017

Original Articles

Explanations for Not Receiving the Seasonal Influenza Vaccine: An Ontario Canada Based Survey

SB Meyer, R Lum

Abstract

Despite evidence of the importance of the seasonal influenza vaccine for both individual and population health, only a third of the Ontario population received the vaccine in 2013/2014. The objective of this study was to identify why Ontarians are not getting the seasonal influenza vaccine. Written responses to the question "Why didn't you get the seasonal flu vaccine in the last flu season?" were deductively analyzed using the Conceptual Model of Vaccine Hesitancy. Inductive coding was also conducted to identify explanations that fall outside of the present model and may be unique to the seasonal influenza vaccine. Data were collected between August and early September, 2014 through a survey in the Region of Waterloo, Ontario.

Overall, 91.4% of responses could be explained using the conceptual model and specifically relate to perceived importance of vaccination (46.8%), moral convictions (19.4%), and past experiences with vaccinations services (14.5%). Notably, explanations related to healthcare professional attitudes, risk perceptions and trust, and subjective norms were identified to a much lesser extent than those discussed above. The remaining 8.6% of responses cannot be explained by the model because they do not relate to hesitancy. Our data contribute to the minimal body of Canadian research investigating low uptake of the seasonal flu vaccine, adding to an evidence-base upon which to inform promotional campaigns. Our data also highlight the utility of the Conceptual Model of Vaccine Hesitancy for the design and analysis of research investigating seasonal flu vaccine refusal or delay.

* * * *

Media/Policy Watch

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

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

The Atlantic

http://www.theatlantic.com/magazine/ Accessed 6 May 2017 [No new, unique, relevant content]

BBC

http://www.bbc.co.uk/ Accessed 6 May 2017 [No new, unique, relevant content]

Economic Times

http://economictimes.indiatimes.com/ Accessed 6 May 2017

Modi government advances immunisation programme deadline to 2018

1 May 2017

...The Prime Minister's Office has advanced the deadline for the Centre's immunisation programme, Mission Indradhanush, by more than a year and asked the health ministry to strive to complete it by December 2018...

The Economist

http://www.economist.com/ Accessed 6 May 2017 [No new, unique, relevant content]

Financial Times

http://www.ft.com/home/uk
[No new, unique, relevant content]

Forbes

http://www.forbes.com/ Accessed 6 May 2017

A New Hope: Vaccine Supply Chains Get More Attention

1 May 2017 Bruce Y. Lee Contributor

...Now, with a just-published special issue of the journal Vaccine entitled "<u>Building Next-Generation Immunization Supply Chains</u>," vaccine supply chains are finally getting more deserved time in the limelight...

Foreign Affairs

http://www.foreignaffairs.com/ Accessed 6 May 2017 [No new, unique, relevant content]

Foreign Policy

http://foreignpolicy.com/ Accessed 6 May 2017 [No new, unique, relevant content]

The Guardian

http://www.guardiannews.com/

Accessed 6 May 2017

Nigeria battles to beat polio and Boko Haram

Northern Nigeria is the frontline in two wars: the disease and the brutal rebels who reject the west's influence

Tracv McVeigh

Saturday 6 May 2017 19.03 EDT

...This is the "flag-off" in Ungogo, Kano state. The party marks the first of four days of intense work by an army of volunteers, mostly young mothers, who will go door to door across <u>Nigeria</u>. Some will pass through thousands of twisting warrens of slums fanning out into the red-orange, mud-built hamlets and reed-thatched huts. Others will visit the crumbling concrete city blocks, slipping drops of polio vaccine into as many of the 30 million Nigerian children under five as they can find.

Their capes bear the slogan: "Lafiyar al'ummarmu hakkin kowa da kowa ne" – "The health of the child is the responsibilty of all." The lunchboxes are filled with ice and polio vaccine. They have marker pens to dab on the finger of each treated child and chalk to mark every house wall they visit, marking which child was vaccinated and when. No one is to be missed out...

New Yorker

http://www.newyorker.com/ Accessed 6 May 2017 [No new, unique, relevant content]

New York Times

http://www.nytimes.com/ Accessed 6 May 2017

Minnesota Sees Largest Outbreak of Measles in Almost 30 Years

Health officials are grappling with the largest outbreak of <u>measles</u> in Minnesota in almost 30 years, which is mainly sickening young children of Somali immigrants who fell under the sway of anti-vaccination activists.

The state has reported <u>44 confirmed cases</u> of measles since April 11, and the outbreak is the largest this year in the United States, which had essentially eradicated the disease in 2000 before <u>discredited research</u> stoked fears of a link between vaccines and <u>autism</u>.

As of Thursday, 11 patients have been hospitalized, Doug Schultz, a spokesman for the Minnesota Department of Health, said on Friday. It is the largest outbreak in the state since 1990, when 460 cases were reported. All of the patients, with the exception of an adult health care worker, were children younger than 10. Most were under 5, he said. May 05, 2017 - By CHRISTOPHER MELE

Julius Youngner, Polio Vaccine Pioneer, Dies at 96

[See Milestones/Perspectives above for full text]

The Opinion Pages | Editorial 1 May 2017

Populism, Politics and Measles

[See Milestones/Perspectives above for full text]

Wall Street Journal

http://online.wsj.com/home-page? wsjregion=na,us& homepage=/home/us
Accessed 6 May 2017
[No new, unique, relevant content]

Washington Post

http://www.washingtonpost.com/Accessed 6 May 2017[No new, unique, relevant content]

Think Tanks et al

Brookings

http://www.brookings.edu/
[No new relevant content]

Center for Global Development

http://www.cgdev.org/page/press-center

Accessed 6 May 2017
[No new relevant content]

Council on Foreign Relations

http://www.cfr.org/ Accessed 6 May 2017 Article

Can Drug Importation Address High Generic Drug Prices?

by Thomas J. Bollyky, Aaron S. Kesselheim May 5, 2017

...we propose a sustainable strategy to address price spikes among U.S. generic drugs and improve patients' access to safe medicines. We begin by outlining the important role of generic medicines in the U.S. health system and the market failures that have contributed to recent price hikes and shortages. Next, we consider the various strategies that have been proposed to address those market failures and the reasons that those strategies are likely to fall short in fixing the problem. Third, we propose a three-pronged approach for increasing competition in the U.S. generic drug market, while minimizing any attendant risks to patient safety or undermining the institutional role of the FDA. This proposal centers on the use of reciprocal drug approval and draws on previous precedents and the existing platforms for regulatory cooperation in the pharmaceutical sector. Last, we apply our proposal to show how it might affect international competition among a cohort of U.S. drugs currently eligible for generic competition, but lacking sufficient competition to achieve substantial price reductions...

CSIS

https://www.csis.org/ Accessed 6 May 2017

New Partnerships Needed After Ebola's Hard Lessons:

Program Manager and Research Associate Chris Millard and I published a new commentary exploring the vital importance of vaccines in both preventing and mitigating the effects of the next pandemic. We argue that three lessons came from the Ebola experience: 1) not having a vaccine at the ready when an outbreak strikes creates huge vulnerabilities and imposes tremendous costs; 2) scrambling to accelerate vaccine development in the middle of an outbreak is expensive and no way to conduct business; and 3) a new approach is needed to create durable partnerships, innovate and act early, and get ahead of the curve in vaccine development against dangerous pathogens. The piece was published by the Thomson Reuters Foundation

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and sustainable development – serving governments, international agencies, INGOs, civil society organizations (CSOs), commercial entities, consortia and alliances. CVEP maintains an academic affiliation with the Division of Medical Ethics, NYU School of Medicine, and an operating affiliation with the Vaccine Education Center of Children's Hospital of Philadelphia [CHOP].

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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.