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

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

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

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

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Election process for the new WHO Director-General

News Release
23 September 2016 | GENEVA - Six candidates have been proposed by Member States of the World Health Organization (WHO) for the position of WHO Director-General.

Member States proposed the following candidates:
:: The Government of Ethiopia has submitted the nomination of Dr Tedros Adhanom Ghebreyesus;
:: The Government of Italy has submitted the nomination of Dr Flavia Bustreo;
:: The Government of France has submitted the nomination of Professor Philippe Douste-Blazy;
:: The Government of the United Kingdom of Great Britain and Northern Ireland has submitted the nomination of Dr David Nabarro;
:: The Government of Pakistan has submitted the nomination of Dr Sania Nishtar;
:: The Government of Hungary has submitted the nomination of Dr Miklós Szócska…

Election process for the WHO Director-General 2017
The process to elect the next Director-General of the WHO is underway, and key steps are as follows:
:: Names of candidates for the next Director-General nominated by Member States were announced on 23 September 2016.
:: In October, Member States and candidates will be given the opportunity to interact in a password-protected web forum hosted on the WHO website.
:: On 1–2 November, a live forum will be held, at which candidates will present their vision to WHO Member States and will also be able to answer questions on their candidacy. The candidates' forum will be webcast on the WHO website in all official languages.
:: In January 2017, WHO's Executive Board will draw up a short list of 5 candidates. Executive Board members will then interview these candidates and nominate 3 of them to go forward to the World Health Assembly in May 2017.
:: At the Seventieth World Health Assembly, Member States will vote in a new Director-General, who will take office on 1 July 2017.

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Zika virus [to 24 September 2016]
Public Health Emergency of International Concern (PHEIC)
http://www.who.int/emergencies/zika-virus/en/

Zika situation report – 22 September 2016
Full report: http://apps.who.int/iris/bitstream/10665/250143/1/zikasitrep22Sep16-eng.pdf?ua=1
Key Updates
:: Countries and territories reporting mosquito-borne Zika virus infections for the first time in the past week:
… Saint Kitts and Nevis
:: Countries in the Western Pacific Region continue to report new cases as seen in Singapore, Philippines, Malaysia and Viet Nam.
…Thailand, in the South-East Asia Region, has also recently reported Zika cases. It is not clear whether the apparent recent increase in the number of reported Zika cases is due to an actual increase in incidence or whether this is the result of enhanced surveillance, testing or awareness.
…The sequencing results from two Zika virus cases reported in Malaysia indicate that both are from the "Asian" lineage but are from slightly different strains. The first imported case is similar to the virus that was circulating in French Polynesia in 2013, i.e., a post-2007 "Asian" strain.

The second locally acquired case is reported to be a similar to a previously circulating Southeast Asian strain of the "Asian" lineage.
…Further sequencing analysis in Singapore indicates that in addition to the locally acquired cases which were caused by viruses from older strains of the "Asian" lineage, an imported case with travel history to Brazil was found to be caused by a virus similar to the strain of the "Asian" lineage currently circulating in the Americas.

:: Countries and territories reporting microcephaly and other central nervous system (CNS) malformations potentially associated with Zika virus infection for the first time in the past week:
… Guatemala

:: Countries and territories reporting Guillain-Barré syndrome (GBS) cases associated with Zika virus infection for the first time in the past week:
… Ecuador

:: The 2016 Summer Paralympic Games closed in Rio de Janeiro, Brazil on 18 September. WHO assesses the individual risk of Zika virus infection in travellers returning from the Paralympic Games as low, albeit not zero. To date, WHO has not received any official notification of Zika cases associated with this event. In accordance with WHO guidance, men and women returning should adopt safer sex practices or consider abstinence for at least 6 months upon return and apply insect repellent for at least 3 weeks upon return to reduce the risk of onward transmission.

Zika Open [to 24 September 2016]
[Bulletin of the World Health Organization]
:: All papers available here
No new papers identified.

European Medicines Agency [to 24 September 2016]
http://www.ema.europa.eu/
21/09/2016
Zika virus infection: plasma- and urine-derived medicines safe to use
Manufacturing processes for these products successfully inactivate or remove virus
Assessments carried out by the European Medicines Agency (EMA) and competent authorities in the EU Member States have confirmed that there is no increased risk of contamination with the Zika virus for patients who take plasma-derived or urine-derived medicines.

Plasma-derived medicines are manufactured from human blood. They are used to treat and prevent serious diseases and include coagulation factors (treatments which help blood to clot) and immunoglobulins (proteins used in patients who need more antibodies in their blood to help fight infections and other diseases). Urine-derived products are manufactured from pooled human urine and include certain hormone-based treatments and urokinase products (medicines used to break up blood clots).

These medicines are produced from body fluids, which might be sourced in parts of the world where the Zika virus is prevalent. EU regulators sought reassurance that there is no risk of the

virus contaminating the final product and thus affecting the patients taking it if the plasma or urine came from donors who had contracted the Zika virus.

EMA's Committee for Medicinal Products for Human Use (CHMP) has addressed the potential risk from Zika virus for plasma-derived medicinal products. The CMDh has coordinated the assessment by EU Member States on the potential risk from Zika virus for urine-derived medicinal products.

The CHMP concluded at its meeting last week that the manufacturing processes used for plasma-derived products, including for example the solvent/detergent method to inactivate viruses, pasteurisation (liquid heat inactivation) and virus filtration, inactivate or remove the Zika virus from the finished product. The CHMP therefore considered that no additional safety measures such as the testing or exclusion of certain plasma donors was necessary.

Concerning urine-derived products, the CMDh, following the assessment of the data, concluded that the manufacturing processes for these products contain complementary steps with inactivation/removal capacity for enveloped viruses, which are considered sufficient for Zika virus safety of these products. Additional safety measures such as the screening of urine donors or donations or the deferral of donors returning from affected areas are not considered necessary.

The findings from these assessments on the viral safety of plasma-derived and urine-derived medicines are available in a report from the CHMP's Biologics Working Party (BWP) published today.

Editor's Note:
Please see CDC announcements on Zika below

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EBOLA/EVD [to 24 September 2016]
http://www.who.int/ebola/en/
"Threat to international peace and security" (UN Security Council)

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

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POLIO [to 24 September 2016]
Public Health Emergency of International Concern (PHEIC)

Polio this week as of 21 September 2016
:: Launching soon: the new look of the Global Polio Eradication Initiative web site! Keep a lookout for the new design, which will allow visitors to see the latest information on the programme, interactive data visualizations and media content including photo essays and videos. Existing resources from our current website will be available on the new site as well.

: Regional outbreak response in Nigeria and the Lake Chad sub-region is continuing. Quality and impact of current outbreak response is being evaluated and analysed, and corrective measures implemented as appropriate. See 'Nigeria' and 'Lake Chad sub-region' sections below for more.

:: Selected Country Updates [excerpts]
No new case activity reported.

Polio Eradicated from All but Three Countries, Saving More than $50 Billion by 2035, Secretary-General Says at Event Charting Global Progress
20 September 2016
SG/SM/18101
Following is UN Secretary-General Ban Ki-moon's message, delivered by Margaret Chan, Director-General of the World Health Organization (WHO), to the event on Polio, Past and Present: Global Progress since the 1916 New York Polio Outbreak, in New York today:

I send my warmest greetings to everyone participating in this important meeting. We are a fortunate generation. One hundred years ago, this country was in the grip of a polio outbreak that affected 27,000 people. Nine thousand of those cases were in New York City, causing a wave of panic throughout that summer.

Public meetings and celebrations were cancelled. Children were banned from crowded places. Hundreds of thousands of information leaflets were distributed advising people to take precautions. Because that was all they could do: take precautions, and hope for the best.

Today, progress in eradicating polio is one of the greatest success stories of the past quarter century. Polio cases have been reduced by 99 per cent. From hundreds of cases each year, now there are fewer than two dozen. We are working hard to eradicate the disease from the final three countries that are still affected: Afghanistan, Nigeria and Pakistan.

The results in human terms are enormous. Millions of people who would have been paralysed are living productive and fulfilling lives. And in financial terms, it is estimated that, by 2035, polio eradication will have saved more than $50 billion around the world.

The development of the polio vaccine by Jonas Salk and his team in the 1950s was a major step. But, the eradication of polio has been made possible by social, economic, educational and humanitarian progress, all around the world. Polio is being beaten by improved literacy, better standards of living and stronger health systems; by technical, operational, political and financial

innovations. It shows us what can be achieved with coordinated efforts, public-private partnerships and common goals.

That is the thinking behind the 2030 Agenda for Sustainable Development, agreed by all countries last year to build a better future for people, planet, peace, prosperity and partnership. The Global Polio Eradication Initiative is a model that shows how operational and technological innovation can deliver general solutions that can be adapted to specific contexts.

It demonstrates how political commitment can be sustained in support of common goals that benefit everyone. And it shows how we can harness the combined power of public authorities, business leaders, religious figures, educators and more to create partnerships that make a real difference to our world.

The Sustainable Development Goals are a long road which we will walk together. Eradicating polio will be a milestone of success on that road. The United Nations and our partners are committed to maintaining the momentum and reaching that milestone as soon as possible. Thank you, and I wish you a successful meeting.

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Yellow Fever [to 24 September 2016]
http://www.who.int/emergencies/yellow-fever/en/

Yellow fever situation report
23 September 2016
Read the full situation report

Key updates
Angola epidemiological update (as of 15 September):
:: The last confirmed case had symptom onset on 23 June.
:: Three of the four laboratory positive cases reported in the previous situation report have been discarded as having recent vaccination history. The remaining case reported in Tchindjenje district in Huambo province is under investigation.
: Phase II of the vaccination campaign has been prepared and will begin shortly in 12 districts in 9 provinces.

Democratic Republic of the Congo epidemiological update (as of 18 September):
:: The last confirmed non-sylvatic case had symptom onset on 12 July.
:: 9 new cases are under investigation, 8 in Kinshasa province and 1 in Lingomono Health Zone in Tshuapa province. A total of 12 cases are under investigation including the first notified case reported in Sud Ubangi province in Bominenge Health Zone (reported in the situation report of 26 August).
: The reactive vaccination campaign in Feshi and Mushenge Health Zones in Kwango province will begin soon.
: Democratic Republic of the Congo is planning a pre-emptive vaccination campaign.

Analysis

The continuing detection and investigation of suspected and laboratory positive cases demonstrate that active surveillance is functioning well in some areas. Nevertheless, it is important to note the inherent difficulties in surveillance and laboratory confirmation capacities. It remains possible that detection of a case could be delayed in some remote areas. A strong and sustained surveillance effort is therefore more crucial than ever.

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MERS-CoV [to 24 September 2016]
http://www.who.int/emergencies/mers-cov/en/

DONs
:: Middle East respiratory syndrome coronavirus (MERS-CoV) – Saudi Arabia
21 September 2016
Between 23 August and 11 September 2016 the National IHR Focal Point of Saudi Arabia reported five (5) additional cases of Middle East Respiratory Syndrome (MERS).
:: Middle East respiratory syndrome coronavirus (MERS-CoV) – Austria
20 September 2016

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WHO & Regional Offices [to 24 September 2016]

At UN, global leaders commit to act on antimicrobial resistance
21 September 2016 - World leaders today signalled an unprecedented level of attention to curb the spread of infections that are resistant to antimicrobial medicines

UN Commission: New investments in global health workforce will create jobs and drive economic growth
20 September 2016 – The Presidents of France and South Africa today called for urgent investments globally to create new jobs in the health sector in order to prevent a projected shortfall of 18 million health workers primarily in low- and lower-middle-income countries, and help countries to maximize the social and economic benefits of increased health employment.

World Rabies Day
Educate. Vaccinate. Eliminate.
Date: 28 September 2016
World Rabies Day is celebrated annually to raise awareness about rabies prevention and to highlight progress in defeating this horrifying disease. 28 September also marks the anniversary of Louis Pasteur's death, the French chemist and microbiologist, who developed the first rabies vaccine.
Today, safe and efficacious animal and human vaccines are among the important tools that exist to eliminate human deaths from rabies while awareness is the key driver for success of communities to engage in effective rabies prevention.

The theme for 2016 is Rabies: Educate. Vaccinate. Eliminate. which emphasises the two crucial actions that communities can do to prevent rabies. It also reflects the global target to eliminate all human deaths from dog-mediated rabies by 2030.

Highlights

New group to "expand access to health and human rights" for women, children and adolescents

September 2016 – Helping to expand access to health and human rights for women, children and adolescents everywhere is the goal of the new High Level Working Group for the Health and Human Rights of Women, Children and Adolescents.

The 71st session of the United Nations General Assembly (UNGA)

September 2016 -- Heads of states and governments from 193 Member States convene to address large movements of refugees and migrants, ways to tackle antimicrobial resistance and progress on the Sustainable Development Goals agreed a year ago.

Weekly Epidemiological Record, 23 September 2016, vol. 91, 38 (pp. 433–440)

Contents

:: WHO Regional Offices

Selected Press Releases, Announcements

WHO African Region AFRO

No new, unique announcements identified.

WHO Region of the Americas PAHO

No new, unique announcements identified.

WHO South-East Asia Region SEARO

No new, unique announcements identified.

WHO European Region EURO

:: From local to global: improved urban health through stronger communication and leadership 23-09-2016

:: From emergency operations to recovery and development 23-09-2016

:: From research to implementation: World Conference on Injury Prevention and Safety Promotion 22-09-2016

:: What is the burden of disease in the Region? 20-09-2016

WHO Eastern Mediterranean Region EMRO

No new, unique announcements identified.

WHO Western Pacific Region

:: Taxing sugar-sweetened beverages could reduce childhood overweight and obesity in the Western Pacific Region

MANILA, 22 September 2016 - In the Western Pacific Region, childhood overweight and obesity are serious public health problems. More than 6.2 million children under 5 years of age are overweight in the Region. The prevalence of overweight among adolescents is increasing at alarming rates, reaching almost 60% in some Pacific island countries and more than 20% in some Asian countries.

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CDC/ACIP [to 24 September 2016]
http://www.cdc.gov/media/index.html
https://www.cdc.gov/vaccines/acip/
FRIDAY, SEPTEMBER 23, 2016
Transcript for CDC Telebriefing: Zika Telebriefing Update

FRIDAY, SEPTEMBER 23, 2016
Florida health officials report on response to Zika in Wynwood; evidence shows aerial spraying likely helped interrupt local transmission
Media Statement
Florida health officials' response this summer to the first identified cases of local transmission and the first identified outbreak of Zika virus infection in the continental United States, including aggressive...

TUESDAY, SEPTEMBER 20, 2016
CDC continues to build US laboratory capacity to rapidly detect Zika virus infection - Press Release

MONDAY, SEPTEMBER 19, 2016
CDC updates guidance for Wynwood (FL) neighborhood with active Zika transmission - Press Release

MMWR Weekly September 23, 2016 / No. 37
:: HIV Testing Experience Before HIV Diagnosis Among Men Who Have Sex with Men — 21 Jurisdictions, United States, 2007–2013
:: Unmet Needs for Ancillary Services Among Men Who Have Sex with Men and Who Are Receiving HIV Medical Care — United States, 2013–2014
:: Update: Influenza Activity — United States and Worldwide, May 22–September 10, 2016
:: *Notes from the Field:* Pediatric Death from Meningococcal Disease in a Family of Romani Travelers — Sarasota, Florida, 2015

October ACIP meeting
October 19-20, 2016
Draft October 19-20, 2016 Meeting Agenda [2 pages]

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Announcements/Milestones/Perspectives

World Health Leaders Agree on Action to Combat Antimicrobial Resistance, Warning of Nearly 10 Million Deaths Annually If Left Unchecked

21 September 2016
GA/11825
World leaders gathered at a high-level meeting on antimicrobial resistance today committed to concerted action to address the phenomenon, which many warned could lead to significant development backslides and up to 10 million deaths annually by 2050 if left unchecked.

Participants stressed that antimicrobial resistance — the ability of microorganisms to adapt to medications such as antibiotics, rendering them ineffective — posed a number of grave threats to humanity, including a possible resurgence in tuberculosis, malaria and HIV/AIDS deaths and food insecurity due to negative impacts on agriculture.

Acting by acclamation, they agreed to a number of actions outlined in a draft political declaration, to be transmitted to the General Assembly for adoption.

By the terms of that text, Member States committed to develop multisectoral national action plans on antimicrobial resistance in line with the World Health Organization (WHO)'s global action plan on the issue. Endorsing a concerted "One Health" approach — which linked various sectors and actors in defence of human, animal and environmental health — they also agreed to mobilize adequate, predictable and sustained resources to implement those programmes and pledged to raise awareness of the phenomenon around the world.

Acknowledging that resistance to antimicrobial medicines was largely due to the inappropriate use of such drugs in the fields of public health, animal, food, agriculture and aquaculture sectors, Member States called on the WHO and other relevant agencies to finalize a global framework to support the development, control, distribution and appropriate use of new antimicrobial medicines, diagnostic tools, vaccines and other interventions.

Among other things, they also called on the Secretary-General to establish an ad hoc inter-agency coordination group, co-chaired by his Executive Office and the WHO, to provide practical guidance for approaches needed to ensure sustained effective global action to address antimicrobial resistance.

"We are losing our ability to protect both humans and animals from life-threatening infections," said Secretary-General Ban Ki-moon in opening remarks. Indeed, he warned, if the issue of antimicrobial resistance was not dealt with quickly and comprehensively, it threatened to make the provision of high-quality, universal health coverage more difficult, if not impossible. Cautioning that such trends were undermining hard-won achievements of the Millennium Development Goals, he urged global leaders to turn their commitments into swift, concerted action.

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Cholera Vaccination Campaign Targets Juba Neighbourhoods in South Sudan

Posted: 09/20/16
South Sudan - Over 23,000 people were vaccinated against cholera in Juba, South Sudan between 17–20 September. The vaccination campaign aims to mitigate the spread of cholera in South Sudan's capital, where the UN and the Ministry of Health have reported nearly 1,800 cholera cases and 12 related deaths since July.

The campaign, funded by the Government of Japan, targeted populations in the Gumbo and Mangaten neighbourhoods, where cholera caseloads have been high, and reached 112 percent of the initial target.

The vaccinations were conducted by the Health Ministry, in collaboration with IOM, the UN World Health Organization, the UN Children's Fund, Health Link and Live Well. In advance of the campaign, volunteers were trained on administration of the vaccine and community messaging.

"The partnership seen in this campaign is outstanding and it is important that we continue to work together to help improve the health of families affected by the conflict in South Sudan," said IOM South Sudan Chief of Mission William Barriga.

"In Juba, like many places across the country, access to safe water can be challenging, meaning that prevention through vaccination is central to keeping families safe," he added. Violence in the capital in July displaced over 15,000 people, disrupting livelihoods and affecting access to public services. In crowded areas and among families with limited access to medical care, early prevention of cholera is crucial to reducing community transmission of the disease, which can spread rapidly.

With support from the USAID Office of U.S. Foreign Disaster Assistance Rapid Response Fund, IOM partners Impact Health Organization, Nile Hope and Mentor Initiative are also conducting hygiene promotion in Juba neighbourhoods and at the UN Mission in South Sudan Tongping base to stem the spread of cholera and water-borne diseases. Messages focus on the importance of personal hygiene and proper handling of water and food.

Of the more than 1.61 million internally displaced persons and 6.1 million people in need of humanitarian aid in South Sudan, the UN estimates that 4.7 million people require lifesaving health care assistance this year, as conflict and displacement increase the risk for epidemics and the spread of preventable diseases.

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Facebook's founder Mark Zuckerberg and wife Priscilla Chan pledge $3bn to fund Chan Zuckerberg Initiative for medical research over the next decade.
21 September 2016
…Medicine has only been a modern science for about a century, and we've made incredible progress so far. Life expectancy has increased by 1/4 of a year per year since then, and if we only continue this trend, the average will reach 100 around the end of this century.
Today, just four kinds of diseases cause the majority of deaths. We can make progress on all of them with the right technology.

Throughout history, most scientific breakthroughs have been preceded by the invention of new tools to help us see problems in new ways -- like the telescope, the microscope and DNA sequencing.

It's not hard to imagine the modern tools required to accelerate breakthroughs in today's four major disease area. So we're going to focus on bringing scientists and engineers together to build these new tools and technologies.

Today, we announced a few steps in this direction:

:: Dr. Cori Bargmann, a world-renowned expert in neuroscience and genetics, is joining the Chan Zuckerberg Initiative to lead this initiative. We are thrilled to welcome her.

:: We are committing to invest $3 billion over the next decade in this initiative to help scientists cure diseases.

:: Our first project is creating the Biohub. We're investing $600 million in a new research hub to bring scientists and engineers together from Stanford, UCSF, Berkeley, and the world-class engineering team we're building at the Chan Zuckerberg Initiative, in order to build some of the new tools I mentioned above.

The science initiative is a long term effort. We plan to invest billions of dollars over decades. But it will take years for these tools to be developed and longer to put them into full use. This is hard and we need to be patient, but it's important.

This is about the future we want for our daughter and children everywhere. If there's a chance that we can help cure all diseases in our children's lifetimes, then we will do our part. Together, we have a real shot at leaving the world a better place for our children than we found it.

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Johns Hopkins University and Michael R. Bloomberg Launch the Bloomberg American Health Initiative

September 15, 2016

$300 MILLION GIFT TO TRANSFORM APPROACH TO TACKLING MAJOR DOMESTIC HEALTH ISSUES

The Johns Hopkins Bloomberg School of Public Health today announced that Bloomberg Philanthropies, founded by businessman, philanthropist, World Health Organization Global Ambassador for Noncommunicable Diseases, and three-term mayor of New York City Michael R. Bloomberg, will give $300 million to create the Bloomberg American Health Initiative. Coinciding with the 100th anniversary of the founding of the school, the gift sets the school and its partners on a path to transform our national approach to modern public health challenges.

The gift focuses on five areas affecting public health — drug addiction, obesity, gun violence, adolescent health, and environmental threats. It provides for:

:: A $100 million endowment to fund 50 public health fellows each year, nominated from organizations located around the nation, to receive their Master of Public Health degrees and be committed to returning to their communities to work in the practice of public health for at least one year. This arrangement will create a public health triangle of collaboration between the master's student, the home community, and the school. The initiative funds their education, training, and living expenses while in the program. By its 10thyear, the program will have a network of more than 400 fellows.

:: A $125 million endowment is intended to fund faculty and their research within the five focus areas outlined above, as well as jump start immediate research needs. This network of 25

faculty members will extend well beyond the Bloomberg School of Public Health, including 10 of the funded faculty members receiving joint appointments in other schools at Johns Hopkins and 12 receiving joint appointments that span more than one department at the Bloomberg School. Further, the Bloomberg American Health Initiative will generate catalytic research outcomes with the potential to spur additional funding from other organizations, foundations, or philanthropists.

:: $75 million to establish scholarships for Johns Hopkins University's new school-wide Doctor of Public Health (DrPH) program and support a biennial public health summit that will bring together Bloomberg fellows, faculty, and partnering organizations to share findings from research and practice to solve major health issues. DrPH candidates play a critical role in practical implementation and evaluation of public health programs at the local and national level.

For more information on the initiative, visit the Bloomberg American Health Initiative website.

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Global Fund [to 24 September 2016]
http://www.theglobalfund.org/en/news/?topic=&type=NEWS;&country=

24 September 2016

Global Fund Donors Pledge Nearly $13 Billion to Help End Epidemics

MONTREAL - At the launch of the Global Fund's Fifth Replenishment, donors pledged over US$12.9 billion for the next three years, demonstrating extraordinary global commitment toward ending the epidemics of AIDS, tuberculosis and malaria for good.

Hosted by Prime Minister Justin Trudeau, who stressed youth engagement as a key to success in global health, the conference welcomed significantly increased pledges from several donors. Canada increased its own contribution by 23 percent, many new partners pledged for the first time, and private sector contributions more than doubled.

The Replenishment Conference raised nearly $1 billion more than the previous replenishment conference in 2013, and benefitted from participation by leaders from countries all over the world, United Nations Secretary General Ban Ki-moon, and Bill Gates, Co-Chair of the Bill & Melinda Gates Foundation.

The amount raised will save 8 million lives, avert 300 million infections, and help build resilient and sustainable systems for health. The conference is only the beginning of a three-year replenishment period, and the Global Fund will actively work to gain further contributions in the coming months and years, with strong advocacy by civil society and partners worldwide…

19 September 2016

African Countries Step Up Contributions to the Global Fund

GENEVA - African countries increased investments in the Global Fund as global health partners seek to galvanize all sources of funding to end AIDS, tuberculosis and malaria as epidemics, and to build resilient and sustainable systems for health.

Benin, Côte d'Ivoire, Kenya, Namibia, Nigeria, Senegal, South Africa, Togo, and Zimbabwe each made contributions to the Global Fund's Fifth Replenishment, hosted by Prime Minister Justin Trudeau of Canada in Montreal on 16-17 September. Altogether, the conference secured pledges of more than $12.9 billion from partners across the world.

Pledges by African countries to the Global Fund are aligned with a far more significant increase of domestic investment in health by African countries - US$10.9 billion committed for

2015-17. For the first time, Africa is now mobilizing more domestic funding for health than foreign funding in the sector…

BMGF - Gates Foundation [to 24 September 2016]
http://www.gatesfoundation.org/Media-Center/Press-Releases
SEPTEMBER 17, 2016
Bill Gates' statement on the outcome of the 5th Global Fund Replenishment Conference for 2017-2019
SEATTLE (September 17, 2016) – "Given the many challenges governments face today, I'm inspired by the generosity of partners at this replenishment. It is a great outcome…

UK attaches strings to $1.4B Global Fund pledge
Devex | 19 September 2016
The United Kingdom's contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria comes with strings attached: The country will withhold 10 percent of its pledge if the Global Fund fails to meet 10 benchmarks for improvement. The unprecedented move takes the U.K. Department for International Development's payment by results agenda — through which organizations receive funding only after achieving impact — to the multilateral stage.

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Gavi [to 24 September 2016]
http://www.gavi.org/library/news/press-releases/
21 September 2016
Gavi and Philips team up to improve immunisation data quality in developing countries
The partnership will help improve the planning, coverage and impact of immunisation programmes to reach more children with vaccines.
New York, 21 September 2016 – Gavi, the Vaccine Alliance and leading health technology company Royal Philips (NYSE: PHG, AEX: PHIA), announced today that they have signed a letter of intent to jointly develop scalable digital transformation plans aimed at improving the quality of immunisation data and its collection in primary and community healthcare. Their joint goal is to help Gavi supported countries improve the planning, coverage and impact of immunisation programmes. The partnership was announced at the Global Partnership for Sustainable Development Data event in New York…

Gavi, the Vaccine Alliance -Annual Progress Report 2015
The 2015 Report focuses on the final year of our 2011-2015 strategy, delivering final results for our key performance indicators and reporting on preparations for our exciting new 2016-2020 mission. There is also a series of country features spread throughout the Report that illustrate our Alliance's impact on immunisation around the world -- from Georgia and Haiti to Liberia and Yemen.

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Industry Watch [to 24 September 2016]

:: **Leading Pharmaceutical Companies Present Industry Roadmap to Combat Antimicrobial Resistance**
20 September 2016
:: Comprehensive roadmap lays out key commitments the pharmaceutical companies pledge to deliver by 2020 to reduce antimicrobial resistance
:: Represents major milestone following the Industry Declaration signed in January 2016 at the World Economic Forum by more than 100 companies and trade associations

NEW YORK, N.Y., September 20, 2016 – Ahead of the United Nations General Assembly (UNGA) High-Level Meeting on Antimicrobial Resistance (AMR), 13 leading pharmaceutical companies today presented a new roadmap that lays out four key commitments they will deliver by 2020 to reduce AMR. The commitments follow the principles identified and agreed upon in the Industry Declaration made at the 2016 World Economic Forum in Davos earlier this year, and reflect the companies' intent to continue to proactively contribute to the global efforts to address AMR. This unprecedented collaboration between the pharmaceutical companies marks a major milestone in the fight against AMR.

In presenting this roadmap, the signatory companies firmly demonstrate their shared ambition to overcome the staggering threat AMR represents for our society, economies, and citizens. We are committed to working to reduce the development of antimicrobial resistance, improve access to high-quality antibiotics, vaccines, and diagnostics, invest in R&D, and collaborate with governments and stakeholders to sustain those investments.

Specifically, this group of diversified companies commit to:
.1 Reduce the environmental impact from the production of antibiotics, including a review of the companies' manufacturing and supply chains, and work with stakeholders to establish a common framework for assessing and managing antibiotic discharge;

.2 Help ensure antibiotics are used only by patients who need them, recognizing this requires concerted efforts from many stakeholders, through continued provider and patient education, an examination of the companies' promotional activities, sharing of surveillance data with public health bodies and healthcare professionals, and collaboration with stakeholders to reduce uncontrolled antibiotic purchase;

.3 Improve access to current and future antibiotics, vaccines, and diagnostics, including working with stakeholders to strengthen global health systems and address access bottlenecks; establishing new business models that balance access needs, appropriate antibiotic use, expanded vaccine coverage and adequate return to companies; and working to reduce the prevalence of substandard/counterfeit antibiotics in high-risk markets; and

.4 Explore new opportunities for open collaborations between industry and the public sector to address challenges in the research and development of new antibiotics, vaccines, and diagnostics, recognizing the value these bring to society…

:: **GSK sets out further steps to address emerging global health security challenges**
19 September 2016
:: Offering to extend its lowest prices for vaccines to refugees
:: Supporting a new roadmap for tackling antibiotic resistance

:: Reaffirming commitment to biopreparedness facility to research vaccines against future public health threats
[Press release excerpts; Editor's text bolding]
As the United Nations General Assembly takes place in New York this week, GSK will set out a series of steps to further address emerging global health challenges, including supporting immunisation for refugees; tackling the continued rise of antimicrobial resistance; and preparing for future public health threats or pandemics. These pledges build on GSK's long-standing and comprehensive commitments to delivering innovative medicines and vaccines and widening access to them; and will support the ambitious Global Goals to improve health, prosperity and sustainable development by 2030.

Extending lowest prices for vaccines to refugees
The current refugee crisis affecting areas such as Syria and South Sudan can leave displaced people unable to access healthcare, and potentially vulnerable to vaccine-preventable disease. In response, **GSK is making a new commitment to supply its essential vaccines to internationally recognised civil society organisations (CSOs) – such as Médecins Sans Frontières – at its lowest prices for use in acute humanitarian situations in circumstances where governments are unable to respond. This will initially apply to GSK's pneumococcal vaccine to help protect children against diseases such as pneumonia**. Working with partners such as Gavi, GSK is proposing to provide Synflorix at the deeply discounted price of $3.05 per dose to charities who fund and deliver immunisation programmes to refugees and displaced people. GSK will explore expanding this offer to other essential vaccines in the future.

For many years GSK has been working with partners to increase access to its vaccines so as many people round the world as possible can benefit from immunisation. This includes supply arrangements with certain charities and product donations in emergencies. **This new pledge is designed to help maintain stable vaccination programmes in acute humanitarian situations where governments are unable to do so, by developing a reliable and predictable supply to CSOs who have stepped in. At the same time, GSK will continue to work with partners to strengthen the long-term capacity of local health systems to support refugees and host communities.**

…Sir Andrew Witty, GSK CEO, said, "I am pleased that we can today offer our pneumococcal vaccine at the lowest price to civil society organisations providing essential immunisation programmes to refugees. While government-led programmes offer the best chance of providing sustainable immunisation, we know that this is not always possible – particularly in a time of crisis. Through this new pledge, we hope to provide consistency and stability for those delivering healthcare to some of our most vulnerable communities."…

…Preparing for future pandemics
As a global leader in vaccines, GSK will this week add its voice to calls for improved global preparedness to respond to global health emergencies. At the Social Good Summit, hosted by the UN Foundation and Mashable in New York on 19 September, Moncef Slaoui, Chairman of Vaccines, GSK, will reiterate the company's support for a more concerted and co-ordinated programme to enhance preparedness against potential future outbreaks.

In the wake of recent global health threats such as Ebola and Zika, there is growing consensus across governments and multinational organisations of the need to better anticipate and prepare for global health threats to avoid devastating consequences for health, economies and global security. **GSK is proposing to create a Biopreparedness Organisation (BPO) – a dedicated, permanent organisation operating on a no-profit, no-loss basis and focused on designing and developing new vaccines against potential public health threats.** The pathogens to be targeted would be selected and prioritised with guidance from independent public health experts.

The BPO would be based at GSK's facility in Rockville in the US. Such a facility requires a collective approach with backing from governments and other organisations. GSK is actively engaging with governments, funders and non-governmental organisations to secure funding to enable the BPO to advance without delay.

Notes to editors
Providing pneumococcal immunisation for refugees & displaced peoples
:: The number of refugees and displaced people worldwide has hit a record high. Governments have a responsibility to care for these populations; however, sometimes their ability to do so is compromised.
:: Where acute humanitarian crises impact a government's ability to provide a sustainable and stable immunisation programme, Civil Society Organisations (CSOs) are sometimes required to provide support or step in.
:: GSK has been working to develop a coherent and sustainable way to help CSOs that are funding and implementing immunisation programmes for refugees and internally displaced populations (IDPs) where the government is unable to do so.
:: GSK is offering its pneumococcal vaccine at the lowest price of $3.05 to CSO immunisation programmes for refugees and IDPs. The hope is to expand this commitment to other essential vaccines in the future.
:: With this offer, internationally recognised CSOs who fund and deliver immunisation programmes for refugees and internally displaced populations will be able to purchase the pneumococcal vaccine at $3.05.
:: This offer is made on the basis that others would not seek to reference this special price that is intended to support refugee populations.
:: GSK will work with its partners to develop a pragmatic process to ensure timely, reliable and predictable supply of pneumococcal vaccines – this will likely involve different organisations helping to manage requests for supplies from CSO…

:: **Emma Walmsley to succeed Andrew Witty as Chief Executive Officer of GlaxoSmithKline**
20 September 2016
GSK today announces that Emma Walmsley, currently Chief Executive Officer (CEO) of GSK's Consumer Healthcare division, is appointed GSK CEO Designate and will succeed Andrew Witty as GSK CEO, when he retires on 31March 2017. Emma will join the GSK Board of Directors from 1 January 2017.
Emma is currently CEO of GSK Consumer Healthcare, one of the world's largest consumer health companies, established in 2015 following completion of GSK's three-part transaction with Novartis.

Prior to this, Emma was President of GSK Consumer Healthcare and has been a member of GSK's Corporate Executive Team since 2011. Emma joined GSK in 2010 from L'Oreal where, over the course of her 17-year career, she held a variety of marketing and general management roles in the UK, Europe and USA. From 2007 she was based in Shanghai as General Manager, Consumer Products for L'Oreal China…

:: **Takeda and Zydus Cadila partner to address the global threat of Chikungunya**
September 20, 2016 08:55 AM Eastern Daylight Time

OSAKA, Japan & AHMEDABAD, India--(BUSINESS WIRE)--Takeda Pharmaceutical Company Limited and Zydus Cadila today announced a partnership to tackle chikungunya, an emerging infectious disease in Africa, Asia and the Indian subcontinent. In recent decades mosquito vectors of chikungunya have spread to Europe and the Americas.i According to the Centers for Disease Control and Prevention (CDC) in the USA, there is currently no vaccine to prevent or medicine to treat chikungunya virus infectionii. The chikungunya virus is most often spread to people by Aedes aegypti and Aedes albopictus mosquitoes, the same vectors that spread dengue and Zika.

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PATH [to 24 September 2016]
http://www.path.org/news/index.php
Announcement | September 17, 2016
PATH joins world leaders in New York City this week to advocate for innovation to implement global goals
New publications
Harnessing the Power of Innovation to Save Mothers and Children

As global health leaders gather to discuss progress achieved by the Every Women, Every Child movement and A Promise Renewed, PATH published a new report that reinforces the vital role innovation will play in achieving global targets for reducing deaths of mothers and children. The report estimates more than six million mother and child lives could be saved by 2030 if just 11 emerging innovations are advanced and scaled up in 24 countries.

Stronger Markets, Increased Access to Maternal Health Supplies

Maternal mortality will also be a topic of conversation in New York, and a new series of papers by PATH highlights that worldwide, too many women lack access to the lifesaving medicines that can prevent the two leading causes of death during pregnancy and childbirth—postpartum hemorrhage and preeclampsia/eclampsia. The papers describe how key market challenges, such as inconsistent availability and poor-quality supplies of oxytocin, misoprostol, and magnesium sulfate are putting women's lives at risk, and provide important recommendations for how advocacy can strengthen markets to better deliver these lifesaving products. Written by PATH in partnership with the Reproductive Health Supplies Coalition (RHSC) and Results for Development Institute (R4D), the papers provide details and recommended actions in three geographies: globally, Bangladesh, and Nigeria.

Announcement | September 15, 2016
PATH Statement on the United Nations Secretary-General's High-Level Panel on Access to Medicines Report

September 15, 2016 – PATH welcomes the United Nations Secretary-General's High-Level Panel on Access to Medicines (High-Level Panel) Report urging swift action to increase global access to health technologies.

PATH applauds the United Nations and members of the High-Level Panel for bringing attention to this important issue. Getting new and improved tools into the hands of everyone who needs them is essential to achieving the Sustainable Development Goals. In particular, PATH agrees with the High-Level Panel's recommendations to increase investments from all countries in research and development for health, and new incentives to bring in the necessary stakeholders to develop health technologies for low-resource settings.

At the same time, PATH calls for further review and discussion of some of the report's recommendations with an eye toward broader access issues and ensuring that future access to innovative lifesaving technologies is not inadvertently put at risk. The High-Level Panel should engage in dialogue with, and accept inputs from the global health innovation community, including nonprofit product developers.

PATH's decades-long experience in developing a range of health technologies, including vaccines, drugs, diagnostics, and devices shows that the failure of innovations to achieve widespread use in low-resource settings is rarely due to a single issue. Access to health innovation is best ensured when products are quality-assured, integrated into well-functioning health systems geared to support health impact and equity goals, and consistently available, affordable, and acceptable. This means supply is reliable and sufficient to meet demand, the price balances what end users can afford with incentives for suppliers, and products are designed to meet the needs of the end user and the health system.

"There is no silver bullet or one-size-fits-all solution to all access challenges. Access is a complex issue," said Dr. David Kaslow, vice president of Product Development and head of the Center for Vaccine Innovation and Access at PATH. "In our experience, the barriers to access are best overcome if approached holistically, through multisectoral partnerships, and with a long-term, sustainable approach."

Read more about PATH's perspective on access based on nearly 40 years of developing health technologies for low-resource settings.

Announcement | September 13, 2016

PATH appoints vice president for Policy and Advocacy

PATH welcomes Carolyn Reynolds in the newly created position of vice president for Policy and Advocacy.

Based in Washington, D.C., Ms. Reynolds will lead PATH's global policy and advocacy portfolio and cultivate engagement with leaders in government, development partners, the private sector and civil society in the United States and around the world to advance forward-looking global health policies and programs, research and development, sustainable financing and other efforts to increase development impact. She will serve as PATH's senior advisor on global health policy and represent PATH in Washington, D.C. and to multilateral organizations…

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FDA [to 24 September 2016]
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm

What's New for Biologics

:: August 31, 2016 Approval Letter - Flucelvax (PDF - 31KB)
Posted: 9/23/2016

:: Final Clinical Review - DAPTACEL (PDF - 414KB)
Posted:9/23/2016
:: Final Clinical Review - Menactra (PDF - 416KB)
Posted: 9/23/2016
:: September 16, 2016 Summary Basis of Regulatory Action - DAPTACEL (PDF - 115KB)
Posted: 9/22/2016
:: September 16, 2016 Summary Basis of Regulatory Action - Menactra (PDF - 222KB)
Posted: 9/22/2016
:: Influenza Virus Vaccine for the 2016-2017 Season
Updated: 9/21/2016
:: Public Meeting: Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act
Posted: 9/20/2016

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Coalition for Epidemic Preparedness Innovations (CEPI) [to 24 September 2016]
http://cepi.net/
Sept. 21, 2016
PaxVax CEO Nima Farzan Joins Board of the Coalition for Epidemic Preparedness Innovations
Newly formed public-private alliance is working to create an arsenal of vaccines to prevent future epidemics from becoming public health emergencies
REDWOOD CITY, Calif., /PRNewswire/ -- PaxVax today announced its President and CEO, Nima Farzan, has been invited to join the interim board of the Coalition for Epidemic Preparedness Innovations (CEPI) as the Biotechnology Innovation Organization (BIO) delegate. CEPI is a new, public-private alliance designed to speed the development of new vaccines to prevent and contain global epidemics. Sparked by recent gaps in vaccine preparedness for outbreaks of Zika and Ebola, CEPI aims to facilitate the creation of an arsenal of vaccines to prevent diseases such as these from becoming public health emergencies in the future….

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EDCTP [to 24 September 2016]
http://www.edctp.org/
The European & Developing Countries Clinical Trials Partnership (EDCTP) aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases in sub-Saharan Africa, with a focus on phase II and III clinical trials.
23 September 2016
Important clarification regarding Call 'Research and clinical management of patients in PRD epidemics in sub-Saharan Africa'
This clarification concerns the EDCTP call for proposals Research and clinical management of patients in PRD epidemics in sub-Saharan Africa.

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European Vaccine Initiative [to 24 September 2016]

http://www.euvaccine.eu/news-events
News 21 September 2016
EVI workshop report on placental malaria vaccine candidates published in Malaria Journal

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AERAS [to 24 September 2016]
http://www.aeras.org/pressreleases
No new digest content identified.

Fondation Merieux [to 24 September 2016]
Mission: Contribute to global health by strengthening local capacities of developing countries to reduce the impact of infectious diseases on vulnerable populations.
http://www.fondation-merieux.org/news
No new digest content identified.

GHIT Fund [to 24 September 2016]
https://www.ghitfund.org/
GHIT was set up in 2012 with the aim of developing new tools to tackle infectious diseases that devastate the world's poorest people. Other funders include six Japanese pharmaceutical companies, the Japanese Government and the Bill & Melinda Gates Foundation.
No new digest content identified

Hilleman Laboratories [to 24 September 2016]
http://www.hillemanlabs.org/
No new digest content identified

Human Vaccines Project [to 24 September 2016]
humanvaccinesproject.org
[Website in development]

IAVI – International AIDS Vaccine Initiative [to 24 September 2016]
https://www.iavi.org/
No new digest content identified

NIH [to 24 September 2016]
http://www.nih.gov/news-events/news-releases
No new digest content identified

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

Vaccines and Global Health: The Week in Review has expanded its coverage of new reports, books, research and analysis published independent of the journal channel covered in Journal Watch below. Our interests span immunization and vaccines, as well as global public health,

health governance, and associated themes. If you would like to suggest content to be included in this service, please contact David Curry at: david.r.curry@centerforvaccineethicsandpolicy.org

EBioMedicine
Article in Press Accepted date: 26 August 2016
The State of Vaccine Confidence 2016: Global Insights Through a 67-Country Survey
Heidi J. Larson PhD, Alexandre de Figueiredo MSc, Zhao Xiahong BSc, William S. Schulz MSc, Pierre Verger PhD, Iain G. Johnston PhD, Alex R. Cook PhD, Nick S. Jones PhD
PII: S2352-3964(16)30398-X
DOI: doi: 10.1016/j.ebiom.2016.08.042
Highlights
:: Overall vaccine confidence is positive, though responses differ between countries.
:: The European region has the lowest confidence in vaccine safety with France the least confident globally.
:: Bangladesh, Ecuador, and Iran reported highest agreement that vaccines are important.
:: Azerbaijan, Russia, and Italy reported most skepticism around vaccine importance.
:: Education increases confidence in vaccine importance and effectiveness but not safety.

This global survey builds on previous studies of vaccines' perceived importance, safety, effectiveness, and religious compatibility. The worldwide survey investigates attitudes towards vaccines on an unprecedented scale, interviewing 65,819 respondents across 67 countries. This can help inform public health agendas by highlighting national and regional variations in attitudes towards vaccines; for example, that the European region is the least confident region towards vaccine safety. One pattern shared by diverse countries worldwide is a worrying gap between high confidence in vaccine importance yet lower confidence in safety, identifying at-risk countries whose vaccine acceptance may be more precarious than previously thought. Meanwhile, factors such as religion, which past research shows to be crucial in some sub-populations, display no consistent pattern at the global scale, emphasizing the importance for future research of understanding the local drivers of vaccine confidence in more detail.

Abstract
Background
Public trust in immunization is an increasingly important global health issue. Losses in confidence in vaccines and immunization programmes can lead to vaccine reluctance and refusal, risking disease outbreaks and challenging immunization goals in high- and low-income settings. National and international immunization stakeholders have called for better monitoring of vaccine confidence to identify emerging concerns before they evolve into vaccine confidence crises.
Methods
We perform a large-scale, data-driven study on worldwide attitudes to immunizations. This survey – which we believe represents the largest survey on confidence in immunization to date – examines perceptions of vaccine importance, safety, effectiveness, and religious compatibility among 65,819 individuals across 67 countries. Hierarchical models are employed to probe relationships between individual- and country-level socio-economic factors and vaccine attitudes obtained through the four-question, Likert-scale survey.
Findings
Overall sentiment towards vaccinations is positive across all 67 countries, however there is wide variability between countries and across world regions. Vaccine-safety related sentiment is

particularly negative in the European region, which has seven of the ten least confident countries, with 41% of respondents in France and 36% of respondents in Bosnia & Herzegovina reporting that they disagree that vaccines are safe (compared to a global average of 13%). The oldest age group (65+) and Roman Catholics (amongst all faiths surveyed) are associated with positive views on vaccine sentiment, while the Western Pacific region reported the highest level of religious incompatibility with vaccines. Countries with high levels of schooling and good access to health services are associated with lower rates of positive sentiment, pointing to an emerging inverse relationship between vaccine sentiments and socio-economic status.
Conclusions
Regular monitoring of vaccine attitudes – coupled with monitoring of local immunization rates – at the national and sub-national levels can identify populations with declining confidence and acceptance. These populations should be prioritized to further investigate the drivers of negative sentiment and to inform appropriate interventions to prevent adverse public health outcomes.

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Journal Watch

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

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

American Journal of Infection Control
September 2016 Volume 44, Issue 9, p963-1082, e145-e166
http://www.ajicjournal.org/current
[Reviewed earlier]

American Journal of Preventive Medicine
October 2016 Volume 51, Issue 4, p411-636, e91-e118
http://www.ajpmonline.org/current
[New issue; No relevant content identified]

American Journal of Public Health
Volume 106, Issue 10 (October 2016)
http://ajph.aphapublications.org/toc/ajph/current
HPV
Human Papillomavirus Vaccination Requirements in US Schools: Recommendations for Moving Forward

American Journal of Public Health: October 2016, Vol. 106, No. 10: 1765–1770Anna L. North, Linda M. Niccolai

ABSTRACT

Safe and effective human papillomavirus (HPV) vaccines have been available and recommended for adolescents for a decade in the United States, yet vaccination rates remain suboptimal. School entry requirements have increased uptake of other vaccines for adolescents and made coverage more equitable. However, only 3 jurisdictions require HPV vaccine for school.

We summarize the current status of HPV vaccine requirements and discuss the rationales for and against these policies. The rationales for requirements include HPV vaccine efficacy and safety, effectiveness of requirements for increasing vaccine uptake and making it more equitable, and use of requirements as "safety nets" and to achieve herd immunity. The rationales against requirements include low parental acceptance of HPV vaccine, the financial burden on educational systems and health departments, and the possibility for alternatives to increase vaccine uptake.

Many challenges to HPV vaccine requirements are addressable, and we conclude with recommendations on how to approach these challenges.

VACCINATION

A Community-Powered, Asset-Based Approach to Intersectoral Urban Health System Planning in Chicago

American Journal of Public Health: October 2016, Vol. 106, No. 10: 1872–1878.

Stacy Tessler Lindau, Katherine Diaz Vickery, HwaJung Choi, Jennifer Makelarski, Amber Matthews, Matthew Davis

ABSTRACT

Objectives. To examine state-level associations between voting patterns and adolescent coverage for at least 1 dose of human papillomavirus (HPV), tetanus-containing (Tdap), and meningococcal (MCV4) vaccination.

Methods. We classified states as "blue" (Democratic affiliation) or "red" (Republican affiliation) based on the Presidential election results in 2012. We used multivariable models to adjust for potential confounding by sociodemographic and health care access characteristics and vaccination policies. For HPV, separate models were fitted for boys and girls.

Results. Adolescent vaccination coverage was significantly higher in blue states than red states for each vaccine ($P < .05$). The adjusted percent differences between blue and red states were 10.2% for HPV among girls, 24.9% for HPV among boys, 6.2% for tetanus-containing vaccine, and 14.1% for MCV4.

Conclusions. State-level voting patterns are independently and significantly associated with coverage for routinely recommended adolescent vaccines. These differences may reflect population-level differences in cultural norms and social values.

Public Health Implications. Strategies to increase coverage at the individual, community, or structural level should consider local political settings that may facilitate or hinder effectiveness.

HIV PREP

Disparities in Uptake of HIV Preexposure Prophylaxis in a Large Integrated Health Care System

American Journal of Public Health: October 2016, Vol. 106, No. 10: e2–e3

.Julia L. Marcus, Leo B. Hurley, C. Bradley Hare, Michael J. Silverberg, Jonathan E. Volk

[No abstract]

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

Annals of Internal Medicine
20 September 2016, Vol. 165. No. 6
http://annals.org/issue.aspx
Research and Reporting Methods
ClinicalTrials.gov and Drugs@FDA: A Comparison of Results Reporting for New Drug Approval Trials
Lisa M. Schwartz, MD, MS; Steven Woloshin, MD, MS; Eugene Zheng, BA; Tony Tse, PhD; and Deborah A. Zarin, MD
Abstract
Background: Pharmaceutical companies and other trial sponsors must submit certain trial results to ClinicalTrials.gov. The validity of these results is unclear.
Purpose: To validate results posted on ClinicalTrials.gov against publicly available U.S. Food and Drug Administration (FDA) reviews on Drugs@FDA.
Data Sources: ClinicalTrials.gov (registry and results database) and Drugs@FDA (medical and statistical reviews).
Study Selection: 100 parallel-group, randomized trials for new drug approvals (January 2013 to July 2014) with results posted on ClinicalTrials.gov (15 March 2015).
Data Extraction: 2 assessors extracted, and another verified, the trial design, primary and secondary outcomes, adverse events, and deaths.
Results: Most trials were phase 3 (90%), double-blind (92%), and placebo-controlled (73%) and involved 32 drugs from 24 companies. Of 137 primary outcomes identified from ClinicalTrials.gov, 134 (98%) had corresponding data at Drugs@FDA, 130 (95%) had concordant definitions, and 107 (78%) had concordant results. Most differences were nominal (that is, relative difference <10%). Primary outcome results in 14 trials could not be validated. Of 1927 secondary outcomes from ClinicalTrials.gov, Drugs@FDA mentioned 1061 (55%) and included results data for 367 (19%). Of 96 trials with 1 or more serious adverse events in either source, 14 could be compared and 7 had discordant numbers of persons experiencing the adverse events. Of 62 trials with 1 or more deaths in either source, 25 could be compared and 17 were discordant.
Limitation: Unknown generalizability to uncontrolled or crossover trial results.
Conclusion: Primary outcome definitions and results were largely concordant between ClinicalTrials.gov and Drugs@FDA. Half the secondary outcomes, as well as serious events and deaths, could not be validated because Drugs@FDA includes only "key outcomes" for regulatory decision making and frequently includes only adverse event results aggregated across multiple trials.
Primary Funding Source: National Library of Medicine.

BMC Cost Effectiveness and Resource Allocation
http://resource-allocation.biomedcentral.com/
(Accessed 24 September 2016)

[The BMC family of websites all down at inquiry]

BMC Health Services Research
http://www.biomedcentral.com/bmchealthservres/content
(Accessed 24 September 2016)
[The BMC family of websites all down at inquiry]

BMC Infectious Diseases
http://www.biomedcentral.com/bmcinfectdis/content
(Accessed 24 September 2016)
[The BMC family of websites all down at inquiry]

BMC Medical Ethics
http://www.biomedcentral.com/bmcmedethics/content
(Accessed 24 September 2016)
[The BMC family of websites all down at inquiry]

BMC Medicine
http://www.biomedcentral.com/bmcmed/content
(Accessed 24 September 2016)
[The BMC family of websites all down at inquiry]

BMC Pregnancy and Childbirth
http://www.biomedcentral.com/bmcpregnancychildbirth/content
(Accessed 24 September 2016)
[The BMC family of websites all down at inquiry]

BMC Public Health
http://bmcpublichealth.biomedcentral.com/articles
(Accessed 24 September 2016)
[The BMC family of websites all down at inquiry]

BMC Research Notes
http://www.biomedcentral.com/bmcresnotes/content
(Accessed 24 September 2016)
[The BMC family of websites all down at inquiry]

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

[Reviewed earlier]

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

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

Clinical Therapeutics
October 2016 Volume 38, Issue 10, Supplement, e1-e32
http://www.clinicaltherapeutics.com/issue/S0149-2918(16)X0014-8
Supplement: Abstracts Presented at the European Association for Clinical Pharmacology and Therapeutics Focus Meeting 06-09 October 2016
Abstracts organized against three themes: Efficacy, Effectiveness, Economics
[Example]
Efficacy
Accelerated Approval Paths: What they do Mean and What they Should Not Mean?
G. Calvo
Hospital Clinic of Barcelona and University of Barcelona School of Medicine, Barcelona, Spain
Abstract
Timely access to medicines aimed to cover unmet medical needs is a priority for regulatory agencies worldwide. In the EU regulatory paths like the approval under exceptional circumstances or conditional approval have been in force over the last decade. Moreover, applicants could request accelerated review of dossiers of drugs with outstanding efficacy or aimed to cover a true unmet need in serious clinical conditions. Similar regulatory figures were also put in place by the FDA years ago. Recently, both FDA and EMA have launched programs to facilitate early access of promising drugs to treat unmet medical needs in serious conditions.

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

Conflict and Health
http://www.conflictandhealth.com/
[Accessed 24 September 2016]
[The BMC family of websites all down at inquiry]

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

Current Opinion in Infectious Diseases
October 2016 - Volume 29 - Issue 5 pp: v-vi,433-537
http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx
[New issue: No relevant content identified]

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

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

Disasters
October 2016 Volume 40, Issue 4 Pages 589–815
http://onlinelibrary.wiley.com/doi/10.1111/disa.2016.40.issue-4/issuetoc
[Reviewed earlier]

Emerging Infectious Diseases
Volume 22, Number 10—October 2016
http://wwwnc.cdc.gov/eid/
Synopses
Vaccine-Derived Polioviruses and Children with Primary Immunodeficiency, Iran, 1995–2014 PDF Version [PDF - 580 KB - 8 pages]
Polio might not be eradicated unless long-term vaccination with inactivated poliovirus vaccine is implemented.

Dispatches
Estimation of Severe Middle East Respiratory Syndrome Cases in the Middle East, 2012–2016 PDF Version [PDF - 410 KB - 3 pages]
J. J. O'Hagan et al.
Our traveler-based estimate was 2.3-fold higher than the number of laboratory-confirmed cases recorded.

Online Reports

Global Capacity for Emerging Infectious Disease Detection, 1996–2014 PDF Version [PDF - 2.66 MB - 9 pages]
S. A. Kluberg et al.
Timeliness of global outbreak discovery and public communication have gradually improved, but progress has slowed in recent years.

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

Epidemiology and Infection
Volume 144 - Issue 12 - September 2016
http://journals.cambridge.org/action/displayIssue?jid=HYG&tab=currentissue
[Reviewed earlier]

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

Eurosurveillance
Volume 21, Issue 38, 22 September 2016
http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678
Surveillance report
Effectiveness of the live attenuated and the inactivated influenza vaccine in two-year-olds – a nationwide cohort study Finland, influenza season 2015/16
by H Nohynek, U Baum, R Syrjänen, N Ikonen, J Sundman, J Jokinen
Although widely recommended, influenza vaccination of children is part of the national vaccination programme only in few countries. In addition to Canada and the United States (US), in Europe Finland and the United Kingdom have introduced live attenuated influenza vaccine (LAIV) for healthy children in their programmes. On 22 June 2016, the US Advisory Committee on Immunizations Practices, voted against further use of LAIV due to no observed vaccine effectiveness (VE) over three consecutive influenza seasons (2013/14 to 2015/16). We summarise the results of a nationwide, register-based cohort study (N=55,258 of whom 8,086 received LAIV and 4,297 TIV); all outcome (laboratory-confirmed influenza), exposure (vaccination) and confounding variable data were retrieved from four computerised national health registers, which were linked via a unique personal identity code assigned to all permanent Finnish residents regardless of nationality. Our study provides evidence of moderate effectiveness against any laboratory-confirmed influenza of the quadrivalent LAIV vaccine (VE: 51%; 95% confidence interval (CI): 28–66%) as well as the inactivated trivalent vaccine (VE: 61%; 95% CI: 31–78%) among two-year-olds during the influenza season 2015/16 in Finland. Based on these data, Finland will continue using LAIV for young children in its National Immunisation Programme this coming influenza season.

Effectiveness of seasonal influenza vaccine for adults and children in preventing laboratory-confirmed influenza in primary care in the United Kingdom: 2015/16 end-of-season results

by R Pebody, F Warburton, J Ellis, N Andrews, A Potts, S Cottrell, J Johnston, A Reynolds, R Gunson, C Thompson, M Galiano, C Robertson, R Byford, N Gallagher, M Sinnathamby, I Yonova, S Pathirannehelage, M Donati, C Moore, S de Lusignan, J McMenamin, M Zambon

The United Kingdom (UK) is in the third season of introducing universal paediatric influenza vaccination with a quadrivalent live attenuated influenza vaccine (LAIV). The 2015/16 season in the UK was initially dominated by influenza A(H1N1)pdm09 and then influenza of B/Victoria lineage, not contained in that season's adult trivalent inactivated influenza vaccine (IIV). Overall adjusted end-of-season vaccine effectiveness (VE) was 52.4% (95% confidence interval (CI): 41.0–61.6) against influenza-confirmed primary care consultation, 54.5% (95% CI: 41.6–64.5) against influenza A(H1N1)pdm09 and 54.2% (95% CI: 33.1–68.6) against influenza B. In 2–17 year-olds, adjusted VE for LAIV was 57.6% (95% CI: 25.1 to 76.0) against any influenza, 81.4% (95% CI: 39.6–94.3) against influenza B and 41.5% (95% CI: −8.5 to 68.5) against influenza A(H1N1)pdm09. These estimates demonstrate moderate to good levels of protection, particularly against influenza B in children, but relatively less against influenza A(H1N1)pdm09. Despite lineage mismatch in the trivalent IIV, adults younger than 65 years were still protected against influenza B. These results provide reassurance for the UK to continue its influenza immunisation programme planned for 2016/17.

Global Health: Science and Practice (GHSP)
June 2016 | Volume 4 | Issue 2
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[Reviewed earlier]

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Volume 11, Issue 9, 2016
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[Reviewed earlier]

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[The BMC family of websites all down at inquiry]

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

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

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

Health Policy and Planning
Volume 31 Issue 8 October 2016
http://heapol.oxfordjournals.org/content/current
Original Articles
Use of traditional medicine in middle-income countries: a WHO-SAGE study
Oyinlola Oyebode, Ngianga-Bakwin Kandala, Peter J Chilton, and Richard J Lilford
Health Policy Plan. (2016) 31 (8): 984-991 doi:10.1093/heapol/czw022
Abstract
It is frequently stated in the scientific literature, official reports and the press that 80% of Asian and African populations use traditional medicine (TM) to meet their healthcare needs; however, this statistic was first reported in 1983. This study aimed to update knowledge of the prevalence of TM use and the characteristics of those who access it, to inform health policy-makers as countries seek to fulfil the WHO TM strategy 2014–23 and harness TM for population health. Prevalence of reported use of TM was studied in 35 334 participants of the WHO-SAGE, surveyed 2007–10. TM users were compared with users of modern healthcare in univariate and multivariate analyses. Characteristics examined included age, sex, geography (urban/rural), income quintile, education, self-reported health and presence of specific chronic conditions. This study found TM use was highest in India, 11.7% of people reported that their most frequent source of care during the previous 3 years was TM; 19.0% reported TM use in the previous 12 months. In contrast <3% reported TM as their most frequent source of care in China, Ghana, Mexico, Russia and South Africa; and <2% reported using TM in the previous year in Ghana, Mexico, Russia and South Africa. In univariate analyses, poorer, less educated and rural participants were more likely to be TM-users. In the China multivariate analysis, rurality, poor self-reported health and presence of arthritis were associated with TM use; whereas diagnosed diabetes, hypertension and cataracts were less prevalent in TM users. In Ghana and India, lower income, depression and hypertension were associated with TM use. In conclusion, TM use is less frequent than commonly reported. It may be unnecessary, and perhaps futile, to seek to employ TM for population health needs when populations are increasingly using modern medicine.

Introduction of pentavalent vaccine in Indonesia: a policy analysis
Panji F Hadisoemarto, Michael R Reich, and Marcia C Castro
Health Policy Plan. (2016) 31 (8): 1079-1088 doi:10.1093/heapol/czw038
Abstract

The introduction of pentavalent vaccine containing Haemophilus influenzae type b antigen in Indonesia's National Immunization Program occurred nearly three decades after the vaccine was first available in the United States and 16 years after Indonesia added hepatitis B vaccine into the program. In this study, we analyzed the process that led to the decision to introduce pentavalent vaccine in Indonesia. Using process tracing and case comparison, we used qualitative data gathered through interviews with key informants and data extracted from written sources to identify four distinct but interrelated processes that were involved in the decision making: (a) pentavalent vaccine use policy process, (b) financing process, (c) domestic vaccine development process and (d) political process. We hypothesized that each process is associated with four necessary conditions that are jointly sufficient for the successful introduction of pentavalent vaccine in Indonesia, namely (a) an evidence-based vaccine use recommendation, (b) sufficient domestic financing capacity, (c) sufficient domestic vaccine manufacturing capacity and (d) political support for introduction. This analysis of four processes that led to the decision to introduce a new vaccine in Indonesia may help policy makers and other stakeholders understand and manage activities that can accelerate vaccine introduction in the future.

Health Research Policy and Systems
http://www.health-policy-systems.com/content
[Accessed 24 September 2016]
[Springer websites down for maintenance]

Humanitarian Exchange Magazine
Number 67 September 2016
http://odihpn.org/magazine/humanitarian-innovation/
Refugees and vulnerable migrants in Europe

This edition of Humanitarian Exchange is dedicated to the humanitarian response to the influx of refugees and vulnerable migrants into Europe over the past year.

One of the most notable features of the European response, as Pamela DeLargy notes in her lead article, is the central role volunteers have played – in stark contrast to the much slower response of international agencies and donors.

Laetitia de Radigues and Ludovico Gammarelli give an overview of the European Commission's response.

Key findings of research led by Coventry University on the complex picture of migration into Greece are summarised by Heaven Crawley.

Jessica Hagen-Zanker and Richard Mallett highlight the limitations of deterrence policies in determining people's migration choices.

Amelia Stoenescu and colleagues report on International Organisation for Migration (IOM) data and information-sharing systems to track movements in the Western Balkans.

Gareth Walker discusses the challenges of addressing the health needs of mobile populations. Returning to the issue of volunteerism, John Borton reflects on the potential implications for humanitarian action.

Emma Eggink and Melinda McRostie give a first-hand account of the evolution of the Starfish Foundation, a grassroots volunteer initiative on Lesvos.

The contribution of Hellenic Red Cross volunteers is highlighted by Kate Latimir.

Rachel Erskine and Katie Robertson outline RedR's training programme for volunteers.

In a pair of articles, Elodie Francart, Michaël Neuman and Angélique Muller reflect on Médecins Sans Frontières (MSF)'s experience in Brussels and northern France in engaging with NGOs, volunteer groups, municipal officials and political activists.

Alexandre Le Clève, Evangeline Masson-Diez and Olivier Peyroux underline the predicament of unaccompanied children in camps in northern France and along the Channel coast. Minh Tram Le and colleagues highlight the importance of infant and young child feeding for refugees stranded in Greece.

The edition ends with articles by Emily Whitehead and Theo Hannides and colleagues reflecting on the findings from an independent evaluation of the Start Network's collaborative response and the findings of Start-funded research on the information and communication needs of refugees in Greece and Germany.

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http://www.infectagentscancer.com/content
[Accessed 24 September 2016]
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http://www.idpjournal.com/content
[Accessed 24 September 2016]
[The BMC family of websites all down at inquiry]

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

International Journal of Epidemiology
Volume 45 Issue 3 June 2016
http://ije.oxfordjournals.org/content/current
[New issue: No relevant content identified]

International Journal of Infectious Diseases
September 2016 Volume 50, p1-90 Open Access
http://www.ijidonline.com/current
[New issue; No relevant content identified]

JAMA
September 20, 2016, Vol 316, No. 11
http://jama.jamanetwork.com/issue.aspx
Viewpoint

Ensuring Respect for Human Research Participants: Institutional Review Boards and Sharing Results From Research

Samuel N. Doernberg, BA; David Wendler, PhD

Excerpt

This Viewpoint proposes that institutional review boards play a larger role in ensuring timely public reporting of clinical trial results, with the goals of promoting medical innovation, reducing publication bias, and maximizing the value of clinical trials.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires that investigators report summary results of eligible clinical trials to ClinicalTrials.gov within 1 year of trial completion. This requirement is in part intended to promote medical innovation by enabling meta-analyses and further research based on the results of clinical trials.1 Sharing trial results helps to counteract a publication bias favoring positive trials that can "distort the evidence base" of clinical guidelines and patient care.2 In addition, sharing the results of clinical trials is important for ethical reasons: it helps to justify exposing participants to the risks of clinical trials and shows respect for those who assume these risks…

Special Communication

Antimicrobial Resistance FREE

Hilary D. Marston, MD, MPH; Dennis M. Dixon, PhD; Jane M. Knisely, PhD; Tara N. Palmore, MD; Anthony S. Fauci, MD

Abstract

Importance

The development of antibiotics is considered among the most important advances of modern science. Antibiotics have saved millions of lives. However, antimicrobial resistance (AMR) threatens this progress and presents significant risks to human health.

Objective

To identify factors associated with AMR, the current epidemiology of important resistant organisms, and possible solutions to the AMR problem.

Data Sources, Study Selection, and Data Synthesis

PubMed (2000-2016), NIH REPORTER, and ClinicalTrials.gov databases were searched for articles and entries related to AMR, focusing on epidemiology, clinical effects of AMR, discovery of novel agents to treat AMR bacterial infections, and nonpharmacological strategies to eliminate or modify AMR bacteria. In addition to articles and entries found in these databases, selected health policy reports and public health guidance documents were reviewed. Of 217 articles, databases, and reports identified, 103 were selected for review.

Results

The increase in AMR has been driven by a diverse set of factors, including inappropriate antibiotic prescribing and sales, use of antibiotics outside of the health care sector, and genetic factors intrinsic to bacteria. The problem has been exacerbated by inadequate economic incentives for pharmaceutical development of new antimicrobial agents. A range of specific AMR concerns, including carbapenem- and colistin-resistant gram-negative organisms, pose a clinical challenge. Alternative approaches to address the AMR threat include new methods of antibacterial drug identification and strategies that neutralize virulence factors.

Conclusions and Relevance

Antimicrobial resistance poses significant challenges for current clinical care. Modified use of antimicrobial agents and public health interventions, coupled with novel antimicrobial strategies, may help mitigate the effect of multidrug-resistant organisms in the future.

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

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

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

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

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

Journal of Health Care for the Poor and Underserved (JHCPU)
Volume 27, Number 3, August 2016
https://muse.jhu.edu/issue/33980
[Reviewed earlier]

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

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

[Reviewed earlier]

Journal of Infectious Diseases
Volume 214 Issue 8 October 15, 2016
http://jid.oxfordjournals.org/content/current
[New issue; No relevant digest content identified]

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

Journal of Medical Ethics
October 2016, Volume 42, Issue 10
http://jme.bmj.com/content/current
Extended essay
Fair subject selection in clinical research: formal equality of opportunity
Douglas MacKay
J Med Ethics 2016;42:672-677 Published Online First: 18 July 2016 doi:10.1136/medethics-2015-103311
Abstract
In this paper, I explore the ethics of subject selection in the context of biomedical research. I reject a key principle of what I shall refer to as the standard view. According to this principle, investigators should select participants so as to minimise aggregate risk to participants and maximise aggregate benefits to participants and society. On this view, investigators should exclude prospective participants who are more susceptible to risk than other prospective participants. I argue instead that investigators should select subjects in accordance with an alternative principle: formal equality of opportunity. According to this principle, investigators must treat all prospective participants the same unless differential treatment is warranted by the scientific goals of the study or the need to promote participants' medically related interests. All prospective participants (1) who meet the scientifically defined eligibility criteria and (2) for whom participation is consistent with their medically related interests should have an equal, formal opportunity to participate in the study. Prospective participants should not be excluded simply because they are more susceptible to risk than others.

Journal of Medical Internet Research
Vol 18, No 7 (2016): July
http://www.jmir.org/2016/7
[Reviewed earlier]

Journal of Medical Microbiology
Volume 65, Issue 8, August 2016
http://jmm.microbiologyresearch.org/content/journal/jmm/65/8;jsessionid=8n8h02en4abqh.x-sgm-live-02
[Reviewed earlier

Journal of Patient-Centered Research and Reviews
Volume 3, Issue 3 (2016)
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[Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)
Volume 5 Issue 24 September 2016
http://jpids.oxfordjournals.org/content/current
[Reviewed earlier]

Journal of Pediatrics
September 2016 Volume 176, p1-228
http://www.jpeds.com/current
[Reviewed earlier]

Journal of Public Health Policy
Volume 37, Issue 1 Supplement, September 2016
http://link.springer.com/journal/41271/37/1/suppl/page/1
[Reviewed earlier]

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

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

The Lancet
Sep 24, 2016 Volume 388 Number 10051 p1249-1348 e6
http://www.thelancet.com/journals/lancet/issue/current
Editorial
Access to medicines—the status quo is no longer an option

The Lancet
Last week, the much anticipated report of the UN Secretary-General's High-Level Panel on Access To Medicines, Promoting innovation & access to health technologies, was published. The independent panel sought recommendations to solve the disjunction between trade and the patent system with fulfilment of the right to health. This misalignment continues to be a barrier to affordable access to essential medicines.

The report's strong focus on the use of human rights as the basis of policies and on access to medicines in all countries is to be commended; as is the open documentation of statements of disagreement among the panel, or that some recommendations were not bold enough. Important were the renewed calls for an international R&D convention and more public financing for R&D. Concrete approaches to improve transparency, good governance, and accountability were all emphasised, including punitive action against parties that pressure countries that use TRIPS flexibilities.

The report was opposed by the US Government and the pharmaceutical industry whose attempts to dilute the report's recommendations and block its release have been widely reported. These tensions are not new. The existing intellectual property (IP) system serves these parties well where public health and human rights considerations are often omitted in pricing decisions and access to medical products and technologies. It is a pity no consensus was reached among panellists on renegotiating TRIPS and a new IP regime.

Nevertheless, the panel's recommendations are an important first step and it will be imperative for Ban Ki-moon to endorse them quickly, especially as momentum to approve the Trans-Pacific Partnership, which also has negative implications for access to medicines, is gathering in the USA. The Lancet Commission on Essential Medicines, to be published on Nov 8, 2016, will provide a timely platform to look at health innovation and access in the much wider context of comprehensive medicine policies. It will provide actionable recommendations that will complement and possibly leverage those of the panel's and reaffirm essential medicines as a keystone of the global health and development agenda.

Articles
Use of quantitative molecular diagnostic methods to identify causes of diarrhoea in children: a reanalysis of the GEMS case-control study
Jie Liu, James A Platts-Mills, Jane Juma, Furqan Kabir, Joseph Nkeze, Catherine Okoi, Darwin J Operario, Jashim Uddin, Shahnawaz Ahmed, Pedro L Alonso, Martin Antonio, Stephen M Becker, William C Blackwelder, Robert F Breiman, Abu S G Faruque, Barry Fields, Jean Gratz, Rashidul Haque, Anowar Hossain, M Jahangir Hossain, Sheikh Jarju, Farah Qamar, Najeeha Talat Iqbal, Brenda Kwambana, Inacio Mandomando, Timothy L McMurry, Caroline Ochieng, John B Ochieng, Melvin Ochieng, Clayton Onyango, Sandra Panchalingam, Adil Kalam, Fatima Aziz, Shahida Qureshi, Thandavarayan Ramamurthy, James H Roberts, Debasish Saha, Samba O Sow, Suzanne E Stroup, Dipika Sur, Boubou Tamboura, Mami Taniuchi, Sharon M Tennant, Deanna Toema, Yukun Wu, Anita Zaidi, James P Nataro, Karen L Kotloff, Myron M Levine, Eric R Houpt
Summary
Background
Diarrhoea is the second leading cause of mortality in children worldwide, but establishing the cause can be complicated by diverse diagnostic approaches and varying test characteristics. We

used quantitative molecular diagnostic methods to reassess causes of diarrhoea in the Global Enteric Multicenter Study (GEMS).

Methods

GEMS was a study of moderate to severe diarrhoea in children younger than 5 years in Africa and Asia. We used quantitative real-time PCR (qPCR) to test for 32 enteropathogens in stool samples from cases and matched asymptomatic controls from GEMS, and compared pathogen-specific attributable incidences with those found with the original GEMS microbiological methods, including culture, EIA, and reverse-transcriptase PCR. We calculated revised pathogen-specific burdens of disease and assessed causes in individual children.

Findings

We analysed 5304 sample pairs. For most pathogens, incidence was greater with qPCR than with the original methods, particularly for adenovirus 40/41 (around five times), Shigella spp or enteroinvasive Escherichia coli (EIEC) and Campylobactor jejuni o C coli (around two times), and heat-stable enterotoxin-producing E coli ([ST-ETEC] around 1·5 times). The six most attributable pathogens became, in descending order, Shigella spp, rotavirus, adenovirus 40/41, ST-ETEC, Cryptosporidium spp, and Campylobacter spp. Pathogen-attributable diarrhoeal burden was 89·3% (95% CI 83·2–96·0) at the population level, compared with 51·5% (48·0–55·0) in the original GEMS analysis. The top six pathogens accounted for 77·8% (74·6–80·9) of all attributable diarrhoea. With use of model-derived quantitative cutoffs to assess individual diarrhoeal cases, 2254 (42·5%) of 5304 cases had one diarrhoea-associated pathogen detected and 2063 (38·9%) had two or more, with Shigella spp and rotavirus being the pathogens most strongly associated with diarrhoea in children with mixed infections.

Interpretation

A quantitative molecular diagnostic approach improved population-level and case-level characterisation of the causes of diarrhoea and indicated a high burden of disease associated with six pathogens, for which targeted treatment should be prioritised.

Funding

Bill & Melinda Gates Foundation.

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

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

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

Medical Decision Making (MDM)
October 2016; 36 (7)
http://mdm.sagepub.com/content/current
[Reviewed earlier]

The Milbank Quarterly
A Multidisciplinary Journal of Population Health and Health Policy
September 2016 Volume 94, Issue 3 Pages 437–694
http://onlinelibrary.wiley.com/doi/10.1111/milq.2016.94.issue-3/issuetoc
Original Investigation
The Mass Production of Redundant, Misleading, and Conflicted Systematic Reviews and Meta-analyses (pages 485–514)
JOHN P.A. IOANNIDIS
Version of Record online: 13 SEP 2016 | DOI: 10.1111/1468-0009.12210
Abstract
Policy Points:
:: Currently, there is massive production of unnecessary, misleading, and conflicted systematic reviews and meta-analyses. Instead of promoting evidence-based medicine and health care, these instruments often serve mostly as easily produced publishable units or marketing tools.
:: Suboptimal systematic reviews and meta-analyses can be harmful given the major prestige and influence these types of studies have acquired.
:: The publication of systematic reviews and meta-analyses should be realigned to remove biases and vested interests and to integrate them better with the primary production of evidence.
Context
Currently, most systematic reviews and meta-analyses are done retrospectively with fragmented published information. This article aims to explore the growth of published systematic reviews and meta-analyses and to estimate how often they are redundant, misleading, or serving conflicted interests.
Methods
Data included information from PubMed surveys and from empirical evaluations of meta-analyses.
Findings
Publication of systematic reviews and meta-analyses has increased rapidly. In the period January 1, 1986, to December 4, 2015, PubMed tags 266,782 items as "systematic reviews" and 58,611 as "meta-analyses." Annual publications between 1991 and 2014 increased 2,728% for systematic reviews and 2,635% for meta-analyses versus only 153% for all PubMed-indexed items. Currently, probably more systematic reviews of trials than new randomized trials are published annually. Most topics addressed by meta-analyses of randomized trials have overlapping, redundant meta-analyses; same-topic meta-analyses may exceed 20 sometimes. Some fields produce massive numbers of meta-analyses; for example, 185 meta-analyses of antidepressants for depression were published between 2007 and 2014. These meta-analyses are often produced either by industry employees or by authors with industry ties and results are aligned with sponsor interests. China has rapidly become the most prolific producer of English-language, PubMed-indexed meta-analyses. The most massive presence of Chinese meta-analyses is on genetic associations (63% of global production in 2014), where almost all results

are misleading since they combine fragmented information from mostly abandoned era of candidate genes. Furthermore, many contracting companies working on evidence synthesis receive industry contracts to produce meta-analyses, many of which probably remain unpublished. Many other meta-analyses have serious flaws. Of the remaining, most have weak or insufficient evidence to inform decision making. Few systematic reviews and meta-analyses are both non-misleading and useful.
Conclusions
The production of systematic reviews and meta-analyses has reached epidemic proportions. Possibly, the large majority of produced systematic reviews and meta-analyses are unnecessary, misleading, and/or conflicted.

Nature
Volume 537 Number 7621 pp449-578 22 September 2016
http://www.nature.com/nature/current_issue.html
[New issue; No relevant digest content identified]

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

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

New England Journal of Medicine
September 22, 2016 Vol. 375 No. 12
http://www.nejm.org/toc/nejm/medical-journal
Perspective
Toward a Shared Vision for Cancer Genomic Data
R.L. Grossman and Others
Free Full Text

Incentives for Clinical Trialists to Share Data
B. Lo and D.L. DeMets
Free Full Text

Data Sharing at a Crossroads
F. Rockhold, P. Nisen, and A. Freeman
Free Full Text

Editorial
The Importance — and the Complexities — of Data Sharing

Jeffrey M. Drazen, M.D., Stephen Morrissey, Ph.D., Debra Malina, Ph.D., Mary Beth Hamel, M.D., and Edward W. Campion, M.D.
N Engl J Med 2016; 375:1182-1183 September 22, 2016 DOI: 10.1056/NEJMe1611027

We at the *Journal* are committed to making the sharing of clinical trial data an effective, efficient, and sustainable part of biomedical research. This issue of the Journal includes three Perspective articles on the topic of data sharing. Grossman et al. describe the Genomic Data Commons, which will initially house raw genomic data and diagnostic, histologic, and clinical outcome data from National Cancer Institute–funded projects.1 Lo and DeMets recommend steps for addressing clinical trialists' primary reservations about sharing their data.2 And Rockhold et al. consider progress to date and a path forward that could avert the creation of a fragmented data-sharing landscape.3 In August 2016, we published four Perspective articles on the same topic — two by experts who favored rapid open access to clinical trial data and two by other experts who were more reserved in their enthusiasm, focusing on the hurdles to be overcome.4-7 With these articles, and with others to come, our goal is to bring to the table a wide variety of opinions about the value, risks, unknowns, and rewards that accompany data sharing in the context of clinical trials. We firmly believe that complex issues are best clarified through open discussion and the airing of various viewpoints. Only by seeing the issue through many sets of eyes can we achieve the clarity we need to move forward. We hope that you will read each of these pieces with this idea in mind. Our enemy is disease and the human toll it takes. We need to use every means possible to come closer to vanquishing the real foe.

One of the best ways to make an idea a reality is to demonstrate its application. To that end, the Journal is sponsoring, with the help of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health, a contest to show how clinical trial data can be used to identify additional advances in human health that can be derived from a given data set. In November 2015, we published the primary outcome of the NHLBI Systolic Blood Pressure Intervention Trial (SPRINT) on the intensive treatment of hypertension.8 We now challenge clinical trialists, data analysts, and any other interested party to reanalyze the published SPRINT data, either alone or in combination with other publicly available data, to derive new insights or ideas. The SPRINT data will be made available on the NHLBI's BioLINCC website on November 1, 2016. We encourage you to use these data to generate new findings with the potential to improve our understanding of disease or patient care by participating in the NEJM SPRINT Data Analysis Challenge (http://challenge.nejm.org). The winners of the Challenge will be awarded prizes and will present their work at a live event at which researchers and patients will explore ways to align incentives for all toward the responsible and effective sharing of clinical trial data.

As we work through these complex issues, we want to make it clear that the Journal is committed to making data sharing part of our everyday business. Just as we introduced the inclusion of clinical trial protocols with the publication of all clinical trial research reports, we are working, in the same spirit of transparency, toward the goal of making data sharing a reality. We urge you to engage in the conversation by commenting on our published pieces at NEJM.org but more important by taking up the SPRINT Challenge.

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

[Reviewed earlier]

Pharmaceutics
Volume 8, Issue 3 (September 2016)
http://www.mdpi.com/1999-4923/8/3
[New issue; No relevant content identified]

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

PLOS Currents: Disasters
http://currents.plos.org/disasters/
[Accessed 24 September 2016]
[No new content identified]

PLoS Currents: Outbreaks
http://currents.plos.org/outbreaks/
Research Article
Experiences and Psychosocial Impact of West Africa Ebola Deployment on US Health Care Volunteers
September 21, 2016 ·
Background: This qualitative study was designed to assess health care volunteers' experiences and psychosocial impacts associated with deployment to the West Africa Ebola epidemic.
Methods: In 2015, using snowball sampling, 16 US health care volunteers who had recently returned from West Africa were recruited for this study. Semi-structured interviews were conducted to collect information associated with each phase of deployment (pre, peri, and post).
Results: Participants reported that they were motivated to volunteer because of a sense of responsibility and feelings of empathy and altruism. Immediately prior to deployment, most reported fear of contagion and death, as well as doubts regarding the adequacy of their training. Family members and close friends expressed high levels of concern regarding participants' decisions to volunteer. During the deployment, participants were fearful of exposure and reported feeling emotionally and physically exhausted. They also reported feeling frustrated by extreme resource limitations, poor management of the mission, lack of clearly defined roles and responsibilities, and inability to provide high quality care. Upon return home, participants felt a sense of isolation, depression, stigmatization, interpersonal difficulties, and extreme stress.
Conclusion: Preparedness of volunteers was suboptimal at each stage of deployment. All stakeholders, including volunteers, sponsoring organizations, government agencies, and professional organizations have a shared responsibility in ensuring that volunteers to medical missions are adequately prepared. This is especially critical for high risk deployments. Effective

policies and practices need to be developed and implemented in order to protect the health and well-being of health care volunteers to the fullest extent possible.

PLoS Medicine
http://www.plosmedicine.org/
(Accessed 24 September 2016)
Research Article
Reporting of Adverse Events in Published and Unpublished Studies of Health Care Interventions: A Systematic Review
Su Golder , Yoon K. Loke, Kath Wright, Gill Norman
Published: September 20, 2016
http://dx.doi.org/10.1371/journal.pmed.1002127
Abstract
Background
We performed a systematic review to assess whether we can quantify the underreporting of adverse events (AEs) in the published medical literature documenting the results of clinical trials as compared with other nonpublished sources, and whether we can measure the impact this underreporting has on systematic reviews of adverse events.
Methods and Findings
Studies were identified from 15 databases (including MEDLINE and Embase) and by handsearching, reference checking, internet searches, and contacting experts. The last database searches were conducted in July 2016. There were 28 methodological evaluations that met the inclusion criteria. Of these, 9 studies compared the proportion of trials reporting adverse events by publication status.
The median percentage of published documents with adverse events information was 46% compared to 95% in the corresponding unpublished documents. There was a similar pattern with unmatched studies, for which 43% of published studies contained adverse events information compared to 83% of unpublished studies.
A total of 11 studies compared the numbers of adverse events in matched published and unpublished documents. The percentage of adverse events that would have been missed had each analysis relied only on the published versions varied between 43% and 100%, with a median of 64%. Within these 11 studies, 24 comparisons of named adverse events such as death, suicide, or respiratory adverse events were undertaken. In 18 of the 24 comparisons, the number of named adverse events was higher in unpublished than published documents. Additionally, 2 other studies demonstrated that there are substantially more types of adverse events reported in matched unpublished than published documents. There were 20 meta-analyses that reported the odds ratios (ORs) and/or risk ratios (RRs) for adverse events with and without unpublished data. Inclusion of unpublished data increased the precision of the pooled estimates (narrower 95% confidence intervals) in 15 of the 20 pooled analyses, but did not markedly change the direction or statistical significance of the risk in most cases.
The main limitations of this review are that the included case examples represent only a small number amongst thousands of meta-analyses of harms and that the included studies may suffer from publication bias, whereby substantial differences between published and unpublished data are more likely to be published.
Conclusions
There is strong evidence that much of the information on adverse events remains unpublished and that the number and range of adverse events is higher in unpublished than in published

versions of the same study. The inclusion of unpublished data can also reduce the imprecision of pooled effect estimates during meta-analysis of adverse events.

PLoS Neglected Tropical Diseases
http://www.plosntds.org/
[Accessed 24 September 2016]
[No new relevant content identified]

PLoS One
http://www.plosone.org/
[Accessed 24 September 2016]
[No new relevant content identified]

PLoS Pathogens
http://journals.plos.org/plospathogens/
(Accessed 24 September 2016)
[No new relevant content identified]

PNAS - Proceedings of the National Academy of Sciences of the United States of America
http://www.pnas.org/content/early/
(Accessed 24 September 2016)
[No new relevant content identified]

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

Preventive Medicine
Volume 90, Pages 1-222 (September 2016)
http://www.sciencedirect.com/science/journal/00917435/90
[New issue; No relevant content identified]

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

Public Health Ethics

Volume 9 Issue 24 September 2016
http://phe.oxfordjournals.org/content/current
[Reviewed earlier]

Public Health Reports
September/October 2016; 131 (5)
http://phr.sagepub.com/content/current
[Reviewed earlier]

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

Reproductive Health
http://www.reproductive-health-journal.com/content
[Accessed 24 September 2016]
[The BMC family of websites all down at inquiry]

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

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

Risk Management and Healthcare Policy
Volume 9, 2016
https://www.dovepress.com/risk-management-and-healthcare-policy-archive56
[Accessed 24 September 2016]
No new content identified]

Science
23 September 2016 Vol 353, Issue 6306
http://www.sciencemag.org/current.dtl
EDITORIAL

Speaking of insects…
May R. Berenbaum
Summary
Given that Aedes aegypti, the main mosquito vector of Zika virus, has been an intense focus of public health attention in the Americas, most recently in Florida, it seems apt that next week, 7000 entomologists from around the world will converge on Orlando, Florida, for the 25th International Congress of Entomology (ICE), where, among other activities, 175 discipline thought-leaders will join policy-makers and other experts to address "Improving the Human Condition through Insect Science." The ICE summit's goals are to define the major global insect-related challenges—from arthropod-borne diseases to the protection of beneficial species—and plan collaborative efforts to meet these challenges through research and technology. These "grand challenges" aren't new. What's new, however, is an explicit effort to address one of the greatest challenges: effective engagement with the public about the value of insect science.

Science Translational Medicine
21 September 2016 Vol 8, Issue 357
http://stm.sciencemag.org/
[New issue: No relevant content identified]

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

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

Vaccine
Volume 34, Issue 41, Pages 4843-5048 (22 September 2016)
http://www.sciencedirect.com/science/journal/0264410X/34/41
Conference report
Challenges and opportunities in RSV vaccine development: Meeting report from FDA/NIH workshop
Pages 4843-4849
Jeffrey N. Roberts, Barney S. Graham, Ruth A. Karron, Flor M. Munoz, Ann R. Falsey, Larry J. Anderson, V. Marshall, Sonnie Kim, Judy A. Beeler
Abstract
Respiratory syncytial virus (RSV) is the most common cause of serious acute lower respiratory illness in infants and young children and a significant cause of disease burden in the elderly and immunocompromised. There are no licensed RSV vaccines to address this significant public health need. While advances in vaccine technologies have led to a recent resurgence in RSV

vaccine development, the immune correlates of protection against RSV and the immunology of vaccine-associated enhanced respiratory disease (ERD) remain poorly understood.
FDA's Center for Biologics Evaluation and Research (CBER) and NIH's National Institute of Allergy and Infectious Diseases (NIAID) organized and co-sponsored an RSV Vaccines Workshop in Bethesda, Maryland on June 1 and 2, 2015. The goal of the conference was to convene scientists, regulators, and industry stakeholders to discuss approaches to RSV vaccine development within the context of three target populations - infants and children, pregnant women, and individuals >60 years of age. The agenda included topics related to RSV vaccine development in general, as well as considerations specific to each target population, such as clinical and serological endpoints. The meeting focused on vaccine development for high income countries (HIC), because issues relevant to vaccine development for low and middle income countries (LMIC) have been discussed in other forums. This manuscript summarizes the discussion of clinical, scientific, and regulatory perspectives, research gaps, and lessons learned.

Influenza vaccination coverages among high risk subjects and health care workers in Spain. Results of two consecutive National Health Surveys (2011–2014)
Original Research Article
Pages 4898-4904
Jenaro Astray-Mochales, Ana López de Andres, Valentín Hernandez-Barrera, Cristina Rodríguez-Rieiro, Pilar Carrasco Garrido, María D. Esteban-Vasallo, Maria Felicitas Domínguez-Berjón, Isabel Jimenez-Trujillo, Rodrigo Jiménez-García
Abstract
Objectives
We aim to describe influenza vaccination coverage for the Spanish population using data from two consecutive nation-wide representative health surveys. The data was analysed by high risk groups, health care workers (HCWs) and immigrants. Also, coverage trends were analysed.
Material and methods
The 2011/12 Spanish National Health Survey (N = 21,007) and the 2014 European Health Interview Survey for Spain (N = 22,842) were analysed. Influenza vaccination status was self-reported. Time trends for were estimated by a multivariate logistic regression model.
Results
Overall vaccination uptake was similar in 2011/12 and 2014, 19.1% and 18.9%, respectively, ($p > 0.05$). 47% of the subjects surveyed were in the groups for which vaccination was recommended with coverages of 41.1% in 2011/12 and 40% in 2014 ($p > 0.05$).
In both surveys, uptake among subjects with a chronic disease was three times higher than uptake in subjects who did not have these diseases.
In 2011/12 and 2014, 20% and 27.6% of health workers were vaccinated. Subjects born outside Spain were vaccinated less frequently than Spanish-born subjects (9.3% vs 20.4% and 8.9% vs 20%).
Within the diseases studied, the best uptake was for patients with heart disease (52.5% in 2011/12 and 51.1% in 2014) and patients with diabetes (50.5% and 51.8%).
Multivariate analysis showed that older age, having a chronic disease or being a HCW increases the possibility of being vaccinated whereas being born outside Spain decreased it.
Conclusions
Seasonal influenza vaccine uptake rates in the recommended target groups, patients with chronic conditions and health care workers, in Spain are unacceptably low and seem to be stable in the post pandemic seasons. This finding should alert health authorities to the need to

work directly with health care providers on the indications for this vaccine and to study strategies that make it possible to increase vaccination uptake.

Rotavirus vaccine effectiveness in Hong Kong children

Original Research Article
Pages 4935-4942
Karene Hoi Ting Yeung, Jacqueline E. Tate, Ching Ching Chan, Martin C.W. Chan, Paul K.S. Chan, Kin Hung Poon, Sylvia Luen Yee Siu, Genevieve Po Gee Fung, Kwok Leung Ng, Iris Mei Ching Chan, Pui Tak Yu, Chi Hang Ng, Yu Lung Lau, E. Anthony S. Nelson
Abstract
Background
Rotavirus is a common infectious cause of childhood hospitalisation in Hong Kong. Rotavirus vaccines have been used in the private sector since licensure in 2006 but have not been incorporated in the government's universal Childhood Immunisation Programme. This study aimed to evaluate rotavirus vaccine effectiveness against hospitalisation.
Methods
This case-control study was conducted in the 2014/2015 rotavirus season in six public hospitals. Hospitalised acute gastroenteritis patients meeting inclusion criteria were recruited and copies of their immunisation records were collected. Case-patients were defined as enrolled subjects with stool specimens obtained in the first 48 h of hospitalisation that tested positive for rotavirus, whereas control-patients were those with stool specimens obtained in the first 48 h of hospitalisation testing negative for rotavirus. Vaccine effectiveness for administration of at least one dose of either Rotarix® (GlaxoSmithKline Biologicals) or RotaTeq® (Merck Research Laboratories) was calculated as 1 minus the odds ratio for rotavirus vaccination history for case-patients versus control-patients.
Results
Among the 525 eligible subjects recruited, immunisation records were seen in 404 (77%) subjects. 31% (162/525 and 126/404) tested positive for rotavirus. In the 404 subjects assessed for vaccine effectiveness, 2.4% and 24% received at least 1 dose of either rotavirus vaccine in case- and control-patients respectively. The unmatched vaccine effectiveness against hospitalisation for administration of at least one dose of either rotavirus vaccines was 92% (95% confidence interval [CI]: 75%, 98%). The matched analyses by age only and both age and admission date showed 96% (95% CI: 72%, 100%) and 89% (95% CI: 51%, 97%) protection against rotavirus hospitalisation respectively.
Conclusions
Rotavirus vaccine is highly effective in preventing hospitalisation from rotavirus disease in young Hong Kong children.

Comparative analysis of the Parent Attitudes about Childhood Vaccines (PACV) short scale and the five categories of vaccine acceptance identified by Gust et al.

Original Research Article
Pages 4964-4968
Omolade Oladejo, Kristen Allen, Avnika Amin, Paula M. Frew, Robert A. Bednarczyk, Saad B. Omer
Abstract
Background
There is a need to develop a standardized tool to aid in identifying, measuring and classifying the unique needs of vaccine-hesitant parents (VHPs). This will also assist in designing tailored

interventions to address these needs. The Parental Attitude about Childhood Vaccines (PACV) short scale developed by Opel et al., and the Gust et al. vaccine acceptance categories have been acknowledged as potentially useful tools to measure parental vaccine hesitancy. The PACV short scale requires further validation. In our study, we evaluated how the Gust et al. vaccine acceptance categories correspond with the PACV short scale.
Methods
As part of a larger study on vaccine attitudes, using the PACV short scale and Gust et al. vaccine acceptance categories, we assessed the correlation between the two measures using Spearman correlation coefficient, and the association between the two measures using the Cochran-Mantel-Haentszel test of association. We used logistic regression modelling to compare the association between a child's up-to-date immunization status and (a) PACV short scale and (b) Gust et al. vaccine acceptance categories.
Results
The PACV short scale and Gust et al. vaccine acceptance categories were positively correlated ($r = 0.6$, $df = 198$, $p < 0.05$), and the Cochran-Mantel-Haentszel test of association yielded a statistically significant association ($p < 0.05$). The two scales similarly predicted children's up-to-date immunization status for all recommended childhood vaccines.
Conclusion
The ability of the PACV short scale to identify and classify parental vaccine hesitancy is similar to classification using Gust et al. vaccine acceptance categories, and both measure linear entities. The PACV short scale is recommended for screening parents at their first pediatric visit because it is easier to administer. A clearer understanding of how to classify parental vaccine hesitancy can be used to design tailored interventions based on these classifications, to address their specific needs.

Modification and validation of the Treatment Self Regulation Questionnaire to assess parental motivation for HPV vaccination of adolescents

Original Research Article
Pages 4985-4990
Deanna C. Denman, Austin S. Baldwin, Emily G. Marks, Simon C. Lee, Jasmin A. Tiro
Abstract
Background
According to Self-Determination Theory, the extent to which the motivation underlying behavior is self-determined or controlled influences its sustainability. This is particularly relevant for behaviors that must be repeated, such as completion of the human papillomavirus (HPV) vaccine series. To date, no measures of motivation for HPV vaccination have been developed.
Methods
As part of a larger study, parents ($N = 223$) whose adolescents receive care at safety-net clinics completed a telephone questionnaire about HPV and the vaccine. We modified the Treatment Self-Regulation Questionnaire to assess parents' motivation for HPV vaccination in both Spanish and English. We used confirmatory factor analysis to test a three-factor measurement model.
Results
The three-factor model fit the data well (RMSEA = 0.04, CFI = 0.98, TLI = 0.96), and the scales' reliabilities were adequate (autonomous: $\alpha = 0.87$; introjected: $\alpha = 0.72$; external: $\alpha = 0.72$). The factor loading strength for one item was stronger for Spanish- than English-speaking participants ($p < 0.05$); all others were equivalent. The intercorrelations among the scales ranged from -0.17 to 0.32, suggesting discriminant factors. The scales displayed the expected pattern of correlations with other psychosocial determinants of behavior. Vaccination

intentions showed a strong correlation with autonomous motivation (r = 0.52), but no correlation with external motivation (r = 0.02), suggesting autonomous motivation may be particularly important in vaccine decision-making.
Conclusion
Findings support the use of three subscales to measure motivation in HPV vaccination and suggest possible cultural differences in motivation.

Re-designing the Mozambique vaccine supply chain to improve access to vaccines
Original Research Article
Pages 4998-5004
Bruce Y. Lee, Leila A. Haidari, Wendy Prosser, Diana L. Connor, Ruth Bechtel, Amelia Dipuve, Hidayat Kassim, Balbina Khanlawia, Shawn T. Brown
Abstract
Introduction
Populations and routine childhood vaccine regimens have changed substantially since supply chains were designed in the 1980s, and introducing new vaccines during the "Decade of Vaccine" may exacerbate existing bottlenecks, further inhibiting the flow of all vaccines.
Methods
Working with the Mozambique Ministry of Health, our team implemented a new process that integrated HERMES computational simulation modeling and on-the-ground implementers to evaluate and improve the Mozambique vaccine supply chain using a system-re-design that integrated new supply chain structures, information technology, equipment, personnel, and policies.
Results
The alternative system design raised vaccine availability (from 66% to 93% in Gaza; from 76% to 84% in Cabo Delgado) and reduced the logistics cost per dose administered (from $0.53 to $0.32 in Gaza; from $0.38 to $0.24 in Cabo Delgado) as compared to the multi-tiered system under the current EPI. The alternative system also produced higher availability at lower costs after new vaccine introductions. Since reviewing scenarios modeling deliveries every two months in the north of Gaza, the provincial directorate has decided to pilot this approach diverging from decades of policies dictating monthly deliveries.
Discussion
Re-design improved not only supply chain efficacy but also efficiency, important since resources to deliver vaccines are limited. The Mozambique experience and process can serve as a model for other countries during the Decade of Vaccines. For the Decade of Vaccines, getting vaccines at affordable prices to the market is not enough. Vaccines must reach the population to be successful.

Vaccine hesitancy among healthcare workers in Europe: A qualitative study
Original Research Article
Pages 5013-5020
Emilie Karafillakis, Irina Dinca, Franklin Apfel, Sabrina Cecconi, Andrea Wűrz, Judit Takacs, Jonathan Suk, Lucia Pastore Celentano, Piotr Kramarz, Heidi J. Larson
Abstract
Healthcare workers (HCWs) are often referred to as the most trusted source of vaccine-related information for their patients. However, the evidence suggests that a number of HCWs are vaccine-hesitant. This study consists of 65 semi-structured interviews with vaccine providers in Croatia, France, Greece, and Romania to investigate concerns HCWs might have about

vaccination. The results revealed that vaccine hesitancy is present in all four countries among vaccine providers. The most important concern across all countries was the fear of vaccine side effects. New vaccines were singled out due to perceived lack of testing for vaccine safety and efficacy. Furthermore, while high trust in health authorities was expressed by HCWs, there was also strong mistrust of pharmaceutical companies due to perceived financial interests and lack of communication about side effects. The notion that it is a doctor's responsibility to respond to hesitant patients was reported in all countries. Concerns were also seen to be country- and context-specific. Strategies to improve confidence in vaccines should be adapted to the specific political, social, cultural and economic context of countries. Furthermore, while most interventions focus on education and improving information about vaccine safety, effectiveness, or the need for vaccines, concerns raised in this study identify other determinants of hesitancy that need addressing. The representativeness of the views of the interviewed HCWs must be interpreted with caution. This a qualitative study with a small sample size that included geographical areas where vaccination uptake was lower or where hesitancy was more prevalent and it reflects individual participants' beliefs and attitudes toward the topic. As HCWs have the potential of influencing patient vaccination uptake, it is crucial to improve their confidence in vaccination and engage them in activities targeting vaccine hesitancy among their patients.

Using the 4 Pillars™ Practice Transformation Program to increase adult Tdap immunization in a randomized controlled cluster trial

Original Research Article
Pages 5026-5033
Mary Patricia Nowalk, Chyongchiou J. Lin, Valory N. Pavlik, Anthony E. Brown, Song Zhang, Krissy K. Moehling, Jonathan M. Raviotta, Jeannette E. South-Paul, Mary Hawk, Edmund M. Ricci, Donald B. Middleton, Suchita A. Patel, Faruque Ahmed, Richard K. Zimmerman

Abstract
Introduction
National adult Tdap vaccination rates are low, reinforcing the need to increase vaccination efforts in primary care offices. The 4 Pillars™ Practice Transformation Program is an evidence-based, step-by-step guide to improving primary care adult vaccination with an online implementation tracking dashboard. This study tested the effectiveness of an intervention to increase adult Tdap vaccination that included the 4 Pillars™ Program, provider education, and one-on-one coaching of practice-based immunization champions.
Methods
25 primary care practices participated in a randomized controlled cluster trial (RCCT) in Year 1 (6/1/2013–5/31/2014) and a pre-post study in Year 2 (6/1/2014–1/31/2015). Baseline year was 6/1/2012–5/31/2013, with data analyzed in 2016. Demographic and vaccination data were derived from de-identified electronic medical record (EMR) extractions. The primary outcomes were vaccination rates and percentage point (PP) changes/year.
Results
The cohort consisted of 70,549 patients ⩾18 years who were seen in the practices ⩾1 time each year, with a baseline mean age = 55 years; 35% were men; 56% were non-white; 35% were Hispanic and 20% were on Medicare. Baseline vaccination rate averaged 35%. In the Year 1 RCCT, cumulative Tdap vaccination increased significantly in both intervention and control groups; in both cities, the percentage point increases in the intervention groups (7.7 PP in Pittsburgh and 9.9 PP in Houston) were significantly higher ($P < 0.001$) than in the control groups (6.4 PP in Pittsburgh and 7.6 PP in Houston). In the Year 2 pre-post study, in both

cities, active intervention groups increased rates significantly more (6.2 PP for both) than maintenance groups (2.2 PP in Pittsburgh and 4.1 PP in Houston; P < 0.001).
Conclusions
An intervention that includes the 4 Pillars™ Practice Transformation Program, staff education and coaching is effective for increasing adult Tdap immunization rates within primary care practices.
Clinical Trial Registry Name/Number: NCT01868334

Acceptance of multiple injectable vaccines in a single immunization visit in The Gambia pre and post introduction of inactivated polio vaccine
Original Research Article
Pages 5034-5039
Olubukola T. Idoko, Lee M. Hampton, Robert B. Mboizi, Schadrac C. Agbla, Aaron S. Wallace, Jennifer B. Harris, Dawda Sowe, Daniel C. Ehlman, Beate Kampmann, Martin O. Ota, Terri B. Hyde
Abstract
Background
As the World Health Organization (WHO) currently recommends that children be protected against 11 different pathogens, it is becoming increasingly necessary to administer multiple injectable vaccines during a single immunization visit. In this study we assess Gambian healthcare providers' and infant caregivers' attitudes and practices related to the administration of multiple injectable vaccines to a child at a single immunization visit before and after the 2015 introduction of inactivated polio vaccine (IPV). IPV introduction increased the number of injectable vaccines recommended for the 4-month immunization visit from two to three in The Gambia.
Methods
We conducted a cross-sectional questionnaire-based survey before and after the introduction of IPV at 4 months of age in a representative sample of all health facilities providing immunizations in The Gambia. Healthcare providers who administer vaccines at the selected health facilities and caregivers who brought infants for their 4 month immunization visit were surveyed.
Findings
Prior to IPV introduction, 9.9% of healthcare providers and 35.7% of infant caregivers expressed concern about a child receiving more than 2 injections in a single visit. Nevertheless, 98.8% and 90.9% of infants received all required vaccinations for the visit before and after IPV introduction, respectively. The only reason why vaccines were not received was vaccine stock-outs. Infant caregivers generally agreed that vaccinators could be trusted to provide accurate information regarding the number of vaccines that a child needed.
Conclusion
Healthcare providers and infant caregivers in this resource limited setting accepted an increase in the number of injectable vaccines administered at a single visit even though some expressed concerns about the increase.

Vaccine: Development and Therapy
https://www.dovepress.com/vaccine-development-and-therapy-archive111
(Accessed 24 September 2016)
[No new content]

Vaccines — Open Access Journal
http://www.mdpi.com/journal/vaccines
(Accessed 24 September 2016)
[No new relevant content]

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

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

Vaccine
Available online 16 September 2016
Stakeholders' perceptions of 10years of the Global Action Plan for Influenza Vaccines (GAP)–Results from a survey
C Nannei, S Goldin, G Torelli, H Fatima, K Kumar… -
Open Access funded by World Health Organization
Abstract
Ten years after the launch of the Global Action Plan for Influenza Vaccines (GAP), the World Health Organization (WHO) surveyed stakeholders to understand their perceptions of what the programme had achieved. This article provides a summary of the findings; the full report will be available on-line on the GAP website in November 2016 (http://www.who.int/influenza_vaccines_plan/en/). Seventy-seven responses were received from stakeholders including medical doctors, national influenza center officials, country immunization programme teams, surveillance and disease centers, policy-makers, researchers, vaccine manufacturers, and non-governmental organizations from 28 countries, representing all six WHO regions.

Respondents cited GAP's biggest successes as capacity building in developing countries; raising international awareness of global needs in the event of a pandemic; and collaborative alignment of influenza stakeholders. The most commonly reported challenges were the limited progress in development of a broadly protective or universal vaccine and the perceived absence of a major increase in seasonal demand. These findings aligned with the perception that less global progress had been made under the third GAP objective, focused on research and development of better vaccines, than on increasing seasonal vaccine use (objective 1) and pandemic vaccine production capacity (objective 2). Respondents explained what they saw as the major challenges to development of better vaccines, including to development of a universal influenza vaccine. The majority of respondents agreed that the goal chosen at the GAP II consultation is still relevant. Results highlighted the importance of promoting research and development of better vaccines, both for facilitating uptake of seasonal vaccines and for ensuring timely vaccine availability in the event of a pandemic. As the GAP concludes its

mandate this year, these findings will contribute to discussions on the impact of programme closure and how to address the key issues facing influenza stakeholders thereafter.

Vaccine
Available online 16 September 2016
A global review of national influenza immunization policies: Analysis of the 2014 WHO/UNICEF Joint Reporting Form on immunization
JR Ortiz, M Perut, L Dumolard, PR Wijesinghe…
Abstract
Introduction
The WHO recommends annual influenza vaccination to prevent influenza illness in high-risk groups. Little is known about national influenza immunization policies globally.
Material and Methods
The 2014 WHO/UNICEF Joint Reporting Form (JRF) on Immunization was adapted to capture data on influenza immunization policies. We combined this dataset with additional JRF information on new vaccine introductions and strength of immunization programmes, as well as publicly available data on country economic status. Data from countries that did not complete the JRF were sought through additional sources. We described data on country influenza immunization policies and used bivariate analyses to identify factors associated with having such policies.
Results
Of 194 WHO Member States, 115 (59%) reported having a national influenza immunization policy in 2014. Among countries with a national policy, programmes target specific WHO-defined risk groups, including pregnant women (42%), young children (28%), adults with chronic illnesses (46%), the elderly (45%), and health care workers (47%). The Americas, Europe, and Western Pacific were the WHO regions that had the highest percentages of countries reporting that they had national influenza immunization policies. Compared to countries without policies, countries with policies were significantly more likely to have the following characteristics: to be high or upper middle income ($p < 0.0001$); to have introduced birth dose hepatitis B virus vaccine ($p < 0.0001$), pneumococcal conjugate vaccine ($p = 0.032$), or human papilloma virus vaccine ($p = 0.002$); to have achieved global goals for diphtheria-tetanus-pertussis vaccine coverage ($p < 0.0001$); and to have a functioning National Immunization Technical Advisory Group ($p < 0.0001$).
Conclusions
The 2014 revision of the JRF permitted a global assessment of national influenza immunization policies. The 59% of countries reporting that they had policies are wealthier, use more new or under-utilized vaccines, and have stronger immunization systems. Addressing disparities in public health resources and strengthening immunization systems may facilitate influenza vaccine introduction and use.

* * * *

Media/Policy Watch

This section is intended to alert readers to substantive news, analysis and opinion from the general media on vaccines, immunization, global; public health and related themes. *Media Watch* is not intended to be exhaustive, but indicative of themes and issues CVEP is actively

tracking. This section will grow from an initial base of newspapers, magazines and blog sources, and is segregated from *Journal Watch* above which scans the peer-reviewed journal ecology.

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

The Atlantic
http://www.theatlantic.com/magazine/
Accessed 24 September 2016
How the Rise of Cities Helped Mosquitoes Thrive
An explorer who searched for ways to avoid *Aedes Aegypti* may have hastened its spread.
21 September 2016

BBC
http://www.bbc.co.uk/
Accessed 24 September 2016
[No new, unique, relevant content]

The Economist
http://www.economist.com/
Accessed 24 September 2016
[No new, unique, relevant content]

Financial Times
http://www.ft.com/home/uk
Accessed 24 September 2016
[No new, unique, relevant content]

Forbes
http://www.forbes.com/
Accessed 24 September 2016
Are We Unprepared For Another Ebola Outbreak?
John LaMattina, Contributor
16 September 2016
…Osterholm is correct in stating that things have gone relatively quiet on Ebola. But does that mean that nothing is happening on the R&D front? Actually, a check of clinicaltrials.gov lists 71 studies ongoing in Ebola, the majority of which involve studying novel vaccines or drugs in humans…

Foreign Affairs
http://www.foreignaffairs.com/
Accessed 24 September 2016
[No new, unique, relevant content]

Foreign Policy

http://foreignpolicy.com/
Accessed 24 September 2016
The Refugee Crisis Is Real: By Madeleine Albright, David Miliband
Which is why we so desperately need a global deal to bolster a broken system. And if the United Nations won't do it, the United States must.
19 September 2016

The Guardian
http://www.guardiannews.com/
Accessed 24 September 2016
[No new, unique, relevant content]

New Yorker
http://www.newyorker.com/
Accessed 24 September 2016
[No new, unique, relevant content]

New York Times
http://www.nytimes.com/
Accessed 24 September 2016
Examining the U.N.'s Record on Urgent Global Challenges
19 September 2016
How well is the United Nations performing on the most vital global challenges of the past decade? We examine the organization's track record on refugees, war and peace, human rights, terrorism, gender equality and climate change, with experts offering their assessments.

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A New DFID-Global Fund Performance Agreement: 10 Benchmarks to Achieve Maximum Impact
22 September 2016

Turns Out, Development Does Bring Development
21 September 2016

The Social Progress Index is an effort of the Social Progress Imperative to create a new and better way to compare the human and social development performance of countries. High on their agenda is to *not* use GDP per capita or other measures of national development, but rather focus on direct measures of human well-being. And it turns out to be a useful measure of the importance of national development.

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

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