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

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

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

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

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Milestones :: Perspectives

New global commitment to end tuberculosis

News release

17 November 2017 | MOSCOW/GENEVA - Today 75 ministers agreed to take urgent action to end tuberculosis (TB) by 2030. The announcement came at the first WHO Global Ministerial Conference on Ending Tuberculosis in the Sustainable Development Era: A Multisectoral Response, which brought together delegates from 114 countries in Moscow. President Vladimir Putin of the Russian Federation opened the Conference, together with Amina J Mohammed, UN Deputy Secretary General, and Dr Tedros Adhanom Ghebreyesus, WHO Director-General.

"Today marks a critical landmark in the fight to end TB," said Dr Tedros. "It signals a long overdue global commitment to stop the death and suffering caused by this ancient killer."
The Moscow Declaration to End TB is a promise to increase multisectoral action as well as track progress, and build accountability. It will also inform the first UN General Assembly High-Level Meeting on TB in 2018, which will seek further commitments from heads of state.

Global efforts to combat TB have saved an estimated 53 million lives since 2000 and reduced the TB mortality rate by 37%. However, progress in many countries has stalled, global targets are off-track, and persistent gaps remain in TB care and prevention.

As a result, TB still kills more people than any other infectious disease. There are major problems associated with antimicrobial resistance, and it is the leading killer of people with HIV.

"One of the main problems has been a lack of political will and inadequate investment in fighting TB," added Dr Tedros. "Today's declaration must go hand-in-hand with increased investment."

The meeting was attended by ministers and country delegations, as well as representatives of civil society and international organizations, scientists, and researchers. More than 1000 participants took part in the two-day conference which resulted in collective commitment to ramp up action on four fronts:
[1] Move rapidly to achieve universal health coverage by strengthening health systems and improving access to people-centered TB prevention and care, ensuring no one is left behind.

[2] Mobilize sufficient and sustainable financing through increased domestic and international investments to close gaps in implementation and research.

[3] Advance research and development of new tools to diagnose, treat, and prevent TB.

[4] Build accountability through a framework to track and review progress on ending TB, including multisectoral approaches.

Ministers also promised to minimize the risk and spread of drug resistance and do more to engage people and communities affected by, and at risk of, TB.

The Russian Federation, host of the first Ministerial Conference to End TB, welcomed the Moscow Declaration. "Tuberculosis is a complex, multi-sectoral problem that requires a systemic

and highly coordinated response to address the conditions which drive the disease," said Professor Veronika Skvortsova, Minister of Health, Russian Federation. "The accountability framework we have agreed to develop marks a new beginning, and, with WHO's support to coordinate and track progress, we expect the Moscow Declaration to lead us forward to the high-level meeting of the UN General Assembly in 2018."

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Ending TB means investing in R&D

Joint statement from Aeras, FIND, and TB Alliance

November 17, 2017

This week, as health ministers, diplomats and other representatives meet to discuss tuberculosis (TB) at the World Health Organization (WHO) Ministerial Conference in Moscow, millions of people are suffering from the disease. The governments around the world can and must end this suffering through a major and sustained investment in TB research and development (R&D).

There were 10.4 million new cases of active TB in 2016—of which only 6 million were diagnosed and notified. Drug-resistant infections are on the rise. There remains a dire need for better, faster-acting drugs, a new vaccine, and technologies that quickly diagnose TB and determine the degree of drug-resistance.

Science is not holding us back, funding and political will to implement is.

The WHO estimates that R&D budgets need more than US$1 billion annually to turn around the odds of patients potentially losing years of their lives to a toxic treatment course, missing the opportunity for treatment due to poor diagnostics, or contracting TB in the first place because of an ineffective vaccine.

The WHO also reports that despite accounting for about 2 percent of deaths globally, TB receives only 0.25 percent of the estimated US$265 billion spent worldwide on medical research each year.

Simply put, TB science is woefully underfunded. Governments must work together to dramatically reshape the investment landscape.

Today, the time needed to treat drug-resistant TB ranges from nine months to two years or more—and yet in common practice the success rate is only about 50 percent. The majority of drugs that these patients are given are probably not helping at all—but they are producing side effects, everything from nausea and dizziness to deafness and kidney failure. For some, the treatment can be worse than the disease itself.

A true point of care test is needed to find the 4 million missing patients every year, where and when they first seek care. New diagnostic technology is critical to ensure that the right treatment regimens are used—right from the start—to prevent the lengthy and arduous road to diagnosis and cure faced by many patients.

Making matters worse, there is no vaccine that can effectively play a major role in eliminating this disease. Today, the Bacillus Calmette–Guérin vaccine is the only TB vaccine available. It is

nearly a century old, only moderately effective in preventing severe TB in infants and young children, and it doesn't adequately protect teens and adults, who are most at risk for developing and spreading TB.

Progress has been made but we need a greater commitment. There are 12 different TB vaccine candidates in clinical trials today, a significant increase from 2000—when there were zero. Data from multiple mid- and late-stage efficacy trials will become available over the next 3 years, providing data that will help optimize and accelerate TB vaccine development. But it will take a significant increase in resources to achieve critical breakthroughs—and to reach success quickly Similarly, only a handful of drug candidates were being tested in clinical trials. Today there are more than 30. Two new experimental treatments show promise—one that might be able to cure all forms of TB except for the most drug-resistant strains (known as extensively drug-resistant TB or XDR-TB), and another that might be able to cure XDR-TB. Both could take substantially less time and money than current treatments.

At first glance, the TB diagnostics pipeline looks healthy. However, emerging game-changers are at risk due to underfunding at the clinical trial stage. In addition, very few diagnostic candidates would address the most critical need—a point of care test for primary care facilities. Diversification of the point of care pipeline, and identification of new biomarkers are urgently needed.

While the meeting in Moscow will inform future discourse on TB, it must also serve as a springboard toward decisive action against the disease. TB is the world's deadliest infectious disease and efforts to curb it remain underfunded. We are calling on governments to make major commitments to fund the R&D that will end TB once and for all.

Catharina Boehme, CEO, FIND
Jacqueline Shea, CEO, AERAS
Mel Spigelman, President and CEO, TB Alliance

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Global Fund Appoints Peter Sands as Executive Director

14 November 2017 *News Release*
GENEVA – The Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria today appointed a new Executive Director: Peter Sands, a former chief executive of Standard Chartered Bank who after a distinguished career in banking immersed himself in a range of global public health projects.

Sands, who is currently Chairman of the World Bank's International Working Group on Financing Pandemic Preparedness, is also a research fellow at the Harvard Global Health Institute and the Mossavar Rahmani Center for Business and Government at Harvard's Kennedy School, where he works on research projects in global health and financial regulation.

"Peter Sands brings exceptional management and finance experience, and a heart for global health," said Aida Kurtović, Board Chair of the Global Fund. "At a time when we face complex challenges, his ability to mobilize resources while managing transformational change is exactly what we need. We expect him to take the Global Fund to the next level."

Sands served as Chief Executive Officer of Standard Chartered PLC from 2006 to 2015, having joined the bank in 2002 as Group Finance Director. Under his leadership, Standard Chartered successfully navigated the turbulence of the global financial crisis in 2007-2009, continuing to support clients and counterparties throughout the worst of the financial stresses and without drawing on government support of any kind...

After stepping down from the bank in 2015, Sands deployed his skills and experience in international finance on global health. Sands served as Chairman of the U.S. National Academy of Medicine's Commission on a Global Health Risk Framework for the Future, which published the influential report on pandemics entitled The Neglected Dimension of Global Security: a Framework to Counter Infectious Disease Outbreaks. Sands is also serving on the U.S. National Academy of Science's Forum on Microbial Threats and Committee on Ensuring Access to Affordable Drugs. Sands has published articles on global health and epidemics in various peer-reviewed journals.

"I am deeply honored to join this extraordinary partnership," Sands said. "Infectious diseases today represent one of the most serious risks facing humankind. If we work together to mobilize funds, build strong health systems and establish effective community responses we will be able to end epidemics, promote prosperity and increase our global health security."…

As new Executive Director, Sands will oversee and guide the implementation of the Global Fund's 2017-2022 strategy, designed to maximize impact against HIV, TB and malaria and build resilient and sustainable systems for health.

The Global Fund is a 21st-century partnership organization designed to accelerate the end of AIDS, tuberculosis and malaria as epidemics. Founded in 2002, the Global Fund is a partnership between governments, civil society, the private sector and people affected by the diseases.

The Global Fund raises and invests nearly US$4 billion a year to support programs run by local experts in countries and communities most in need. The Global Fund has been consistently rated as one of the most effective and transparent organizations in the development sector.

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WHO welcomes appointment of new Executive Director of the Global Fund

14 November, 2017 – WHO welcomes the appointment of Peter Sands as the new Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Gavi welcomes new Global Fund Executive Director

12 November 2017 – Gavi collaborates with the Global Fund in the vast majority of Gavi-supported countries.

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FDA announces comprehensive regenerative medicine policy framework

Comprehensive regenerative medicine policy framework to spur innovation, efficient access to potentially transformative products, while ensuring safety & efficacy
November 16, 2017 –
Today the U.S. Food and Drug Administration announced a comprehensive policy framework for the development and oversight of regenerative medicine products, including novel cellular therapies.

The framework – outlined in a suite of four guidance documents – builds upon the FDA's existing risk-based regulatory approach to more clearly describe what products are regulated as drugs, devices, and/or biological products. Further, two of the guidance documents propose an efficient, science-based process for helping to ensure the safety and effectiveness of these therapies, while supporting development in this area. The suite of guidance documents also defines a risk-based framework for how the FDA intends to focus its enforcement actions against those products that raise potential significant safety concerns. This modern framework is intended to balance the agency's commitment to safety with mechanisms to drive further advances in regenerative medicine so innovators can bring new, effective therapies to patients as quickly and safely as possible. The policy also delivers on important provisions of the 21st Century Cures Act.

"We're at the beginning of a paradigm change in medicine with the promise of being able to facilitate regeneration of parts of the human body, where cells and tissues can be engineered to grow healthy, functional organs to replace diseased ones; new genes can be introduced into the body to combat disease; and adult stem cells can generate replacements for cells that are lost to injury or disease. This is no longer the stuff of science fiction. This is the practical promise of modern applications of regenerative medicine," said FDA Commissioner Scott Gottlieb, M.D. "But this field is dynamic and complex. As such, it has presented unique challenges to researchers, health care providers, and the FDA as we seek to provide a clear pathway for those developing new therapies in this promising field, while making sure that the FDA meets its obligation to ensure the safety and efficacy of the medical products that patients rely upon. Alongside all the promise, we've also seen products marketed that are dangerous and have harmed people. With the policy framework the FDA is announcing today, we're adopting a risk-based and science-based approach that builds upon existing regulations to support innovative product development while clarifying the FDA's authorities and enforcement priorities. This will protect patients from products that pose potential significant risks, while accelerating access to safe and effective new therapies."

The framework includes two final guidance documents and two draft guidance documents.

New Final Guidance Documents
The two final guidance documents clarify the FDA's interpretation of the risk-based criteria manufacturers use to determine whether a product is subject to the FDA's premarket review. The first guidance provides greater clarity around when cell and tissue-based products would be excepted from the established regulations if they are removed from and implanted into the same individual within the same surgical procedure and remain in their original form. The second final guidance helps stakeholders better understand how existing regulatory criteria apply to their products by clarifying how the agency interprets the existing regulatory definitions "minimal manipulation" and "homologous use." As this field advances, the FDA has noted that there are a growing number of regenerative medicine products subject to FDA premarket

authorization. These guidance documents will help explain how the FDA will provide a risk-based framework for its oversight. The policy framework defines how we intend to take action against unsafe products while facilitating continued innovation of promising technologies…

New Draft Guidance Documents

The two draft guidances provide important information to help spur development and access to innovative regenerative therapies. The first draft guidance, which builds off the regenerative medicine provisions in the 21st Century Cures Act, addresses how the FDA intends to simplify and streamline its application of the regulatory requirements for devices used in the recovery, isolation, and delivery of regenerative medicine advanced therapies (RMATs), including combination products. The guidance specifies that devices intended for use with a specific RMAT may, together with the RMAT, be considered to comprise a combination product.

The second draft guidance describes the expedited programs that may be available to sponsors of regenerative medicine therapies, including the new Regenerative Medicine Advanced Therapy (RMAT) designation created by the 21st Century Cures Act, Priority Review, and Accelerated Approval. In addition, the guidance describes the regenerative medicine therapies that may be eligible for RMAT designation – including cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, as well as gene therapies that lead to a durable modification of cells or tissues (including genetically modified cells)…

Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA's comprehensive new policy approach to facilitating the development of innovative regenerative medicine products to improve human health

November 16, 2017 –

One of the most promising fields of science is the area of cell-based therapies and their use in regenerative medicine. These new technologies, most of which are in early stages of development, hold transformative promise for patients.

Given this area's rapid growth, dynamism and complexity, this field has also presented unique challenges to researchers, health care providers and the FDA. We need to provide a clear, efficient pathway for product developers, while making sure that we meet our obligation to help ensure the safety and efficacy of these medical products so that patients can benefit from these novel therapies.

To achieve these goals, today we're taking steps to advance an innovative framework for how we intend to apply the existing laws and regulations that govern these products. Our aim is to make sure we're being nimble and creative when it comes to fostering innovation, while taking steps to protect the safety of patients.

The FDA originally established a regulatory framework for these products that went into effect in 2005. But in the last decade, we've seen improbable advances that hold out great hope for patients. I believe that with the ability to facilitate the regeneration of parts of the human body, we're bearing witness to the beginning of a paradigm shift in the practice of medicine.

These concepts are no longer the stuff of science fiction, but rather real-life science where cells and tissues can be engineered to grow healthy, functional organs to replace diseased ones;

where new genes can be introduced into the body to combat disease; and where adult stem cells can generate replacements for cells that are lost to injury or illness. The promise of this technology is why the FDA is so committed to encouraging and supporting innovation in this field.

But the rapid growth and promise of this field has increasingly sowed the ground for the entry of some unscrupulous actors, who have opportunistically seized on the clinical potential of regenerative medicine to make deceptive claims to patients about unproven and, in some cases, dangerous products. By exploiting the lack of consumer understanding of this area, as well as the fear and uncertainties posed by the diseases these bad actors claim to treat, they're jeopardizing the legitimacy and advancement of the entire field. This underscores the importance of having a clear regulatory framework for developers, and ensuring that those who skirt these regulations are held accountable.

To realize the full potential of regenerative medicine, we need to support the innovation pursued by responsible product developers – who represent the vast majority of the field – to help ensure that they clearly understand where the regulatory lines are drawn. We must advance a modern, efficient and least burdensome framework that recognizes the breakneck speed of advancement in the products we're being asked to evaluate, while ensuring patient safety. That is the goal of the policy we're announcing today.

To achieve this balance, embedded in our comprehensive framework are many proposed novel and modern approaches to regulation, where we intend to adapt our regulatory model to meet the revolutionary nature of the products we're being asked to evaluate.

One example is how we're considering innovative trial designs whereby individual academic investigators would follow the same manufacturing protocols and share combined clinical trial data in support of approval from the FDA. This is an innovative way of making sure that small investigators who are working with cells that are being manufactured in ways that render them subject to our current laws and regulations -- because the cells are, for example, more than "minimally manipulated" -- can nonetheless seek the FDA's approval through a less burdensome process.

There are other similarly proposed novel approaches embedded in our broad policy framework. Our goal is to achieve a risk-based and science-based approach to support innovative product development, while clarifying the FDA's authorities and enforcement priorities and making sure we are protecting patients.

The suite of four guidance documents we are making public today also delivers on important provisions of the 21st Century Cures Act, including our continued promise to fully implement the Regenerative Medicine Advanced Therapy (RMAT) designation program, which is designed to expedite the development and review of regenerative medicine advanced therapies.

We understand that there will be questions and it will take time for product developers to determine whether their products require FDA approval. Our policy will allow product manufacturers that time to engage with the FDA to determine if they need to submit a marketing authorization application and, if so, seek guidance on how to submit their application to the FDA for approval.

To be clear, we remain committed to ensuring that patients have access to safe and effective regenerative medicine products as efficiently as possible. We are also committed to making sure we take action against products being unlawfully marketed that pose a potential significant risk to their safety. The framework we're announcing today gives us the solid platform we need to continue to take enforcement action against a small number of clearly unscrupulous actors. With this balanced approach, we're well positioned to support and help advance breakthrough science, like regenerative medicine, and promote responsible and flexible regulation that leverages science to advance public health…

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Editor's Note:
We are pleased to begin regular coverage of news and announcements from the Africa CDC…overdue…

Africa CDC [to 18 November 2017]
https://au.int/en/africacdc
November 07, 2017
Africa Partnership and Coordination Forum agree on joint priorities to fast track implementation of the Catalytic Framework to end AIDS, TB and eliminate Malaria in Africa by 2030
Johannesburg, 07 November 2017- The African Union Commission (AUC) convened regional and continental partners last week to discuss joint priorities to support countries end AIDS, TB and Malaria by 2030. In attendance were: African Union Organs, Regional Economic Communities, Regional Health Organisations, development partners, civil society the private sector and invited guests.

"We have the science and tools to end AIDS, TB and Malaria by 2030. The continental targets set for the three diseases can be achieved with sustained leadership, ownership, sustained financing, effective partnerships and accountability," said Dr. Richard Kamwi, former health minister of Namibia who is the current Goodwill Ambassador of Elimination 8 and Africa CDC Champion.

The *Catalytic Framework to end AIDS, TB and Eliminate Malaria in Africa by 2030* is a continental framework that enunciates key policy issues, strategic priorities, targets and accountability mechanisms…

07 November 2017
African countries launch framework to tackle the threat of antibiotic resistant infections
Annecy, France - Africa CDC launched its framework to fight antibiotic resistant infections during the eighth edition of the Advanced Courses on Diagnostics convened by the Fondation Mérieux. Antibiotic resistant infections occur when bacteria, viruses, and other microorganisms change in ways that make medications ineffective against them. In Africa, antibiotic resistance is already a major problem for malaria, tuberculosis, typhoid, meningitis, gonorrhea, and dysentery. Recognising the urgent need for action, the World Health Assembly adopted the

Global Action Plan to address the challenge in May 2015. The Africa CDC Framework describes priorities for African Union Member States to improve diagnosis and treatment of, collect more accurate data about, and strengthen policies to address antibiotic resistance.

'Africa CDC developed a remarkably comprehensive framework, fully aligned with the Global Action Plan and the Global Antimicrobial Resistance Surveillance System which if fully implemented will address the growing threat of antibiotic resistant infections', said Dr Marc Sprenger, Director of the Antimicrobial Resistance Secretariat at the World Health Organisation who chaired the launch.

"Antimicrobial resistance is a major threat to Africa's economic growth and structural transformation goals. We need to urgently strengthen partnerships and leverage our existing assets across Africa to fully implement the Africa CDC Framework for Antimicrobial Resistance," said Dr. John Nkengasong, the Director of the Africa Centres for Disease Control and Prevention…

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Featured Journal Content

Nature
Volume 551 Number 7680 pp271-398 16 November 2017
http://www.nature.com/nature/current_issue.html
World View
Immunization needs a technology boost
Tracking who receives vaccines is essential, but will be impossible without innovations in digital technologies, says Seth Berkley.
Today, about 80% of infants living in the world's 73 poorest countries receive routine immunizations, a measure currently assessed by whether they have been given a full course of a vaccine regime to prevent diphtheria, pertussis and tetanus. In 2000, only about 60% received such protection. That progress is great, but achieving 100% coverage will require better insight into which children are missing out.

For that, we need a new approach: the global health community must move to digital systems. My organization, Gavi, the Vaccine Alliance, spends an average of nearly US$2 billion a year on getting vaccines to children in the poorest countries. It has also invested tens of millions of dollars in innovations to monitor immunization.

Current methods for measuring immunization coverage are based on how many vaccine doses are distributed — not how many children are fully immunized. Doses delivered are much easier to count, but knowing which children are covered is much more important. That picture is vague. Surveys done to plug this knowledge gap are rare, costly and — to be reliable — require mothers to have retained paper-based child health cards.

Putting the child at the centre of tracking efforts is not as simple as it sounds. Tens of millions of children have no formal record of their existence — especially those living in remote, impoverished or vulnerable communities. This global identity crisis is so important that it has its

own indicator (number 16.9) under the United Nations' Sustainable Development Goals (SDGs) intended to ensure that everyone has a legal identity by 2030. Right now, unregistered births are one of the biggest barriers to achieving another SDG, which aims to end preventable deaths of children under five and achieve universal health coverage, with access to affordable essential vaccines for all, by 2030.

Digital technology and social media offer an opportunity. The technology sector is on a mission to equip everyone on the planet with a digital and online presence. And the innovations that will help to achieve that goal are exactly those that could aid the global public-health community in vaccinating every child.

Many relevant technologies are largely in place already. Big data, for example, can help public-health officials to anticipate the spread of disease and hone vaccination campaigns. Geospatial mapping and drones are already being used in Nigeria to identify communities that have not received polio vaccines, and in Rwanda to deliver blood needed for transfusions for mothers who haemorrhage after giving birth.

One of the biggest needs is for affordable, secure digital identification systems that can store a child's medical history, and that can be accessed even in places without reliable electricity. That might seem a tall order, but it is both achievable and necessary. Technology is already intertwined with vaccine delivery. For example, Google.org — the charitable arm of Google — and Gavi are working together to scale-up wireless temperature monitoring to provide real-time data on refrigerators used to store medications. This will notify workers when the refrigerators are starting to fail, and generally ensure that vaccines are kept at safe temperatures. We are also supporting the use of cloud-based databases to track vaccines along the supply chain.

Other projects help to inform us of who receives vaccines. We are working with a company in India called Khushi Baby, which creates off-grid digital health records. A necklace worn by infants contains a unique identification number on a short-range communication chip. Community health workers can scan the chip using a mobile phone, enabling them to update a child's digital record even in remote areas with little phone coverage. In the Indian state of Rajasthan, Khushi Baby has tracked more than 15,000 vaccination events of thousands of children across 100 villages.

We still have a long way to go. We should be more ambitious in defining what 100% vaccination coverage means. Although the common measure of routine immunization coverage suggests that only one in five children misses out, the reality is much bleaker. The current measurement leaves out at least 8 of the 11 antigens that the World Health Organization (WHO) recommends be included in vaccines given to all infants. Among the missing ones are the highly contagious measles. Also missing are antigens for pneumococcus, which causes pneumonia, and rotavirus, which causes severe diarrhoea — the two biggest killers globally of children under five.

Our analysis suggests that just 7% of infants in the 73 poorest countries — those that most need our attention — are fully immunized. That means that more than nine of every ten children in these countries are not getting the minimum recommended protection against infectious diseases.

A UN expert group is meeting this week in Bahrain to review indicators for the SDGs. Expanding indicators to include all the WHO-recommended antigens will help. And in theory, governments have already signed up to finding a solution to the problem of birth registration. Both moves are essential to improve understanding of how many children are fully immunized. A third essential ingredient is information technologies targeted at helping the developing world. If we want to make sure that preventable childhood deaths are actually prevented, we need to go digital.

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Emergencies

POLIO

Public Health Emergency of International Concern (PHEIC)

Polio this week as of 15 November 2017 [GPEI]

:: Underlining their commitment to a polio-free world for all future generations, Italy has provided €4.5 million to deliver polio vaccines in Afghanistan and Pakistan.

[In Afghanistan, the contribution will be used to support and train vaccinators and social mobilizers in generating demand for vaccination, the delivery of vaccines and monitoring whether vaccination activities are well-implemented. In Pakistan, the contribution will support vaccination campaigns in the most challenging areas of the country, as well as the immunization of communities that are at particularly high risk due to their mobility, through tactics such as giving vaccine established transit points. The Bill & Melinda Gates Foundation have matched Italy's contribution, doubling its impact to €9 million…]

Summary of newly-reported viruses this week:

…***Afghanistan:*** One new wild poliovirus type 1 (WPV1) case, reported in Kandahar province. One new WPV1 positive environmental sample, collected from Kandahar province.

… ***Pakistan:*** Six new WPV1 positive environmental samples, one collected from Punjab province, two collected from Sindh province, and three collected from Balochistan province.

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Syria cVDPV2 outbreak situation report 22: 14 November 2017

Situation update 14 November 2017

14 November 2017 *[Editor's text bolding]*

:: No new cases of circulating vaccine-derived poliovirus type 2 (cVDPV2) were reported this week. The total number of cVDPV2 cases remains 63. All confirmed cases to date have had onset of paralysis before 25 August 2017.

:: Inactivated polio vaccine activities aimed at reaching children aged 2–23 months are ongoing. IPV will be offered alongside bOPV as part of the subnational immunization days in 6 districts of Damascus and 200 hotels in the city, 3 areas of Rural Damascus, 2 districts of Homs and 1 district of Aleppo with large internally displaced populations from Deir Ez-Zor.

:: Almost 3000 children under 5 have received all routine immunization antigens in newly accessible areas of Deir Ez-Zor city between 7 and 10 November in opportunistic vaccination activities.

:: A joint mission between the World Health Organization and the local health authority to visit newly accessible areas of Aleppo was conducted this week. The mission also met with the Aleppo University Hospital and Aleppo Pediatric Association to advocate for acute flaccid paralysis surveillance and to support ongoing immunization activities to reach IDPs from infected areas.

:: **The advisory group on mOPV2 vaccine provision met this week to review the revised risk assessment for Syria cVDPV2 outbreak and discuss contingency plans for outbreak response. The group endorsed, in principle, the proposal to preposition approximately 1 million doses mOPV2 in Damascus (pending receipt of formal vaccine request from the Ministry of Health) to enable rapid response in the event of any ongoing outbreak response activities**

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Devex: Exclusive: The Gates Foundation picks a partner to share lessons learned from polio eradication
By Catherine Cheney
16 November 2017
SAN FRANCISCO — The Johns Hopkins Bloomberg School of Public Health has received a new grant to translate the lessons learned from polio eradication to other global health initiatives, the Bill & Melinda Gates Foundation told Devex.

Polio is one of the top priorities of the largest foundation in the world, and in their 2017 annual letter, Bill and Melinda Gates said they think it is possible that polio could be eliminated this year. At the Reaching the Last Mile summit in Abu Dhabi this week, panelists talked about the near eradication of both polio and Guinea worm disease, and what lessons smallpox — the only infectious disease to be wiped off the face of the planet — might offer. But as the Gates Foundation funds this effort to get to zero case of polio, its program staff wants to make sure to improve upon one of the failures of the smallpox eradication effort by documenting the lessons learned.

Dr. Olakunle Alonge, assistant professor at JHSPH, will lead this new grant, $3.7 million over five years, resulting from a request for proposals called "Applying the Lessons Learned from Polio Eradication to Global Health." Working with the Global Polio Eradication Initiative, Alonge and a team of partners from seven countries — Nigeria, India, Afghanistan, Ethiopia, the Democratic Republic of Congo, Bangladesh, and Indonesia — will develop courses and clinics that capture the best practices of the polio eradication effort. The goal, said Alonge, is to capture the lessons learned and prevent this knowledge from being lost so that systems and strategies can be repurposed, not recreated….

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WHO Grade 3 Emergencies [to 18 November 2017]
The Syrian Arab Republic
:: Syria cVDPV2 outbreak situation report 22: 14 November 2017

[See Polio above]

Iraq - *No new announcements identified.*
Nigeria - *No new announcements identified.*
South Sudan - *No new announcements identified.*
Yemen - *No new announcements identified.*

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WHO Grade 2 Emergencies [to 18 November 2017]
Myanmar
:: Mortality and Morbidity Weekly Bulletin - Volume No 5: 12 November 2017
…4.1 Second round of Oral Cholera Vaccination Campaign
…From 4-9 November 2017, the second round of OCV was conducted targeting 182,317 FDMNs between 1 and 5 years. As of 9 November 2017, a total of 199,472 persons were reported to have been vaccinated, representing 109% (199,472/182,317) of the target population (table 2). Oral cholera vaccines represent a tool to fight cholera and are licensed as two-dose regimens with 2-4 weeks between doses. Evidence from previous studies suggests that a single dose of oral cholera vaccine might provide substantial direct protection against cholera….

Niger
:: Rift Valley fever in Niger
November 2016 -- Rift Valley Fever (RVF) is caused by a virus transmitted by mosquitoes and blood feeding flies that usually affects animals (commonly cattle and sheep) but can also involve humans. In humans the disease ranges from a mild flu-like illness to severe haemorrhagic fever that can be lethal. When livestock are infected the disease can cause significant economic losses due to high mortality rate in young animals and waves of abortions in pregnant females

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

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UN OCHA – L3 Emergencies
The UN and its humanitarian partners are currently responding to three 'L3' emergencies. This is the global humanitarian system's classification for the response to the most severe, large-scale humanitarian crises.
Syrian Arab Republic
:: 16 Nov 2017 WFP Condemns Destruction of Humanitarian Food Supplies in Eastern Ghouta Area of Syria

Yemen

:: Statement by the Humanitarian Community on the Blockade in Yemen | 16 November 2017
:: Yemen: Impact of the closure of seaports and airports on the humanitarian situation - Situation Update 2 | 15 November 2017
:: Ensuring Yemen's lifeline: the criticality of all Yemeni ports
:: Yemen: Key messages on the continued closure of Yemen's ports – 13 November 2017

DRC
:: Democratic Republic of the Congo Overview (November 2017) 16 Nov 2017
The humanitarian situation in the Democratic Republic of the Congo (DRC) has deteriorated dramatically over the past year. The crisis has deepened and spread, affecting people in areas previously considered stable and stretching the coping mechanisms of people in areas already impacted. A surge in violent conflict and intercommunal tensions has forced more than 1.7 million people to flee their homes in 2017 – an average of more than 5,500 people per day. Today, the total number of internally displaced people in the DRC has reached 4.1 million, which is the highest number of any country on the African continent. Insecurity has had a devastating impact on people's ability to access food, and 7.7 million people across the DRC are facing severe food insecurity – a 30 per cent increase from the same time last year. The situation is further complicated by political uncertainty and economic downturn.

:: Under-Secretary-General for Humanitarian Affairs and Emergency Relief Coordinator, Mark Lowcock - Remarks at the Member States briefing on the Democratic Republic of the Congo - 16 November 2017

Iraq
:: Earthquake in northeast Iraq 14 November 2017 – 12:30, Flash Update #3 [EN/AR/KU]
:: Humanitarian partners are rushing to help the victims of the earthquake [EN/AR/KU] 13 Nov 2017

WHO airlifts medical supplies to treat wounded in Islamic Republic of Iran-Iraq earthquake
16 November 2017, Cairo, Egypt – WHO has airlifted trauma kits and medical supplies to the Islamic Republic of Iran to support the treatment of thousands people injured as a result of the recent earthquake in the Islamic Republic of Iran-Iraq border region…

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UN OCHA – Corporate Emergencies
When the USG/ERC declares a Corporate Emergency Response, all OCHA offices, branches and sections provide their full support to response activities both at HQ and in the field.
ROHINGYA CRISIS
:: ISCG Situation Update: Rohingya Refugee Crisis, Cox's Bazar - 16 November 2017

Ethiopia
:: 15 Nov 2017 Ethiopia: Humanitarian Response Situation Report No.15 (October 2017)

Nigeria
:: Fact Sheet NE Nigeria: Pulka, Gwoza LGA (November 2017)
:: Fact Sheet NE Nigeria: Rann, Kala/Balge LGA (November 2017)

Somalia - *No new announcements identified*

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

EBOLA/EVD [to 18 November 2017]
http://www.who.int/ebola/en/
- *No new announcements identified.*

MERS-CoV [to 18 November 2017]
http://www.who.int/emergencies/mers-cov/en/
- *No new announcements identified.*

Yellow Fever [to 18 November 2017]
http://www.who.int/csr/disease/yellowfev/en/
[See Milestone above]

Zika virus [to 18 November 2017]
http://www.who.int/csr/disease/zika/en/
- *No new announcements identified.*

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WHO & Regional Offices [to 18 November 2017]

Highlights
Preterm birth
November 2017 – Every year, an estimated 15 million babies are born preterm (before 37 completed weeks of gestation), and this number is rising. Preterm birth complications are the leading cause of death among children under 5 years of age, responsible for approximately 1 million deaths in 2015.

Nutrition Report highlights an increase in malnutrition in Africa
November 2017 – A newly released nutrition report by WHO has revealed that undernutrition is still persistent in the region and the number of stunted children has increased. The Report also a growing number of children under five years old are overweight.

River blindness: shifting to surveillance and elimination
November 2017 – After years of painstaking control and prevention activities, the world is finally edging to eliminate river blindness. Latest data show globally almost 133 million people received treatment in 2016, compared with 46 million in 2005.

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Progress towards rubella and congenital rubella syndrome control and elimination
17 November 2017

A new report published in todays' edition of the WHO Weekly Epidemiological Record shows that 53 more countries introduced rubella vaccine into their national immunization schedules since 2000. This led to a decline in cases by 97% from 2000-2016. But, improved disease surveillance and stronger country commitment are still needed to reach elimination goals.

WHO recommends that all countries that have not yet introduced rubella vaccine should consider doing so using existing, well-established measles immunization programmes.

Weekly Epidemiological Record, 17 November 2017, vol. 92, 46 (pp. 701–716)
:: Global routine vaccination coverage, 2016
::Progress in rubella and congenital rubella syndrome control and elimination – worldwide, 2000–2016

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WHO Regional Offices
Selected Press Releases, Announcements
WHO African Region AFRO
:: Ghanaians urged to seek advice from qualified health practitioners before taking antibiotics 17 November 2017
:: Women and Girls should be empowered to strengthen their capacity to prevent Type 2 Diabetes 17 November 2017
:: WHO's Africa Nutrition Report highlights an increase in malnutrition in Africa. 16 November 2017
:: International Health Emergency Response plan on Marburg virus disease 15 November 2017
:: Plague in Madagascar - Disease Outbreak News Update 15 November 2017
:: WHO implements Emergency Response Plan 15 November 2017
:: WHO strengthening the capacity of frontline healthcare workers in Yei River State, Central Equatoria hub to improve the management of cases of priority diseases in South Sudan 14 November 2017
:: South Sudan conducts Polio Outbreak Simulation Exercise to strengthen Polio outbreak preparedness and response 14 November 2017

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

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

WHO European Region EURO
:: Tuberculosis (TB) research and innovation among key priorities at global conference to end TB 17-11-2017
:: Planning cities to boost physical activity 14-11-2017
:: Turkey takes strong action to reduce antibiotic consumption and resistance 13-11-2017
:: Every infection prevented is an antibiotic treatment avoided 13-11-2017

WHO Eastern Mediterranean Region EMRO
:: WHO airlifts medical supplies to treat wounded in Islamic Republic of Iran-Iraq earthquake 16 November 2017
:: WHO delivers urgent health assistance for earthquake trauma patients 15 November 2017
:: Government of Italy boosts efforts to eradicate polio and improve child nutrition in Afghanistan 14 November 2017

WHO Western Pacific Region
No new digest content identified.

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CDC/ACIP [to 18 November 2017]
http://www.cdc.gov/media/index.html
https://www.cdc.gov/vaccines/acip/index.html
Wednesday, November 15, 2017
CDC Encourages Safe Antibiotic Prescribing and Use - Press Release
November 13, 2017, kicked off U.S. Antibiotic Awareness Week and World Antibiotic Awareness Week. The Centers for Disease Control and Prevention (CDC) recognizes this week with an updated educational effort, *Be Antibiotics Aware: Smart Use, Best Care*, to support the nation's efforts to combat antibiotic resistance through improved use of these life-saving medications…

MMWR News Synopsis for November 16, 2017
Global Routine Vaccination Coverage, 2016
In recent years, vaccination coverage rates have remained the same. This suggests the need to improve access to and completion of vaccinations for hard-to-reach populations in order to reduce global morbidity and mortality from vaccine-preventable diseases.
Substantial progress in global routine vaccination coverage has been made in the past 40 years since the establishment of the World Health Organization (WHO) Expanded Program on Immunization (EPI). In 2016, the global vaccination coverage rate with vaccines to prevent tuberculosis, diphtheria, tetanus, pertussis, polio, and measles was ≥85 percent. However, 33 percent of countries still are not meeting the target requirements needed to reach and sustain high vaccination coverage. Targeted strategies are needed to improve access to vaccination and to increase the number of children who are fully protected from vaccine-preventable diseases.

Rubella and Congenital Rubella Syndrome Control and Elimination — Global Progress, 2000–2016
The accelerated introduction of rubella-containing vaccine (RCV) into national immunization schedules is a significant step toward. rubella elimination. For regions to achieve rubella elimination, as has been achieved in the Americas, a strong commitment is required in all countries to introduce rubella-containing vaccine and increase the quality of rubella routine and campaign immunization activities. Countries and international partners should take advantage of opportunities provided by existing measles-elimination activities.
Rubella is the leading vaccine-preventable cause of birth defects in the world. Rubella during pregnancy can cause miscarriage, fetal death, stillbirth, and congenital malformations known as congenital rubella syndrome (CRS). During 2000-2016, 53 countries introduced RCV into their

national immunization schedules. By the end of 2016, 152 (78 percent) of 194 countries were using rubella vaccine. Reported rubella cases declined 97 percent, from 670,894 cases in 102 countries in 2000 to 22,361 cases in 165 countries in 2016. The WHO Americas region achieved rubella and CRS elimination in 2015, and 33 of 53 countries in the European region have eliminated endemic rubella and CRS. The Western Pacific Region also has a rubella elimination goal (no countries verified).

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Announcements

AERAS [to 18 November 2017]
http://www.aeras.org/pressreleases
No new digest content identified.

BMGF - Gates Foundation [to 18 November 2017]
http://www.gatesfoundation.org/Media-Center/Press-Releases
No new digest content identified.

CEPI – Coalition for Epidemic Preparedness Innovations [to 18 November 2017]
http://cepi.net/
No new digest content identified.

EDCTP [to 18 November 2017]
http://www.edctp.org/
The European & Developing Countries Clinical Trials Partnership (EDCTP) aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases in sub-Saharan Africa, with a focus on phase II and III clinical trials
Latest news
15 November 2017
EU action against antimicrobial resistance: EDCTP's contribution
Antimicrobial resistance and improper use of antibiotics are a potential global threat to healthcare. During the European Antibiotic Awareness Week…

European Medicines Agency [to 18 November 2017]
http://www.ema.europa.eu/ema/
17/11/2017
Towards a single development programme for new antibiotics in EU, Japan and US
EMA, PMDA and FDA to further align data requirements and explore options to streamline paediatric development ...

16/11/2017

Improving the availability of vaccines for animals within the EU
CVMP agrees proposals to increase clarity for when field efficacy trials are needed in the development of veterinary vaccines
The Committee for Veterinary Medicinal Products (CVMP), at its November meeting, accepted recommendations to clarify the need for conducting field efficacy trials, i.e. trials in animals under real-life conditions in the field, to support the authorisation of veterinary vaccines. Improving clarity on this topic will facilitate the availability of veterinary vaccines in the European Union (EU).

These recommendations were made by the joint European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) Steering Group on veterinary vaccine availability on the basis of the outcome of a joint EMA/HMA stakeholder focus group meeting held in June 2017, which brought together regulators, industry and academic experts.

According to EU legislation, the efficacy and safety of veterinary vaccines should be demonstrated in laboratory trials, and then supplemented by data from field trials, unless an acceptable justification can be provided for not providing this data. The role of veterinary field trials is primarily to confirm that the performance of the product observed under controlled experimental conditions is verified under actual conditions of use.

According to veterinary vaccine developers, field trials can be challenging to carry out because of practical matters and due to issues related to trial design whilst adding only limited value to an authorisation dossier. A common issue encountered is connected to trials where animals are not exposed to the disease under real-life conditions, leading to inconclusive outcomes, while conducting these trials can be very costly…

15/11/2017
EMA to work with stakeholders to improve the product information for EU medicines
Stakeholder feedback sought on ongoing electronic initiatives ...

European Vaccine Initiative [to 18 November 2017]
http://www.euvaccine.eu/news-events
No new digest content identified.

FDA [to 18 November 2017]
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm
November 16, 2017 –
FDA announces comprehensive regenerative medicine policy framework
[See Milestones above for more detail]

November 16, 2017 –
Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA's comprehensive new policy approach to facilitating the development of innovative regenerative medicine products to improve human health
[See Milestones above for more detail]

Fondation Merieux [to 18 November 2017]
http://www.fondation-merieux.org/
November 13, 2017
African countries launch framework to tackle the threat of antibiotic resistant infections

Annecy, 07 November 2017- Africa CDC launched its framework to fight antibiotic resistant infections during the eighth edition of the Advanced Courses on Diagnostics convened by the Fondation Mérieux.

The Advanced Course on Diagnostics (ACDx) was organized October 29-November 3 at Les Pensières Center for Global Health by the Mérieux Foundation and the London School of Hygiene & Tropical Medicine (LSHTM). This eighth edition trained more than 38 scientists and decision-makers from 20 countries…

Gavi [to 18 November 2017]
http://www.gavi.org/library/news/press-releases/
12 November 2017
Pneumonia vaccine saves 500,000 lives in world's poorest countries
Over 109 million children in the developing world have now received pneumococcal conjugate vaccine (PCV).
Geneva - The rollout of pneumonia vaccine has prevented the deaths of over half a million children in developing countries over the past decade, Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance, said today.

Since 2007, 109 million children have received pneumococcal conjugate vaccine (PCV), which protects against the leading cause of pneumonia, with the support of Gavi. Vaccination coverage in Gavi-supported countries has now reached 41%, up from 35% in 2015 and almost equaling the global average of 42%.

"Hundreds of thousands of children in the world's poorest countries are alive today thanks to pneumococcal vaccine," said Dr Berkley. "I'm immensely proud of the role Gavi has played in expanding access to this lifesaver over the past ten years, but millions of children remain unprotected. This is an entirely preventable, treatable disease that still takes the lives of more children than any other illness, causing untold needless suffering. We cannot afford to lose focus in the fight against pneumonia."

This year marks the tenth anniversary of the launch of the Advance Market Commitment (AMC). Children in the poorest countries typically received newly developed vaccines more than a decade later than children in the richest countries. With help from the AMC developing countries began to introduce the latest formulations of PCV as soon as a year after they were first made available.

Funded by Italy, UK, Canada, Russia, Norway and the Bill and Melinda Gates Foundation, this unique financing mechanism has allowed eligible countries to access affordable PCV vaccines at a cost of less than 10% of the US market price. Gavi has now helped 58 countries across Africa and Asia to introduce the vaccine into their routine immunisation programmes…

GHIT Fund [to 18 November 2017]
https://www.ghitfund.org/
GHIT was set up in 2012 with the aim of developing new tools to tackle infectious diseases that devastate the world's poorest people. Other funders include six Japanese pharmaceutical •
No new digest content identified.

Global Fund [to 18 November 2017]
http://www.theglobalfund.org/en/news/?topic=&type=NEWS;&country=
News
Global Fund Appoints Peter Sands as Executive Director
14 November 2017
The Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria today appointed a new Executive Director: Peter Sands, a former chief executive of Standard Chartered Bank who after a distinguished career in banking immersed himself in a range of global public health projects.
[See Milestones above for more detail]

Hilleman Laboratories [to 18 November 2017]
http://www.hillemanlabs.org/
No new digest content identified.

Human Vaccines Project [to 18 November 2017]
http://www.humanvaccinesproject.org/media/press-releases/
No new digest content identified.

IAVI [to 18 November 2017]
https://www.iavi.org/
November 13, 2017
IAVI's Fran Priddy Talks Scientific Challenges at AtlanticLIVE's Vaccines + Immunity
What's missing in HIV vaccine development? If you guessed political will or buy-in from *pharmaceutical companies, you'd be wrong.*
According to Fran Priddy, IAVI's Chief Medical Officer, it's actually the virus itself, she explained at AtlanticLIVE's Vaccines + Immunity event on November 9 in Philadelphia. The event convened top health officials and vaccine experts from both the private and public sectors.
That's not to say that HIV vaccine research efforts are deficient, however. Priddy's point is that HIV is an extraordinarily challenging and elusive virus and why, 30 years later, scientists are still trying to understand how the body produces HIV antibodies and how to harness that knowledge in a vaccine.
"The science is really key for HIV," she said. "That's really why it's been such a long road."
Priddy joined Leonard Friedland of GSK and David B. Weiner of the Wistar Institute for a panel on the latest science, which includes a roster of 260 new vaccines in development by America's biopharmaceutical companies. She highlighted the last decade's HIV vaccine progress, such as the discovery of broadly neutralizing antibodies, which has led to a

renaissance in the field. As important, she discussed the hurdles facing vaccine product development in light of these successes…

IFFIm
http://www.iffim.org/library/news/press-releases/
No new digest content identified.

IVAC [to 18 November 2017]
http://www.jhsph.edu/research/centers-and-institutes/ivac/index.html
Latest IVAC News [Undated]
Mathu Santosham, MD, MPH, wins the 2017 Prince Mahidol Award
IVAC's Senior Advisor recognized for landmark scientific contribution to controlling Hib, pneumococcal disease

Mathu Santosham, MD, MPH, has received the Prince Mahidol Award 2017 in the field of Public Health, which recognizes "outstanding contribution in the field of public health for the sake of the well-being of the peoples."

Santosham, who serves as Director Emeritus of the Johns Hopkins Center for American Indian Health and Special Advisor in the International Vaccine Access Center at the Johns Hopkins Bloomberg School of Public Health, has been recognized for his landmark scientific contribution to the control of Hib and pneumococcal disease around the world.

The Prince Mahidol Award was established in 1992 to honor the late Prince Mahidol of Songka, the Royal Father of His Majesty the King of Thailand. Prince Mahidol modernized medical services and education in Thailand and is known to the country as the "Father of Modern Medicine and Public Health." Dr. Santosham will jointly receive the award with Professor Porter Warren Anderson Jr., Dr. Rachel Schneerson, and Dr. John B. Robbins…

IVI [to 18 November 2017]
http://www.ivi.int/
No new digest content identified.

MSF/Médecins Sans Frontières [to 18 November 2017]
http://www.doctorswithoutborders.org/news-stories/press/press-releases
Press release
Yemen: Blockade by Saudi-Led Coalition Hindering Medical Aid

SANA'A, YEMEN/NEW YORK, NOVEMBER 17, 2017—The Saudi-led coalition's continuing blockade of Yemen's ports and airports is significantly hindering the efforts of Doctors Without Borders/Médecins Sans Frontières (MSF) and other humanitarian organizations to provide lifesaving assistance to people in the war-torn country.

For the past 12 days, MSF has not received authorization from the Saudi-led coalition to fly into Yemen's capital, Sana'a, which is essential to bring medical supplies and staff to patients in need.

Press release

Doctors Without Borders Brings Interactive Exhibition on Refugee Crisis to the Santa Monica Pier
November 15, 2017
The international medical humanitarian organization Doctors Without Borders/Médecins Sans Frontières brings its exhibition on the plight of more than 65 million refugees and internally displaced people to Santa Monica this week. Forced From Home illustrates individual stories of the world's displaced people, and helps visitors better understand the medical humanitarian consequences of the global refugee crisis.

Press release
MSF Welcomes Suspension of Harmful Intellectual Property Measures in New TPP Trade Deal
November 14, 2017
Ministers from the eleven countries assessing the Trans-Pacific Partnership (TPP) trade deal have suspended many of the damaging provisions that would have restricted access to medicines and vaccines, a victory for millions of people who rely on affordable medicines worldwide.

NIH [to 18 November 2017]
http://www.nih.gov/news-events/news-releases
November 16, 2017
National organizations support outreach efforts for NIH's All of Us Research Program
— Groups will help raise awareness about the initiative to engage 1 million or more volunteers in health research.

November 14, 2017
Three decades of responding to infectious disease outbreaks
— NIAID director Anthony S. Fauci, M.D., highlights lessons from AIDS to Zika.
Article : CI Paules, et al. What recent history has taught us about responding to emerging infectious disease threats. Annals of Internal Medicine DOI: 10.7326/M17-2496 (2017).

PATH [to 18 November 2017]
http://www.path.org/news/index.php
Press release | November 15, 2017
A Structural Clue to Attacking Malaria's 'Achilles Heel'
TSRI and PATH collaboration provides blueprint for design of a next-generation vaccine
Washington DC, and La Jolla California, November 15, 2017—Researchers from The Scripps Research Institute (TSRI) and PATH's Malaria Vaccine Initiative (MVI) have shed light on how the human immune system recognizes the malaria parasite through investigation of antibodies generated from the RTS,S malaria vaccine—work that could boost the development of a more potent vaccine against the global killer.
In a study published this week in the journal Proceedings of the National Academy of Sciences, the researchers provide an atomic-level view of how human antibodies bind to an important malarial surface protein, the circumsporozoite protein [CSP], to protect against the malaria parasite. These new structures could potentially help scientists enhance the efficacy and

duration of RTS,S, the world's most advanced malaria vaccine to date, which has shown partial protection against the disease in a large-scale Phase 3 clinical trial.

The RTS,S vaccine was the outcome of a long-standing collaboration between PATH and GSK that began in 2001 and involved research institutions in Africa and around the world. RTS,S is the first and, to date, the only vaccine to show a protective effect against malaria among young children in Phase 3 clinical trials.

Efforts continue to enhance the vaccine's efficacy and duration of protection against malaria, a major public health problem that infects millions of people each year. An estimated 429,000 people died from the mosquito-borne illness in 2015 and 212 million people were infected...

Press release | November 14, 2017

Multi-sector partnership supports detection and treatment of childhood tuberculosis in Vietnam

Nghe An, Vietnam, November 14, 2017—Increasing numbers of children in four districts of Vietnam's Nghe An province are being protected against tuberculosis (TB) through a partnership focused on strengthening detection, treatment, and management of the deadly disease.

The Breath for Life project, a partnership between PATH, the Nghe An Tuberculosis and Lung Disease Hospital, and Johnson & Johnson, has supported public and private health care workers and facilities to increase the detection and early treatment of children with TB, and to increase the number of children taking preventive treatment due to being in close contact with people who have contracted the illness.

Through the Breath for Life project's focus on improved detection, 148 children were diagnosed with TB in the districts of Dien Chau, Quynh Luu, Nam Dan, and Yen Thanh in 2016, double the 74 diagnosed in these districts in 2015. In the first nine months of 2017, an additional 87 children were diagnosed with TB. The increased number of diagnoses means that more children with previously undetected TB are now being treated…

Sabin Vaccine Institute [to 18 November 2017]
http://www.sabin.org/updates/pressreleases
No new digest content identified.

UNAIDS [to 18 November 2017]
http://www.unaids.org/en
Update

China focuses on strengthening HIV prevention

16 November 2017

The International Symposium on the Prevention and Control of HIV in China was held in Beijing, China, on 13 and 14 November to discuss China's evolving HIV epidemic. The symposium was sponsored by China's National Health and Family Planning Commission and the Ministry of Science and Technology, with the support of UNAIDS, the World Health Organization and the United States Centers for Disease Control and Prevention.

The meeting aimed to put forward new strategies for preventing HIV through sexual transmission…

Update

United Nations Deputy Secretary-General and Geneva-based leaders discuss the future of global health in 2030 Agenda
15 November 2017

UNICEF [to 18 November 2017]
https://www.unicef.org/media/
16 November 2017
UN Leaders appeal for immediate lifting of humanitarian blockade in Yemen – Millions of lives at imminent risk
NEW YORK/GENEVA, 16 November 2017 – "While the Saudi-led military coalition has partially lifted the recent blockade of Yemen, closure of much of the country's air, sea and land ports is making an already catastrophic situation far worse. The space and access we need to deliver humanitarian assistance is being choked off, threatening the lives of millions of vulnerable children and families.

Statement by UNICEF South Asia Regional Director, Jean Gough, from Afghanistan and Pakistan border
SPIN BOLDAK, Afghanistan, 11 November 2017 – "The town of Spin Boldak on Afghanistan's southern border with Pakistan is at the epicentre of the global effort to eradicate polio.
[See Polio above for more detail]

Wellcome Trust [to 18 November 2017]
https://wellcome.ac.uk/news
News / Published: 16 November 2017
Ayurvedic Man: our new exhibition exploring 'the knowledge of long life'
'Ayurvedic Man: Encounters with Indian medicine', Wellcome Collection's latest exhibition, shines a light on some of the treasures in our archives, from intricate anatomical diagrams and surgical tools, to erotic manuals and spiritual manuscripts

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BIO [to 18 November 2017]
https://www.bio.org/insights/press-release
No new digest content identified.

DCVMN – Developing Country Vaccine Manufacturers Network [to 18 November 2017]
http://www.dcvmn.org/
No new digest content identified.

IFPMA [to 18 November 2017]
http://www.ifpma.org/resources/news-releases/
No new digest content identified.

PhRMA [to 18 November 2017]
http://www.phrma.org/press-room
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

No new digest content identified.

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Journal Watch

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

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

American Journal of Infection Control
November 01, 2017 Volume 45, Issue 11, p1175-1296, e119-e148
http://www.ajicjournal.org/current
[Reviewed earlier]

American Journal of Preventive Medicine
November 2017 Volume 53, Issue 5, p567-744, e155-e200
http://www.ajpmonline.org/current
[Reviewed earlier]

American Journal of Public Health
November 2017 107(11)
http://ajph.aphapublications.org/toc/ajph/current
[Reviewed earlier]

American Journal of Tropical Medicine and Hygiene

Volume 97, Issue 4, 2017
http://www.ajtmh.org/content/journals/14761645/97/4
[Reviewed earlier]

Annals of Internal Medicine
7 November 2017 Vol: 167, Issue 9
http://annals.org/aim/issue
[Reviewed earlier]

BMC Cost Effectiveness and Resource Allocation
http://resource-allocation.biomedcentral.com/
(Accessed 18 November 2017)
[No new digest content identified]

BMJ Global Health
October 2017; volume 2, issue 4
http://gh.bmj.com/content/2/4?current-issue=y
[Reviewed earlier]

BMC Health Services Research
http://www.biomedcentral.com/bmchealthservres/content
(Accessed 18 November 2017)
Research article
Seasonal influenza vaccination of healthcare workers: systematic review of qualitative evidence
Results
Twenty-five studies were included in the review. HCWs may be motivated to accept vaccination to protect themselves and their patients against infection. However, a range of beliefs may act as barriers to vaccine uptake, including concerns about side-effects, scepticism about vaccine effectiveness, and the belief that influenza is not a serious illness. HCWs value their autonomy and professional responsibility in making decisions about vaccination. The implementation of interventions to promote vaccination uptake may face barriers both from HCWs' personal beliefs and from the relationships between management and employees within the targeted organisations.
Conclusions
HCWs' vaccination behaviour needs to be understood in the context of HCWs' relationships with each other, with management and with patients. Interventions to promote vaccination should take into account both the individual beliefs of targeted HCWs and the organisational context within which they are implemented.
Authors: Theo Lorenc, David Marshall, Kath Wright, Katy Sutcliffe and Amanda Sowden
Citation: BMC Health Services Research 2017 17:732
Published on: 15 November 2017

BMC Infectious Diseases
http://www.biomedcentral.com/bmcinfectdis/content
(Accessed 18 November 2017)
Research article
Varicella zoster virus-associated morbidity and mortality in Africa – a systematic review
Varicella zoster virus (VZV) causes varicella and herpes zoster. These vaccine preventable diseases are common globally. Most available data on VZV epidemiology are from industrialised temperate countries and ...
Authors: Hannah Hussey, Leila Abdullahi, Jamie Collins, Rudzani Muloiwa, Gregory Hussey and Benjamin Kagina
Citation: BMC Infectious Diseases 2017 17:717
Published on: 14 November 2017

BMC Medical Ethics
http://www.biomedcentral.com/bmcmedethics/content
(Accessed 18 November 2017)
[No new digest content identified]

BMC Medicine
http://www.biomedcentral.com/bmcmed/content
(Accessed 18 November 2017)
[No new digest content identified]

BMC Pregnancy and Childbirth
http://www.biomedcentral.com/bmcpregnancychildbirth/content
(Accessed 18 November 2017)
[No new digest content identified]

BMC Public Health
http://bmcpublichealth.biomedcentral.com/articles
(Accessed 18 November 2017)
[No new digest content identified]

BMC Research Notes
http://www.biomedcentral.com/bmcresnotes/content
(Accessed 18 November 2017)
[No new digest content identified]

BMJ Open
November 2017 - Volume 7 - 11
http://bmjopen.bmj.com/content/current

[Reviewed earlier]

Bulletin of the World Health Organization
Volume 95, Number 11, November 2017, 729-792
http://www.who.int/bulletin/volumes/95/11/en/
[Reviewed earlier]

Child Care, Health and Development
November 2017 Volume 43, Issue 6 Pages 783–946
http://onlinelibrary.wiley.com/doi/10.1111/cch.v43.6/issuetoc
[Reviewed earlier]

Clinical and Experimental Vaccine Research
Volume 6(2); July 2017
http://ecevr.org/
[Reviewed earlier]

Clinical Therapeutics
October 2017 Volume 39, Issue 10
http://www.clinicaltherapeutics.com/current
[Reviewed earlier]

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

Conflict and Health
http://www.conflictandhealth.com/
[Accessed 18 November 2017]
[No new digest content identified]

Contemporary Clinical Trials
Volume 60, Pages 1-126 (September 2017)
http://www.sciencedirect.com/science/journal/15517144/60?sdc=1
[Reviewed earlier]

Current Opinion in Infectious Diseases
December 2017 - Volume 30 - Issue 6
http://journals.lww.com/co-infectiousdiseases/pages/currenttoc.aspx

[Reviewed earlier]

Developing World Bioethics
December 2017 Volume 17, Issue 3 Pages 141–216
http://onlinelibrary.wiley.com/doi/10.1111/dewb.2017.17.issue-3/issuetoc
GENERAL EDITORIAL
Research ethics and the Zika legacy in Brazil (pages 142–143)
Debora Diniz and Ilana Ambrogi
Version of Record online: 12 NOV 2017 | DOI: 10.1111/dewb.12175
[No abstract]

ARTICLES
Social Responsibility and the State's Duty to provide Healthcare: An Islamic Ethico-Legal Perspective (pages 205–214)
Aasim I. Padela
Version of Record online: 30 DEC 2016 | DOI: 10.1111/dewb.12140
Abstract
The United Nations Educational, Scientific and Cultural Organization's (UNESCO) Declaration on Bioethics and Human Rights asserts that governments are morally obliged to promote health and to provide access to quality healthcare, essential medicines and adequate nutrition and water to all members of society. According to UNESCO, this obligation is grounded in a moral commitment to promoting fundamental human rights and emerges from the principle of social responsibility. Yet in an era of ethical pluralism and contentions over the universality of human rights conventions, the extent to which the UNESCO Declaration can motivate behaviors and policies rests, at least in part, upon accepting the moral arguments it makes. In this essay I reflect on a state's moral obligation to provide healthcare from the perspective of Islamic moral theology and law. I examine how Islamic ethico-legal conceptual analogues for human rights and communal responsibility, ḥuqq al-'ibād and farḍ al-kifāyah and other related constructs might be used to advance a moral argument for healthcare provision by the state. Moving from theory to application, I next illustrate how notions of human rights and social responsibility were used by Muslim stakeholders to buttress moral arguments to support American healthcare reform. In this way, the paper advance discourses on a universal bioethics and common morality by bringing into view the concordances and discordances between Islamic ethico-legal constructs and moral arguments advanced by transnational health policy advocates. It also provides insight into applied Islamic bioethics by demonstrating how Islamic ethico-legal values might inform the discursive outputs of Muslim organizations.

Development in Practice
Volume 27, Issue 8, 2017
http://www.tandfonline.com/toc/cdip20/current
[Reviewed earlier]

Disaster Medicine and Public Health Preparedness
Volume 11 - Issue 5 - October 2017

https://www.cambridge.org/core/journals/disaster-medicine-and-public-health-preparedness/latest-issue
Original Research
Evaluating the Impact of Pharmacies on Pandemic Influenza Vaccine Administration
Joy Schwerzmann, Samuel B. Graitcer, Barbara Jester, David Krahl, Daniel Jernigan, Carolyn B. Bridges, Joseph Miller
https://doi.org/10.1017/dmp.2017.1
Published online: 21 February 2017, pp. 587-593
Abstract
The objective of this study was to quantify the potential retail pharmacy vaccine administration capacity and its possible impact on pandemic influenza vaccine uptake.
We developed a discrete event simulation model by use of ExtendSim software (Imagine That Inc, San Jose, CA) to forecast the potential effect of retail pharmacy vaccine administration on total weekly vaccine administration and the time needed to reach 80% vaccination coverage with a single dose of vaccine per person.
Results showed that weekly national vaccine administration capacity increased to 25 million doses per week when retail pharmacist vaccination capacity was included in the model. In addition, the time to achieve 80% vaccination coverage nationally was reduced by 7 weeks, assuming high public demand for vaccination. The results for individual states varied considerably, but in 48 states the inclusion of pharmacies improved time to 80% coverage.
Pharmacists can increase the numbers of pandemic influenza vaccine doses administered and reduce the time to achieve 80% single-dose coverage. These results support efforts to ensure pharmacist vaccinators are integrated into pandemic vaccine response planning. (Disaster Med Public Health Preparedness. 2017;11:587–593)

Disasters
October 2017 Volume 41, Issue 4 Pages 629–851
http://onlinelibrary.wiley.com/doi/10.1111/disa.2017.41.issue-4/issuetoc
[Reviewed earlier]

EMBO Reports
01 November 2017; volume 18, issue 11
http://embor.embopress.org/content/18/11?current-issue=y
[Reviewed earlier]

Emerging Infectious Diseases
Volume 23, Number 11—November 2017
http://wwwnc.cdc.gov/eid/
[New issue; No digest content identified]

Epidemics
Volume 20, Pages 1-102 (September 2017)
http://www.sciencedirect.com/science/journal/17554365
[Reviewed earlier]

Epidemiology and Infection
Volume 145 - Issue 15 - November 2017
https://www.cambridge.org/core/journals/epidemiology-and-infection/latest-issue
Mumps
Original Papers
An outbreak of mumps with genetic strain variation in a highly vaccinated student population in Scotland
L. J. WILLOCKS, D. GUERENDIAIN, H. I. AUSTIN, K. E. MORRISON, R. L. CAMERON, K. E. TEMPLETON, V. R. F. DE LIMA, R. EWING, W. DONOVAN, K. G. J. POLLOCK
https://doi.org/10.1017/S0950268817002102
Published online: 14 September 2017, pp. 3219-3225
Respiratory infections
Influenza vaccination status and outcomes among influenza-associated hospitalizations in Columbus, Ohio (2012–2015)
P. N. ZIVICH, L. TATHAM, K. LUNG, J. TIEN, C. E. BOLLINGER, J. K. BOWER
https://doi.org/10.1017/S0950268817002163
Published online: 16 October 2017, pp. 3284-3293

The European Journal of Public Health
Volume 27, Issue 5, October 2017
https://academic.oup.com/eurpub/issue/27/5
[Reviewed earlier]

Global Health Action
Volume 10, 2017 – Issue 1 [In Progress]
http://www.tandfonline.com/toc/zgha20/10/1?nav=tocList
[Reviewed earlier]

Global Health: Science and Practice (GHSP)
September 2017 | Volume 5 | Number 3
http://www.ghspjournal.org/content/current
[Reviewed earlier]

Global Public Health
Volume 12, 2017 Issue 12
http://www.tandfonline.com/toc/rgph20/current
[Reviewed earlier]

Globalization and Health
http://www.globalizationandhealth.com/
[Accessed 18 November 2017]

Research

Challenges to implementing Gavi's health system strengthening support in Chad and Cameroon: results from a mixed-methods evaluation

Since 2005, Gavi has provided health system strengthening (HSS) grants to address bottlenecks affecting immunization services. This study is the first to evaluate the Gavi HSS implementation process in either Chad or Cameroon…

Conclusions

Though Chad and Cameroon both critically needed support to strengthen their weak health systems, serious challenges drastically limited implementation of their Gavi HSS programs. Implementation of future HSS programs in these and similar settings can be improved by transparent and reliable procedures and communication from Gavi, proposals that account for countries' programmatic capacity and the potential for delayed disbursements, implementation practices that foster learning and adaptation, and an early emphasis on developing managerial and other human resources.

Emily Dansereau, Yodé Miangotar, Ellen Squires, Honoré Mimche and Charbel El Bcheraoui
Globalization and Health 2017 13:83
Published on: 16 November 2017

Commentary

Patent landscape of neglected tropical diseases: an analysis of worldwide patent families

"Neglected Tropical Diseases" (NTDs) affect millions of people in Africa, Asia and South America. The two primary ways of strategic interventions are "preventive chemotherapy and transmission control" (PCT), a...

Folahanmi Tomiwa Akinsolu, Vitor Nobre de Paiva, Samuel Santos Souza and Orsolya Varga
Globalization and Health 2017 13:82
Published on: 14 November 2017

Health Affairs
November 2017; Vol. 36, No. 11
http://content.healthaffairs.org/content/current
Issue Focus: Global Health Policy
[Reviewed earlier]

Health and Human Rights
Volume 19, Issue 1, June 2017
http://www.hhrjournal.org/
[Reviewed earlier]

Health Economics, Policy and Law
Volume 12 - Issue 4 - October 2017
https://www.cambridge.org/core/journals/health-economics-policy-and-law/latest-issue
SPECIAL ISSUE: Healthcare and Health Innovation in Europe: Regulating for public benefit or for commercial profit?
[Reviewed earlier]

Health Policy and Planning
Volume 32, Issue 9 November 2017
http://heapol.oxfordjournals.org/content/current
[Reviewed earlier]

Health Research Policy and Systems
http://www.health-policy-systems.com/content
[Accessed 18 November 2017]
Research
Towards fair and effective North–South collaboration: realising a programme for demand-driven and locally led research
At the turn of the 90s, studies showed that health research contributed little to health and development in low- and middle-income countries because it was oriented towards international priorities and dominated by researchers from the North. A new approach to North–South collaboration was required that would support demand-driven and locally led research in the South. The aim of this study was to analyse the development and functioning of a programme for demand-driven and locally led research in Ghana that was supported by a North–South collaboration.
Maarten Olivier Kok, John Owusu Gyapong, Ivan Wolffers, David Ofori-Adjei and Elis Joost Ruitenberg
Published on: 13 November 2017

Humanitarian Exchange Magazine
http://odihpn.org/magazine/the-humanitarian-consequences-of-violence-in-central-america/
Number 70 October 2017
Special Feature: The Lake Chad Basin: an overlooked crisis?
by Humanitarian Practice Network October 2017
The 70th edition of Humanitarian Exchange, co-edited with Joe Read, focuses on the humanitarian crisis in Nigeria and the Lake Chad Basin. The violence perpetrated by Boko Haram and the counter-insurgency campaign in Nigeria, Cameroon, Chad and Niger has created a humanitarian crisis affecting some 17 million people. Some 2.4 million have been displaced, the vast majority of them in north-eastern Nigeria. Many are living in desperate conditions, without access to sufficient food or clean water. The Nigerian government's focus on defeating Boko Haram militarily, its reluctance to acknowledge the scale and gravity of the humanitarian crisis and the corresponding reticence of humanitarian leaders to challenge that position have combined to undermine the timeliness and effectiveness of the response…
[Reviewed earlier]

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)
Volume 13, Issue 10 2017
http://www.tandfonline.com/toc/khvi20/current
[Reviewed earlier]

Infectious Agents and Cancer
http://www.infectagentscancer.com/content
[Accessed 18 November 2017]
[No new digest content identified]

Infectious Diseases of Poverty
http://www.idpjournal.com/content
[Accessed 18 November 2017]
[No new digest content identified]

International Health
Volume 9, Issue 5, 1 September 2017
http://inthealth.oxfordjournals.org/content/current
[Reviewed earlier]

International Journal of Community Medicine and Public Health
Vol 4, No 11 (2017)
http://www.ijcmph.com/index.php/ijcmph/issue/view/32
[Reviewed earlier]

International Journal of Epidemiology
Volume 46, Issue 5, 1 October 2017
https://academic.oup.com/ije/issue/46/5
[Reviewed earlier]

International Journal of Human Rights in Healthcare
Vol. 10 Issue: 4 2017
http://www.emeraldinsight.com/toc/ijhrh/10/4
[Reviewed earlier]

International Journal of Infectious Diseases
November 2017 Volume 64, p1-106
http://www.ijidonline.com/issue/S1201-9712(17)X0011-8
[Reviewed earlier]

JAMA
November 14, 2017, Vol 318, No. 18, Pages 1731-1840
http://jama.jamanetwork.com/issue.aspx
Viewpoint
The Critical Role of Biomedical Research in Pandemic Preparedness

Hilary D. Marston, MD, MPH; Catharine I. Paules, MD; Anthony S. Fauci, MD
JAMA. 2017;318(18):1757-1758. doi:10.1001/jama.2017.15033

In this Viewpoint, Anthony Fauci and colleagues review rapid research responses to recent infectious disease outbreaks as a way of emphasizing the strategies and collaborations necessary to prepare for a next unknown pandemic.

JAMA Pediatrics
November 2017, Vol 171, No. 11, Pages 1025-1132
http://archpedi.jamanetwork.com/issue.aspx
[Reviewed earlier]

JBI Database of Systematic Review and Implementation Reports
November 2017 - Volume 15 - Issue 11
http://journals.lww.com/jbisrir/Pages/currenttoc.aspx
Editorial
Opportunities and challenges in a world of data abundance
Holly, Cheryl
JBI Database of Systematic Reviews and Implementation Reports. 15(11):2597-2598, November 2017.

Since their debut in the 1980s, the publication rate of systematic reviews has rapidly accelerated. In 2014, more than 8000 systematic reviews were indexed on MEDLINE, a three-fold increase over the last decade.1 Systematic reviews organize the discrete pieces of information contained in primary studies and other reports into a coherent body of evidence for use to inform healthcare decisions and policy in support of patient care and to engage stakeholders. Currently, much of the work in systematic review methodology is focused on developing guidance for reliable approaches to scoping, searching, appraising, synthesizing and grading evidence.1,2 Accordingly, there are now widely disseminated standards on how to complete a systematic review, which has increased interest in the conduct of systematic reviews and allowed this proliferation in publication. The challenge and opportunity in this proliferation is how to engage in this new world of data abundance, keeping in mind expediency, efficiency and complexity.

Expediency

While systematic reviews are considered to be the gold standard in evidence synthesis, they are not without their limitations. Despite the need for systematic review evidence to inform clinical practice and policy, the best evidence is not always used due to lack of knowledge, time, skills and/or resources to translate knowledge into meaningful and useful informaton.2 For example, a systematic review can require between six months to twoyears to complete, whereas decision makers, whose needs are generally time-sensitive and emergent, often require up-to-date evidence more quickly than this. The rapid review is a new methodology that has emerged to address this need. Although the definition of a rapid review varies, typically it is characterized by a strong focus on the specific needs of a particular decision maker and by methodological shortcuts.3,4 Results of rapid reviews have been characterized by a reduced scope, omission of dual data abstraction and critical appraisal, and conduct by only one reviewer. While there is no evidence to suggest that rapid reviews are misleading, there is a need to ensure credibility and technical quality.2 The opportunity lies in developing a standardized approach to rapid reviews that does not sacrifice validity for expediency.

Efficiency

Umbrella or overviews of systematic reviews, which involve the synthesis of results from multiple systematic reviews, has emerged as an organized means to address an abundance of data. These reviews take advantage of previous research syntheses, bringing an efficiency that enables a broad understanding of a wide-scope topic in a shorter timeframe.[5] An umbrella review can be conducted to identify factors that may influence the treatment-outcome effect in the same or different populations, map evidence and identify gaps for primary researchers, or examine discordance or similarity in findings and conclusions across reviews.[6] This information is important to clinicians and patients as it aids in understanding what patients will benefit most, who is least likely to benefit, and who is at greatest risk of experiencing adverse outcomes. There are, however, unique issues to the conduct of an umbrella review that differ from a traditional review. Chief among these are how to handle overlapping primary studies, i.e. when one primary study appears in one or more systematic review.[5] The challenge is how to handle the overlap of primary studies when they are included in more than one review so that their results are not being used multiple times, violating the principles of independence of data.

Complexity

While methods for conducting systematic reviews on distinct treatments, such as medication regimens, are well-defined, these methods may be inadequate for systematic reviews of the complex interventions often encountered in health care. Complex interventions are those in which a number of elements must work together to achieve the best outcomes, such as chronic disease management or smoking cessation programs.[7] Such complexity is influenced by multiple factors, including patient characteristics and behavior, social determinants of health, differing contexts as well as the interventions themselves.[7] They need to be tailored to be effective. The challenge and opportunity here is to determine what methods can best elucidate recommendations that work best, under what circumstances and for what subgroup, given the interactions in the dual challenge of intervention complexity (multiple components) and pathway complexity (multiple causal pathways, feedback loops, synergies, and/or moderators of effect).[8] Consideration needs to be given to qualitative and mixed method reviews to overcome the limits of measurement-based research, which often focus on the easily observed and easily measured effects, rather than the context and acceptability of an intervention.[4,5]

Journal of Community Health
Volume 42, Issue 6, December 2017
https://link.springer.com/journal/10900/42/6/page/1
[Reviewed earlier]

Journal of Epidemiology & Community Health
November 2017 - Volume 71 - 11
http://jech.bmj.com/content/current
[New issue; No digest content identified]

Journal of Evidence-Based Medicine
August 2017 Volume 10, Issue 3 Pages 153–240
http://onlinelibrary.wiley.com/doi/10.1111/jebm.2017.10.issue-3/issuetoc
[Reviewed earlier]

Journal of Global Ethics
Volume 13, Issue 2, 2016
http://www.tandfonline.com/toc/rjge20/current
[Reviewed earlier]

Journal of Health Care for the Poor and Underserved (JHCPU)
Volume 28, Number 3, August 2017
https://muse.jhu.edu/issue/36769
[Reviewed earlier]

Journal of Immigrant and Minority Health
Volume 19, Issue 6, December 2017
https://link.springer.com/journal/10903/19/6/page/1
Original Paper
Drugs Delivery by Charities: A Possible Epidemiologic Indicator in Children of Undocumented Migrants
S Bini, A Clavenna, AE Rigamonti, A Sartorio…
Abstract
Describing the health status of a population is difficult, especially in the case of irregular migrants who are now a growing population in western Countries. Data for children of these families are almost inexistent. In the absence of databases on this peculiar pediatric population, we analyzed drugs dispensation by a major Charity to have an insight into their health needs. This observational retrospective study was carried out during the entire 2015 and enrolled 628 undocumented children. A cohort of 8438 adult patients belonging to the same ethnic groups was used for comparison. Respiratory drugs were those most commonly prescribed, followed by those for skin and ocular diseases and by those for gastrointestinal disorders. Also in adults respiratory medications were the most dispensed, but almost in equal measure than cardiovascular drugs.To our knowledge this is the first study on the health needs of undocumented children residing in a western Country. The method we used seems to be a useful method for epidemiological analysis. As could be expected, respiratory and skin diseases ranked first, possibly owing to environmental factors.

Journal of Immigrant & Refugee Studies
Volume 15, Issue 3, 2017
http://www.tandfonline.com/toc/wimm20/current
Statelessness, Irregularity, and Protection in Southeast Asia
Introduction to the Special Issue
[Reviewed earlier]

Journal of Infectious Diseases
Volume 216, Issue 8, 15 November 2017
https://academic.oup.com/jid/issue

MAJOR ARTICLES AND BRIEF REPORTS
VIRUSES
Human Papillomavirus (HPV) Prevalence in Male Adolescents 4 Years After HPV-16/18 Vaccination
Tuomas Lehtinen; Anna Söderlund-Strand; Tiina Petäjä; Tiina Eriksson; Sakari Jokiranta ...
The Journal of Infectious Diseases, Volume 216, Issue 8, 15 November 2017, Pages 966–968, https://doi.org/10.1093/infdis/jix415
vvvAlthough the quadrivalent human papillomavirus (HPV) vaccine is known to reduce HPV infection in men, this is the first report that HPV prevalence rates are also reduced among men given the bivalent HPV vaccine.

Journal of Medical Ethics
November 2017 - Volume 43 - 11
http://jme.bmj.com/content/current
[Reviewed earlier]

Journal of Medical Internet Research
Vol 19, No 11 (2017): November
http://www.jmir.org/2017/11
[Reviewed earlier]

Journal of Medical Microbiology
Volume 66, Issue 11, November 2017
http://jmm.microbiologyresearch.org/content/journal/jmm/66/11
[Reviewed earlier]

Journal of Patient-Centered Research and Reviews
Volume 4, Issue 4 (2017)
http://digitalrepository.aurorahealthcare.org/jpcrr/
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[Reviewed earlier]

Journal of the Pediatric Infectious Diseases Society (JPIDS)
Volume 6, Issue suppl_1, 1 September 2017,
https://academic.oup.com/jpids/issue
State of the Art Diagnosis of Pediatric Invasive Fungal Disease: Recommendations From the Joint European Organization for the Treatment of Cancer/Mycoses Study Group (EORTC/MSG) Pediatric Committee
[Reviewed earlier]

Journal of Pediatrics
November 2017 Volume 190, p1-294

http://www.jpeds.com/current
[New issue; No digest content identified]

Journal of Public Health Management & Practice
November/December 2017 - Volume 23 - Issue 6
http://journals.lww.com/jphmp/pages/default.aspx
[New issue; No digest content identified]

Journal of Public Health Policy
Volume 38, Issue 4, November 2017
https://link.springer.com/journal/41271/38/4/page/1
[Reviewed earlier]

Journal of the Royal Society – Interface
01 September 2017; volume 14, issue 134
http://rsif.royalsocietypublishing.org/content/current
[Reviewed earlier]

Journal of Travel Medicine
Volume 24, Issue 5, 1 September – October 2017
https://academic.oup.com/jtm/issue/24/5
[Reviewed earlier]

Journal of Virology
November 2017, volume 91, issue 22
http://jvi.asm.org/content/current
[New issue; No digest content identified]

The Lancet
Nov 18, 2017 Volume 390 Number 10109 p2215-2324 e39-e40
http://www.thelancet.com/journals/lancet/issue/current
Comment
Where is the science in humanitarian health?
Ronald J Waldman, Michael J Toole

Humanitarian medicine is more than a technical exercise
Vickie Hawkins, André Heller Pérache

Research ethics and evidence for humanitarian health
Dónal O'Mathúna, Chesmal Siriwardhana

Articles

Attacks against health care in Syria, 2015–16: results from a real-time reporting tool

Mohamed Elamein, Hilary Bower, Camilo Valderrama, Daher Zedan, Hazem Rihawi, Khaled Almilaji, Mohammed Abdelhafeez, Nabil Tabbal, Naser Almhawish, Sophie Maes, Alaa AbouZeid

Summary

Background

Collecting credible data on violence against health services, health workers, and patients in war zones is a massive challenge, but crucial to understanding the extent to which international humanitarian law is being breached. We describe a new system used mainly in areas of Syria with a substantial presence of armed opposition groups since November, 2015, to detect and verify attacks on health-care services and describe their effect.

Methods

All Turkey health cluster organisations with a physical presence in Syria, either through deployed and locally employed staff, were asked to participate in the Monitoring Violence against Health Care (MVH) alert network. The Turkey hub of the health cluster, a UN-activated humanitarian health coordination body, received alerts from health cluster partners via WhatsApp and an anonymised online data-entry tool. Field staff were asked to seek further information by interviewing victims and other witnesses when possible. The MVH data team triangulated alerts to identify individual events and distributed a preliminary flash update of key information (location, type of service, modality of attack, deaths, and casualties) to partners, WHO, United Nations Office for the Coordination of Humanitarian Affairs, and donors. The team also received and entered alerts from several large non-health cluster organisations (known as external partners, who do their own information-gathering and verification processes before sharing their information). Each incident was then assessed in a stringent process of information-matching. Attacks were deemed to be verified if they were reported by a minimum of one health cluster partner and one external partner, and the majority of the key datapoints matched. Alerts that did not meet this standard were deemed to be unverified. Results were tabulated to describe attack occurrence and impact, disaggregated where possible by age, sex, and location.

Findings

Between early November, 2015, and Dec 31 2016, 938 people were directly harmed in 402 incidents of violence against health care: 677 (72%) were wounded and 261 (28%) were killed. Most of the dead were adult males (68%), but the highest case fatality (39%) was seen in children aged younger than 5 years. 24% of attack victims were health workers. Around 44% of hospitals and 5% of all primary care clinics in mainly areas with a substantial presence of armed opposition groups experienced attacks. Aerial bombardment was the main form of attack. A third of health-care services were hit more than once. Services providing trauma care were attacked more than other services.

Interpretation

The data system used in this study addressed double-counting, reduced the effect of potentially biased self-reports, and produced credible data from anonymous information. The MVH tool could be feasibly deployed in many conflict areas. Reliable data are essential to show how far warring parties have strayed from international law protecting health care in conflict and to effectively harness legal mechanisms to discourage future perpetrators.

Funding

None.

Series

Health in humanitarian crises

Evidence on public health interventions in humanitarian crises

Karl Blanchet, Anita Ramesh, Severine Frison, Emily Warren, Mazeda Hossain, James Smith, Abigail Knight, Nathan Post, Christopher Lewis, Aniek Woodward, Maysoon Dahab, Alexander Ruby, Vera Sistenich, Sara Pantuliano, Bayard Roberts

Summary

Recognition of the need for evidence-based interventions to help to improve the effectiveness and efficiency of humanitarian responses has been increasing. However, little is known about the breadth and quality of evidence on health interventions in humanitarian crises. We describe the findings of a systematic review with the aim of examining the quantity and quality of evidence on public health interventions in humanitarian crises to identify key research gaps. We identified 345 studies published between 1980 and 2014 that met our inclusion criteria. The quantity of evidence varied substantially by health topic, from communicable diseases (n=131), nutrition (n=77), to non-communicable diseases (n=8), and water, sanitation, and hygiene (n=6). We observed common study design and weaknesses in the methods, which substantially reduced the ability to determine causation and attribution of the interventions. Considering the major increase in health-related humanitarian activities in the past three decades and calls for a stronger evidence base, this paper highlights the limited quantity and quality of health intervention research in humanitarian contexts and supports calls to scale up this research.

Health in humanitarian crises

Public health information in crisis-affected populations: a review of methods and their use for advocacy and action

Francesco Checchi, Abdihamid Warsame, Victoria Treacy-Wong, Jonathan Polonsky, Mark van Ommeren, Claudine Prudhon

Summary

Valid and timely information about various domains of public health underpins the effectiveness of humanitarian public health interventions in crises. However, obstacles including insecurity, insufficient resources and skills for data collection and analysis, and absence of validated methods combine to hamper the quantity and quality of public health information available to humanitarian responders. This paper, the second in a Series of four papers, reviews available methods to collect public health data pertaining to different domains of health and health services in crisis settings, including population size and composition, exposure to armed attacks, sexual and gender-based violence, food security and feeding practices, nutritional status, physical and mental health outcomes, public health service availability, coverage and effectiveness, and mortality. The paper also quantifies the availability of a minimal essential set of information in large armed conflict and natural disaster crises since 2010: we show that information was available and timely only in a small minority of cases. On the basis of this observation, we propose an agenda for methodological research and steps required to improve on the current use of available methods. This proposition includes setting up a dedicated interagency service for public health information and epidemiology in crises.

Health in humanitarian crises

Recurrent failings of medical humanitarianism: intractable, ignored, or just exaggerated?

Sandro Colombo, Enrico Pavignani

Summary

Humanitarian health workers operate in dangerous and uncertain contexts, in which mistakes and failures are common, often have severe consequences, and are regularly repeated, despite being documented by many reviews. This Series paper aims to discuss the failures of medical humanitarianism. We describe why some of these recurrent failings, which are often not identified until much later, seem intractable: they are so entrenched in humanitarian action that they cannot be addressed by simple technical fixes. We argue that relief health-care interventions should be contextualised. Perhaps medical humanitarianism deserves a better reputation than the one at times tarnished by unfair criticism, resulting from inapplicable guiding principles and unrealistic expectations. The present situation is not conducive to radical reforms of humanitarian medicine; complex crises multiply and no political, diplomatic, or military solutions are in sight. Relief agencies have to compete for financial resources that do not increase at the same pace as health needs. Avoiding the repetition of failures requires recognising previous mistakes and addressing them through different policies by donors, stronger documentation and analysis of humanitarian programmes and interventions, increased professionalisation, improved, opportunistic relationships with the media, and better ways of working together with local health stakeholders and through indigenous institutions.

Lancet Global Health
Nov 2017 Volume 5 Number 11 e1047-e1160
http://www.thelancet.com/journals/langlo/issue/current
[Reviewed earlier]

Lancet Infectious Diseases
Nov 2017 Volume 17 Number 11 p1099-1218 e334-e382
http://www.thelancet.com/journals/laninf/issue/current
[Reviewed earlier]

Lancet Public Health
Nov 2017 Volume 2 Number 11 e483-e528
http://thelancet.com/journals/lanpub/
[Reviewed earlier]

Lancet Respiratory Medicine
Nov 2017 Volume 5 Number 11 p835-908 e31-e34
http://www.thelancet.com/journals/lanres/issue/current
[Reviewed earlier]

Maternal and Child Health Journal
Volume 21, Issue 11, November 2017
https://link.springer.com/journal/10995/21/11/page/1
[Reviewed earlier]

Medical Decision Making (MDM)
Volume 37, Issue 8, November 2017
http://mdm.sagepub.com/content/current
[Reviewed earlier]

The Milbank Quarterly
A Multidisciplinary Journal of Population Health and Health Policy
September 2017 Volume 95, Issue 3 Pages 447–682
http://onlinelibrary.wiley.com/doi/10.1111/milq.2017.95.issue-3/issuetoc
[Reviewed earlier]

Nature
Volume 551 Number 7680 pp271-398 16 November 2017
http://www.nature.com/nature/current_issue.html
World View
Immunization needs a technology boost
Tracking who receives vaccines is essential, but will be impossible without innovations in digital technologies, says Seth Berkley.
[See Featured Journal Content above for full text]

Nature Medicine
November 2017, Volume 23 No 11 pp1243-1384
http://www.nature.com/nm/journal/v23/n11/index.html
[Reviewed earlier]

Nature Reviews Immunology
November 2017 Vol 17 No 11
http://www.nature.com/nri/journal/v17/n11/index.html
[Reviewed earlier]

New England Journal of Medicine
November 16, 2017 Vol. 377 No. 20
http://www.nejm.org/toc/nejm/medical-journal
Sounding Board
Data Sharing from Clinical Trials — A Research Funder's Perspective
Robert Kiley, Tony Peatfield, Jennifer Hansen, and Fiona Reddington
N Engl J Med 2017; 377:1990-1992 November 16, 2017 DOI: 10.1056/NEJMsb1708278

The Wellcome Trust, the Medical Research Council, Cancer Research UK, and the Bill and Melinda Gates Foundation share a common vision for maximizing the value of data that are generated through the trials we fund. We are committed to ensuring that the data from published clinical trials can be accessed by researchers so they can validate key findings, stimulate further inquiry, and ultimately deliver lifesaving results.

The sharing of data during the outbreak of Ebola virus disease in West Africa that began in 2014 helped researchers to trace the origins of the final few cases and bring the epidemic under control.[1] And the challenge organized by the Journal to encourage researchers to use data from the Systolic Blood Pressure Intervention Trial (SPRINT) demonstrated the vast potential for those data to be reused to develop new applications and uncover new knowledge.[2]

The recent announcement by the International Committee of Medical Journal Editors (ICMJE) on data-sharing statements for clinical trials[3] is a step in the right direction but falls short of realizing our vision. The ICMJE has not mandated data sharing as a requirement for publication, and we find the example statements it provides to be vague and open to interpretation. Crucially, the requirements do not recognize that some research funders already have mandates for data sharing.

Policy

As funders of medical research, we recognize the importance of the appropriate sharing of clinical-trial data for reasons of transparency, good practice, and accelerated dissemination of results to the broader community. There is now a clear consensus that the results of all clinical trials must be reported in a timely manner, as set out in a joint statement by the World Health Organization regarding public disclosure of results from clinical trials.[4] In addition, all our organizations have implemented data-sharing policies requiring that the data from studies we have funded will be made available to other researchers at the time of publication. This requirement applies equally to clinical trials.

These policies, however, do not mean that such data have to be openly available for anyone to access on the Web. We fully recognize that some data — and especially clinical-trial data — may contain sensitive, personal information about research participants, and these data need to be shared in a manner that protects participants' privacy and confidentiality and respects the terms under which they consented to take part in the study. Such an approach might include the use of managed-access procedures, whereby requests to access data are reviewed by an independent committee, and of data-access agreements that place appropriate restrictions on how the data may be used.

As funders, we also recognize the many challenges to data sharing[5] — most notably, those related to resources, equity, and incentives.

Resources

Sharing data is not a cost-free activity. Data need to be collected, preserved, curated, and stored in standardized formats in order to be useful to the scientific community. We need to support technical solutions that enable researchers to easily discover, access, and reuse the data in order to reap the benefits of accelerating discovery, enabling research reproducibility, and preventing redundancy. In addition, funding bodies are increasingly requiring that researchers develop data-management plans as part of research proposals, and we support the justified costs of delivering these plans as an integral part of funding the research. We anticipate that the data-sharing statements required by the ICMJE can, in part, be derived from researchers' data-management-and-sharing plans.

Funders are actively working in partnership to support the development of community resources that facilitate access to clinical-trial data and reduce the burden on trialists. In particular, our organizations are planning to participate in the ClinicalStudyDataRequest.com platform,[6] which currently includes trial data from 13 pharmaceutical companies, as a mechanism for listing and providing managed access to data from clinical trials that we have funded.

Equity

Particular concerns have been raised over the effect of more stringent requirements for sharing data from clinical trials that are conducted in low-income and middle-income countries — specifically, that requiring researchers in such countries to share data with better-resourced groups elsewhere may put them at an unfair disadvantage and that benefits will not necessarily be shared with the communities that participated in the research.

Our organizations are strongly committed to establishing trusted and equitable systems for data-access governance in these settings, which may include terms that require users to contribute to training and capacity development or to share the resulting outcomes. However, the fundamental requirement to ensure that data are accessible at the time of publication still holds firm.

Incentives

Arguably, the biggest challenge to data sharing is the sense that researchers are not given incentives to share data — and worse, many researchers believe they are disadvantaging themselves by doing so. A recent survey of Wellcome Trust–funded researchers showed that the potential loss of publication opportunities — along with the belief that publishing is the only currency for successful grant funding and academic advancement — was a key factor in the inhibition of data sharing.[7]

As funders, we need to tackle this issue head-on and demonstrate that we value the sharing of data — as well as other outputs, such as software and materials (e.g., antibodies, cell lines, and reagents) — and will take these outputs into account when reviewing grant and job applications. In parallel, we will make it clear that we focus on the scientific content of an article, rather than its publication metrics or the name of the journal in which it was published. We commit to clearly communicating these values to the members of our grant-reviewing panels.

But we need to do more. The Wellcome Trust is reexamining its grant-application process to see how it can shift the emphasis from publications to a wider set of outputs. The Wellcome Innovator Awards program invites applicants to describe their key achievements and the significance in their field. These statements can be supported with reference to peer-reviewed articles, but also with other research outputs, such as patents, data sets, software, and materials.[8] Such a model could be applied more broadly. Asking applicants to explain how they support the values of open research — transparency, reproducibility, and early access to results — is also worthy of consideration.[9]

More broadly, there is a need to support and foster community-wide efforts in this realm. Such efforts include accelerating the uptake of consistent approaches for data citation that allow the use of data to be acknowledged and tracked. The recently announced initiative exploring the

value of awarding "data authorship" to researchers whose data are used or reused is also one we are following with interest.10

Conclusions
Medical research saves lives, and as the challenges in our world continue to outweigh the resources, collaboration and cooperation among members of the global research community will be essential in maximizing the effect of funded research. It is simply unacceptable that the data from published clinical trials are not made available to researchers and used to their fullest potential to improve health.

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November 2017, VOLUME 140 / ISSUE 5
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Volume 35, Issue 11, November 2017
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[No new digest content identified]

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http://currents.plos.org/outbreaks/
[Accessed 18 November 2017]
Excess Mortality Related to Chikungunya Epidemics in the Context of Co-circulation of Other Arboviruses in Brazil
November 13, 2017 · Research Article
Introduction: Chikungunya is an emerging arbovirus that reached the Western Hemisphere at the end of 2013. Studies in the Indian Ocean and India suggest that passive surveillance systems cannot recognize many of deaths associated with chikungunya, which can be inferred by an increase in the overall mortality observed during chikungunya epidemics.
Objective: We assess the mortality associated with chikungunya epidemics in the most affected states in Brazil, from 2015 and 2016.

Methods: We studied the monthly mortality by age group, comparing a period without epidemics to a chikungunya epidemic period, which we defined arbitrarily as consecutive months with incidences of more than 50 cases/100,000 persons.
Results: We obtained official data from the National System of Reported Diseases (SINAN) and the Mortality Information System (SIM), both maintained by the Ministry of Health. We identified a significant increase in the all-cause mortality rate during chikungunya epidemics, while there was no similar mortality in the previous years, even during dengue epidemics. We estimated an excess of 4,505 deaths in Pernambuco during the chikungunya epidemics (47.9 per 100,000 persons).The most affected age groups were the elderly and those under 1 year of age, and the same pattern occurred in all the states.
Discussion: Further studies at other sites are needed to confirm the association between increased mortality and chikungunya epidemics indifferent age groups. If these findings are confirmed, it will be necessary to revise the guidelines to recognize the actual mortality associated with chikungunya and to improve therapeutic approaches and protective measures in the most vulnerable groups.

PLoS Medicine
http://www.plosmedicine.org/
(Accessed 18 November 2017)
Perspective
Evidence-based restructuring of health and social care
Aziz Sheikh
Perspective | published 14 Nov 2017 PLOS Medicine
https://doi.org/10.1371/journal.pmed.1002426
Governments around the world are grappling with how to respond to the challenges resulting from the epidemiological transition. Of particular concern is the increasing number of people living—for several decades—with 1 or more non-communicable disorders. The policy focus is centred on moving care away from the expensive specialist-dominated hospital sector to more community-based longitudinal care. The United Kingdom's 2012 Health and Social Care Act, which gave control in England for the commissioning of care to clinicians working through Clinical Commissioning Groups (CCGs), represents one of the most ambitious and costly policy experiments to date [1]. This had the aims of supporting local decision-making, promoting innovation, and focusing attention on public health measures which, it was anticipated, would result in reductions in the need for specialist outpatient appointments and hospitalisations. In this issue of PLOS Medicine, however, James Lopez Bernal and colleagues report the results of their study finding that these benefits were not realised and that the intervention may have been associated with increased referrals to specialists [2].

The need to restructure care
There is now across the world increasing policy interest in the need to restructure health and social care such that it is better suited to the needs of people living with long-term conditions. Although the emergence of the specialist hospital sector was an appropriate response to cater to the large numbers of people affected by life-threatening infectious disease epidemics, the burden of disease now predominantly arises from noncommunicable disorders. The use of hospitals as the mainstay of care for people living with long-term conditions is inconvenient for patients and an inefficient use of public resources.

The policy focus is therefore on seeing whether patients can be better managed in community care contexts where they can receive longitudinal care in close proximity to where they live, with an emphasis on supported self-management and coordination of care, and with a greater focus on population-based preventive care than is possible in hospital-dominated health systems [3].

Integrating health and social care

Bradley and Taylor's investigations in The American Health Care Paradox threw into sharp relief the need to consider expenditure on both health and social care in order to understand the relationship between expenditure and health outcomes [4]. This analysis, which has been widely debated in health policy circles, has underscored the need to integrate health and social care budgets in order to maximise the potential for health gains; for example, modest investments in home adaptations and mobility aids may be the difference between an individual's ability to manage independently and a prolonged hospital admission.

Although the need to integrate health and social care policy is now widely appreciated, achieving this has proven challenging. The United Kingdom's 2012 Health and Social Care Act represents one of the most important policy experiments in this respect [1]. In essence, this has involved passing financial control of local National Health Service (NHS) budgets to general practitioners through CCGs who were charged with procuring services on behalf of their patients. The underpinning assumption was that needs assessment and provision of care are best managed by those who are locally grounded. The Act thus resulted in a major shift of control and resources from the hospital sector to those providing front-line care, but as demonstrated by Lopez Bernal et al., this did not translate into a reduction of hospitalisations and was associated with an increased number of specialist outpatient referrals [2].

Challenges to and opportunities for evidence-based policymaking

Health is largely won or lost on the basis of major health policy decisions, but these are seldom evaluated [5]. The reasons are complex, including the time and costs of undertaking such evaluations and the distinct possibility that they may reveal inconvenient truths. Politicians, especially those operating in liberal democracies such as the United Kingdom, are vulnerable to the effects of adverse publicity associated with what are often perceived as 'failed' government initiatives. These political challenges are real and not easily overcome until such time as there is a cross-party, longer-term approach to restructuring care.

More promising is that in many contexts it is now possible to exploit routinely collected data, thereby greatly reducing the time and costs of evaluating major policy initiatives on the restructuring of health and social care. This is well illustrated by the Lopez Bernal et al. study, which will have been undertaken much more rapidly and at a fraction of the cost of generating primary data [2]. As the United Kingdom's data assets continue to mature, in addition to major recent government investments to make routine data more liquid—by improving access to and the ability to link data—and developing data science capacity, it will become possible to answer an increasing array of health policy questions within rapid timeframes at minimal costs. There is thus now, at least in the United Kingdom, the opportunity for a step-change in our ability to move towards evidence-based policymaking. What remains is the political maturity to see the value in such evaluations and, where necessary, iterate the policy approach in the light of their findings.

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Surgeon General's Perspective
Charting the Course to End HIV Transmission in the United States
Sylvia Trent-Adams, PhD, RN, FAAN
RADM, US Public Health Service
Deputy Surgeon General
First Published September 21, 2017; pp. 603–605

Research
Ranking States on Coverage of Cancer-Preventing Vaccines Among Adolescents: The Influence of Imprecision
Anne R. Waldrop, MD, Jennifer L. Moss, PhD, Benmei Liu, PhD, Li Zhu, PhD
First Published August 30, 2017; pp. 627–636
Abstract
Objectives:
Identifying the best and worst states for coverage of cancer-preventing vaccines (hepatitis B [HepB] and human papillomavirus [HPV]) may guide public health officials in developing programs, such as promotion campaigns. However, acknowledging the imprecision of coverage and ranks is important for avoiding overinterpretation. The objective of this study was to examine states' vaccination coverage and ranks, as well as the imprecision of these estimates, to inform public health decision making.
Methods:
We used data on coverage of HepB and HPV vaccines among adolescents aged 13-17 from the 2011-2015 National Immunization Survey-Teen (n = 103 729 from 50 US states and Washington, DC). We calculated coverage, 95% confidence intervals (CIs), and ranks for vaccination coverage in each state, and we generated simultaneous 95% CIs for ranks using a Monte Carlo method with 100 000 simulations.
Results:
Across years, HepB vaccination coverage was 92.2% (95% CI, 91.8%-92.5%; states' range, 84.3% in West Virginia to 97.0% in Connecticut). HPV vaccination coverage was 57.4% (95%

CI, 56.6%-58.2%; range, 41.8% in Kansas to 78.0% in Rhode Island) for girls and 31.0% (95% CI, 30.3%-31.8%; range, 19.0% in Utah to 59.3% in Rhode Island) for boys. States with the highest and lowest ranks generally had narrow 95% CIs; for example, Rhode Island was ranked first (95% CI, 1-1) and Kansas was ranked 51st (95% CI, 49-51) for girls' HPV vaccination. However, states with intermediate ranks had wider and more imprecise 95% CIs; for example, New York was 26th for girls' HPV vaccination coverage, but its 95% CI included ranks 18-35.
Conclusions:
States' ranks of coverage of cancer-preventing vaccines were imprecise, especially for states in the middle of the range; thus, performance rankings presented without measures of imprecision could be overinterpreted. However, ranks can highlight high-performing and low-performing states to target for further research and vaccination promotion programming.

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17 November 2017 Vol 358, Issue 6365
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Policy Forum

Racing for academic glory and patents: Lessons from CRISPR

By Arti K. Rai, Robert Cook-Deegan

Science17 Nov 2017 : 874-876 Restricted Access

Overly broad patents must be reined in

Summary

The much-publicized dispute over patent rights to CRISPR-Cas9 gene-editing technology highlights tensions that have been percolating for almost four decades, since the U.S. Bayh-Dole Act of 1980 invoked patents as a mechanism for promoting commercialization of federally funded research. With the encouragement provided by Bayh-Dole, academic scientists and their research institutions now race in dual competitive domains: the quest for glory in academic research and in the patent sphere. Yet, a robust economic literature (1, 2) argues that races are often socially wasteful; the racing parties expend duplicative resources, in terms of both the research itself and the legal fees spent attempting to acquire patents, all in the pursuit of what may be a modest acceleration of invention. For CRISPR, and future races involving broadly useful technologies for which it may set a precedent, the relationship between these competitive domains needs to be parsed carefully. On the basis of legal maneuvers thus far, it appears that the litigants will try for broad rights; public benefit will depend on courts reining them in and, when broad patents slip through, on updating Bayh-Dole's pro-commercialization safeguards with underused features of the Act.

Perspectives

Advancing dengue vaccine development

By Mark B. Feinberg, Rafi Ahmed

Science17 Nov 2017 : 865-866 Restricted Access

Insights into the natural history of dengue virus infection guide vaccine development

Summary

Dengue virus (DENV) is a member of the viral genus Flavivirus, which also includes yellow fever virus (YFV) and Zika virus (ZIKV). DENV infection is a major and growing global health threat: There are ~400 million cases of infection, ~500,000 hospitalizations, and ~12,500 deaths now estimated to occur each year (1). Dengue represents the most common mosquito-borne disease in humans (1). A remarkable 50% of the world's population now lives in regions where DENV transmission is manifest. Dengue is associated with a wide spectrum of clinical outcomes, ranging from mild febrile illnesses to dengue hemorrhagic fever to the most severe clinical presentation of dengue shock syndrome, which is characterized by profound systemic cytokine activation, vascular leakage, and shock—this carries a high risk of death. On page 929 of this issue, Katzelnick et al. (2) analyzed DENV infection outcome data gleaned from the long-term followup of a cohort of Nicaraguan children (2). They found that the risk of severe dengue disease upon subsequent DENV infection correlated with baseline DENV antibody concentrations (titers), which has implications for DENV vaccination approaches.

Reports

Antibody-dependent enhancement of severe dengue disease in humans

By Leah C. Katzelnick, Lionel Gresh, M. Elizabeth Halloran, Juan Carlos Mercado, Guillermina Kuan, Aubree Gordon, Angel Balmaseda, Eva Harris

Science17 Nov 2017 : 929-932 Full Access

A long-term Nicaraguan pediatric cohort reveals that a narrow range of preexisting antibody titers increases the risk of severe dengue disease.

Editor's Summary

Too much or too little—better than some

Dengue fever is caused by a mosquito-transmitted flavivirus resembling Zika virus. Both viruses can cause severe diseases in humans with catastrophic sequelae. It has been suspected in humans, and shown in animal models, that the host's immune responses can make disease worse. Katzelnick et al. examined data from a long-term study of Nicaraguan children exposed to dengue virus (see the Perspective by Feinberg and Ahmed). They confirmed that antibody-dependent enhancement of disease occurs at a specific range of antibody concentrations. Low levels of antibody did not enhance disease, intermediate levels exacerbated disease, and high antibody titers protected against severe disease. These findings have major implications for vaccines against flaviviruses. Indeed, recent vaccine trials have shown evidence of severe disease in some recipients who were previously exposed to virus.

Science, this issue p. 929; see also p. 865

Abstract

For dengue viruses 1 to 4 (DENV1-4), a specific range of antibody titer has been shown to enhance viral replication in vitro and severe disease in animal models. Although suspected, such antibody-dependent enhancement of severe disease has not been shown to occur in humans. Using multiple statistical approaches to study a long-term pediatric cohort in Nicaragua, we show that risk of severe dengue disease is highest within a narrow range of preexisting anti-DENV antibody titers. By contrast, we observe protection from all symptomatic dengue disease at high antibody titers. Thus, immune correlates of severe dengue must be evaluated separately from correlates of protection against symptomatic disease. These results have implications for studies of dengue pathogenesis and for vaccine development, because enhancement, not just lack of protection, is of concern.

Science Translational Medicine

15 November 2017 Vol 9, Issue 416

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November 2017 Volume 22, Issue 11 Pages 1361–1462

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Volume 35, Issue 48, Part A Pages 6469–6582 (4 December 2017)
http://www.sciencedirect.com/journal/vaccine/vol/35/issue/48/part/PA
Harmonising Immunisation Safety Assessment in Pregnancy - Part II
Introduction
Safety assessment of immunization in pregnancy
Open access
Pages 6469–6471
Sonali Kochhar, Jorgen Bauwens, Jan Bonhoeffer, GAIA Project Participants
In pregnancy, immunological and physiological changes may increase a woman's risk of infections and their sequelae. The immature immune system of the fetus and neonate pose an additional risk of infection and associated complications for the developing infant, including preterm birth [1,2]. In 2016, it was estimated that neonatal death accounted for approximately 45 percent of mortality among children less than five years of age [3]. Immunization in pregnancy has emerged as an important and successful public health intervention globally to reduce mortality and morbidity among pregnant women, their developing fetuses and neonates, and infants [4]. It may become a key strategy to address neonatal mortality in particular. This is particularly true in low and middle-income countries (LMIC) where the burden of vaccine-preventable diseases is the greatest and access to basic health services is limited.

An important aim of vaccinating pregnant women is to increase pathogen-specific antibodies in the mother to protect against some of the leading causes of morbidity in pregnant women [5]. Also, high and protective levels of immunoglobulin G may be transferred across the placenta from the vaccinated mother to the fetus [6]. This may reduce risk of transmitting infections to the infant and may also directly provide passive immunity early in life, which is a period of vulnerability for the infant [6]. The success of maternal tetanus vaccination demonstrates this principle and is part of routine care in many countries: 41 out of 59 countries achieved Maternal and Neonatal Tetanus (MNT) elimination as a result of the MNT Elimination programme in conjunction with the World Health Organization (WHO) and UNICEF [7]. Influenza and pertussis vaccines are being increasingly recommended as an integral part of immunization in pregnancy programs. These programs have demonstrated the feasibility and effectiveness of immunization in pregnancy programs in high, middle and low-income countries. New vaccines are being developed to prevent infections in pregnant women and infants, including against Group B streptococcus, respiratory syncytial virus, and cytomegalovirus [4].

Immunization in pregnancy is currently an underutilized strategy and public awareness and acceptance could be improved. Despite evidence for their safety and effectiveness in both mothers and their infants, vaccine uptake in pregnancy remains low for influenza and moderate for pertussis vaccine. The uptake of the influenza vaccine in pregnancy rarely exceeds 50 percent in developed countries, even in countries with national vaccination strategies in place. For example, 50 percent of women in the US were vaccinated against influenza just before or during pregnancy in the 2015–16 influenza season [8]. Influenza and pertussis vaccine uptake in pregnancy in England was around 42 percent and 60 percent, respectively in 2015–2016. The UK has among the highest coverage rates globally, indicating the scale of potential improvement [9]. The coverage of seasonal influenza vaccination in the 2014–15 influenza season in pregnant women in five EU Member States was between 0.3% and 56.1% (median

23.6%). No country achieved the EU target of 75 percent coverage among the risk groups) [10]. In LMIC, influenza vaccine coverage amongst pregnant women is negligible in 35 of the 64 tropical countries that recommend seasonal influenza vaccination for pregnant women [11].

Barriers to vaccination in pregnancy are complex and vary depending on the country and population. The safety of vaccines administered during pregnancy is a key consideration for pregnant women, healthcare providers, vaccine manufacturers, investigators, regulators, ethics committees and communities [4]. There is a need for a globally harmonised approach to actively monitor the safety of vaccines used in immunization programs for pregnant women [12].

Historically, there was little standardization of case definitions for adverse events following immunization (AEFI) [13]. This resulted in limited comparisons of safety data across vaccine trials and studies in pre- and post-licensure settings. The Brighton Collaboration (BC) was formed in 2000 to help to overcome this shortcoming [14]. Today, BC case definitions are used and recommended for use by normative bodies such as the World Health Organization (WHO), the US FDA, the European Medicines Agency, the US Centers for Disease Control and Prevention (CDC), and the European Centre for Disease Prevention and Control (ECDC) [15].

The GAIA (Global Alignment of Immunization Safety Assessment in Pregnancy) project (http://gaia-consortium.net), coordinated by the Brighton Collaboration Foundation (BCF) and funded by the Bill and Melinda Gates Foundation, was initiated in 2015 for an initial period of two years (2015–2016). This was a response to the World Health Organization's call for a globally harmonised approach to actively monitor the safety of vaccines and immunization in pregnancy programs with a specific focus on LMIC needs and requirements [12]. In the GAIA project, experts from 13 organisations (BCF, US National Institute of Health, WHO, Global Healthcare Consulting, University of Washington, Baylor College of Medicine, Monash Institute of Medical Research, St. George's University of London, Erasmus University Medical Center, Cincinnati Children's Hospital, Public Health Agency Canada, Synapse Research Management Partners and International Alliance for Biological Standardization) collaborated with over 200 volunteers worldwide who participated in 25 specific working groups [16].

During the GAIA project, a global functional network of experts was created, bringing together experts in vaccinology, maternal health, and neonatology from academia, public health institutes, regulatory agencies, investigators and vaccine manufacturers from LMIC and high-income countries. GAIA outputs include a landscape analysis of available standards and guidance documents, comprising regulatory guidance pertinent to immunization in pregnancy from the Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the International Conference on Harmonisation [4].

Further, GAIA has developed two guideline documents for a harmonised conduct of clinical trials of vaccines in pregnant women [17,18]. This includes recommendations for harmonised collection, analysis and presentation of safety data, provides guidance on the prioritisation and classification of data to be collected, as well as guidance on study design, applicable in various settings, including LMICs. The WHO Global Advisory Committee on Vaccine Safety (GACVS) provided a highly supportive assessment of the GAIA guidelines for clinical trials and considered them to be timely and useful [19]. These guidelines may also inform safety monitoring of vaccines already recommended for pregnant women (tetanus, influenza and pertussis).

The GAIA partners developed the first set of over 21 standardized case definitions of prioritized obstetric and neonatal outcomes based on the standard Brighton Collaboration process [20]. The first 10 definitions were published in a special issue of the journal Vaccine in December 2016. They comprise five obstetric (hypertensive disorders of pregnancy, maternal death, non-reassuring foetal status, pathways to preterm birth and postpartum haemorrhage) and five neonatal outcomes (congenital anomalies, neonatal death, neonatal infections, preterm birth and stillbirth) [21]. These were complemnted with definitions and assessment algorithms of enabling terms (e.g., gestational age).

Moreover, a searchable database of terms (glossary), concept definitions and ontology of over 3000 terms related to key events for monitoring immunization in pregnancy was developed (https://evs.nci.nih.gov/ftp1/GAIA/About.html). A map of disease codes across coding terminologies, including MedDRA and ICD, was created to enable pooling of data from various sources. An online tool for automated case classification (single case or batch classification) of events according to the standardized case definitions has also been developed [12].

An investigator workshop assessing the usefulness and applicability of GAIA guidelines and case definitions in clinical trials and observational studies in LMIC, and an internatonal consensus conference were held at the National Institute of Health (NIH) [22].

In this special issue, the next set of 11 case definitions including five obstetric outcomes (abortion, antenatal bleeding, gestational diabetes, dysfunctional labour, foetal growth retardation) and six neonatal outcomes (low birth weight, small for gestational age, neonatal encephalopathy, respiratory distress, failure to thrive and microcephaly) are published. In the light of the important public health benefit of immunization in pregnancy in particularly LMIC and the significant challenges of conducting research in low resource settings especially with pregnant women, the paper by Kochhar et al. highlights pertinent aspects of study design, regulatory and safety monitoring considerations in these settings.

The GAIA outputs are already being increasingly utilized in the field of immunization in pregnancy and maternal and child health by key stakeholders such as clinical trialists, investigators, regulators, and industry. Useful next steps would be monitoring the implementation of GAIA outputs and a structured assessment of their current field use in addition to systematic evaluation of GAIA output performance and the impact on data quality. This could guide refinement of tools, and updates of guidelines and case definitions in cyclical revision periods. A second way to stimulate scientific progress could be by developing additional guidelines and tools requested by investigators and key stakeholders, and establishing a central resource that may provide investigators and stakeholders with the standards and tools they need.

The GAIA guidelines, definitions and tools will be applicable in immunization in pregnancy pre- and post-licensure safety and pharmacovigilance surveillance systems and may help supporting enhanced surveillance and collection of safety data that can be consolidated and compared across sites, countries, and programs worldwide. A standardized approach to safety data collection and reporting is likely to improve the acceptability and implementation of immunizations in pregnancy and subsequently help reduce illness and death among pregnant women and infants globally.

Research considerations
Immunization in pregnancy clinical research in low- and middle-income countries – Study design, regulatory and safety considerations
Open access
Pages 6575–6581
Sonali Kochhar, Jan Bonhoeffer, Christine E. Jones, Flor M. Muñoz, ... Steven Hirschfeld
Abstract
Immunization of pregnant women is a promising public health strategy to reduce morbidity and mortality among both the mothers and their infants. Establishing safety and efficacy of vaccines generally uses a hybrid design between a conventional interventional study and an observational study that requires enrolling thousands of study participants to detect an unknown number of uncommon events. Historically, enrollment of pregnant women in clinical research studies encountered many barriers based on risk aversion, lack of knowledge, and regulatory ambiguity. Conducting research enrolling pregnant women in low- and middle-income countries can have additional factors to address such as limited availability of baseline epidemiologic data on disease burden and maternal and neonatal outcomes during and after pregnancy; challenges in recruiting and retaining pregnant women in research studies, variability in applying and interpreting assessment methods, and variability in locally acceptable and available infrastructure. Some measures to address these challenges include adjustment of study design, tailoring recruitment, consent process, retention strategies, operational and logistical processes, and the use of definitions and data collection methods that will align with efforts globally

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(Accessed 18 November 2017)
[No new digest content identified]

Value in Health
October–November 2017 Volume 20, Issue 9
http://www.valueinhealthjournal.com/current
ISPOR 20th Annual European Congress Research Abstracts
[Reviewed earlier]

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

EID Journal
Volume 23, Supplement—December 2017
Research

Centers for Disease Control and Prevention Public Health Response to Humanitarian Emergencies, 2007–2016

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Abstract
Humanitarian emergencies, including complex emergencies associated with fragile states or areas of conflict, affect millions of persons worldwide. Such emergencies threaten global health security and have complicated but predictable effects on public health. The Centers for Disease Control and Prevention (CDC) Emergency Response and Recovery Branch (ERRB) contributes to public health emergency responses by providing epidemiologic support for humanitarian health interventions. To capture the extent of this emergency response work for the past decade, we conducted a retrospective review of ERRB's responses during 2007–2016. Responses were conducted across the world and in collaboration with national and international partners. Lessons from this work include the need to develop epidemiologic tools for use in resource-limited contexts, build local capacity for response and health systems recovery, and adapt responses to changing public health threats in fragile states. Through ERRB's multisector expertise and ability to respond quickly, CDC guides humanitarian response to protect emergency-affected populations.

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Media/Policy Watch

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

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

The Atlantic
http://www.theatlantic.com/magazine/
Accessed 18 November 2017
[No new, unique, relevant content]

BBC
http://www.bbc.co.uk/
Accessed 18 November 2017
[No new, unique, relevant content]

The Economist
http://www.economist.com/
Accessed 18 November 2017
[No new, unique, relevant content]

Financial Times
http://www.ft.com/home/uk
Accessed 18 November 2017

Forbes
http://www.forbes.com/
Accessed 18 November 2017
[No new, unique, relevant content]

Foreign Affairs
http://www.foreignaffairs.com/
Accessed 18 November 2017
[No new, unique, relevant content]

Foreign Policy
http://foreignpolicy.com/
Accessed 18 November 2017[
No new, unique, relevant content]

The Guardian
http://www.guardiannews.com/
Accessed 18 November 2017
[No new, unique, relevant content]

New Yorker
http://www.newyorker.com/
Accessed 18 November 2017
[No new, unique, relevant content]

New York Times
http://www.nytimes.com/
Accessed 18 November 2017
U.N. Pleads for End of Yemen Blockade or 'Untold Thousands' Will Die

The heads of three U.N. agencies urged the Saudi-led military coalition on Thursday to lift its blockade of Yemen, warning that "untold thousands" would die if it stayed in place.
November 17, 2017 - By REUTERS -

Wall Street Journal
http://online.wsj.com/home-page?_wsjregion=na,us&_homepage=/home/us
Accessed 18 November 2017
[No new, unique, relevant content]

Washington Post
http://www.washingtonpost.com/
Accessed 18 November 2017
Vaccine Shortage Complicates Efforts To Quell Hepatitis A Outbreaks
Stephanie O'Neill | Kaiser Health News · National · Nov 14, 2017

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Think Tanks et al

Brookings
http://www.brookings.edu/
Accessed 18 November 2017
[No new relevant content]

Center for Global Development
http://www.cgdev.org/page/press-center
Accessed 18 November 2017
[No new relevant content]

Council on Foreign Relations
http://www.cfr.org/
Accessed 18 November 2017
[No new relevant content]

CSIS
https://www.csis.org/
Accessed 18 November 2017
[No new relevant content]

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Vaccines and Global Health: The Week in Review *is a service of the Center for Vaccines Ethics and Policy (CVEP) which is solely responsible for its content, and is an open access*

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

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