



READY2RESPOND THE POWER OF PREPAREDNESS

Ready2Respond Brings a New, Collaborative Approach to the Long- Standing Challenge of Vaccine Access in Low- and Middle-Income Countries

(Source: An article by Marie Mazur of Ready2Respond)

Creating the systems that will ensure low- and middle-income countries (LMICs) will have sustained, equitable access to vaccines – including those for seasonal influenza – has been a complex challenge for decades.

While vaccination remains the greatest tool for limiting illness and death, many countries still lack the vaccine delivery systems to keep their populations safe. Not only do influenza programs reduce the number of deaths and illnesses each year, they are also a mechanism to strengthen overall preparedness for epidemics and pandemics.

Countries in which seasonal influenza vaccination programs were present before the 2009 influenza pandemic were better able to import and use vaccines much faster than countries without such programs. Early data show that having a seasonal influenza vaccination program in place has reinforced an efficient COVID-19 response.

The COVID-19 pandemic has brought the issue of vaccine access into high relief. Indeed, as of January 31, 2022, just 11.18% of people in low-income countries had received at least one dose of COVID-19 vaccine compared with 67.53% of people in high-income countries. Moreover, influenza vaccines are underused in LMICs; 49 percent of world's population receive only 5 percent of influenza vaccine doses annually.

Need for Innovative Solutions is Urgent

The World Health Organization has noted that the global failure to share COVID-19 vaccines equitably is taking its toll on some of the world's poorest and most vulnerable people. New variants of concern mean that the risks of infection have increased in all countries for people who are not yet protected by vaccination. The implications of these disparities could not be more obvious: We truly are "one world" and our collective health and economic wellbeing are inextricably linked.

A new coalition, Ready2Respond, has taken a fresh look at the issue and aims to show that, in LMICs where flu prevention programming is in place, including sustained access to influenza vaccines, communities are measurably better positioned to maintain their economic stability throughout the next respiratory virus pandemic, whenever it may strike.

Representing over 50 organizations from various sectors related to the vaccination ecosystem, including vaccine suppliers, vaccine delivery companies, **trade associations such as IFPW, IFPMA, DCVMN and BIO**, government agencies, non-government organizations, academic institutions and philanthropies such as Wellcome Trust, Ready2Respond marked its one-year anniversary in December 2021. The coalition's participants are now working to close the most problematic gaps in the vaccine deployment systems found in underserved economies.

Using Flu & COVID Vaccination Programs as Readiness Blueprints

While initially created to address seasonal and pandemic influenza

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Around the Globe...

- ◆ In South Africa, malaria cases are being misdiagnosed as COVID-19. Both malaria and COVID-19 have similar non-specific early symptoms including fever, chills, headaches, fatigue, and muscle pain. Undiagnosed and untreated malaria rapidly progresses to severe illness, with a potentially fatal outcome. Patients must remember to inform their healthcare provider of their recent travel, particularly to neighboring countries and malaria risk areas in South Africa, so that the healthcare provider is made aware of the possibility of malaria.

- ◆ In its first public safety alert in six years, the **U.S. Drug Enforcement Administration (DEA)** is warning about a dramatic increase in fake prescription drugs being sold on the black market containing a potentially lethal dose of fentanyl. The DEA stated that the counterfeit pills — made to look like real opioid medications such as *oxycodone*, *Percocet* or *Adderall* — are being sold on the street by dealers or online, including through social media platforms. "If you have a smartphone and you're sitting on the sofa at home, your drug dealer is right there in your hands," DEA spokesperson Anne Edgecomb said in a statement.

- ◆ The Government of the Republic of Congo has taken receipt of an additional 200,000 COVID-19 vaccine doses, developed by Chinese healthcare group, the **China National Pharmaceutical Group Corporation (Sinopharm)**. The initiative is part of China's official strategy to build Sino-African relations, through vaccine diplomacy. The donation was received by *Jean-Ignace Tendelet*, Chief of Staff at the Congolese Ministry of Health; *Max Henri Monka*, Chief of Staff at the Congolese Ministry of International Cooperation; in collaboration with *H.E. Ma Fulin*, Chinese Ambassador to the Republic of Congo.

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Strategic Training Executive Programme (STEP) 2.0 Aims to Strengthen Zambia's Supply Chain

(Source: Kali Bechtold and Kevin Etter, Yale Global Health Leadership Initiative and Gavi the vaccine alliance)

The Strategic Training Executive Programme (STEP) 2.0, a six-month leadership solution for supply chain managers, launched its first fully virtual course (vSTEP) in October 2021, engaging 30 professionals at the national and sub-national level in Zambia. Participants are paired with a private sector expert from GlaxoSmithKline (GSK), Johnson & Johnson, or Merck and engage in a curriculum facilitated by Yale's Global Health Leadership Initiative that has been adapted to be relevant and feasible during the COVID-19 pandemic. At the end of the programme, participants will have completed individual transformation projects that diagnose and address a complex supply chain challenge within their sphere of influence.

STEP 2.0 includes practical skills building in adaptive leadership, change management, and strategic communication, equipping supply chain professionals to ensure the availability of critical vaccines and essential medicines in even the most challenging contexts. The programme traditionally includes a series of preparatory assignments, a five-day in person forum, and follow up private sector coaching culminating in support of a transformational challenge.

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Ready2Respond (cont.)...

in LMICs, Ready2Respond quickly expanded its scope when COVID-19 began to emerge. Ready2Respond aims to empower LMICs to use seasonal influenza and COVID-19 endemic vaccination programs as a public health blueprint for epidemic and pandemic readiness.

In 2021, Ready2Respond conducted an extensive in-country survey geared toward gaining a deeper understanding of how individual vaccine program managers in LMICs view their respective public health landscapes and the challenges they may be facing in ensuring access to vaccines.

Study results show a systemic lack of influenza burden of disease data across the board. This lack has contributed to flu being less prioritized among LMIC decision makers and others. As a first, short-term goal, Ready2Respond has committed to generating original, evidence-based data sets for use in building the economic case for influenza programming and readiness as the highest priority in LMIC public health programs at the country level.

Ready2Respond is also selectively investing in developing tools to strengthen countries' vaccine demand planning capabilities. This should result in more robust vaccine supply access from the private sector and from donating organizations such as COVAX.

Unparalleled in today's pandemic preparedness ecosystem, this novel approach to collaboratively resolving challenges that have been hindering the equitable access and deployment of vaccines is a tangible contribution to pandemic preparedness.

The outcomes will be relevant to existing and next generation influenza and COVID-19 vaccines and to future adult respiratory vaccines, such as RSV. We are all in this together and the solutions will come from us all. If you have an interest in becoming involved in or supporting the work Ready2Respond is doing, please contact the organization today.

An Estimated 1.2 Million Deaths Blamed on Antibiotic Resistant Bacterial Infections in 2019

(Source: A Staff article by World Pharma News)

More than 1.2 million people died in 2019 as a direct result of antibiotic-resistant bacterial infections, according to the most comprehensive estimate to date of the global impact of antimicrobial resistance (AMR). The analysis of 204 countries and territories, published in *The Lancet*, reveals that AMR is now a leading cause of death worldwide, higher than HIV/AIDS or malaria with many hundreds of thousands of deaths occurring due to common, previously treatable infections - such as lower respiratory and bloodstream infections - because the bacteria that cause them are now resistant to treatment.

The report highlights an urgent need to scale up action to combat AMR and outlines immediate actions for policymakers that will help save lives and protect health systems. These include optimizing the use of existing antibiotics, taking greater action to monitor and control infections, and providing more funding to develop new antibiotics and treatments.

Study co-author Professor Chris Murray, of the Institute for Health Metrics and Evaluation at the University of Washington, USA, said: "These new data reveal the true scale of antimicrobial resistance worldwide, and are a clear signal that we must act now to combat the threat. Previous estimates had predicted 10 million annual deaths from antimicrobial resistance by 2050, but we now know for certain that we are already far closer to that figure than we thought. We need to leverage this data to course-correct action and drive innovation if we want to stay ahead in the race against antimicrobial resistance."

Until now no estimates have covered all locations and a broad range of pathogens and drug combinations. The new Global Research on Antimicrobial Resistance (GRAM) report estimates deaths linked to 23 pathogens and 88 pathogen-drug combinations in 204 countries and territories in 2019.

Statistical modelling was used to produce estimates of the impact of AMR in all locations - including those with no data - using 471 million individual records obtained from systematic literature reviews, hospital systems, surveillance systems, and other data sources. Disease burden was estimated in two ways: deaths caused directly by AMR (i.e. deaths that would not have occurred had the infections been drug susceptible and therefore more treatable), and deaths associated with AMR (i.e. where a drug-resistant infection was implicated in deaths, but resistance itself may or may not have been the direct cause). Deaths caused by and associated with AMR were calculated for 204 countries and territories and reported for 21 global regions and seven super-regions.

The analysis shows AMR was directly responsible for an estimated 1.27 million deaths worldwide, and associated with an estimated 4.95 million deaths, in 2019. HIV/AIDS and malaria have been estimated to have caused 860,000 and 640,000 deaths, respectively, in 2019.[2] Drug-resistance in lower respiratory infections - such as pneumonia - had the greatest impact on AMR disease burden, causing more than 400,000 deaths and associated with more than 1.5 million deaths. Drug resistance in bloodstream infections - which can lead to the life-threatening condition sepsis - caused around 370,000 deaths and was associated with nearly 1.5 million deaths. Drug resistance in intra-abdominal infections - commonly caused by appendicitis - led directly to around 210,000 deaths and was associated with around 800,000. While AMR poses a threat to people of all ages, young children were found to be at particularly high risk, with around one in five deaths attributable to AMR occurring in children aged under five years. Deaths caused directly by AMR were estimated to be highest in Sub-Saharan Africa and South Asia, at 24 deaths per 100,000 population and 22 deaths per 100,000 population, respectively. AMR was associated with 99 deaths per 100,000 in Sub-Saharan Africa and 77 deaths per 100,000 in South Asia. In high-income countries, AMR led directly to 13 deaths per 100,000 and was associated with 56 deaths per 100,000.

STEP (cont.)...

The virtual STEP (vSTEP) includes weekly live, virtual seminars and monthly coaching sessions with private sector coaches. Preliminary results show high levels of participant engagement, including attendance in live virtual sessions and routine completion of programme requirements. The vSTEP Zambia course has been made possible through financial support from GSK to the International Federation of Pharmaceutical Wholesalers, Inc. (IFPW) Foundation's collaborations with Gavi. For more information, please contact Lynka Ineza, Programme Manager at the Yale Global Health Leadership Initiative.

A New Kind of Vaccine Inequality

(Source: An article by Anthony Faiola for the Washington Post)

After a trying period of vaccine hoarding by wealthy countries, the last 40 days of 2021 saw more doses shipped to countries in need through the U.N.-backed Covax program than in the rest of last year combined, according to the World Health Organization's vaccine director.

Distribution campaigns on the ground can take months to ramp up, and a host of developing countries now receiving shipments are facing a combination of rollout challenges similar to those witnessed during the early-stage campaigns in the United States and Europe. This includes where, when and how many vaccines can be made available on a regular

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UNICEF Supporting Fast-Tracking of Ultra-Cold Chains for a Billion COVID-19 Vaccine Doses

(Source: An article by Anahitta Shirzad of UNICEF for Global Immunization News)

A billion COVID-19 vaccine doses, which need to be stored in temperatures colder than winters in Antarctica, are headed to 92 low- and lower-middle income countries and UNICEF is working hard to ensure Ultra-Cold Chains (UCCs) are in place to receive and preserve them.

Having already delivered and installed over 487 units of UCCs in 57 countries for over 126 million doses of COVID-19 vaccines, UNICEF is in advanced stages of installing 251 units in an additional 10 countries that will be able to store over 70 million doses of COVID-19 vaccines.

Additionally, UNICEF is supporting UCC in another 25 countries through technical assistance. “Efficiencies at scale is our driving motto with our teams clocking 12 days as the average lead time from the receipt of UCCs at port of entry to installation and functionality test,” said Michelle Seidel, UNICEF Senior Advisor for Immunization. “We are looking at bringing the average time down to 10 days for the entire process of clearance, re-gassing, distribution and tests if we can get quicker in-country custom clearances,” she added.

The existing vaccine cold chains in countries are typically designed for vaccine storage at +2 C to +8 C, and -20 C degrees but Pfizer-BioNTech vaccine requires temperatures between -60 C and -86 C. The availability of Ultra-Low Temperature (ULT) freezers is extremely limited in most of the low- and lower-middle income countries. UNICEF Supply Division is procuring, installing as well as training recipient countries to handle and monitor UCC in partnership with other UN agencies, governments, multilateral institutions as well as private sector entities.

Most importantly, 43% of ULT freezers are headed for the African region. To ensure a full continuum of support, UNICEF is also deploying 75 Vaccine Management Specialists in 40 countries to ensure every vaccine dose counts, and is effectively used in a manner that is also sensitive to vaccine expirations.

Vaccine Inequity (cont.)...

basis, as well as how to convince the vaccine resistant to roll up their sleeves. On top of that, they are confronting additional complications from often harder-to-access populations and limited resources, particularly poorly funded health-care systems.

The World Bank, U.N. agencies, the Gavi vaccine alliance and charities have rolled out efforts and funding to bolster distribution programs in the developing world. But critics contend that not enough resources are being allocated to help poorer countries get shots in arms. This is resulting in countless vaccines sitting around and waiting to be used as the clock on expiration dates ticks down.

According to research by the international humanitarian organization CARE, 32 low- and middle-income countries have used less than half of the vaccines they've received from the Covax program, bilateral donations and other sources. Developing countries “don't have the ability to distribute because there hasn't been the corresponding investment, and if they were going to do that, they would have to make such serious tradeoffs in their health systems,” Emily Janoch, CARE's director of knowledge management said.

Kate O'Brien, the World Health Organization's vaccine director, stated that distribution funding “is absolutely an issue that we're experiencing and hearing about from countries, that the funding that's needed at the peripheral level where the funding is actually spent is not what it needs to be.” Much has been made, perhaps unjustly, about vaccine hesitancy

in poorer nations. South Africa delayed coronavirus vaccine shipments in November just ahead of the omicron explosion, with resistance cited as one factor. But experts have said that while particular countries may face a relative excess of vaccine hesitancy regardless of their economic level, there is no evidence that reluctance is any greater on average in the developing world than in the United States or Europe. They are, however, combating resistance later on in the pandemic due to massive delays in access, and are doing it with fewer resources than richer nations that have funded expensive marketing and mobilization campaigns and publicity stunts.

“Studies after studies are showing that 80 percent of our population is ready to take vaccines if they are available,” John Nkengasong, director of the Africa Centers for Disease Control and Prevention, told a World Economic Forum virtual conference in January. “No one can dispute it.”

Vaccine access still remains an issue in many countries. But increasingly, logistical challenges, staffing problems and doses offered too close to their expiration date — a particular problem with donated vaccines from the West — are replacing access as the primary obstacle. UNICEF this month announced that developing nations had rejected 100 million doses of vaccines that were too close to their expiration date, and their ground games for storage and distribution were not strong enough to ensure use before expiry. African nations are confronting particular challenges with underfunded health-care systems.

Additionally, CARE has also stated that the actual cost for vaccine rollouts in developing countries has been vastly under-calculated by international donors.

Around the Globe (cont.)...

- ◆ Counterfeit versions of HIV meds—mostly of *Biktary* and *Descovy*—worth over US\$250 million were sold in the United States during the past two years, alleges **Gilead Sciences**, which manufactures the drugs and has sued the illegal distributors. *Biktary* and *Descovy* are used as HIV treatment; *Descovy* may also be prescribed as pre-exposure prophylaxis to prevent HIV.

- ◆ Two major developments underline how dramatically Omicron continues to affect the response to the pandemic. The **U.S. Food and Drug Administration (FDA)** effectively revoked the authorizations of the COVID-19 monoclonal antibody therapies sold by **Regeneron Pharmaceuticals** and **Eli Lilly** saying they likely don't work in people infected with the Omicron variant. That leaves only one authorized monoclonal antibody therapy, **GlaxoSmithKline** and **Vir Biotechnology's sotrovimab**. Also, **Pfizer** and **BioNTech** announced a trial of a Omicron-specific version of their Covid-19 vaccine, saying that while the currently available boosters protect against Omicron, the trial will help prepare for future vaccination strategies.

- ◆ In a new meta-analysis of randomized, placebo-controlled COVID-19 vaccine trials, researchers at **Beth Israel Deaconess Medical Center (BIDMC)** compared the rates of adverse events reported by participants who received the vaccines to the rates of adverse events reported by those who received a placebo containing no vaccine. Nearly a third of participants who received the placebo reported at least one adverse event, with headache and fatigue being the most common. The team's findings are published in *JAMA Network Open*. Investigators in the Program in Placebo Studies at BIDMC, said, “Collecting systematic evidence regarding these nocebo responses in vaccine trials is important for COVID-19 vaccination worldwide, especially because concern about side effects is reported to be a reason for vaccine hesitancy.”

(Sources: Bloomberg, Company Press Releases, Energy Capital Power Newsletter, NPR, and Outbreak News Today)