FIU FLORIDA INTERNATIONAL UNIVERSITY

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Baylor College of Medicine

NATIONAL SCHOOL OF TROPICAL MEDICINE

COVID-19 VACCINES:

A GLOBAL EXPERTS' SUMMIT

February 26, 2021

REPORT

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COVID-19 Vaccines Experts' Summit
February 26, 2021

Welcome message from Florida International University

Dr. Carlos Espinal
Director, Global Health Consortium, Robert Stempel College of Public Health & Social Work, Florida International University

Dr. Carlos Espinal opened the Summit, hosted by the President's Office of Florida International University in collaboration with the Global Health Consortium at the Robert Stempel College of Public Health and Social Work. He thanked the Pan American Health Organization, the World Health Organization (PAHO / WHO), and the National School of Tropical Medicine at the Baylor College of Medicine for being partners in the event. He also thanked the distinguished panel of globally recognized experts for bringing to this Summit the latest scientific information on COVID-19 vaccines and the impact of the ongoing vaccination strategies worldwide.

Dr. Tomás R. Guilarte
Dean, Robert Stempel College of Public Health & Social Work, Florida International University

Dr. Tomás R. Guilarte, Dean of Robert Stempel College of Public Health and Social Work, thanked President Mark Rosenberg for initiating this Summit, following the success of the annual Global Health Conference hosted in October 2020. This conference welcomed more than 2,500 attendees from over 60 countries participating in a virtual event focused on COVID-19 and other communicable diseases. He emphasized the importance of focusing on health disparities and those in marginalized communities. In thanking the over 4,600 Summit registrants, he felt confident that they would continue further discussion on developing the incredible advances made over the past few months.

Dr. Mark B. Rosenberg
President, Florida International University

Dr. Mark. B. Rosenberg, President of Florida International University, summarized the history of FIU and its commitment to the upward mobility of students. FIU had been created by the Florida State Legislature with an explicit international mandate to bring people together to find solutions to common problems. President Rosenberg underscored the importance of the timing of this Summit. He stressed our responsibility to develop cutting-edge research and to find a way of turning words into deeds. This could be achieved by working collaboratively, opening new pathways and creating new opportunities to bring an end to this pandemic.

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Session 1: COVID-19 Vaccination: The Global Challenge

COVID-19 vaccines are currently being distributed out to the world, bringing hope but also raising issues on equity and inequalities in who gets the vaccine.

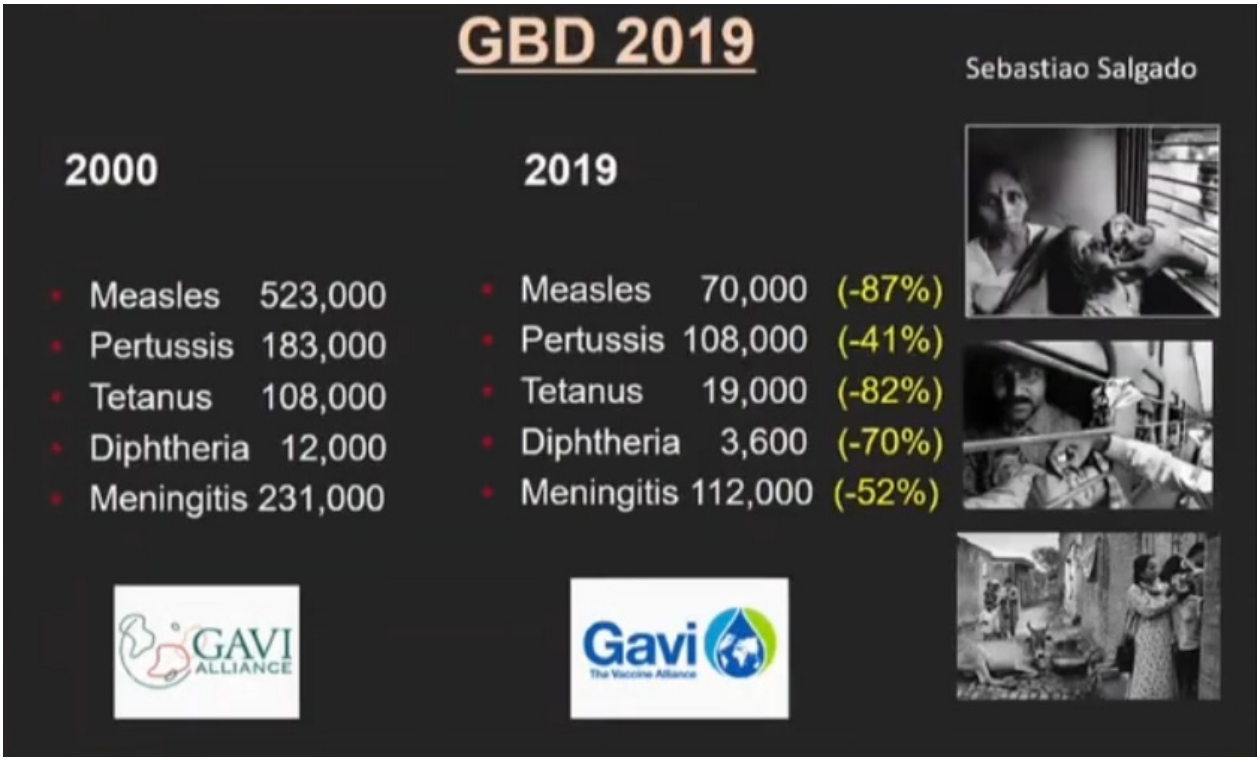
Dr. Francisco Becerra
Regional Adviser, Global Health Consortium, Florida International University, Former Assistant Director, PAHO

Dr. Francisco Becerra opened this Session, greeted and introduced the speakers and panelists.

Dr. Peter Hotez
Dean, National School of Tropical Medicine, Baylor College of Medicine, Houston, Texas, USA

Preventing the next pandemic: Vaccine diplomacy in a time of anti-science

The overall global governance of vaccines and immunizations has been effective. There have been tremendous gains in terms of children's vaccinations, thanks to the financial support of the Bill & Melinda Gates Foundation, to the GAVI Alliance in partnership with the World



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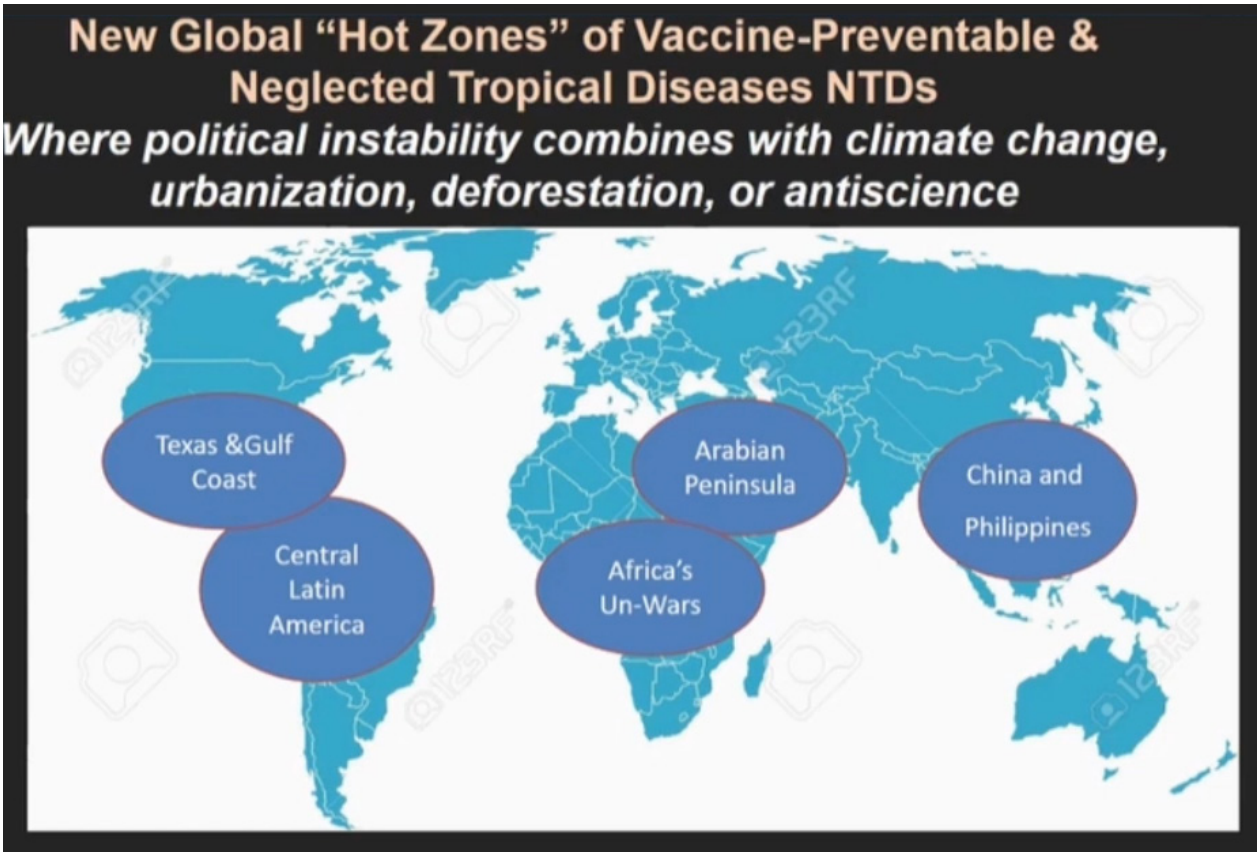

Health Organization, the Pan American Health Organization, UNICEF, the World Bank, and of course to pharmaceutical companies and academia.

These global health programs have resulted in fabulous progress and declines in the number of children dying from preventable diseases such as measles, whooping cough, diphtheria, and meningitis.

Despite these amazing gains, there has been a halt, or even a reversal of the results in some regions of the world, as a result of social determinants: poverty, war, political instability and also the rise of the anti-science. Other factors such as urbanization, deforestation and climate change combine with inequities to bring about these devastating drawbacks in public health.

These are some of the regions where there has been a sharp return to preventable diseases.

These are mainly countries and regions where political instability combines with climate change, urbanization, deforestation or anti-science. Many of these changes began relatively recently around the early 2010's. For instance, in the Arabian Peninsula, there has been a collapse of the health system infrastructure followed by the return of cholera, cutaneous leishmaniasis and vaccine-preventable diseases including measles and polio. Besides war and political instability, the region also has had unprecedented temperatures of 50°C. Some believed that the desperation for water resources may have fueled a lot of the conflicts. This showed how factors combined to bring back disease. In Africa, the violence of Boko Haram in Nigeria and its denial of medical science poses a high risk of bringing back polio and measles. In

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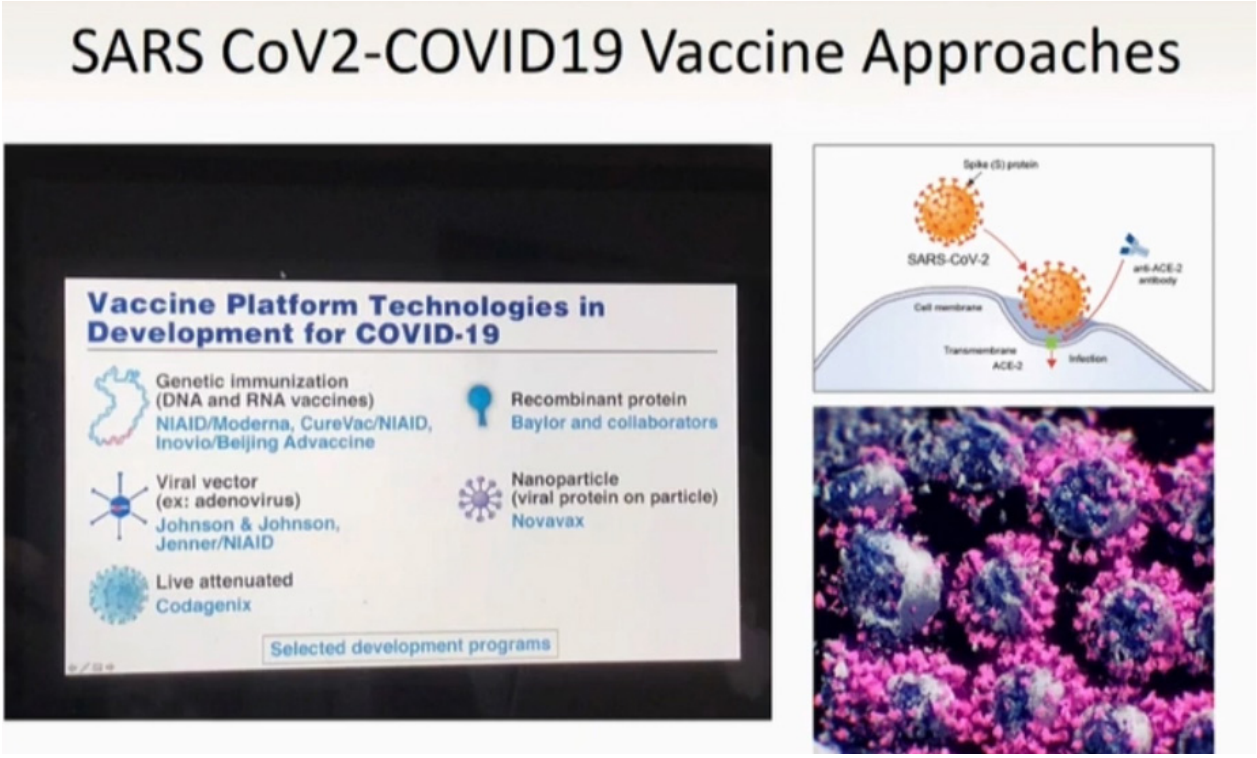

central Latin America, especially in Venezuela, the socio-economic collapse and political instability has brought back measles and other vaccine-preventable diseases. People have been desperate for employment. Some sleeping in illegal gold mines without bed nets and exposed to malaria. Venezuelans have left their country, crossing the border into the Amazon region of Brazil or into Colombia, coming into contact with indigenous groups, transmitting measles, and now COVID-19.

Social determinants impact COVID-19, as well as other diseases such as tuberculosis, dengue, Leishmaniasis, Chagas disease and parasitic worm infections. Poor people living in low-income neighborhoods in G-20 countries are the most affected. In the new global health scenario, the inequalities between wealthy countries and poor countries are giving way to the poor among the wealthy, both in high and low-middle income countries.

The rapid development of the new COVID-19 vaccines has been possible thanks to years of research over the last decades. Inducing strong virus neutralizing antibodies against the spike protein provides the basis for all COVID-19 vaccines. All of them work in different ways, but with the same goal of delivering the virus neutralizing antibodies against the spike protein.

The anti-vaccine groups claim that they do not trust COVID-19 vaccines precisely because of their rapid development, when in fact they are the result of a 10-year program, like that of any other vaccine. Unfortunately, this has not been communicated accurately.

There is evidence that COVID-19 vaccines may stop viral transmission. However, several vaccines need to be in use to achieve such a goal, as well as increased immunization coverage, including adolescents and children. Improving communication to halt the anti-vaccine movement is fundamental.

Operation Warp Speed, which focuses on vaccine development in the United States, has three production waves. The first included

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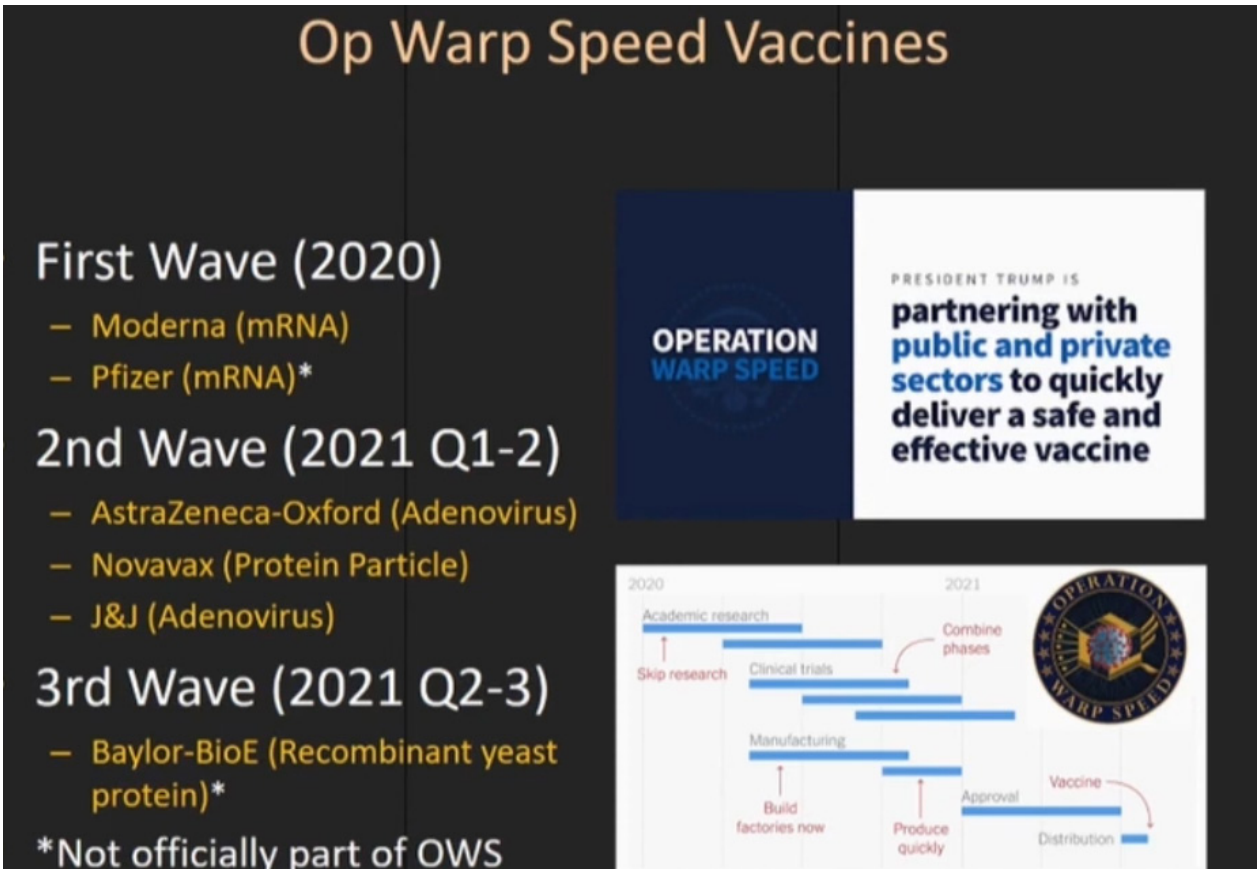
two mRNA vaccines (Moderna and Pfizer); the second wave of vaccines is starting now. They will probably be authorized under emergency use (the adenovirus vaccine by AstraZeneca-Oxford; the protein particle vaccine by Novovax, and the adenovirus vaccine by Johnson & Johnson). Finally, the third wave of vaccines is expected to be available later this year (the recombinant yeast protein vaccine being developed by Baylor and Biological E, based in Hyderabad, India).

I am often asked which vaccine I would take, and my answer is I would take any. They all work the same way, by inducing virus neutralizing antibodies. What we do not know for any of them is what the durability of protection will be, and also if they will be effective for the new variants.

The first variants that seem to be rising very quickly are coming out of South Africa and the UK. This country is also reporting that the strain is leading to higher mortality, thus causing a lot of concern about the next wave of the pandemic.

The high rate of coverage and success in Israel was done despite high circulation of the UK strain. Yet, the greater problem from a vaccine point of view is the South African variant, since it has an additional mutation resulting in reduced levels of virus neutralizing antibody. Vaccines that induce low levels of virus neutralizing antibody will no longer protect against the South African variant.

This slide shows the levels of protection with Pfizer, Moderna, Novovax, Johnson & Johnson and AstraZeneca-Oxford, all working pretty well against the original variants but with a significant decline versus ZA (South African variant).



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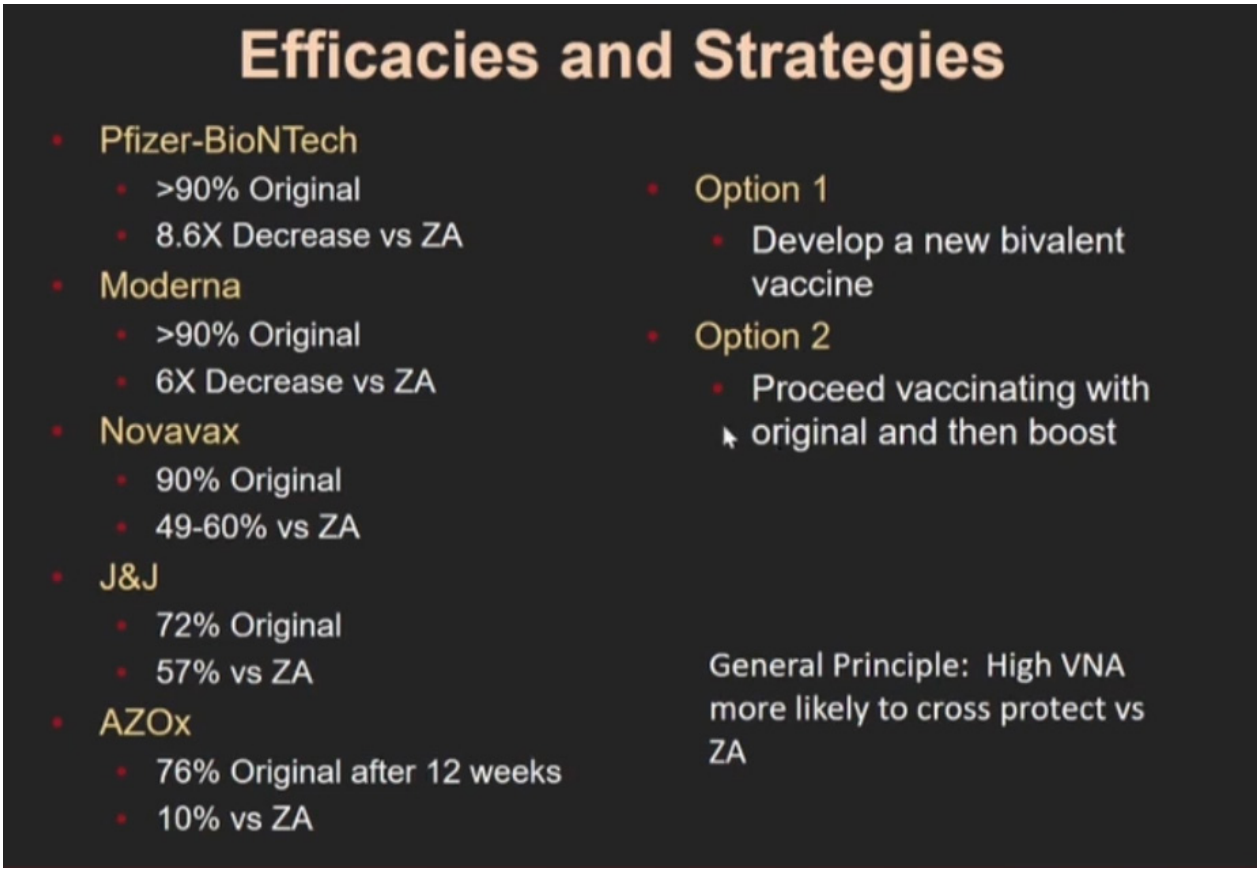

The Russian vaccine by Gamaleya also starts with a low level of virus neutralizing antibody. I might not be protected against the South African variant - same as the two Chinese vaccines: the Sinovac inactivated virus vaccine and the Cansino adenovirus vaccine.

The question now is if new bivalent vaccines with the original strain combined with the South African variant should be developed, or if people should be vaccinated with the original, and then receive a booster dose with the South African equivalent.

Most scientists are leaning to that second direction, yet the problem to be faced is that the two mRNA vaccines are probably not going to reach many LMIC, because of the difficulty in scaling production and the onerous import requirements. So these countries would be unprotected against the South African variant.

We are currently looking at producing a low-cut, low-cost coronavirus vaccine that could be scaled for production. The vaccine is being developed in collaboration with the Bill & Melinda Gates Foundation and Biological E, one of the big vaccine producers based in Hyderabad, India. This is a recombinant protein vaccine, refrigerated at four degrees and produced with the same technology used to for recombinant Hepatitis B vaccine, with a 40-year track record. Thus, the vaccine will be potentially suitable for children and infants and will probably be the least expensive of the COVID-19 vaccines.

I would like to finalize by stressing that we are dealing with a very aggressive, globalized anti-science empire that came out of Texas in the US and is now extending into Russia and Western Europe. How we deal with them is going to be determinant not only of COVID-19 vaccines but of the credibility of science itself. ■

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Session 1: COVID-19 Vaccination: The Global Challenge

Dr. Annelies Wilder-Smith
Member, WHO-IVB-SAGE Working Group on COVID-19 Vaccines,
London, UK

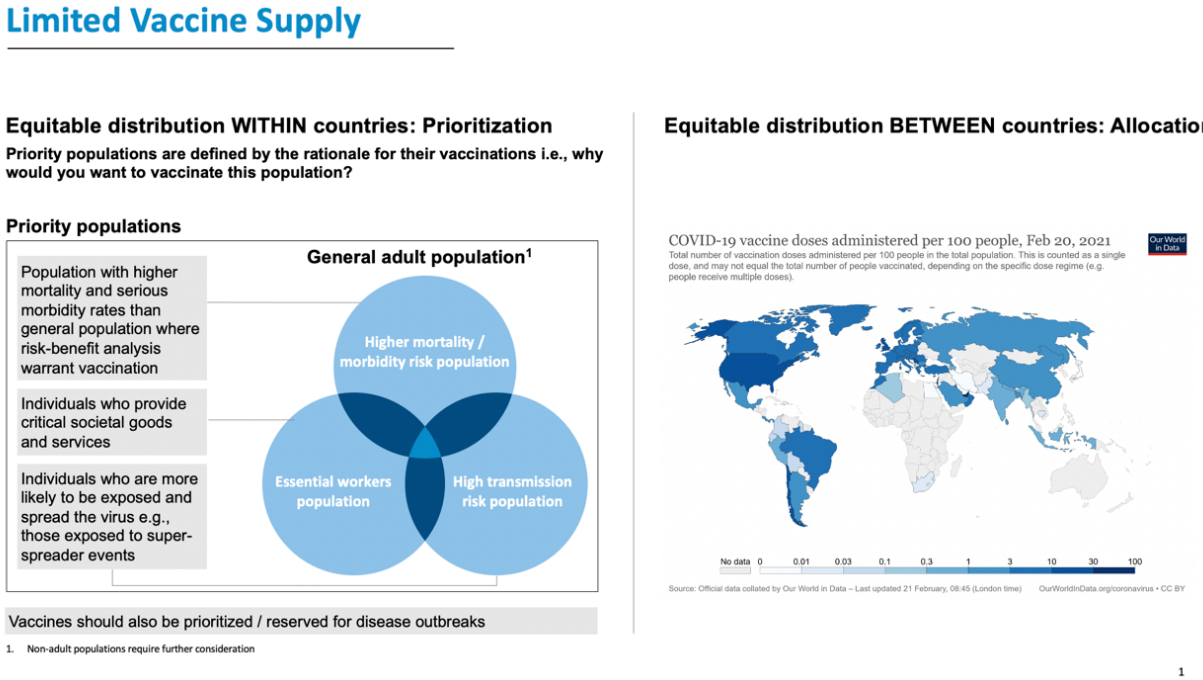
Deploying COVID-19 vaccine equitably

Despite the unprecedented speed in the development of the COVID-19 vaccines, the current challenge is how best to maximize their use when facing a limited supply. Deploying vaccines equitably has two angles; one is equitable distribution within countries, and the other is equitable distribution between countries.

Vaccine deployment within the countries should follow the prioritization road map: 1) populations with higher mortality and serious morbidity because of underlying medical conditions; 2) essential workers, particularly in healthcare; 3) the high transmission risk population. The roadmap for prioritization is meant to help countries make decisions with a limited supply. The strategy initially focuses on direct reduction of morbidity and mortality, maintenance of most critical essential services, and reciprocity.

However, at a global level, the three priority groups at higher risk reach 1,900 million people (persons above the age of 65 are already 703 million, less than 65 years old with underlying conditions are about 1,064 million, workers in health and social care are 136 million). These numbers confirm that with the current limited supply of vaccines, not even coverage of the high-risk target populations can be achieved.

In April 2020, the Access to COVID-19 Tools (ACT) Accelerator was created for the development of much needed COVID-19 diagnostics, therapeutics and vaccines.



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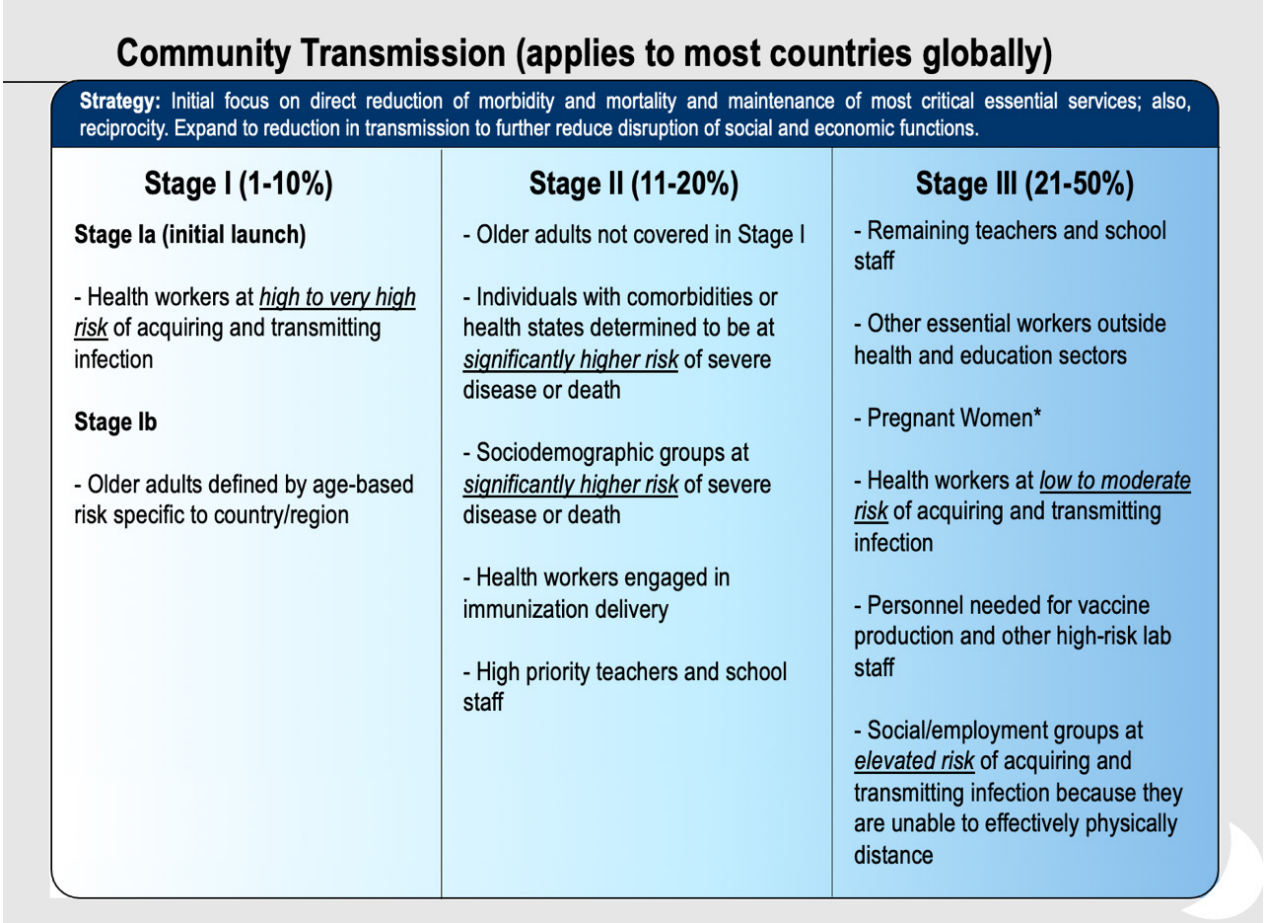


Community Transmission (applies to most countries globally)

Strategy: Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions.

Stage I (1-10%)	Stage II (11-20%)	Stage III (21-50%)
Stage Ia (initial launch) - Health workers at *high to very high risk* of acquiring and transmitting infection **Stage Ib** - Older adults defined by age-based risk specific to country/region	- Older adults not covered in Stage I - Individuals with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death - Sociodemographic groups at *significantly higher risk* of severe disease or death - Health workers engaged in immunization delivery - High priority teachers and school staff	- Remaining teachers and school staff - Other essential workers outside health and education sectors - Pregnant Women* - Health workers at *low to moderate risk* of acquiring and transmitting infection - Personnel needed for vaccine production and other high-risk lab staff - Social/employment groups at *elevated risk* of acquiring and transmitting infection because they are unable to effectively physically distance

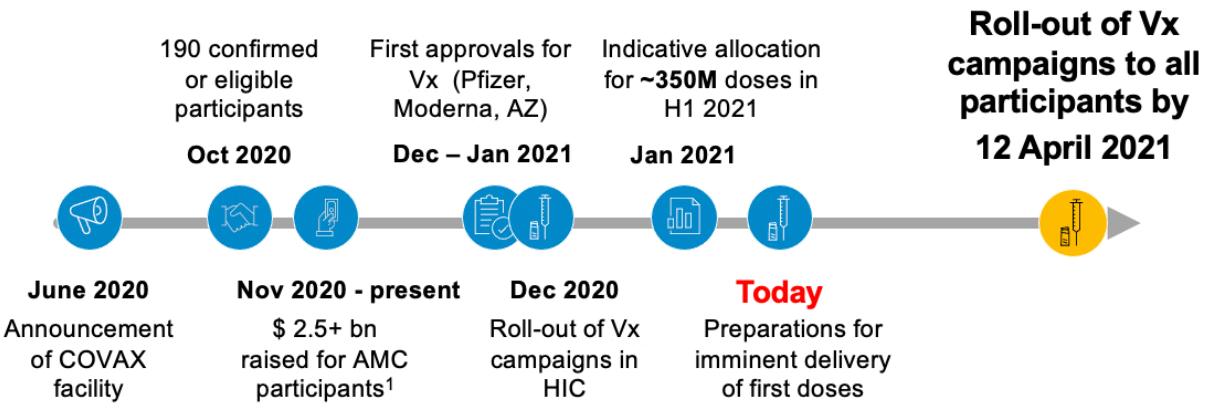
The COVAX Pillar: GAVI, CEPI and WHO working together with industrial and developing country manufacturers, is one of these accelerators. COVAX specifically focuses on the development, manufacture and delivery of COVID-19 vaccines for the world. The goals are to end the acute phase of the pandemic and to deliver 2 billion doses by the end of 2021, to guarantee fair and equitable access to COVID-19 vaccines for all participants, and to support the largest actively managed portfolio of vaccine candidates globally.

To date, over 190 countries have joined the COVAX pillar. All countries are invited to participate by making a commitment to purchase doses, and a contribution in the form of cash and doses. Participating countries will receive access to vaccines at the negotiated price. The COVAX Advance Market Commitment (AMC) guarantees manufacturer-specific contingent volumes and market-wide demands.

The goal is that every country will at least have received some vaccines by April 12th, 2021. The first shipment was made to Ghana in February 24th, marking the beginning of global rollout.

Although the initial COVAX supply is really low, an incremental growth is forecasted as manufacturing scales up, but also as more vaccines become available. The next figure shows in green the secured volumes as of today, 1.6 billion doses by the end of December, although the aim is to exceed 2 billion doses. In gray are volumes that are still under active negotiation.

Covax from June to Today



The next figure shows how COVAX plans to allocate this supply by region.

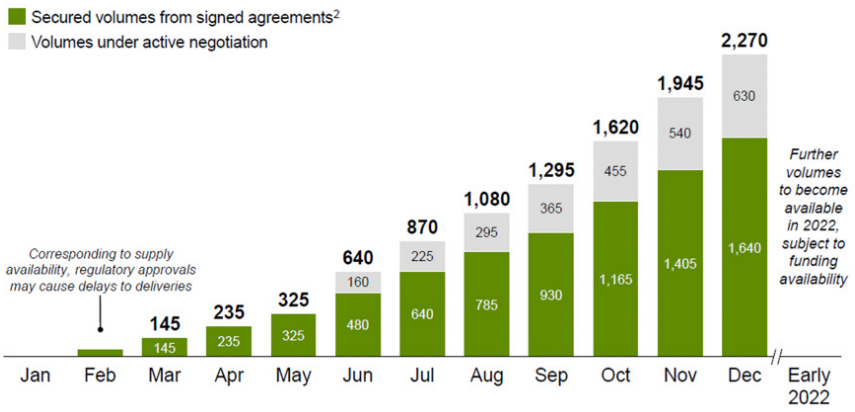
Countries must be ready to receive the vaccines. The pathway to vaccine use in each country depends on the regulatory authorization and the import approval, which so far has caused some delays. Other factors are the procurement mechanism in each country, and the existence of a national deployment vaccine plan.

To help countries in their preparation to rollout COVID-19 vaccines, GAVI, WHO and

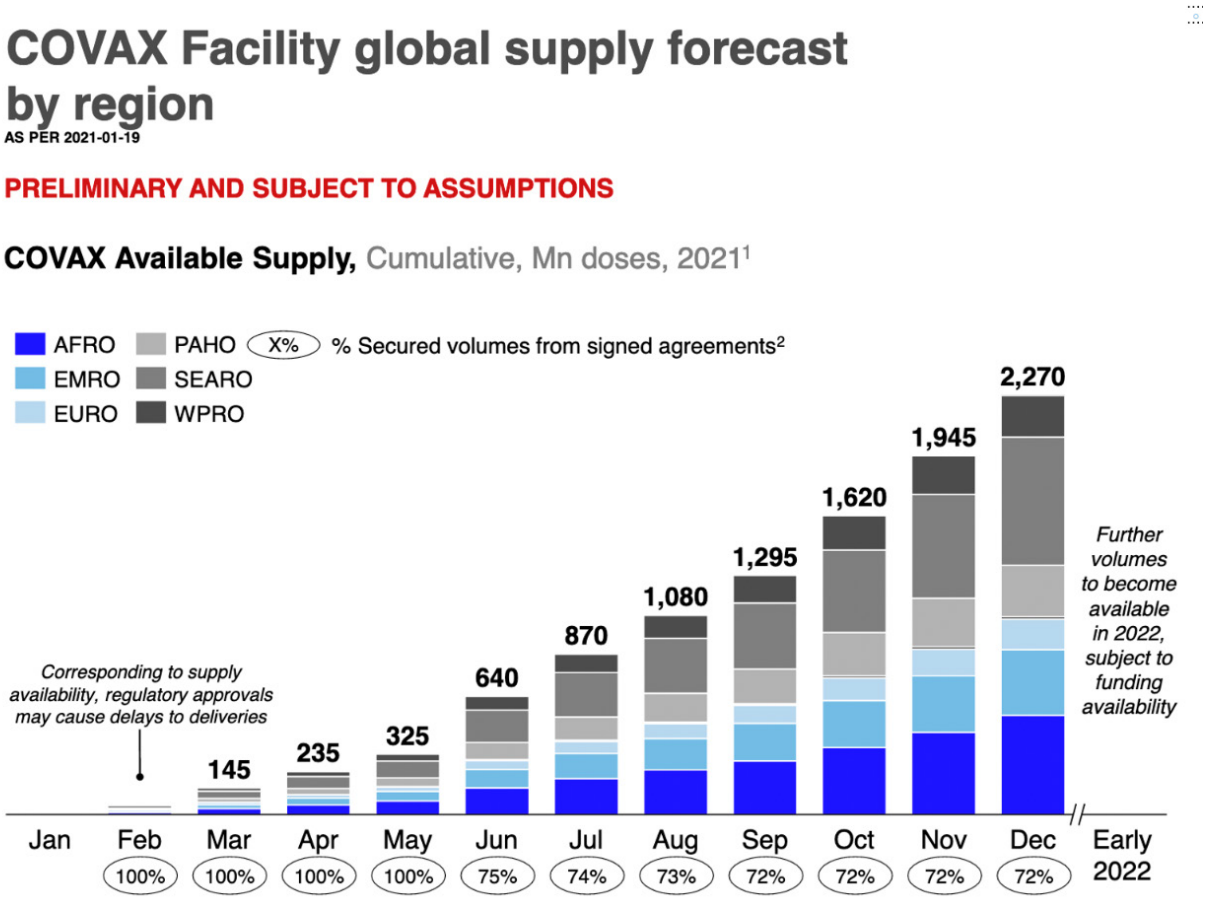
Preliminary understanding of COVAX available supply

Preliminary – Subject to change to assumptions

As per 19 January 2021



1 Supply refers to volumes of vaccine available from the manufacturer. Timing of forecasts is based on anticipated release of doses from manufacturers. Volumes for expected single-dose regimen vaccine candidates doubled to ensure comparability across vaccine candidates. Volumes have been rounded to the nearest 5M (except for those smaller than 5M), and so totals may not equal sum of segments.
2 Signed agreements include legally-binding agreements, memoranda of understanding, and statements of intent.



UNICEF developed a vaccine introduction toolbox, which is a repository for resources and training documents accessible in different languages.

The public health and societal crisis posed by COVID-19 will start to be addressed once high coverage of those at the highest risk of deaths is achieved (80% of people aged 60 and above). The universal vaccine coverage necessary to interrupt COVID-19 will probably be achieved by the end 2022 or even 2023, unless additional manufacturing capabilities surge in the upcoming months. ■

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Dr. Stanley Okolo
Director General, West African Health Organization,
Bobo-Dioulasso,Burkina Faso

Access to COVID-19 vaccines and equality in West Africa

West Africa includes several countries but not all of them are part of the West Africa Health Organization (WAHO). Geographically, Mauritania and Cameroon are part of West Africa, but they are not part of our economic West African community (ECOWAS) of 15 countries (8 francophone, 5 anglophone, and 2 lusophone) - with 380 million inhabitants, the largest regional population in Africa.

The history of WAHO started back in 1960, but the first Director General was only appointed in April 2000. So the organization has been operational for 21 years. WAHO's objective is to attain the highest possible health standards for the people in the subregion through cooperation and by harmonizing policies and pooling resources of the member states.

The first case of COVID-19 in our region occurred in Lagos on February 27, 2020. Since then, there have been about 384,280 cases and 4,927 deaths. At the moment, in the second wave, there are about 41,065 active cases.

The region agreed on a common strategy of increased surveillance that has continued with some success in varying degrees. WAHO raised a significant amount of money, including internal and external funds used to provide countries with COVID-19 materials and critical medical supplies, and to set up online training to build the appropriate capacity in all health care aspects around the pandemic.

West Africa has four sources to access COVID-19 vaccines: 1) COVAX; 2) the African Vaccines Acquisition Task Team (AVATT), an African union-led initiative; 3) pooled procurement through ECOWAS and WAHO;

Vaccines for Priority Groups in West Africa

Member State	Total population	Total coverage for 50% of Population: priority groups	Population to be covered by COVAX (20%)	Deficit (30%) of the population to cover - priority groups	Vaccines from COVAX (2 doses)	Outstanding Vaccines to cover 30% deficit- 2 doses	Estimated cost of deficit ($4/dose)
Benin	12,153,717	6,076,858.5	2,430,743	**3,646,116**	4,861,487	7,292,231	29,168,924
Burkina Faso	20,286,250	10,143,125	4,057,250	**6,085,875**	8,114,500	12,171,750	48,687,000
Cape Verde	556,614	278,307	111,323	**166,984**	222,646	333,969	1,335,878
Cote d' Ivoire	26,441,530	13,220,765	5,288,306	**7,932,459**	10,576,612	15,864,919	63,459,676
Ghana	31,137,035	15,568,518	6,227,407	**9,341,111**	12,454,814	18,682,222	74,728,888
Guinea	13,166,858	6,583,429	2,633,372	**3,950,057**	5,266,743	7,900,116	31,600,463
Guinea Bissau	1,972,532	986,266	394,506	**591,760**	789,013	1,183,520	4,734,080
The Gambia	2,423,126	1,211,563	484,625	**726,938**	969,250	1,453,877	5,815,506
Liberia	5,069,269	2,534,635	1,013,854	**1,520,781**	2,027,708	3,041,561	12,166,244
Mali	20,306,101	10,153,051	4,061,220	**6,091,831**	8,122,440	12,183,661	48,734,644
Niger	24,286,250	12,143,125	4,857,250	**7,285,875**	9,714,500	14,571,750	58,287,000
Nigeria	206,634,303	103,317,152	41,326,861	**61,990,291**	82,653,721	123,980,582	495,922,327
Sierra Leone	7,993,057	3,996,529	1,598,611	**2,397,918**	3,197,223	4,795,835	19,183,340
Senegal	16,786,296	8,393,148	3,357,259	**5,035,889**	6,714,518	10,071,778	40,287,112
Togo	8,297,645	4,148,823	1,659,529	**2,489,294**	3,319,058	4,978,587	19,914,348
Total	398,182,329	198,755,295	79,636,466	119,253,179	159,272,932	238,506,358	954,025,430

Priority Groups 50%
Frontline HW (3%)
Older Adults (>60) 7%
Other adults with comorbidities (15%)
Essential Services personnel (25%)

and 4) bilateral arrangements.
To date, some countries like Morocco, Algeria, Egypt, South Africa, Ghana and Senegal have received vaccines (Ghana received the first shipment from COVAX, and Senegal through a donation from China). Unfortunately, this is a drop in the ocean compared to what we require, and we know that we will not get the vaccines needed for the sub-region, neither through COVAX nor through AVATT.

Our challenges are to target availability of the remaining volumes in the short term, and manufacturing in the medium to long term. There are three manufacturing facilities in the sub-region, one in Senegal, one in Nigeria and one in Ghana.They are nearly ready to undertake the task in partnership with other manufacturers. The challenges remain logistics issues and vaccine acceptance, which only in Senegal is less than 60%. ■

Panel Discussion

Dr. Luis Andrés de Francisco Serpa
Director, Family, Health Promotion and Life Course, PAHO/WHO, Washington, D.C., USA

Over a hundred million people have been infected with COVID-19 and there have been 2.5 million deaths worldwide. In the region of the Americas, over 50 million people have been infected, the US having passed the tragic milestone of 500,000 people who have died of COVID-19 complications.
Countries need to prepare to receive the vaccines and make sure they will be able to roll them out correctly to the right people, following the allocation system that has been defined by WHO.
PAHO is supporting the member countries in the mechanisms needed to distribute vaccines, and in their preparedness to receive the vaccines once they are available. Currently, 33 countries in the region have provided information on their progress towards being prepared for vaccine deployment.
Thanks to PAHO's Revolving Fund mechanism, accelerated authorization for vaccines is possible in the region, and this helps some regulatory processes move forward.
Another challenge in the national COVID-19 vaccine deployment and vaccination plan, is to ensure that COVID vaccines do not take all resources, to look at decentralization of human resources, and to look both at childhood and adult vaccination.
PAHO is working closely with COVAX on the prioritization road map and allocation pattern. Each country will need a very specific strategy to vaccinate the target groups while decentralizing distribution and vaccination.

Dr. Oscar Franco
Professor of Epidemiology and Public Health, Institute of Social and Preventive Medicine (ISPM), University of Bern, Switzerland

The most important immediate challenges of COVID-19 in Europe are the new variants that are threatening to spin the epidemic out of control, the lack of speed in the distribution and

implementation of the vaccination programs which is also hampered by an increased degree of skepticism towards the vaccines and by the economic situation that is affecting the region. Finally, there is a lack of coordination in the responses to all of these factors.

The first variant was reported in February 2020 in the north of Italy, which replaced the initial variant of the pandemic.

After the catastrophe that occurred in Europe during the first half of 2020, the summer brought a new spirit that was taken by many as a sign of relaxation. By the end of June, a new variant was reported in the north of Spain, which is believed to have been brought back to different countries throughout Europe, causing the new peaks that occurred in October and November. By that time, the British variant appeared in the region of Kent in England, although it was only reported in December. The Brazilian (Manaos) and the South African variants have also spread throughout Europe and outside of the European region. The distribution of the variants per time and per country is available at www.covariants.org.

These variants are threatening the distribution of the vaccines in the region. Rollout of COVID-19 vaccines in Europe is well below what was expected. While the United Kingdom vaccinated over 25% of its population, the country doing the best in Europe is Serbia with 12%, while most of the countries are around 3% - 5%. This slow deployment in some cases is due to the delay in logistics, while in others it is caused by unfulfilled agreements, and regulatory issues.

There are population groups who are skeptical about receiving the vaccine in European countries. In France, about half of the population would not accept the vaccine. In Germany there has been rejection of the Astra Zeneca-Oxford vaccine. While 1.5 million doses of this vaccine arrived in the country, only 189,000 have been administered. This rejection is based on the lack of information about the effectiveness of the vaccine in people over 65 years old.

It is very important to improve genomic vigilance, to understand how the mutations are occurring, how the variants are forming, and how the vaccine programs can respond.

Distribution and availability of vaccines must improve, and public health scientists and workers must do a better job in communicating and explaining why vaccination is so important.

Obesity, diabetes, hypertension are risk factors for increased morbidity and mortality due to COVID-19, and they have all been impacted by lockdowns. All these diseases may be modified by lifestyle and behavior, providing people a better response to the disease or a better evolution. Healthy lifestyle also modifies the response of individuals to the vaccine, and it also helps pandemic preparedness. Countries not only need to get ready to .vaccinate their populations. They should also help improve lifestyle and behavior to face this crisis and those that we will be living through in the next decades, which are issues related to planetary health.

Mr. Thomas Cueni
Director General, International Federation of Pharmaceutical Manufacturers (IFPMA)
Geneva, Switerland

People are disappointed by the delayed rollout of vaccines and low scaling up of production capacity.

Back in May and June of 2020, most people who knew about vaccine development said that we would be lucky if we could count on a significant volume of vaccines by the summer of 2021. There are already two messenger RNA vaccines approved and available. A few months ago, Dr. Hotez said that he would take any vaccine exceeding 50% efficacy … who at

that time would have expected vaccines with over 90% efficacy rates and that actually one of the reasons there has been apprehension about taking a vaccine in Germany or France was that if there are several vaccines with 90% plus efficacy rates, why should people take one which only reaches 70%?

Amazing progress has been made in science. The success that we have seen over the last few months at fabulous speed is also due to unprecedented collaboration not only within the industry, but also between the industry and international organizations, adding to the efforts of the regulatory agencies.

The world moved from concern about vaccine hesitancy, to euphoria about having effective vaccines, to anger and panic because many thought that once these vaccines were approved, billions of doses would be rolled out. Global vaccine capacity pre COVID-19 was estimated at 3.5 billion doses per year for all the vaccines combined, and now the need is over 10 billion doses.

This is not business as usual, and poses big challenges. There have been efforts within the industry, companies that are not traditional vaccine manufacturers now producing vaccines, or companies whose projects were delayed now rendering support to those whose vaccines are almost ready. We have also seen extraordinary collaborative efforts within COVAX.

Companies forecasted a potential vaccine output of 500 million doses in December, when actually about 20 million doses were manufactured. Vaccine manufacturing is a very complex biological process, and the yields cannot be taken for granted. There are multiple examples of where bottlenecks can occur, some are unavoidable while others, such as export restrictions or controls, can be avoided collectively, of course respecting anti-trust compliance. We can really make the impossible happen.

Discussion

Dr. Francisco Becerra:
The pandemic has had an impact on immunization programs globally. From the PAHO perspective, having one of the best regions with vaccination coverage in the world, how is the pandemic going to impact the traditional and permanent vaccine programs?

Dr. Luis Andrés de Francisco Serpa:
Unfortunately, even though there has been very strong advocacy and investment, we have seen a decrease in coverage. It is very important that we keep and maintain the immunization programs going. At the beginning of the pandemic people were not going to the immunization centers for fear of COVID. Therefore, we set some protocols for safe vaccination. However, the issue now is that the deployment of COVID-19 vaccines must be organized as an additional branch of the regular immunization programs. If it is not the case, both programs will be impacted.

Dr. Francisco Becerra:
Dr. Hotez, you mentioned that science has proven that when needed, we can move from research platforms that were already established for other vaccines very quickly to a COVID-19 vaccine, and this is very important. Yet, I think that probably in this rush to have the vaccines, we missed an enormous communication opportunity.

Dr. Peter Hotez:
In the US there was no communication plan for Operation Warp Speed. Communication was left to the pharma CEOs who, generally speaking, were poor communicators. That situation left a vacuum which was filled by what has become a globalized anti-vaccine and anti-science movement. There are now more than 480 fake anti-vaccine websites. Furthermore, this movement expanded to Western Europe. Russia is the single largest

promoter of fake anti-vaccine information. All communications are being drowned out by massive misinformation and disinformation, which is now globalized and has become a full-on anti-science empire, and it will continue, unless we show our appetite to really fight it, and this is not happening so far.

Dr. Francisco Becerra:
Dr. Wilder-Smith, in your role at SAGE, do you think that the delay caused by some regulatory agencies is linked to the delay of COVAX deployment?

Dr. Annelies Wilder-Smith:
Indeed, the SAGE process is very closely linked to either an emergency use listing or to a stringent regulatory authority, which means it is a bit biased towards the Western vaccines, that have gone through stringent regulatory authorities. Yet, we need to continue stringent reviews and not to cut corners. Even if we lose a few weeks in the process, we will gain them in confidence.

Dr. Francisco Becerra:
Professor Okolo, you showed a slide in which Morocco had already vaccinated over 7% of the population. How can an African country such as Morocco share lessons learned and how could this also be achieved by other countries in Africa?

Dr. Stanley Okolo:
The Africa CDC sometimes meets with the Ministers of Health of all African countries, and we share ideas and experiences. I would like to ask the panel what do they think about one of the things that puts countries upfront in terms of benefiting from vaccines, which is participating in clinical trials? TB or HIV new drugs trials go to Africa. Why could not Africa also have the vaccine trials during the pandemics?

Dr. Francisco Becerra:
I think that this is also a question of inequalities in terms of research sites in African countries, not only for vaccines but also for a lot of medication that is being produced by the pharmaceutical companies.

COVID-19 Vaccines Experts' Summit

February 26, 2021

Session 2: SARS-CoV-2 New Variants, New Waves, and Vaccines: Strategies to Preserve the Public Benefits of Vaccination

The race between science and SARS-CoV-2 is the current challenge. Global health is now facing the new variants of COVID-19, the lack of vaccines, and inequities.

Dr. María Elena Bottazzi
Associate Dean, National School of Tropical Medicine, Baylor College of Medicine
Houston, Texas, USA

Dr. María Elena Bottazzi opened this session setting the scene, greeting and introducing all speakers and panelists.

Dr. Ester Sabino
Associate Professor, Department of Infectious and Parasitic Diseases, University of São Paulo, Brazil

Resurgence of COVID-19 in Manaus, Brazil despite high seroprevalence: what is the role of natural herd immunity?

The evolution of the epidemic in Brazil shows us a long peak in May, coincident with the period of the elections in Brazil, with varied patterns in the different cities. We carried out a study in seven of these cities to better understand the attack rate of COVID-19.

Approximately 1,000 monthly blood samples from adult patients 16 to 65 years old were studied from February 2020 through February

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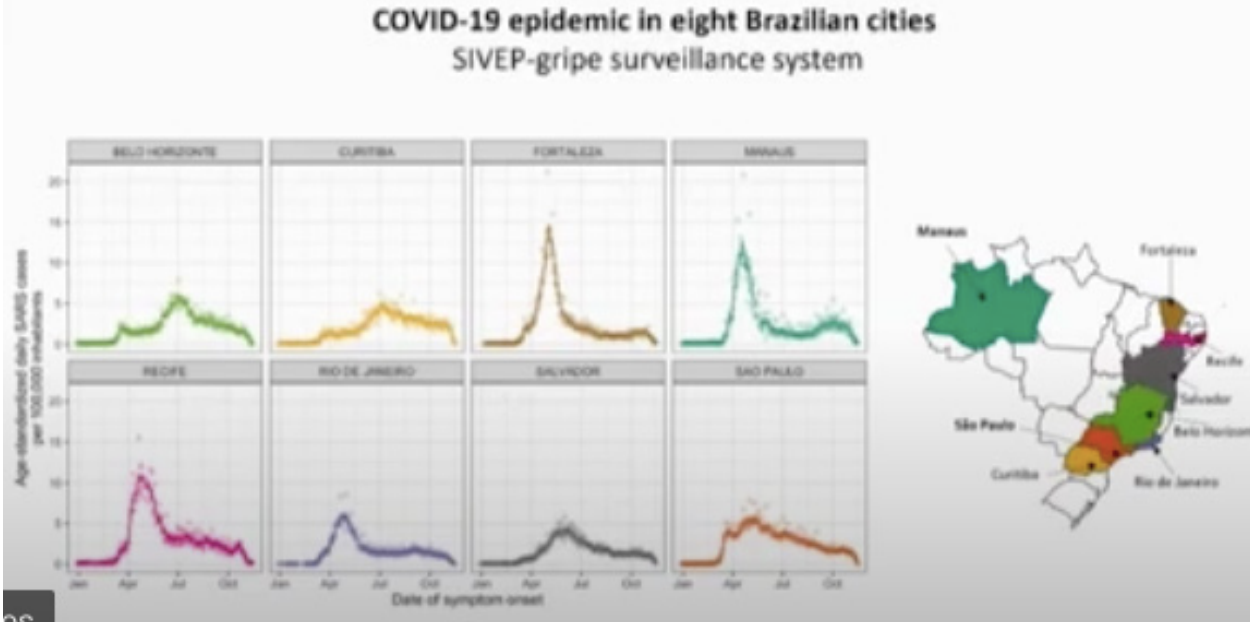

2021. Samples were geographically stratified using the donor's zip code. The study was both retrospective and real time, using Abbott SARS-CoV-2 IgG chemiluminescence assay. We found a uniform geographical distribution. Corrections factors were age and gender, blood donors were mostly among the youngest population and there were more men than women. A second correction factor was the decline in sensitivity in samples from asymptomatic individuals and the antibody waning over time among plasma donors. Thus, for example in São Paulo, positivity reached 11% and then stabilized, but by correction factors we assume that São Paulo must have reached 20%. Manaus reached almost 75% percent and Fortaleza also had elevated levels, while Recife and El Salvador stayed in the middle and Bello Horizonte had lower levels.

The prevalence of antibodies to SARS-CoV-2 is an estimate of the attack rate in Manaus and provides an estimate of the extent of COVID-19 spread in the absence of effective mitigation. The theoretical herd immunity threshold for a complete mixed population is around 60.7% and Manaus was above this number. Therefore, any future increase would be suggestive of reinfection, the introduction of a new variant, or the loss of immunity. The marked increase in infection rates finally confirmed a new and more transmissible lineage.

Several hypotheses were drawn to explain the resurgence of SARS-CoV-2 in Manaus: 1) the attack rate could have been overestimated; 2) a general decrease in immune protection against SARS-CoV-2 after the first exposure; 3) the new lineages could be better at evading the immunity generated by a previous infection; 4) the lineages circulating in the second wave may have higher inherent transmissibility compared to pre-existing lineages circulating in Manaus.

The new variant was detected in January, with over 17 mutations, three of which were similar to the African strain. It is important to note that there was also another strain in Manaus now known to be circulating throughout Brazil: it did not have many mutations, but one was associated with the UK mutant.

The P.1 lineage from Manaus is more transmissible, but it remains unknown how more transmissible, how frequently reinfection occurs, and how effective the vaccines available in Brazil would be against this specific strain. Over 100,000 people have travelled within the country since December, so a rapid expansion of this variant across the country is expected to occur soon. ■

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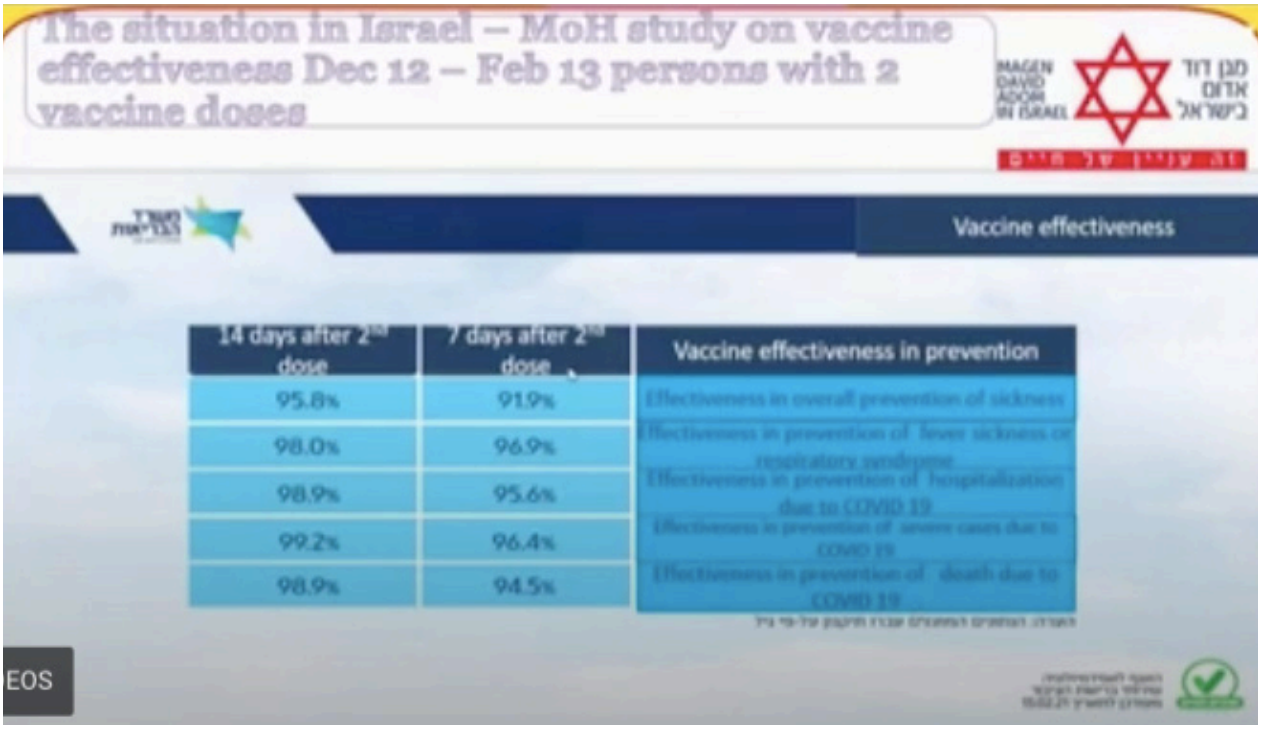
Mr. Chaim Rafalowski
Disaster Management and EU Projects Coordinator, Magen David Adom
Tel-Aviv, Israel

Israel vaccination program: a model for implementation and impact estimation

Israel is a country of 22,000 square kilometers and a population of 9.3 million inhabitants. This is an important fact in regards to the vaccination program in the country.
There are in total about 600,000 persons who are recovering from COVID-19 and will not be vaccinated at this stage, and about 2.5 million children, 16 years old and younger who will also not be vaccinated. That leaves a total of six million people that can be vaccinated. Out of them, as of February 25, 2021, 4.6 million have already been vaccinated, and about half of them have received the two doses.
Considering the population over 60 years old, both those who are vaccinated and those who are recovering from COVID-19, the protection factor in Israel is 92%. For the age group 50 to 59 protection is about 76%, around 150,000 people are still to be vaccinated in this age group. There are more than 400 vaccination sites, mainly through HMOs, representing Israel's primary health care system and are present throughout the country.
The Magen David Adom, as a mobile organization, covers vaccination at all long-term care facilities for the elderly and for people with disabilities. All these groups are already fully vaccinated.
The municipality of Tel Aviv is targeting the



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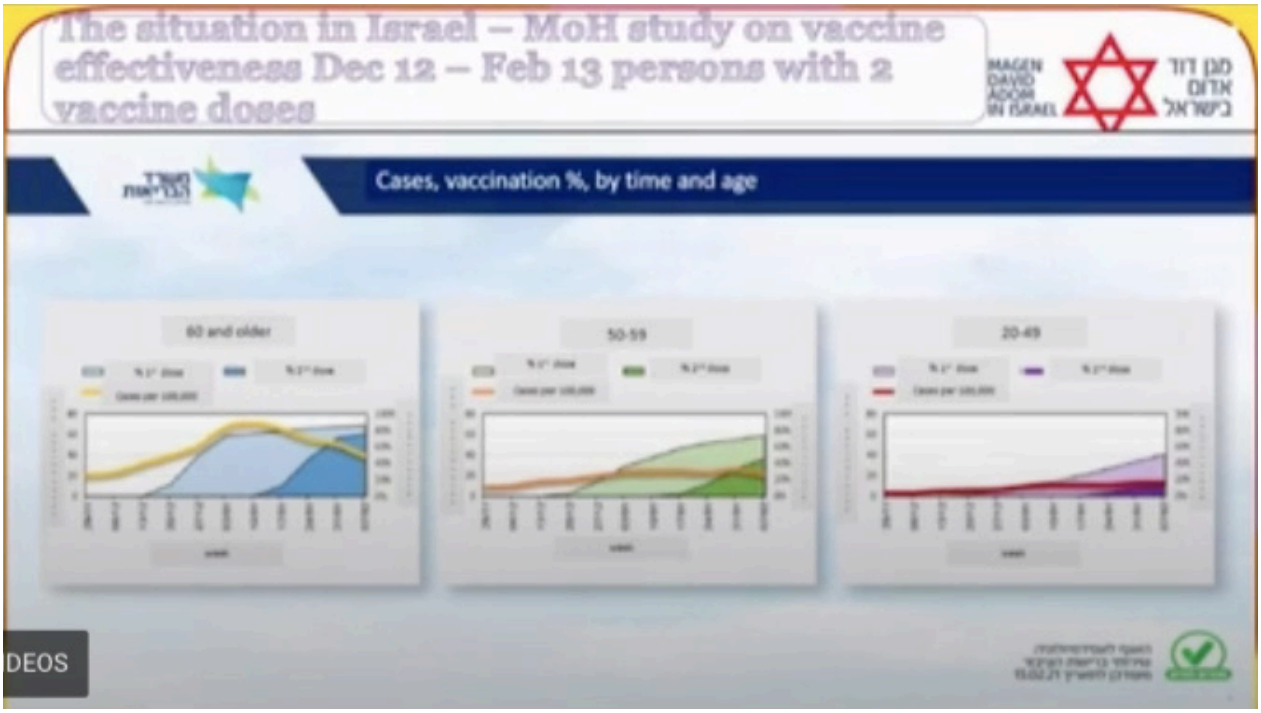

young population. Their campaign is carried out in pubs, where a free non-alcoholic drink is offered to those who get vaccinated. So young people get a drink and a shot at the same time, and of course they post it on social networks, which motivates their peers to vaccinate as well.

A large study was conducted by the Ministry of Health on the impact of the Pfizer vaccine, the only one in use in Israel. This slide shows the effectiveness of the vaccine in preventing disease, fever, respiratory syndrome, hospitalization, severe cases, and death after 7 days, and after 14 days when the effectiveness is 99% both to prevent severe disease and death.

In this slide, the lighter color shows the results one week after vaccination, the darker is two weeks, and the curve is the ratio of cases per 100,000 cases. The impact mainly on people 60 years old and over shows a trend that will continue: the vaccine is way more effective on the elderly. The same trend is seen when comparing hospitalization.

It is important to consider that the vaccination program in Israel is centrally managed by the Ministry of Health through a dedicated unit in charge of procurement and deployment of vaccines and supplies.

Each organization or institution administering vaccines must present a plan. The vaccines are received three days after approval, and monitoring is done on a daily and hourly basis to adjust accordingly.

Vaccinations began in mid-December with a shortage of nursing staff. The first group vaccinated were people over 60, those in the front line of health care and long-term care facility residents. The second group were pregnant women, who were prioritized since the UK variant was causing severe cases and deaths in this population. To allow classes to resume, teachers were also vaccinated, as well as 16- to 18-year old students. Israel has now opened vaccinations to everyone over the age of 16. The challenge was that vaccination was taking place at the peak of the third wave. In January alone, there were over 1,500 deaths due to COVID-19.

One of the greatest challenges was the transfer of information because, unlike during

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normal vaccination times, organizations were vaccinating people from different HMOs. The information was sent from the vaccinating center to the system, and from there to another system which creates the proof of vaccination or immunity. A dedicated IT system was developed to run the whole operation.

A major challenge was the decision to vaccinate all residents in Israel, including irregular migrants. The discussion on how to deal with doses left unused at the end of each day was also relevant, the decision being to not waste any vaccines.

Another challenge is to design the logistical process to vaccinate all those who reach the minimum age, as well as to vaccinate migrants.

Vaccine confidence is also an issue. Approaching religious leaders both in the Muslim and the ultra-orthodox Jewish communities was successful. There was a strong anti-vaccination campaign which slightly impacted the second dose (2% loss)

Among the lessons learned is the advantage of integrating the public, and public efforts with the flexibility to carry out effective vaccination. Another key aspect has been the role of volunteers in dealing with hesitancy.

Finally, maintaining precautions in a highly vaccinated community is also a major challenge that must be addressed. Israel is seeing a new peak in cases, with high concern due to the new variants. ■

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Dr. Marco Safadi
Head of Department, Pediatric Infectious Diseases, Santa Casa Medical School
São Paulo, Brazil

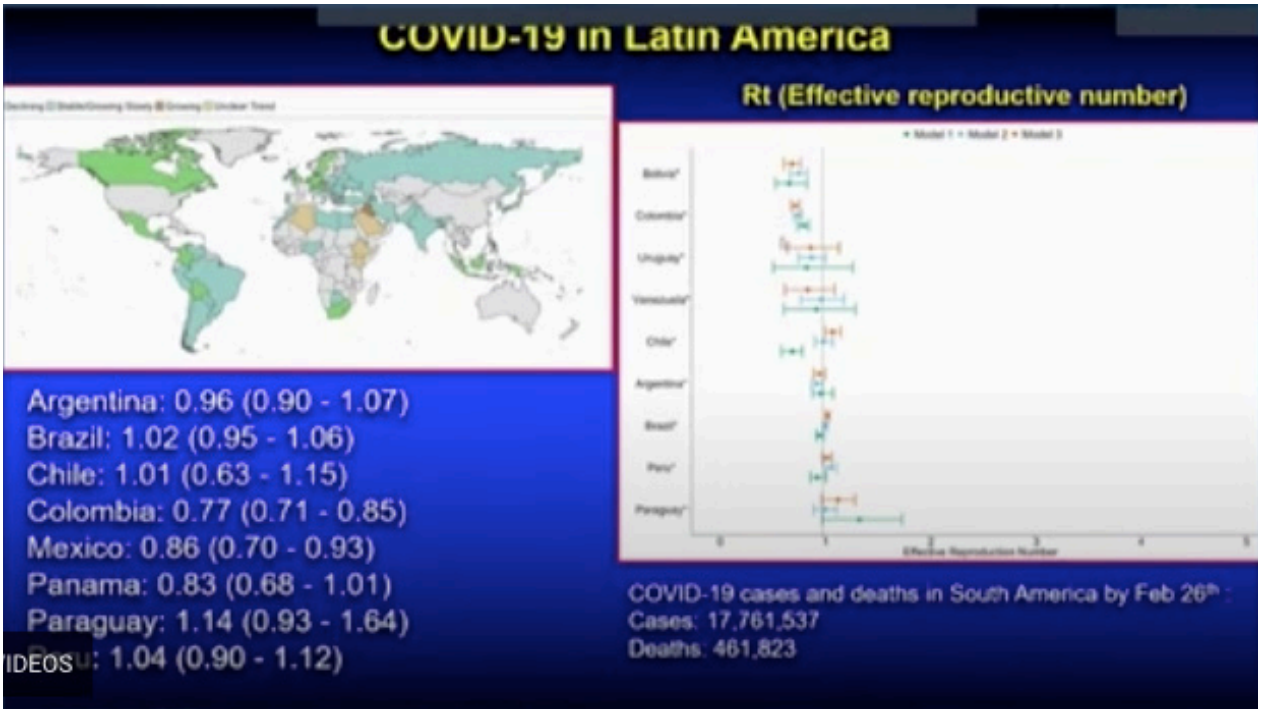
COVID-19 vaccine implementation in Latin America

The current disease rates in Latin America, probably one of the hardest hit regions in the world, will be highlighted. This data from the Imperial College shows how transmission is growing in some South American countries, particularly Brazil.

Almost 18 million cases have been reported in the region, and approximately 560,000 deaths. The comparison of deaths from influenza (2019) vs COVID-19 (2020) shows that 12% of the deaths occurred in children and adolescents and 50% in adults above 60 years of age for influenza 2019, and that less than 1% of deaths in children and adolescents and 72% of deaths in adults above 60 years of age for COVID-19 in 2020.
This is the same comparison, for Brazil only.

This has been one of the lowest influenza seasons with 0.1 death per 100,000 inhabitants comparing to almost 90 deaths per 100,000 inhabitants for COVID-19. The case fatality rates of severe acute respiratory syndrome in hospitalized patients were 13% vs. 33% for COVID-19.

In Latin America, Panama is the country with the highest incidence, with approximately 77 cases per thousand inhabitants. Chile and Panama are testing approximately 500 tests per thousand population, this is a key factor to evaluate the reliability of this data on incidence rates.



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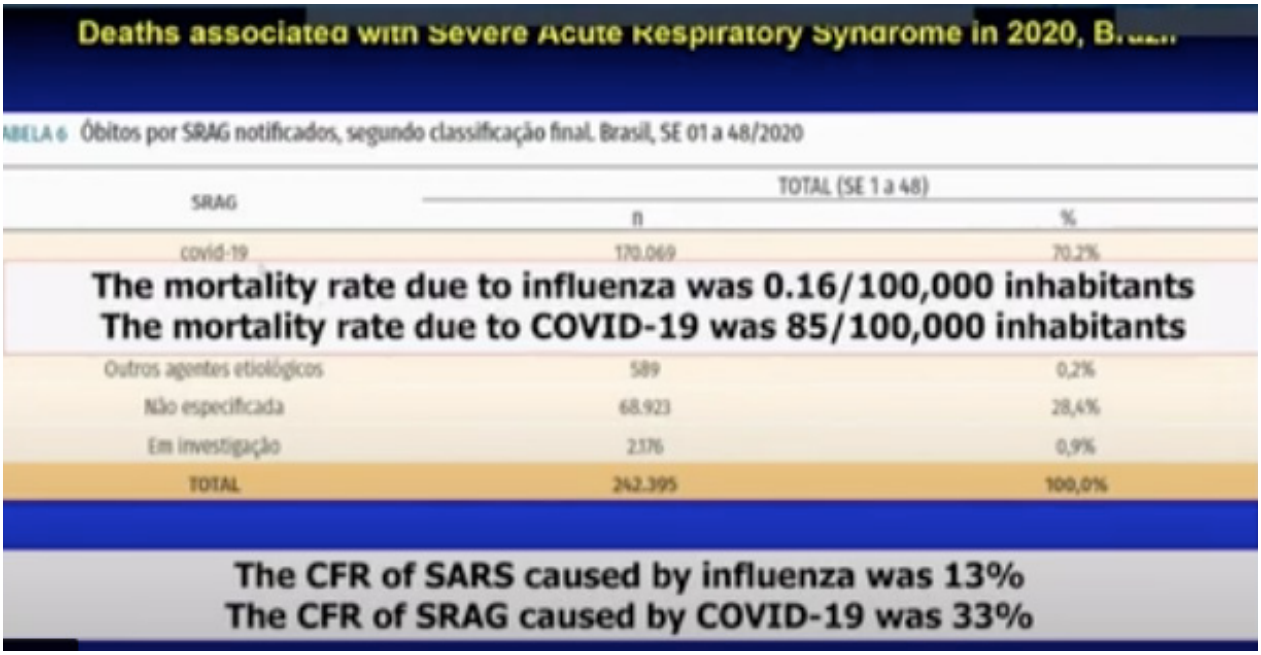
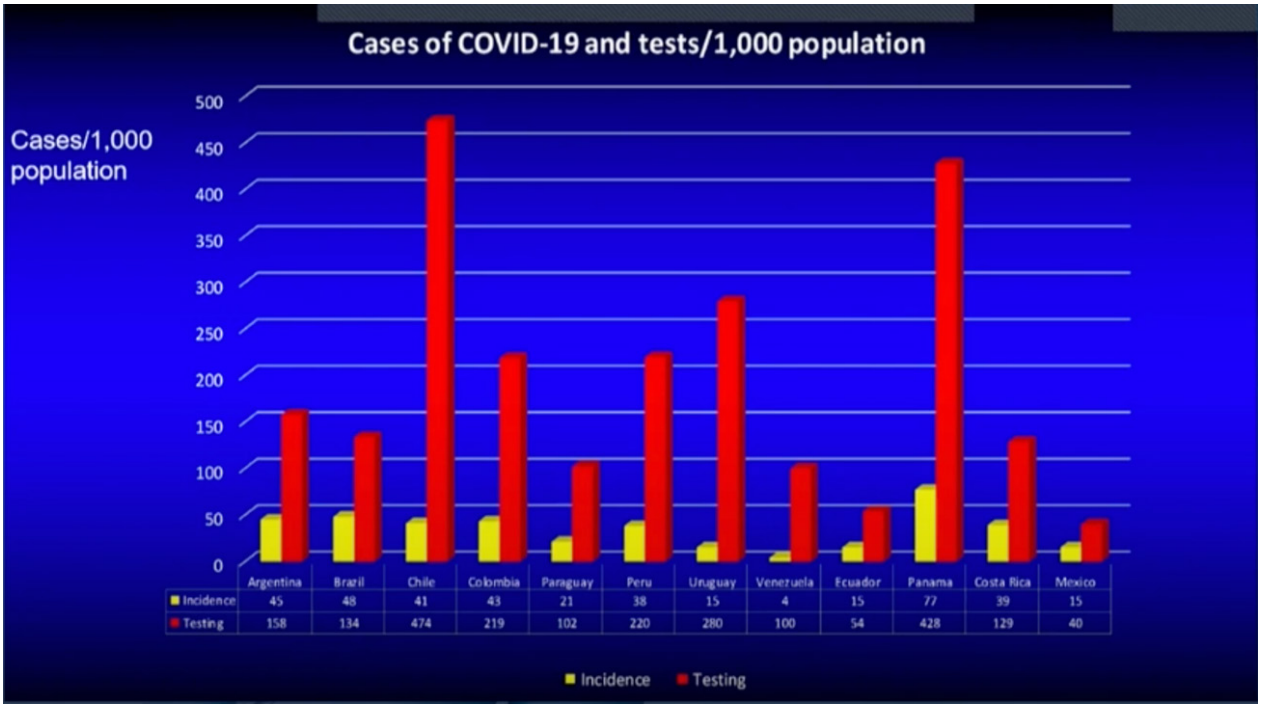


Mexico is the country with the highest case fatality rate at almost 10%, followed by Ecuador, Argentina and Peru.

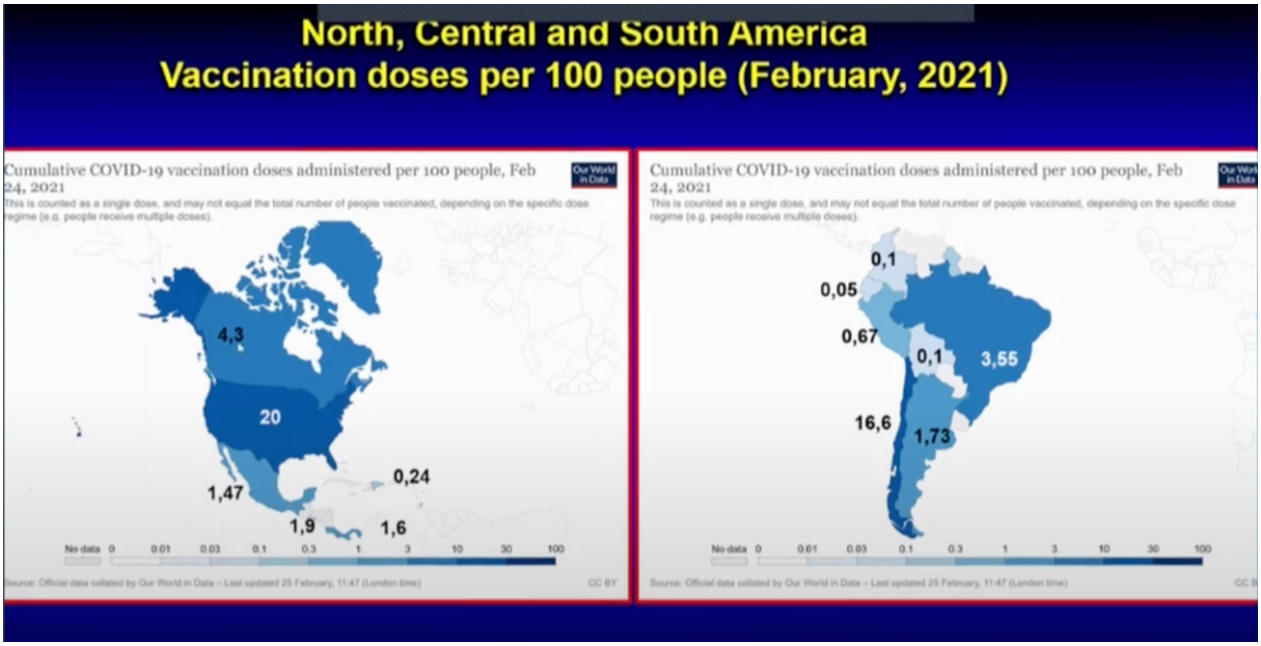
Three countries were the first to start vaccination programs against COVID-19 in Latin America almost at the same time in late December: Mexico, Chile, and Costa Rica. This slide shows the different vaccines that are being used in the region as of today.

This map from Johns Hopkins shows the



cumulative COVID-19 vaccine doses per 100 inhabitants administered by country in the region led by Chile, USA, and Brazil.

COVAX's challenging goal is to deliver over 2 billion doses to almost 200 countries in less than one year. 37 Latin American countries participate in COVAX, out of which 10 will receive free vaccines due to their economic condition or population size. The first countries in the region that will receive vaccines from COVAX are Bolivia, Colombia, El Salvador and Peru.



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Brazil, with over 200 million inhabitants, started vaccination in early January 2021, so far only with the Sinovac and the AstraZeneca-Oxford vaccines. The target in Brazil is approximately 80 million people, almost the same number of people that are annually vaccinated against influenza in the country.

The priority groups are the elderly, healthcare workers, people living in long-term facilities, and indigenous populations, in an effort to equitably distribute vaccines in the Amazonia. Amazonia is already the state with the highest proportion of vaccinated inhabitants, although far below the goal in the region that is facing a tremendous impact of COVID-19.

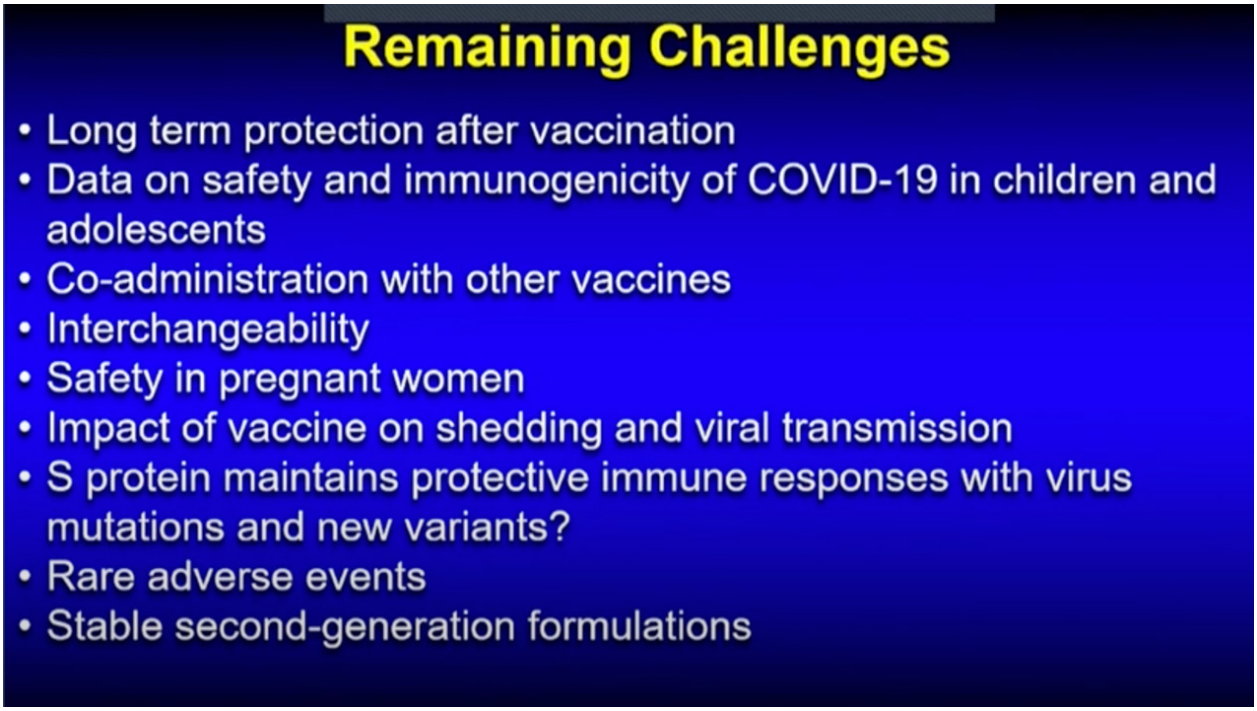
Chile is using AstraZeneca-Oxford, Pfizer and Sinovac vaccines. The ambitious plan in Chile is to immunize approximately 16 million people, of the total 19 million inhabitants, reaching six million vaccinated by end of March 2021. They may end up achieving it since to date already 3 million people have been immunized, almost half of them were 65 years of age and over.

Argentina made an agreement too with AstraZeneca-Oxford to locally produce the vaccine in partnership with Mexico and these will be just distributed to all Latin America.

Argentina is using Sputnik and claims that 60 million doses will be administered across the country by mid-2021. Colombia has recently started the program and plans to vaccinate 35 million people by the end of the year, with many of the vaccines available. Mexico is administering at least five vaccines as part of their five-stage roll out plan, which started in December. We are seeing progress here.

Unfortunately, there have been ambiguous situations in three countries in Latin America. Peru vaccinated at least 500 people with Sinovac while the vaccine was still in clinical trials. Argentina was involved in the scandal of VIP vaccinations, and in Chile almost 40,000 people were vaccinated before their time in the priority plan.

The remaining challenges for the region are summarized in this slide.



Session 2: Panel Discussion

Dr. Aileen Marty
Distinguished University Professor of Infectious Diseases, Department of Translational Medicine, Herbert Wertheim College of Medicine, Florida International University

There are 182 vaccines that are in pre-clinical development for COVID-19, 74 that are in clinical development, of which only 7 are currently in use worldwide. Today in the United States there are discussions about whether or not to grant an emergency authorization to the Johnson & Johnson vaccine, which would bring the number to 8 authorized vaccines. We are in a race between science and the virus and everything that can be done, including being highly effective in vaccinating and ideally using the best possible vaccines, will get us ahead of the virus and bring us back to a sense of normality as fast as possible. It is clear from the data presented by Israel that the vaccines are having an effect. In Florida, our data from vaccinating the elderly is also showing excellent results in terms of what is happening in long-term care facilities and nursing homes.

Dr. Cuauhtémoc Ruiz
Chief, Unit Chief of Comprehensive Family Immunization, Department of Family, Health Promotion and Life Course, PAHO/WHO, Washington, D.C., USA

Vaccine confidence is one of the challenges and all the questions that people have about vaccines: their nationalities, effectiveness, safety, the number of doses, how the new variants will be dealt with.
Equity is a main concern in the Americas and worldwide. COVAX is trying to give all countries access to the vaccine. Thirty-seven countries in the region are participating in COVAX, 9 of which will receive financial support from WHO. To date the number of doses is really small, so a prioritization route map was proposed to focus on saving lives.
Countries in the Americas have wide experience in vaccinations and in the elimination of preventable diseases. As Dr. Safadi commented, in South America countries deploy over 100 million doses of flu vaccine, mostly administered to adults and the elderly. This experience will be key to advance COVID vaccinations successfully.
32 countries in the Americas are already vaccinating for COVID, none has received vaccines through COVAX yet. These countries either produce the vaccine, like the United States or Brazil, or have bilateral agreements, like Panama, Mexico, Colombia, Peru. Other countries receive donations, like most Caribbean countries.
At the same time, it is key to maintain the

regular programs of immunization, which have been highly affected by the pandemic. This demands the political and financial support of the countries.

Dr. María Elena Bottazzi
Associate Dean, National School of Tropical Medicine, Baylor College of Medicine
Houston, Texas, USA

Dr. Rafalowski, is Israel in a position to recommend the strategy be replicated?

Mr. Chaim Rafalowski
Disaster Management and EU Projects Coordinator, Magen David Adom
Tel-Aviv, Israel

Israel started vaccinating with the idea that everyone would rush and would queue for hours just waiting for the vaccine, and it was like that at the beginning but then it changed. Now we are in that race that Dr. Marti mentioned because we have the vaccines, but we do not have the people that are queuing to be vaccinated. We underestimated the concerns of people on the issues around vaccination. So that is challenge number one. The second challenge is fighting this idea that since people get their vaccines, after two doses plus one week the problem is over. This is a global challenge. It has a lot to do with human nature, with the fatigue that we are all facing after one year with the idea that we want to retake our normal lives, while in fact we still must keep taking precautions.

Dr. María Elena Bottazzi
Dr. Safadi, we know that Latin America is complicated, but at the same time as through PAHO's revolving fund and certainly through the high annual coverage rates obtained for flu, and many other pediatric vaccines, it is probably one of the regions that has the best access to delivery and distribution.

Marco Safadi
Head of Department, Pediatric Infectious Diseases, Santa Casa Medical School
São Paulo, Brazil

Latin America has managed to reach high coverage rates for different vaccines and there is high acceptance and low hesitancy compared to other regions, I am confident that once we have the tools and the instruments, deployment of COVID-19 vaccines will be successful.
Going back to the point that we were discussing, I think that the short-term effectiveness and impact data regarding the effect of the vaccine is really convincing, but we have to be cautious about translating in vitro neutralization studies with these variants to real world data, where

there might be a different scenario.
Two efficacy studies were done in South Africa that show the efficacy of two vaccines against the South African variant, which may be similar to some of the variants circulating worldwide. I am confident that the vaccines will really help us achieve the main goal of preventing severe disease and hospitalizations.

Dr. Peter Hotez
Dean, National School of Tropical Medicine,
Baylor College of Medicine
Houston, Texas, USA

I think there is a mixed story here. There is good news in terms of the performance of the vaccines. We knew the vaccines were going to keep people out of the hospital in the ICU, but now we know it is clearly going to halt virus transmission as well if we can get people two doses and high levels of virus neutralizing antibodies. At least this is true of the Pfizer vaccine. We do not know about the others, but I suspect they will as well. This means that any given country could potentially interrupt virus transmission and get back to a normal quality of life if they have access to the vaccines.
Unfortunately, despite the best efforts from global leaders to create COVAX, it is still not working as well as we hoped. The US is looking after itself, Israel is looking after itself, the UK is looking after itself, but they are leaving the rest of the world, especially low- and middle-income countries, without vaccines. For these countries, Pfizer, Biotech and Moderna will not have a substantial role. Merck is out. Sanofi is terribly delayed. The vaccines from Russia and China are of uncertain quality and produce low levels of virus neutralizing antibody, and likely will not work against the South African variant. So there are few options. There is Johnson & Johnson, which is promising, but they are having trouble scaling production. AstraZeneca-Oxford is a good vaccine, but it does not seem to work well against the South African variant. We are trying to come in with our recombinant protein vaccine, that hopefully will be scaled up. Maybe there will be a couple of others, but my conclusion is that we went so heavy in the direction of innovation to develop vaccines, that we may have lost perspective and did not really look after the LMICs in a way that provided them with enough of the old school, durable vaccines, those some people call "people's vaccines". Hopefully, it is not too late to correct it. I think that in the future, vaccines will be easier to scale up, we will figure out a way to make them stable at room temperature but not now, and that is going to be the big crisis globally. ■

Closing remarks

Dr. María Elena Bottazzi and Dr. Carlos Espinal thanked everyone for the privilege of their attendance at this extraordinary meeting. Until vaccines reach every person, they promised future events to give the opportunity to share knowledge, experiences and to further learn about this global threat, hopefully before these variants take over the world. ■