GVIRF 2021

Global Vaccine and Immunization Research Forum

Day 1 February 22/23	Day 2 February 23/24	Day 3 February 24/25	
Keynote: Anthony Fauci, Director, NIAID/NIH with Lee Hall, NIAD/NIH	Keynotes: Bill Gates, Co-chair, Bill & Melinda Gates Foundation Anuradha Gupta, Deputy CEO, Gavi, the Vaccine Alliance	Keynote: Soumya Swaminathan, Chief Scientist, WHO	
Plenary 1: Epidemic and Pandemic Preparedness and Response George F. Gao, China CDC Barney Graham, NIAID/NIH Ana Maria Henao-Restrepo, WHO Jerome Kim, IVI Helen Rees, WRHI Melanie Saville, CEPI Debra Yeskey, CEPI	Plenary 2: HIV, TB & Malaria Vaccine R&D Update Norman Baylor, Biologics Consulting Linda-Gail Bekker, U. of Cape Town Graham Brown, U. of Melbourne Ann Ginsberg, BMGF James Kublin, Fred Hutchinson CRC Sodiomon B. Sirima, Groupe de Recherche Action en Santé Lucky Slamet, Badam Pom	Workshop 7: Immune Responses over the Life Course Galit Alter, Ragon Institute Martin Friede, WHO Shirin Heidari, WHO Tobias Kollmann, Telethon Kids Institute Anis Larbi, Beckman Coulter Janet McElhaney, Health Sciences North Lois Privor-Dumm, Johns Hopkins IVAC	
Concurrent Workshops	Concurrent Workshops	Ajoke Sobanjo-ter Meulen, BMGF Sing Sing Way, CCHMC	
Workshop 1: Innovations in Vaccine Manufacturing Antu Dey, IAVI Jian Dong, WuXi Vaccines Rajat Goyal, IAVI Ahd Hamidi, Batavia Biosciences Harish Iyer, BMGF Casey Selwyn, BMGF Anant Shah, Merck	Workshop 4: Controlled Human Infection Models Norman Baylor, Biologics Consulting Chris Chiu, Imperial College London Gagandeep Kang, CMC Vellore Melissa Kapulu, KEMRI-WT Mike Levine, U. Maryland School of Medicine Annie Mo, NIAID/NIH Andrew Pollard, U. Oxford Jetsumon Prachumsri, Mahidol U.	Workshop 8: Prioritizing Vaccine R&D Bill Hausdorff, PATH Peter Hotez, Baylor College of Medicine Hun Kim, SK Bioscience Jerome Kim, IVI Younbeen Kim, RIGHT Fund Morena Makhoana, Biovac Jo Mulligan, UK FCDO BT Slingsby, Catalys Pacific Hiro Suzuki, MHLW JP Rajeev Venkayya, Takeda Margo Warren, Access to Medicine	
Workshop 2: Emerging Platforms Nathalie Garcon, BIOASTER Sarah Gilbert, U. of Oxford Florian Krammer, Mt. Sinai Christian Mandl, Vaccines, Viral Vectors Lynda Stuart, BMGF Kanta Subbarao, WHO Collaborating Centre for Influenza	Workshop 5: New & Improved Vaccines Ananda Bandyopadhyay, BMGF Robert Bergquist, Geospatial Health Peter Dull, BMGF Aimée Kreimer, NCI/NIH Kathleen Neuzil, CVD Sushant Sahastrabuddhe, IVI	Workshop 9: Building and Sustaining Uptake Simone Carter, UNICEF Julie Leask, U. Sydney Lisa Menning, WHO Anna Ong-Lim, U. Philippines Lucky Slamet, Badam Pom	
Workshop 3: Innovation in Vaccination Jon Abramson, Wake Forest Alejandro Cravioto, UNAM Matthew Downham, CEPI David Durrheim, U. Newcastle Suresh Jadhav, Serum Institute of India Jim Janimak, GlaxoSmithKline Gagandeep Kang, CMC Vellore Bernhards Ogutu, KEMRI Jim Robinson, CEPI Marcel Tanner, STPHI Fred Were, U. Nairobi Darin Zehrung, PATH	Workshop 6: Vaccine Development to Access Narendra Arora, INCLEN Trust Fred Binka, University of Health and Allied Sciences, Ho Ghana Joshua Chu, CHAI Alejandro Cravioto, UNAM Birgitte Giersing, WHO Ian Hudson, BMGF David Kaslow, PATH Deepali Patel, Gavi Sai Prasad, Bharat Biotech International Rino Rappuoli, GSK Vaccines	Plenary 3: Shaping the Future: Equitable Access for All Daniel Feikin, WHO Richard Hatchett, CEPI Gagandeep Kang, CMC Vellore Kim Mulholland, MCRI Robin Nandy, UNICEF Hanna Nohynek, Finnish Inst. for Health and Welfare Katherine O'Brien, WHO Samir Sodha, WHO Collins Tabu, Ministry of Health, Kenya Chris Wolff, BMGF	

Keynote sessions are 30 minutes long. Plenaries and workshops are 90 minutes long.

Day 1 Keynote Address

<u>Block 1</u>: February 22, 13:00 – 13:30 UTC <u>Block 2</u>: February 23, 00:00 – 00:30 UTC

Context and Purpose of GVIRF

Lee Hall, Chief, Parasitology & International Programs Branch at US National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)

Keynote Address: Vaccinology in the context of pandemic preparedness: The COVID-19 experience Anthony Fauci, Director, NIAID/NIH

Plenary 1: Epidemic and Pandemic Preparedness and Response

Block 1: February 22, 13:30 – 15:00 UTC Block 2: February 23, 00:30 – 02:00 UTC

Outbreak response: from Ebola in the DRC to the COVID-19 pandemic

Ana Maria Henao-Restrepo, World Health Organization (WHO)

CEPI approach for pandemic preparedness and putting it into action for COVID

Melanie Saville, Coalition for Epidemic Preparedness Innovation (CEPI)

Rapid (and precise) COVID-19 vaccine development enabled by prototype pathogen preparedness Barney Graham, NIAID/NIH

Block 1 Discussion

Helen Rees, Wits Reproductive Health Institute

(chair)

Ana Maria Henao-Restrepo, WHO

Melanie Saville, CEPI

Barney Graham, NIAID/NIH

Block 2 Discussion

George F. Gao, Chinese Center for Disease

Control and Prevention (chair)

Barney Graham, NIAID/NIH

Jerome Kim, International Vaccine Institute

Debra Yeskey, CEPI

Vaccines are central to epidemic and pandemic preparedness. However, the sporadic and unpredictable nature of Emerging Infectious Disease (EID) outbreaks makes advanced stockpiling of these critical medical countermeasures incredibly difficult. As a result, vaccine development for outbreak response is largely reactive, relying on a "warm-base" of global infectious disease research that is expected to quickly mobilize to combat a new pathogen of concern. The response to the 2014-15 Ebola outbreak in West Africa benefited from more than a decade of biodefense research aimed at developing filovirus vaccines, yet none of the vaccine candidates under study were positioned to deploy early in the outbreak. Now SARS-CoV-2 finds the research and public health communities responding to a novel coronavirus. Although experience with SARS-CoV-1 and MERS outbreaks and continued advancements in "plug-and-play" platform technologies enabled the development of multiple safe and effective SARS-CoV-2 vaccines ready for deployment with unprecedented speed, these vaccines still came too late to prevent millions of deaths worldwide. How can the promise of vaccines be realized to combat sporadic and unpredictable outbreaks?

This plenary session will set the stage by summarizing the global response that led to the declaration of the end of the most recent Ebola outbreak in the Democratic Republic of the Congo in November 2020, and to the ongoing response to the COVID-19 pandemic. The successes, gaps and opportunities will be highlighted – especially in regard to developing and implementing vaccines for global, emergency use.

Two approaches to develop vaccines for pandemic preparedness will also be presented. The "priority-pathogen approach" identifies the pathogens that experts think are most likely to cause an outbreak, then develops vaccine candidates for those pathogens and stockpiles a specified number of doses of vaccine for rapid deployment. In contrast, the "prototype-pathogen approach" systematically develops vaccine candidates against "representative" pathogens within viral families causing human disease with zoonotic and pandemic potential. This approach assumes that the basic knowledge, reagents and techniques utilized for the prototype pathogen could be readily adapted to rapidly develop a vaccine for a closely related emerging pathogen. Both approaches rely heavily on the importance of employing and advancing rapid, "plug-and-play"-platform technologies that can be used to accelerate the development of vaccines in response to EID outbreaks.

Lastly, the panel will consider the need for fair and equitable access to these vaccines during an epidemic or pandemic as a critical part of preparedness.

Concurrent Workshops

Workshop 1: Innovations in Vaccine Manufacturing

<u>Block 1</u>: February 22, 15:00 – 16:30 UTC <u>Block 2</u>: February 23, 02:00 – 03:30 UTC

The ERVEBO® experience: lessons learned and being learned

Anant Shah, Merck

Vaccine manufacturing at lab scale: A paradigm shift to more affordable vaccines

Ahd Hamidi, Batavia Biosciences

Not enough to go around: Vaccine manufacturing for the COVID-19 pandemic

Casey Selwyn, Bill & Melinda Gates Foundation

Block 1 Discussion Block 2 Discussion

Antu Dey, International AIDS Vaccine Initiative Rajat Goyal, International AIDS Vaccine Initiative

(chair) (chair)

Anant Shah, Merck Anant Shah, Merck

Ahd Hamidi, Batavia Biosciences Harish Iyer, Bill & Melinda Gates Foundation

Casey Selwyn, Bill & Melinda Gates Foundation Jian Dong, WuXi Vaccines

Many existing vaccines are manufactured using legacy processes such as egg-based production, batch processing and filling, and aseptic processing. The industry has been slow to incorporate new technologies that might be able to reduce operating costs, capital requirements and the need for human intervention, and thereby improve efficiency and quality. Costs and capacity remain a prohibitive barrier to the development and introduction of novel vaccines, limiting access to both existing and new vaccines — a challenge thrown into stark relief by the expedited development of COVID-19 vaccines.

Innovations across Chemistry, Manufacturing and Controls (CMC) processes, from bioprocessing to batch release tests, provide opportunities to help bridge this "second Valley of Death" and establish a more sustainable and responsive vaccine development ecosystem. This session will provide an overview of key challenges and cost drivers and include discussion of emerging systems and technologies that aim to address them. Learnings from Ervebo vaccine development and manufacturing scale up in response to the 2014-2016 Ebola outbreak in West Africa and challenges

faced in the current COVID-19 vaccine development effort will frame a forward-looking discussion on how emerging CMC technologies can be integrated to establish a more sustainable, flexible, and efficient manufacturing ecosystem for both routine and pandemic-responsive vaccines.

Workshop 2: Emerging Platforms

Block 1: February 22, 15:00 – 16:30 UTC Block 2: February 23, 02:00 - 03:30 UTC

Nucleic acid vaccines: Is it all done? Christian Mandl, Vaccines and Viral Vectors

Viral vectored vaccine platform technologies

Sarah Gilbert, University of Oxford

Adjuvants

Nathalie Garcon, BIOASTER Technology Research Institute

Universal Influenza Vaccines

Kanta Subbarao, WHO Collaborating Centre for Reference and Research on Influenza

Block 1 Discussion

Christian Mandl, Vaccines and Viral Vectors (chair) Christian Mandl, Vaccines and Viral Vectors (chair)

Nathalie Garcon, BIOASTER Natalie Garcon, BIOASTER

Kanta Subbarao, WHO Collaborating Centre for

Reference and Research on Influenza

Mount Sinai Lynda Stuart, Bill & Melinda Gates Foundation

Block 2 Discussion

Sarah Gilbert, University of Oxford Florian Krammer, Icahn School of Medicine at

Immunoprophylaxis is an effective strategy for disease prevention and has greatly improved public health worldwide. Conventional vaccine approaches, such as inactivating or attenuating the respective pathogen, have successfully decreased the burden of many infectious diseases but have not worked for many others. Alternative approaches are being employed to address unmet medical needs. Rapidresponse technology platforms are also needed as new threats develop. In recent decades, the number of strategies has been significantly expanded. In this workshop, we will discuss existing and new vaccine and immunoprophylaxis platforms that have the potential to tackle current global health challenges such as COVID-19 and influenza.

This session will include key updates on Emerging Vaccines Platforms, Adjuvants, and Universal Influenza Vaccines. Each speaker will present on overview of technology platforms in the field and describe applications for specific infectious disease targets and indications. The speakers will discuss preclinical data, clinical trial data, manufacturing, formulation, delivery, and regulatory pathways. In addition, the speakers will discuss how platforms are or could be used for rapid response and deployment to combat pandemics such as COVID-19 and Influenza.

The panel will engage in an integrated discussion on vaccine and therapeutic immunization strategies and how these technology platforms will address the increasing challenges in new vaccine development.

Workshop 3: Innovation in Vaccination

<u>Block 1</u>: February 22, 15:00 – 16:30 UTC <u>Block 2</u>: February 23, 02:00 – 03:30 UTC

A conversation on the challenges and opportunities for innovation in vaccination

Jon Abramson, Wake Forest School of Medicine

Alejandro Cravioto, Universidad Nacional Autónoma de México

Transformative concepts for mass vaccination and pandemic response

Matthew Downham, Coalition for Epidemic Preparedness Innovations (CEPI)

Considerations for mass deployment of innovative vaccines in low- and middle-income country immunization programs

Fred Were, University of Nairobi

Block 1 Discussion Block 2 Discussion

Bernhards Ogutu, Kenya Medical Research David Durrheim, U. Newcastle (chair)

Institute (chair) Darin Zehrung, PATH

Jim Robinson, CEPI Gagandeep Kang, Christian Medical College,

Marcel Tanner, Swiss Tropical and Public Health Vellore

Institute Suresh Jadhav, Serum Institute of India Pvt. Ltd.

Jim Janimak, GlaxoSmithKline

Availability and use of vaccine product innovations that ease delivery will be critical to achieving the IA2030 vaccination coverage and equity goals. Despite this need, vaccine product innovations intended for use in in resource constrained settings have suffered from slow development or low uptake over the last two decades, hampering their potential to demonstrate impact. Vaccine product innovations in combination with traditional pediatric vaccines have been slow to advance.

The COVID-19 pandemic has created urgency and opportunity for novel technologies and approaches to respond to the current pandemic, with unprecedented investment, partnership and momentum to accelerate development and prepare for deployment of COVID-19 vaccines as they become available. In addition to preparing for future pandemics, these technologies could also be applied to EPI vaccines to address existing coverage and equity gaps.

This session will review some of the novel vaccination technologies that have emerged in the response to the COVID-19 pandemic, their status of development, use cases and strategies for deployment. It will also consider the perspectives of country readiness, end-user acceptability, vaccine hesitancy, pharmacovigilance and program suitability, especially for innovations and vaccines that are intended for rapid roll out. The panel will discuss the challenges and opportunities for innovative vaccine product development and use, in the context of the COVID-19 pandemic and beyond.

Day 2 Keynote Addresses

<u>Block 1</u>: February 23, 13:00 – 13:30 UTC <u>Block 2</u>: February 24, 00:00 – 00:30 UTC

Keynote Address: The lessons of COVID-19 for vaccine development

Bill Gates, Co-chair, Bill & Melinda Gates Foundation

Keynote Address: Innovating from research to impact at scale—the role of the Gavi Alliance

Anuradha Gupta, Deputy CEO, Gavi, the Vaccine Alliance

Plenary 2: HIV, TB & Malaria Vaccine R&D Update

<u>Block 1</u>: February 23, 13:30 – 15:00 UTC <u>Block 2</u>: February 24, 00:30 – 02:00 UTC

Current status and future prospects for human immunodeficiency virus (HIV) vaccines

Linda-Gail Bekker, Desmond Tutu HIV Research Centre, University of Cape Town

Update on progress in tuberculosis (TB) vaccine development

Ann Ginsberg, Bill & Melinda Gates Foundation

Current status of malaria vaccines

Sodiomon B. Sirima, Groupe de Recherche Action en Santé (GRAS)

Block 1 Discussion

Norman Baylor, Biologics Consulting Group (chair)
Linda-Gail Bekker, University of Cape Town
Ann Ginsberg, Bill & Melinda Gates Foundation

Sodiomon B. Sirima, GRAS

Block 2 Discussion

Lucky Slamet, Badam Pom (chair)

Norman Baylor, Biologics Consulting Group (chair)
Ann Ginsberg, Bill & Melinda Gates Foundation
James Kublin, Fred Hutchinson Cancer Research

Center

Graham Brown, University of Melbourne

This session will give multiple perspectives on progress in development of HIV, TB, and malaria vaccines during the Decade of Vaccines, with an emphasis on progress in the past two years. To highlight cross-cutting issues and capture a regional perspective on these high priority vaccines, short vaccine-specific updates will be juxtaposed with a panel discussion across all three vaccines.

Concurrent Workshops

Workshop 4: Controlled Human Infection Models for Vaccine Research and Development

Block 1: February 23, 15:00 – 16:30 UTC

Block 2: February 24, 02:00 – 03:30 UTC

Controlled human malaria infection (CHMI)—tool for accelerating vaccine development Melissa Kapulu, KEMRI-Wellcome Trust Research Programme (KEMRI-WT)

Typhoid controlled human infection model (CHIM)

Andrew Pollard, University of Oxford

Respiratory virus controlled human infection during inter-pandemic and pandemic times Chris Chiu, Imperial College London

Block 1 Discussion

Annie Mo, NIAID/NIH (chair) Melissa Kapulu, KEMRI-WT

Andrew Pollard, University of Oxford **Chris Chiu**, Imperial College London

Block 2 Discussion

Gagandeep Kang, Christian Medical College,

Vellore (chair)

Melissa Kapulu, KEMRI-WT

Jetsumon Prachumsri, Mahidol University **Mike Levine**, University of Maryland School of

Medicine

Norman Baylor, Biologics Consulting Group

In recent years, Controlled Human Infection (CHI) models have been increasingly utilized to support vaccine R&D efforts. They have now been conducted in endemic regions where diseases are prevalent and other low- and middle-income countries as well. There have been discussions on the use of CHI to address the pressing COVID-19 R&D issues and these are currently planned in the UK. CHI models have been used as alternative approaches to shorten vaccine development timeline and reduce development cost, and to carry out basic vaccinology and immunology research.

This plenary will present several CHI use cases to illustrate the utility of the models, and highlight scientific, regulatory, and ethical challenges and opportunities for vaccine R&D communities.

Workshop 5: New & Improved Vaccines on the Horizon

Block 1: February 23, 15:00 – 16:30 UTC Block 2: February 24, 02:00 – 03:30 UTC

Salmonella typhi vaccines, development and deployment

Sushant Sahastrabuddhe, International Vaccine Institute (IVI)

Schistosomiasis vaccines, development and role in elimination

Robert Bergquist, Geospatial Health

Single dose human papillomavirus (HPV) vaccination

Aimée Kreimer, National Cancer Institute, US National Institutes of Health (NCI/NIH)

Improved vaccines: Novel oral polio vaccine (OPV)

Ananda Bandyopadhyay, Bill & Melinda Gates Foundation

Block 1 Discussion Block 2 Discussion

Kathleen Neuzil, University of Maryland Center for **Kathleen Neuzil**, CVD (chair) Vaccine Development & Global Health (CVD, chair) **Sushant Sahastrabuddhe**, IVI

Robert Bergquist, Geospatial Health Ananda Bandyopadhyay, Bill & Melinda Gates

Aimée Kreimer, NCI/NIH Foundation

Peter Dull, Bill & Melinda Gates Foundation Peter Dull, Bill & Melinda Gates Foundation

During the last decade significant progress has been made towards the development and delivery of vaccines to combat various infectious diseases for which vaccines are not yet available. This session will review advances in approaches and technologies for recently WHO pre-qualified typhoid conjugate vaccines and early work on nontyphoidal *Salmonella* vaccine development. In addition, updates on schistosomiasis vaccine development and its potential role in elimination of schistosomiasis will be presented.

Although safe and effective vaccines against polio and HPV have been in use for some time, new challenges have required developers to think differently to maintain or accelerate control. This workshop will also review the data from the novel OPV2 vaccine, a critical new tool to address vaccine-derived strains which recently became the first vaccine ever to receive an Emergency Use Listing by the WHO. It will also review the emerging data that suggest high and durable protection afforded by just a single dose of the existing HPV vaccines which has the potential to accelerate efforts as part of the recently launched WHO Cervical Cancer Elimination strategy.

Workshop 6: Vaccine Development to Access: is there a role for early policy consideration?

Block 1: February 23, 15:00 – 16:30 UTC

Block 2: February 24, 02:00 – 03:30 UTC

Vaccine development to access: Opportunities, risks and potential valleys of death David Kaslow, PATH

Vaccine development to access: Is there a role for earlier policy consideration? Rino Rappuoli, GSK Vaccines

Building the concept of WHO Vaccine Preferred Policy Profiles (PPoP)

Birgitte Giersing, World Health Organization

Block 1 Discussion

Alejandro Cravioto, Universidad Nacional Autónoma de México (UNAM, chair)

Deepali Patel, Gavi

Fred Binka, University of Health and Allied

Sciences, Ghana

Narendra Arora, The INCLEN Trust International Ian Hudson, Bill & Melinda Gates Foundation

Block 2 Discussion

Alejandro Cravioto, UNAM (chair)

David Kaslow, PATH

Joshua Chu, Clinton Health Access Initiative **Sai Prasad**, Bharat Biotech International, Ltd.

While there has been significant progress in overcoming the translational gap in recent years (transitioning a candidate from bench to early phase clinical testing), many candidates continue to face uncertainty on the path through late-stage product development and licensure to policy and sustainable implementation. (Piot et al, 2019, doi.org/10.1038/s41586-019-1656-7) The investment and resource required following phase II trials (clinical proof of concept) are typically the most budget and labor intensive—associated with significant risk and opportunity cost, particularly for vaccines that are targeted exclusively to low- and middle-income countries (LMICs).

The urgency of the COVID-19 pandemic response has propelled the use of novel technologies for antigen design, manufacturing and delivery; and necessitated the use of adaptive trial designs with flexibility to modify the course of studies in accordance with pre-specified rules (Black et al, 2020, doi.org/10.1016/j.smim.2020.101413). The first COVID-19 vaccine was licensed 10 months after the genetic sequence for the spike protein became available, followed by record rates for regulatory approvals and policy recommendations. Effectiveness data is being collected as we speak. However, for endemic vaccines in the pipeline, effectiveness data will be needed before policy recommendation, financing and introduction. As we consider how to innovate and accelerate the pathway to first licensure for these endemic vaccines, particularly for those that are intended for use in LMICs, we need to ensure we understand the data and evidence needs to inform decision making for implementation.

In this session, we will discuss the apparent perception of a 'guidance gap' between WHO Preferred Product Characteristics (PPCs) that describe product attributes that meet expectations for programmatic use), and data/evidence expectations for WHO policy recommendation. We evaluate examples of pipeline vaccines for which earlier (pre-phase III) consideration of evidence required for policy could better prepare the post-licensure pathway and mitigate against a delay between vaccine licensure and uptake, and finally discuss the concept and potential value of developing of Preferred Policy Profiles (PPoPs) to articulate the anticipated recommendation for use.

Day 3 Keynote Address

Block 1: February 24, 13:00 – 13:30 UTC Block 2: February 25, 00:00 – 00:30 UTC

Keynote Address: Research for equity

Soumya Swaminathan, Chief Scientist, World Health Organization (WHO)

Concurrent Workshops

Workshop 7: Immune Responses over the Life Course

<u>Block 1</u>: February 24, 13:30 – 15:00 UTC <u>Block 2</u>: February 25, 00:30 – 02:00 UTC

Protection of newborn infants through vaccination

Tobias Kollmann, Telethon Kids Institute and Perth Children's Hospital

Correlates of protection against SARS-CoV-2

Galit Alter, Ragon Institute of MGH, MIT, and Harvard

The immune response in older adults

Anis Larbi, Beckman Coulter Life Sciences

Block 1 Discussion Block 2 Discussion

Martin Friede, WHO (chair) Martin Friede, WHO (chair)

Anis Larbi, Beckman Coulter Life Sciences Tobias Kollmann, Telethon Kids Institute

Sing Sing Way, Cincinnati Children's Hospital Ajoke Sobanjo-ter Meulen, Bill & Melinda Gates

Medical Center Foundation

Shirin Heidari, WHO Lois Privor-Dumm, Johns Hopkins International

Janet McElhaney, Health Sciences North Research Vaccine Access Center

Institute

The immune system changes over the life course, affecting both susceptibility to infection and responses to vaccines. By understanding these changes, we can design better vaccines and immunization schedules.

This session will review changes in the immune system in three critical life stages: the first few weeks of life as the immune system is first exposed to infection and needs to rapidly undergo a maturation; later infancy and adulthood where factors such as gender and pregnancy play roles in infection, disease progression, and vaccine efficacy; and later adult life when immune senescence begins to disrupt the immune system, decreasing vaccine responses, increasing susceptibility to new infections, and allowing the re-awakening of latent infections such as shingles.

At each of these life-stages we need to be considering the vaccine schedule to optimally use the immune response while minimizing susceptibility to infection. We can also consider adapting vaccines to the immune system at that age, for example using high-dose or adjuvanted vaccines in older adults, neonate-specific immune stimulation in younger infants, and priming early teens for infections they may encounter later in life.

These life-stage specific immune variations are still poorly understood. One intended outcome from the panel and audience discussion of this session will be identifying the research activities that need to be undertaken and the populations that need to be included in clinical trials.

Workshop 8: Prioritization for Vaccine R&D

Block 1: February 24, 13:30 – 15:00 UTC

Block 2: February 25, 00:30 – 02:00 UTC

Decision-making and prioritization of vaccines to address public health needs in low- and middle-income countries: A case study

Bill Hausdorff, PATH

Prioritization of vaccines for global health

Jerome Kim, International Vaccine Institute

The state of play: Industry vaccine trends from the Access to Medicine Index

Margo Warren, Access to Medicine Foundation

Block 1 Discussion

Peter Hotez, National School of Tropical Medicine at Baylor College of Medicine (chair)

Morena Makhoana, Biovac

Rajeev Venkayya, Global Vaccine Business Unit,

Takeda Pharmaceutical Co. Ltd

Jo Mulligan, UK Foreign, Commonwealth and

Development Office

Block 2 Discussion

BT Slingsby, Catalys Pacific (chair)

Hun Kim, SK Bioscience **Younbeen Kim**, RIGHT Fund

Hiro Suzuki, Ministry of Health, Labour and

Welfare, Japan

Who funds vaccine R&D and how do they set their priorities? How are funding decisions made, and who participates in them? These questions are especially pressing now that COVID-19 has accelerated the introduction of new technologies, new funding models and even new global health players, and introduced new and unanticipated dynamics into the already complicated question of vaccine R&D prioritization.

This session will review how prioritization decisions have been made in the past, how global health decision-making processes have evolved, and how lessons from COVID-19 might influence future decisions. Speakers from industry, funders, and governments will discuss the impact of these new dynamics, including the inevitable tensions that arise when having to choose between competing priorities.

We will explore opportunities to align stakeholders across the global health landscape to create better continuity between policy makers, funders, manufacturers, and end-users. We will also discuss the guardrails and potential new rules that must be considered in light of lessons from COVID-19, including the role of new, untested technologies vs. the tried-and-true models that have dominated vaccine R&D to date.

Finally, we will delineate the other global health decisions and voices that need to contribute to R&D prioritization decisions in order to further public health goals such as pandemic preparedness, capacity building and continuity of effort against poverty-associated diseases.

Workshop 9: Building and Sustaining Uptake

Block 1: February 24, 13:30 – 15:00 UTC

Block 2: February 25, 00:30 – 02:00 UTC

Summary of the latest evidence and open research questions

Julie Leask, University of Sydney

Evidence and lessons learned on social sciences analytics around vaccination in the Democratic Republic of the Congo

Simone Carter, UNICEF

Case Study: the Philippines

Anna Ong-Lim, University of the Philippines

Block 1 Discussion

Lisa Menning, WHO (chair)

Julie Leask, University of Sydney

Simone Carter, UNICEF

Anna Ong-Lim, University of the Philippines

Block 2 Discussion

Lucky Slamet, Badam Pom (chair) **Julie Leask**, University of Sydney

Simone Carter, UNICEF

Anna Ong-Lim, University of the Philippines

The recent focus on vaccination in the context of the COVID-19 pandemic has raised many questions about the multiple conditions that need to converge to support and sustain high uptake. While aspects are specific to COVID-19 vaccines – such as the prioritized target populations – many general principles apply to any vaccine across the life-course. Whether for COVID-19 or other vaccine-preventable diseases, these considerations offer a stark reminder that people-centered and resilient programs are needed more than ever to achieve disease elimination and eradication targets, and to extend the benefits of vaccines equitably, across the life course.

To effectively address these challenges with the design of robust interventions, we must begin by assessing the full range of behavioral and social drivers of vaccination. These involve the thoughts and feelings of individuals, social processes and practical or access-related factors. Some countries have seen reductions in public confidence in vaccination or increasing complacency. Anti-vaccination activism is a worldwide phenomenon with the capacity to spread misinformation rapidly. Negative messages online can affect intention to vaccinate, particularly in an environment of mistrust - but it's not always about the vaccine, and often what is below the surface. Health systems that have earnt the trust and support of local communities by reliably providing quality services before rumors hit or a crisis unfolds have a powerful advantage.

This session examines the state of the art in what is known about the drivers of vaccination at individual, community and societal levels; interventions to improve uptake; and methods for building the resilience of immunization programs in countries.

Plenary 3: Shaping the Future: Equitable Access for All

Block 1: February 24, 15:00 – 16:30 UTC Block 2: February 25, 02:00 – 03:30 UTC

The enduring dilemma of 20 million unvaccinated children: Equity and access solutions in IA2030 Katherine O'Brien, Immunization, Vaccines, and Biologicals, World Health Organization

Impact of COVID-19 on coverage and equity

Samir Sodha, WHO

Has COVID-19 has created new opportunities to improve Vaccine Equity and Access?

Richard Hatchett, Coalition for Epidemic Preparedness Innovations

Block 1 Discussion Block 2 Discussion

Daniel Feikin, WHO (chair) Robin Nandy, UNICEF (chair)

Samir Sodha, WHO Gagandeep Kang, Christian Medical College,

Collins Tabu, Ministry of Health, Kenya Vellore

Hannah Nohynek, Finnish Institute for Kim Mulholland, Murdoch Children's Research

Health and Welfare Institute

Chris Wolff, Bill & Melinda Gates Foundation

This session will address equitable access of vaccines and immunization. The theme of equity and access of vaccines is a lynchpin of initiatives for the next decade of immunization, highlighted in Immunization Agenda 2030 and Gavi 5.0, and for wider initiatives such as the Sustainable Development Goals. Despite the success of immunization programs in reducing childhood morbidity and mortality, 20 million children remained un- or under-vaccinated each year at the beginning of the decade. This session will explore the reasons for the persistent problem of zero-dose children and new strategies to address it as part of IA2030.

This conversation of equity and access became derailed by the COVID-19 pandemic. This session will address how COVID-19 had worsened inequities in vaccination of the world's children, and how the global response to the pandemic offers new opportunities to address inequities.

Close of Meeting

GVIRF 2021 Scientific Organizing Committee

Jean-Pierre Amorij, UNICEF, Amsterdam, Netherlands

Narendra Arora, The INCLEN Trust International, New Delhi, India

Norman Baylor, Biologics Consulting Group, Inc., VA, USA

Ralf Clemens, GRID Europe Consulting, Portugal

David Durrheim, Hunter New England Area Health Service and Professor of Public Health, University of Newcastle, Australia

Gagandeep Kang, The Wellcome Trust Research Laboratory, Division of Gastrointestinal Sciences, Christian Medical College, Vellore, India

Jerome Kim, International Vaccine Institute, Seoul, Republic of Korea

Robin Nandy, UNICEF, New York, USA

Kathleen Neuzil, Centre for Vaccine Development, University of Maryland School of Medicine, Baltimore, USA

Bernhards Ogutu Ragama, Kenya Medical Research Institute, Kenya

Alexander Precioso, Clinical Trials Division, Instituto Butantan, São Paulo, Brazil

Helen Rees, Wits Reproductive Health and HIV Research Institute, University of the Witwatersrand, Johannesburg, South Africa

Lucky Slamet, Technical Consultant for Badam Pom, Indonesia

Secretariat and Session Organizers

Bill & Melinda Gates Foundation	US National Institute of Allergy and Infectious Diseases		World Health Organization
Kristen Earle	Lee Hall	Christina McCormick	Martin Friede
Peter Dull	Andrew Ford	Annie Mo	Marc Perut
Jessica Martinez	Shahida Baqar	Theodore Pierson	Daniel Feikin
Angela Hwang	Paula Bryant	Patricia Strickler-	Birgitte Giersing
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