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Translating **science** into **global** health impact

The Rockefeller Foundation

Delivering vaccines for emerging infectious diseases: harnessing the power of innovative partnerships

WHITE PAPER

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ON THE COVER

Health care worker Ravi Chhayajyoti carries COVID-19 vaccines to a vaccination center on Aug. 2, 2021 in Doti District in far-western Nepal. Image: © UNICEF/UN0501467/Laxmi Prasad Ngakh

Annie Musonda at Nkwazi Clinic in Zambia. Image: © IAVI

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We would like to thank the members of the summit planning and white paper production group: Rose Catlos, Lillian Greer, Swati Gupta, Andy Kilianski, Hester Kuipers, Shelly Malhotra, Jennifer Maple, Gabriella Quintard, Nicole Sender, and Karie Youngdahl.

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ABBREVIATIONS

ADVANCE	Accelerate the Development of Vaccines and New Technologies to Combat the AIDS Epidemic, a 10-year cooperative agreement with the U.S. Agency for International Development (USAID), through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)
BARDA	Biomedical Advanced Research and Development Authority
CAPEX	capital expenditure
CEPI	Coalition for Epidemic Preparedness Innovations
CFR	case fatality rate
COVAX	COVID-19 Vaccines Global Access
EDCTP	European and Developing Countries Clinical Trials Partnership
EIDs	emerging infectious diseases
HICs	high-income countries
IP	intellectual property
LMICs	low- and middle-income countries
mRNA	messenger ribonucleic acid
ODA	Overseas Development Aid
PEPFAR	United States President's Emergency Plan for AIDS Relief
PDP	product development partnership
R&D	research and development
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization

Foreword

Over the past 20 years, emerging infectious diseases (EIDs) have caused deadly local and regional outbreaks and have at times swept the globe in pandemic waves — COVID-19, of course, being the most devastating in its toll. One fact of the 21st century is that new patterns of climate and human migration, travel, and interaction with the natural world will continue to contribute to unpredictable outbreaks of infectious diseases, known and as yet unknown. We will need to address these new threats effectively or suffer the consequences for our inaction or incompetence.

In the early fall of 2022, when mpox had been spreading globally for a few months, when an outbreak of rare Sudan ebolavirus disease was simmering in Uganda, and when COVID-19 was still causing more than 400 deaths a day in the U.S., IAVI and The Rockefeller Foundation convened a unique meeting entitled **Delivering vaccines for emerging infectious diseases: harnessing the power of innovative partnerships**. The objective of the meeting was to spark strategic discussions on how to galvanize partnerships to address vaccine development and access for EIDs. The link between the two organizations has a long history — The Rockefeller Foundation was IAVI's founding donor, responsible for its establishment in 1996 as a public-private product development partnership (PDP) to address factors that impeded progress on HIV vaccine development.

In more recent years, IAVI has expanded its scope of work beyond HIV to apply its skills, innovations, and expertise to other infectious diseases that disproportionately affect people living in low- and middle-income countries (LMICs), and The Rockefeller Foundation rose to address the challenges of COVID-19 by investing in pandemic prediction, preparedness, and response. On the occasion of IAVI's 25th anniversary year — delayed slightly by the pandemic — the two organizations planned a meeting to bring together partners working across the globe, and across the public and private spheres, to examine what recent EID outbreaks have taught us, and how we can meet the challenges of the future with more effective partnerships for EID vaccine development.

The discussions were open, honest, and thought-provoking. This publication summarizes those conversations and insights by some of the brightest minds working in global health on how to avoid repeating the mistakes of the past — how to break the boom/bust cycle of emergency response and then waning interest in an EID, and how to ensure that people living in LMICs have equitable access to vaccines developed to prevent EIDs.

On behalf of IAVI and The Rockefeller Foundation, and the passionate, committed attendees of the summit we convened, we hope you find this publication valuable. And we invite you to help us continue the conversation so that we are prepared with the partnership strategies and collaborative frameworks needed to ensure vaccines to prevent the next EID will be available and accessible to all.

Sincerely,

Mark Feinberg, M.D., Ph.D., President and CEO, IAVI

Bruce Gellin, M.D., MPH, Senior Vice President and Chief, Global Public Health, The Rockefeller Foundation

The link between the two organizations has a long history — **The Rockefeller Foundation was IAVI's founding donor**, responsible for its establishment in 1996 as a public-private product development partnership to address factors that impeded progress on HIV vaccine development.

Porters carry COVID-19 vaccines to health facilities in Jumla District in Nepal's remote far-west region. Image: © UNICEF/UN0431111/Laxmi Prasad Ngakhusi

Introduction

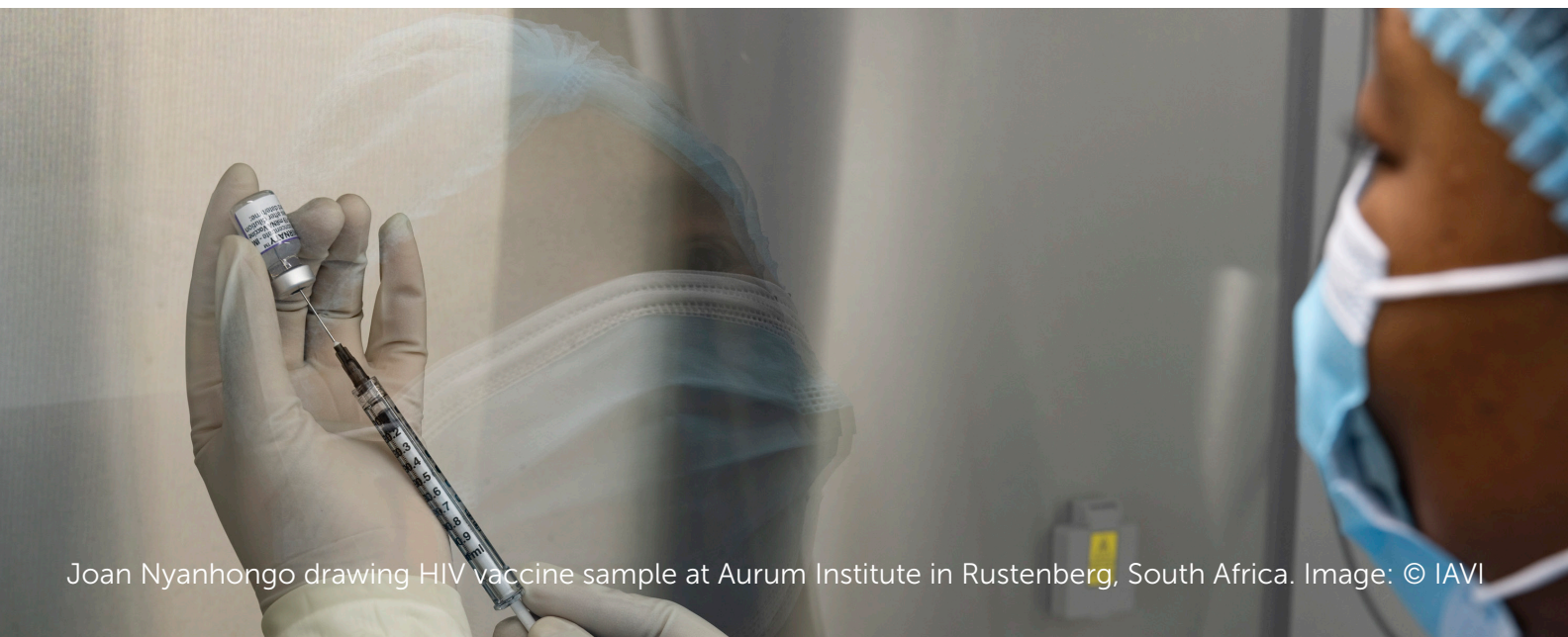
Efficacious COVID-19 vaccines were developed quickly during the first year of the pandemic and distributed, though not globally and equitably, soon after. However, this rapid response is not the norm during EID outbreaks. Rather, a more common response to a new EID is for researchers and developers to engage in a flurry of activities until the outbreak abates, followed by loss of urgency and lack of progress on projects that had been taken up with great energy. This white paper, which was developed to reflect the thinking of a group of experts gathered in New York City and virtually on September 16, 2022, presents an informal analysis and set of recommendations to harness the power of innovative partnerships to improve EID vaccine development.

The summit consisted of two panel discussions and three concurrent working groups preceded by reflections from Mark Feinberg, M.D., Ph.D., president and CEO of IAVI; Swati Gupta, Dr.P.H., M.P.H., vice president, emerging infectious diseases and epidemiology, IAVI; Bruce Gellin, M.D., M.P.H., chief, global public health strategy, The Rockefeller Foundation; Sir Jeremy Farrar, director of Wellcome; and Rajiv Shah, M.D., president of The Rockefeller Foundation. They offered their perspectives on past, present, and emerging challenges in pandemic preparedness and how to fill the gaps in EID vaccine R&D. Their remarks framed two expert panel discussions moderated by Apoorva Mandavilli, global health reporter, The New York Times, covering lessons learned from COVID-19 and future directions. One of the most important directions is horizontal, they concluded, and should see existing disease- and discipline-specific institutions work together in new ways.

During a panel entitled "Innovative partnerships for EID vaccine R&D," panelists prioritized as must-haves sustained regulatory readiness and global coordination, backed by strong communication. Though COVID-19 offers a roadmap for rapid mobilization and data-gathering during an outbreak, they said, substantial work remains to assemble agreed-upon trial protocols and designs for faster implementation. Panelists noted that building public trust during "peacetime" is essential to address issues such as vaccine hesitancy and uneven uptake. They also cited the need to include equity considerations in all aspects of product development and identified a major obstacle: competing health priorities, especially in regions where outbreaks are most likely to originate. Chronic threats such as lack of clean water and malnutrition can easily overshadow preparation for future threats, they said.

The need to focus on community-felt health needs re-emerged during a panel entitled "Ensuring equity in EID vaccine access and impact." Strengthening access to basic life-saving interventions, as well as regional capacity and immunization systems, they argued, could further enhance public trust in science during peacetime and allow public health practitioners to shift their focus to vaccine delivery and uptake during a crisis. In addition to systems, public perception plays an important role in vaccine development and ultimately access. Viewing health as a human right and pandemic vaccines as global public goods, for example, could help ensure that policymakers prioritize sustainable funding for EID vaccine R&D and delivery. But funding alone won't win the race; strong community engagement and advocacy are needed to keep preparedness front of mind between outbreaks.

The panels were followed by a dialogue between Feinberg and IAVI's founding CEO Seth Berkley, CEO of Gavi, the Vaccine Alliance, in which they reflected on IAVI's inception, impact, and evolution beyond HIV vaccines. The conversation expanded into broader issues in pandemic preparedness and echoed themes that emerged earlier in the day, including the need for new models of public-private partnership, vaccine hesitancy, hostility toward science, vaccine nationalism, and lessons learned from previous outbreak responses. The conversation was both a conclusion to the morning programming and catalyst for three subsequent working groups assembled to tackle specific issues in EID vaccine access, financing, and R&D, respectively.



Joan Nyanhongo drawing HIV vaccine sample at Aurum Institute in Rustenberg, South Africa. Image: © IAVI

Executive summary

This executive summary distills the discussions among experts representing a breadth of organizations working on various aspects of EID preparedness and response at the September 16 EID summit organized by IAVI and sponsored by The Rockefeller Foundation. In particular, the experts in attendance considered gaps and opportunities for partnerships to enable EID vaccine R&D, sustainable financing, and access. Their recommendations are summarized below.

1 R&D PARTNERSHIPS: ACCELERATING THE DEVELOPMENT OF VACCINES FOR EIDS

Participants identified the most pressing gaps in EID vaccine development that could be bridged through R&D partnerships. Much of their perspective was informed by recent experiences with COVID-19, but also encompassed past EID response, such as occurred during the 2014-16 West African Ebola outbreak.

GAPS

- Lack of trust among stakeholders.
- Lack of resource and sample sharing in geographic areas of EID prevalence.
- Little access to early financing, which impedes accelerated advancement of vaccine candidates and research on diseases that have yet to "emerge."
- Failure to sustain partnerships during "peacetime."

OPPORTUNITIES FOR ACTION

The group identified several key actions:

1. **Continue collective discussions targeted toward solutions.** The group noted that they rarely get the chance to discuss these issues with those outside of their own organizations or subject area. Continuing the dialogue among stakeholders must be a future action of the EID community, and this dialogue should span R&D, policy, access, and funding to ensure that all these perspectives are represented.

2. **Focus on building trust.** The working group's primary suggestion was to engage R&D communities in trust-building exercises as these communities emerge from the COVID-19 pandemic. In addition, the group noted the need to better understand trust gaps that exist in LMICs and communities that have been disproportionally affected by EIDs and COVID-19.

3. **Sustain the partnerships forged during the COVID-19 pandemic.** Beyond the emergency phase of COVID-19, we must continue to foster successful partnerships by continuing coronavirus R&D and identifying targets for R&D with similar attributes that could emerge in the future.

2 ACCESS PARTNERSHIPS: ENSURING PROMPT AND EQUITABLE ACCESS FROM DAY ZERO THROUGH "THE LAST MILE"

This working group noted the failure of traditional market forces to catalyze investment and access for diseases that primarily affect resource-limited settings and highlighted the need for innovative new models of collaboration. With a growing pipeline of public sector supported vaccines to address EIDs, the need to define sustainable and equitable models for vaccine manufacturing, financing, procurement, affordable access, and scale up is an urgent priority.

GAPS

- Resource-limited countries are over reliant on externally subsidized EID responses, so that local needs are not met.

- Existing business models prioritize the development of vaccines with significant market in high-income settings.

- When vaccines have dual-market relevance, they are distributed or deployed inequitably.

OPPORTUNITIES FOR ACTION

New, paradigm-shifting approaches will be needed to ensure an architecture for innovation, supply, and scale up of vaccines to meet local epidemics of regional relevance. The group recommended several actions that need to be taken to deliver this new paradigm:

1. **Define a sustainable business model for EID vaccine development.** This will involve identifying strategies to prepare for shifts in vaccine production to allow both for manufacturing surge capacity and stockpile production. Regionally driven procurement mechanisms could pool buying power and consolidate demand. Robust analyses will be needed to define needs and markets.

2. **Strengthen national and regional leadership.** Few countries have the buying power to sustain vaccine markets on their own and developing regional supply and procurement models will help foster sustainability. Regional hubs will need access to intellectual property (IP), while in parallel building their own research and development capacity to cultivate local innovation. Global investment is needed to supplement regional investment to achieve these aims.

3. **Ensure clear and binding commitments for future accessibility of products.** We must develop binding access criteria that are enforced early on and along the product development continuum for EID vaccines investments. Additionally, we must leverage funder resources more strategically to deliver this goal.

4. **Create an enabling ecosystem.** Strengthened routine immunization delivery will support readiness so that countries can pivot to meet EID needs. The same holds for production capacity. Investments made in establishing regional production of routine vaccines can serve as a stepping-stone. Other necessary parts of this enabling environment include legislative frameworks to ensure access and the creation of alternative incentives for developers.

3 FUNDING PARTNERSHIPS: CREATING A SUSTAINABLE FINANCING ECOSYSTEM TO ADVANCE EID DEVELOPMENT AND DEPLOYMENT

Discussions on partnerships for financing EID vaccine development addressed major gaps in funding EID vaccine R&D that exist across the end-to-end product development continuum from discovery research through product rollout and uptake.

GAPS

- Funding for global health often comes from national governments' Overseas Development Aid (ODA) programs, which typically target the economic development and welfare of developing countries. However, EID preparedness and response needs do not align well with ODA agendas and are not currently being supplemented by domestic resources in LMICs.

- Failure of agencies working on EID vaccine development to coordinate on shared priorities, leading to lack of efficiencies and synergies.

OPPORTUNITIES FOR ACTION

To bring together the fragmented funding environment and accelerate new opportunities, participants made the following recommendations:

1. **Change the conversation around R&D and develop compelling shared messaging so that all stakeholders are aware of opportunities and needs.** Discussants recommended that global health organizations should frame EID research to highlight how it is broadly beneficial for health systems strengthening and for global economic security.

2. **Identify new partners and new partnership models, especially within industry, and devise innovative ways to engage them.** This especially includes the need seek out new funders from the private sector. Innovative financing mechanisms, such as advance market commitments or a new form of an insurance fund, should be employed.

3. **Better align current funders and partners to fill the gaps in the EID vaccine product development continuum.** To achieve this, participants noted that leaders — whether that is a single person or an organization — are needed to better coordinate between developers and funders, to proactively plan product development efforts, and to map out roles and responsibilities.

4. **Clearly differentiate the unique requirements of EID vaccine development and deployment from other global health needs.** This should be accompanied by a realistic view of how these unique needs affect financing efforts, and an emphasis on harnessing domestic resources to establish a robust, sustainable platform for EID vaccine funding.

Common response to a new EID is for **researchers and developers to engage in a flurry of activities until the outbreak abates**, followed by loss of urgency and lack of progress on projects that had been taken up with great energy.

Kgothatso Ntau in the storage room of Aurum Institute in Rustenberg, South Africa. Image: © IAVI

Accelerating the development of vaccines for EIDs

The challenges of EID vaccine development necessitate building R&D partnerships to better tackle the breadth of EID threats that could lead to future pandemics. The overall lack of EID vaccine availability illustrates how international EID expertise and infrastructure is not adequately being utilized. Challenges around relevant animal model development, availability of common reagents, complex regulatory pathways, and use of different platform technologies further highlight the value and strong need for partnerships across the R&D spectrum. To help determine the best partnership mechanisms to reduce risk from EID outbreaks via vaccine development (and integration of pathogen surveillance/characterization into R&D), a working group on R&D partnerships was convened to start the interdisciplinary discussion on the most pressing gaps in EID vaccine development that could be bridged through R&D partnerships. With these gaps identified, the working group was then charged with brainstorming potential opportunities within these gap areas. This meeting convened by The Rockefeller Foundation and IAVI is the starting point for these discussions, and the working group was charged with continued collaboration in these areas. Follow-up workshops are planned to generate more detailed solutions to the gaps identified across the EID vaccine R&D continuum.

The R&D-focused working group discussion started with lessons learned from R&D partnerships in accelerated EID R&D and included key areas of improvement to consider from Ebola virus vaccine trials in West Africa in 2014-2016[1], the areas of public-private collaboration initiated by COVAX[2], and examples of partnerships in R&D critical for COVID-19 vaccine realization[3]. The group also solicited expert commentary from leaders in the vaccine R&D field to prime the discussion on gaps and solutions. The group was asked to consider three question categories for discussion. These included:

- What examples can we point to of unique R&D partnerships created in response to COVID-19 or other EIDs in the recent past? What has worked? What hasn't worked?

- Based on these examples and collective experience, what are key gaps in realizing EID vaccine delivery that can be addressed by R&D partnerships?

- How do we address the highest priority gaps through partnership? Are there existing models that can be applied to the priority gaps or are novel approaches needed?

After summarizing the current state of R&D partnerships and learnings from the COVID-19 pandemic, working group members then identified gaps and

prioritized them through a brainstorming and scoring exercise. The top four gaps that emerged were:

1. Trust – broadly defined here and applicable to trust amongst R&D partners, trust in R&D by local populations affected by EIDs, and trust among institutions performing research and funding vaccine development.

2. Resource and sample sharing – norms needed for sharing resources (reagents, data, lab bandwidth, etc.) and samples in areas of EID prevalence and sharing to enhance work done locally.

3. Early financing access – rapid acceleration of vaccine candidates or research done on diseases that have yet to "emerge" requires early access to financing, especially as much of the EID R&D community lacks substantial flexible funding.

4. Sustainable "peacetime" partnerships – teaming and partnerships are always more effective in crises when regular working relationships are given time to grow and mature. Mechanisms are needed to sustain partnerships built in times of crisis and create new ones critical for preparedness ahead of the next outbreak.

Other gaps identified include weak links between disease surveillance and countermeasures development (COVID-19 variants as a good example), unclear trigger points for the release of emergency EID resources, how many cases at what case fatality rate constitute an "outbreak of concern," need for better coordination for field trials, and the need to clearly prioritize diseases of relevance to funding agencies and outbreak preparedness groups.

In addition to gap identification and prioritization, working group members discussed solution-finding. For example, many fruitful partnerships were forged during the COVID-19 pandemic. The global community is benefitting from the collaborations that produced existing COVID-19 vaccines and therapeutics, which are now advancing to develop transmission-blocking next-generation COVID-19 vaccines. The group stressed the importance of finding ways to sustain these partnerships beyond the emergency of COVID-19 R&D. This can be done through continued coronavirus R&D (such as pan-CoV approaches) and identifying targets for R&D with similar attributes that are poised for future emergence. COVID-19 also highlighted the need for partnerships targeted at developing equitable and accessible vaccines. The inequities in access to medical products for emerging infectious diseases will remain a problem beyond COVID-19. Any sustained R&D partnership efforts must maintain a focus on equity and accessibility.

R&D does not happen in a vacuum and convening groups of subject matter experts representing the diversity of global vaccine R&D is critical to creative problem solving. Working group members identified the need to continue our collective discussions targeted toward solutions as a critical next step. The largest gap — centered on trust — was discussed at length. The working group's primary suggestion was to engage R&D communities in trust-building exercises as these communities emerge from the COVID-19 pandemic. In addition, the group noted the need to better understand trust gaps that exist in LMICs and communities disproportionally affected by EIDs and COVID-19. Group members expressed their desire for additional fora to discuss these issues in their subject matter expertise bubble. Continuing the dialogue between these stakeholders must be a future action of the EID community and needs to span R&D, policy, access, and funding.

R&D does not happen in a vacuum, and convening groups of subject matter experts representing the **diversity of global vaccine R&D is critical to creative problem solving**. Working group members identified the need to continue our collective discussions targeted towards solutions as a critical next step. The largest gap — centered on trust — was discussed at length.

[1]Gupta et al. 2018. Unprecedented pace and partnerships: the story of and lessons learned from one Ebola vaccine program. Expert Review of Vaccines. 17(10): 913-923. doi.org/10.1080/14760584.2018.1527692

[2]Savoy and Mendez Leal. 2021. Beyond COVAX: The Importance of Public-Private Partnerships for Covid-19 Vaccine Delivery to Developing Countries. CSIS Report. csis.org/analysis/beyond-covax-importance-public-private-partnerships-covid-19-vaccine-delivery-developing

[3]Druedahl et al. 2021. Collaboration in times of crisis: A study on COVID-19 vaccine R&D partnerships. Vaccine. 39(42): 6291–6295. doi.org/10.1016%2Fj.vaccine.2021.08.101

Devi Pandian, training officer at YRGCARE speaking informally to women in the community to create awareness about AIDS in Kotturpuram, Chennai, India. Image: © IAVI

Ensuring prompt and equitable access from day zero through "the last mile"

With a growing pipeline of public sector supported vaccines to address EIDs, the need to define sustainable and equitable models for vaccine manufacturing, financing, procurement, and deployment is an urgent priority. Alongside adequate and equitable supply, products must be suitable for deployment across settings and backed by robust supply chains, delivery channels, and community demand. This session aimed to determine mechanisms and strategies to facilitate access to EID vaccines, so they reach and are used by communities most at risk.

Inequities in COVID-19 vaccine access have highlighted for resource-limited countries the perils of over-reliance on externally subsidized responses and catalyzed novel models of equitable global access. Existing business models prioritize the development of vaccines with significant market in high-income settings. Even when vaccines have dual-market relevance, they are distributed or deployed inequitably.

Participants agreed that a paradigm shift is needed to ensure both innovation in and supply of EID vaccines and should include the following factors:

1. Sustainable business model
2. National and regional leadership
3. Clear and binding access commitments
4. Enabling ecosystem

Sustainable business model

Sustainability strategies must balance the supply and demand of priority EID vaccines, both for outbreaks and routine delivery. This will require a portfolio inclusive of diverse vaccine platforms fit for both needs. Balancing these complexities will be challenging given the significant capital investment needed to initiate vaccine production and the reality that managing production of biologics "is not like managing a bakery, in which supply can readily be swapped."

The business model for EID vaccines will differ based on epidemiology but could include a range of models responsive to emerging needs. For vaccines for which there is limited commercial market, stockpiles will be needed to ensure on-hand supply. Additionally, for some products, a "freezer" model can be

explored whereby products are advanced until Phase IIb/III and then put "on ice," so they can be reanimated rapidly if and when needed. Establishment of regionally driven pooled procurement mechanisms, modeled after the Pan American Health Organization approach, could consolidate demand and buying power for regional supply. Increased manufacturing capacity is a priority for Africa, which currently relies primarily on imported technologies and has faced vaccine supply insecurity. However, fill-finish is not a solution to supply insecurity if all raw materials need to be imported or if regional manufacturers lack access to IP. Further analyses are needed to define upfront capex investment requirements; establish sourcing and supply chain for production materials; and to determine a sustainable pricing, financing, and portfolio strategy.

National and regional leadership

As one participant noted, "countries do not want to be served," but rather, they want to have their own platforms, capacity, and infrastructure to ensure a coordinated and sustainable response to priority EID needs. But few countries have the buying power to sustain vaccine markets on their own. Regional supply and procurement models will help foster sustainability. The shift from globally driven models to fully operational, regional supply models will require political leadership, careful planning, and capacity strengthening investments.

Regional hubs will need to build local R&D capacity. Investment in research infrastructure, universities, academics, and career paths to retain talent domestically are critical. Global partners must support this investment by facilitating knowledge and technology transfer, including training in areas relevant to vaccine development, such as lipid formulations, nanoparticle production, biomanufacturing, and regulatory strengthening. The Partnership for African Vaccine Manufacturing, the mRNA hub in South Africa, the USAID-supported ADVANCE program, and the biomanufacturing hub in South Korea reflect strong examples of initiatives fostering regional autonomy.

Participants agreed that intra-regional issues and hierarchies will continue to create power imbalances. Multilateral, global mechanisms will still play a critical role; however, trust must be rebuilt post-pandemic.

Clear and binding access commitments

Participants agreed that those who finance vaccine research, development, and procurement — including donors, development banks, pooled procurers, and government purchasers — must use their buying power, platforms, and resources to incentivize and reward novel access-oriented business models and insist on affordability and equity provisions for new vaccines.

Participants felt that as a community, we need to clearly define "access" and create binding access criteria that are enforced early on and throughout product development. Novel business models and strategies will be required to overcome structural barriers along the product development continuum in four areas: availability, accessibility, affordability, and acceptability.

Access requirements for donors include:

- Funding the right incentives and absorbing risk to enable alternative business models for EID vaccines. Committing resources toward subsidizing novel approaches and helping new access-focused initiatives weather rough patches and high start-up costs.

- Supporting information-sharing, data transparency, and tech transfer — including with technology hubs and PDPs, who can help broker access for other geographies.

- Committing some portion of products to a regional stockpile.

- Tiered pricing models.

Enabling ecosystem

Several factors will support regional sustainability and preparedness:

- Strong and resilient regional health systems that support immunization across age strata to enable countries to pivot to meet emerging EID needs.

- Investments in and diversification of regional vaccine production across different vaccine platforms.

- Political will, ownership, and accountability at the national and regional levels, including legislative frameworks to enshrine access principles.

- Creation of alternative incentives toward timely licensure in LMICs.

- More systematic market-shaping measures that realign incentives with public health ends.

- Capital flows that catalyze investment in alternative, access-friendly EID vaccine research, development, manufacturing, and scale up, particularly for diseases that lack a dual market.

Finally, funders can and should support novel, access-oriented business models, including regionally. With high initial capital expenses and the need to build up demand volumes, African regional industry is likely to struggle with high expenses and low revenue that will make it difficult to compete with the low costs for vaccines afforded by India and China. As we advance novel approaches, funders can also be instrumental in helping to mitigate unintended consequences, including the potential for brain drain, high initial launch prices, and initial demand fragmentation.

As a community, we need to **clearly define "access" and create binding access criteria** that are enforced early on and throughout product development.

Nurse Failuzi Kijje taking Fausta Nakaketo's blood pressure readings in Entebbe, Uganda. Image: © IAVI

Creating a sustainable financing ecosystem to advance EID vaccine development and deployment

High-level global health leaders representing funders, implementors, multilaterals, research, and advocacy organizations convened to discuss the financing picture for EID vaccine development and deployment as well as how the current R&D partnership models should adapt in a post-COVID-19 world. One clear area of consensus is the field does not need another vertical funding initiative — new institutions will likely only lead to donor fatigue and dilution of advocacy messages. The current set of partners in the space is strong; however, major gaps in the end-to-end continuum exists. Some of these must be filled with new partners (most notably increased private sector engagement), but a concerted effort to better align current players could accelerate product development.

The current funding landscape is fragmented and discontinuous, leaving critical gaps along the development continuum such as late-stage development, with no sustainable model for greater coordination between actors and funders. Participants compared the landscape to a "conductor-less orchestra" and noted that achieving true alignment will require proactive planning. It also requires a leader to take on this challenge on in a holistic way, mapping roles and responsibilities along the end-to-end continuum. More effort needs to be invested in funding coordination, not only to ensure activities are synergized and not duplicated, but also to create maximum funding flexibility, especially within U.S. government agencies with differing mandates. For example, BARDA may be working on a relevant countermeasure and USAID should be planning for funding to carry that product forward where the BARDA mission stops. Currently too much time is spent finding money around the fringes of agency responsibilities.

EID research and pandemic preparedness efforts should not follow the same funding model as other poverty-related and neglected diseases. There has been an overreliance on ODA funding and a need to change the narrative from ODA toward global health security. This is not a foreign assistance problem; it is a domestic issue and therefore financing from domestic resources (finance, health, and defense budgets) should be included.

As evidenced with COVID-19, national self-interest plays a part and the way countries bridge ODA funding.

A multi-stakeholder financing investment involving different types of donors, partner countries, and private sectors actors is needed. We need to find ways to better coordinate the public and private capital in an environment that remains reliant on the private sector for a significant amount of innovation and the funding that they bring to the table. Public sector actors and pharmaceutical companies need to convene a non-threatening constructive forum to co-create solutions that work within the constraints these companies face. Stronger effort is necessary to define what incentives and partnership models work for them. One idea is to standardize the finance process to a common system and thereby reduce high transaction costs, similar to a venture capital model. Another suggestion is to link public and private capital to deliverables such as access.

The group also suggested looking to new private sector companies who are most vulnerable to the economic instability caused by pandemics (e.g., airline and cruise line industries, parts of the vaccine industry, multi-national corporations, and large banks). Global health organizations can engage these companies by stressing that collaboration on preparedness can help prevent/mitigate global economic downturns caused by EID outbreaks.

Bringing disparate partners together requires changing the narrative. We need to define the collective asks for financing R&D that is needed so that the multiple advocacy actors involved in pandemic preparedness efforts can amplify a uniform message. There should be shared messaging around what is needed, how it is needed, where it should come from, and how success will be measured. The CEPI-led 100 Days Mission, an ambition to have safe and effective vaccines within 100 days of an epidemic or pandemic threat being identified, was a good place for dialogue; however, the conversation fizzled and the field does not have adequate funding commitments toward this moonshot. EID vaccine R&D needs a more consistent and compelling story to maintain momentum. EID research should be put in the context of how it is broadly beneficial for health system strengthening. Similar to COVID-19, these threats are global problems requiring global solutions and the involvement of multiple stakeholders.

Challenges in developing cohesive messaging were raised, mainly that there is not an agreed upon definition of "end-to-end" as well as the research aspect of R&D. EID research encompasses products targeted to both current and future threats and known and unknown diseases. Since there is not a traditional market, especially in between epidemics, an end-to-end financing mechanism does not exist. We have to distinguish between the objectives in R&D during an inter-crisis period and what we're going to do in an intra-crisis period — as well as where the financing is. An alternative is to invest in cross-cutting vaccine technologies and trusted platforms — technologies that will lift all boats and will make it cheaper and faster to make vaccines when we need them. Other potential options are to look to contingent financing before the next crisis, innovative financing mechanisms like advance market commitments or some type of an insurance fund that would allow countries to access funds on day-zero of the next pandemic — both at the local level for procurement but also to kick-start the R&D.

One afternoon was not enough time to solve the financing dilemma, but the group was able to outline a path forward:

1. Changing the conversation and ensuring compelling joint messaging so that all stakeholders are singing from the same songbook.

2. Identifying new partners/partnership models, especially within industry, and innovative ways to engage them.

3. Better alignment of current funders and partners to fill the gaps in the continuum.

4. Differentiating the unique requirements of EID vaccine development and deployment and outlining how those impact financing efforts.

Bringing disparate partners together requires changing the narrative. We need to define the collective asks for financing R&D that is needed so that the multiple advocacy actors involved in pandemic preparedness efforts can **amplify a uniform message**. There should be shared messaging around what is needed, how it is needed, where it should come from, and how success will be measured.

Summary and next steps

Equitably developed and delivered EID vaccines are an urgent global priority. At an EID vaccine summit organized by IAVI and sponsored by The Rockefeller Foundation, experts and stakeholders looked across 25 years of outbreak response and vaccine development, identifying critical gaps and opportunities in the areas of R&D, equitable access, and financing. Their reflections make clear that science and funding galvanized for COVID-19 and the 2014-16 West African Ebola outbreaks, for example, provide important starting models that warrant further refinement, particularly in risk mitigation. While an ideal model doesn't yet exist, multi-sector partnerships that harness and encourage scientific innovation, build in access considerations early and across the product development continuum, and which are backed by sustainable and flexible funding are most likely to be successful. Such a model (or models) will need to be collectively nurtured in the long term to share the significant risks currently being absorbed by product developers.

Without centralized coordination and leadership — underpinned by strong community engagement and support — our efforts will invariably fall short, and the boom/bust cycle of EID vaccine development is bound to persist with grave consequences for low- and middle-income countries. True preparedness will be achieved only when communities most affected by EIDs are included as equal stakeholders throughout the product development process, including locally led science, development, and delivery. Further discussions are critical to determine clear roles and responsibilities for the range of stakeholders currently leading in pandemic preparedness — and to determine whether additional mechanisms are required going forward.

True preparedness will be achieved only when communities most affected by EIDs are included as equal stakeholders throughout the product development process, including locally led science, development, and delivery.

Annex 1: participants

Event participants

Labeeb Abboud
Michael Anderson
Monisha Ashok
Ripley Ballou
Hamilton Bennett
Seth Berkley
Colin Brown
Courtney Carson
Cristina Cassetti
Rose Catlos
Ana Cespedes
Katerina Chapman
Tatum Chidlaw
Isaac Chikwanha
Jennifer Cohn
Beth-Ann Coller
Chris Cooper
Anne Ercolini
Olayinka Fagbayi
Jeremy Farrar
Mark Feinberg
Mike Frick
Simon Funnell
Bruce Gellin
Julie Gerberding
Janet Ginnard
Gabriela Gomez
Rajat Goyal
Rebecca Grais
Lillian Greer
Anthony Griffiths
Marion Gruber
Swati Gupta*
Shanelle Hall

Cory Hallam
Sarah Han
Mark Harrington
Jon Heinrichs
Ike James
Etleva Kadilli
Kent Kester
Andy Kilianski*
Catherine Kirtane
Hester Kuipers*
Sandra Kweder
Dagna Laufer
Christopher Lavodo
Luciana Leite
Joanne Liu
Nicole Lurie
Sharonann Lynch
Michael Makanga
Shelly Malhotra*
Apoorva Mandavilli
Monique K Mansoura
Jennifer Maple*
Hilary Marston
Alejandra Martin Lopez
Robert Matiru
Gavin Morrow
Jamie Nishi
Rosalind O'Mahony
Gustavo Palacios
Chris Parks
Mohammed Pate
Stanley Plotkin
Gabriella Quintard
Vanessa Raabe

Suzane Ramos da Silva
Julien Rashid
Helen Rees
Judit Rius Sanjuan
Eva Ros Guerrero
Sangeetha Sagar
Andrew Scholl
Lewis Schrager
Nina Schwalbe
Louis Schwartz
Doug Shaffer
Raj Shah
Mae Shieh
Susan Silbermann*
Annie Simonds
Eric Skjeveland
Sara Smyth
Maria Souza
Sarah Spronk
Jagmeet Sra
Soumya Swaminathan
Kena Swanson
Marta Tufet Bayona
Ekaterina Vert-Wong
Nuno Viegas
Keiko Watanabe
Charlie Weller
Aaron Wilson
Daniel Wolfe
Rong Xu
Karie Youngdahl
Maoli Yuan

*Denotes workgroup facilitator.

Annex 2: panel discussions and speakers

Panel discussions

Moderated by
Apoorva Mandavilli
Global Health Reporter
The New York Times

Innovative partnerships for EID vaccine R&D

Cristina Cassetti
Deputy Director
Division of Microbiology & Infectious Diseases U.S. National Institute of Allergy & Infectious Diseases

Nicole Lurie
Executive Director
Preparedness and Response
CEPI

Michael Makanga
Executive Director
EDCTP Secretariat

Hilary Marston
Chief Medical Officer
U.S. FDA

Kena Swanson
Vice President, Viral Vaccines
Pfizer

Ensuring equity in EID vaccine access and impact

Natasha Bilimoria
Deputy Assistant Administrator
Bureau of Global Health
USAID

Julie Gerberding
CEO
Foundation for the National Institutes of Health

Eva Kadilli
Director
Supply Division
UNICEF

Joanne Liu
Professor
School of Population & Global Health
McGill University

Muhammad Pate
Professor
Public Health Leadership
Harvard T.H. Chan School of Public Health

Soumya Swaminathan
Chief Scientist
World Health Organization

Speakers

Keynote, remarks, dialogues

Seth Berkley
CEO
Gavi, the Vaccine Alliance

Jeremy Farrar
Director
Wellcome

Mark Feinberg
CEO and President
IAVI

Bruce Gellin
Chief, Global Public Health Strategy
The Rockefeller Foundation

Swati Gupta
Vice President, Emerging Infectious Diseases and Epidemiology
IAVI

Rajiv Shah
President
The Rockefeller Foundation

Annex 3: program

iavi 25 years of innovation, partnerships, access

The Rockefeller Foundation

An IAVI x The Rockefeller Foundation Event

IAVI 25-Year Anniversary Summit

Delivering vaccines for emerging infectious diseases (EIDS): harnessing the power of innovative partnerships

September 16, 2022

MEETING AGENDA

Light Breakfast 8:30 AM

Welcome 9:00 AM - 9:30 AM

Speakers

- **Swati Gupta**, Vice President, Emerging Infectious Diseases and Epidemiology, IAVI
- **Mark Feinberg**, CEO and President, IAVI
- **Bruce Gellin**, Chief, Global Public Health Strategy, The Rockefeller Foundation

Keynote 9:30 AM - 10:15 AM

Speaker

- **Jeremy Farrar**, Director, Wellcome

Panel 1: Innovative Partnerships for EID Vaccine R&D

10:15 AM - 11:15 AM | Moderator: Apoorva Mandavilli, Journalist, New York Times

Panelists

- **Cristina Cassetti**, Deputy Director, Division of Microbiology and Infectious Diseases, NIAID
- **Nicole Lurie**, Executive Director, Preparedness and Response, CEPI
- **Michael Makanga**, Executive Director, The European and Developing Countries Clinical Trials Partnership (EDCTP) Secretariat
- **Hilary Marston**, Chief Medical Officer, U.S. FDA
- **Kena Swanson**, Vice President, Viral Vaccines, Pfizer

Break 11:15 AM - 11:30 AM

Panel 2: Ensuring Equity in EID Vaccine Access and Impact

11:30 AM - 12:30 PM | Moderator: Apoorva Mandavilli, Journalist, New York Times

Panelists

- **Natasha Bilimoria**, Deputy Assistant Administrator, Bureau of Global Health, USAID
- **Julie Gerberding**, CEO, Foundation for the National Institutes of Health
- **Eva Kadilli**, Director, Supply Division, UNICEF
- **Joanne Liu**, Professor, School of Population & Global Health, McGill University
- **Muhammad Pate**, Julio Frenk Professor of Public Health Leadership, Harvard T.H. Chan School of Public Health
- **Soumya Swaminathan**, Chief Scientist, World Health Organization

Lunch 12:30 PM - 1:15 PM | At Convene

Remarks & Dialogue 1:15 PM - 1:45 PM

Speakers

- **Rajiv Shah**, President, The Rockefeller Foundation
- **Mark Feinberg**, CEO and President, IAVI
- **Seth Berkley**, CEO, Gavi, the Vaccine Alliance

Workgroups 1:45 PM - 3:25 PM

1. **R&D Partnerships:** Accelerating the Development of Vaccines for EIDs
2. **Access Partnerships:** Ensuring Prompt and Equitable Access from Day 0 through "The Last Mile"
3. **Funding Partnerships:** Creating a Sustainable Financing Ecosystem to Advance EID Vaccine Development and Deployment

Break 3:25 PM - 3:40 PM

Workgroup Reports 3:40 PM - 4:20 PM

Each workgroup shares their key takeaways and next steps.

Conclusions 4:20 PM - 4:30 PM

Speakers

- **Bruce Gellin**, Chief, Global Public Health Strategy, The Rockefeller Foundation
- **Mark Feinberg**, CEO and President, IAVI

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PEPFAR
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UKaid from the British people
From the People of Japan
सत्यमेव जयते Ministry of Science & Technology Government of India
EDCTP
CEPI | New vaccines for a safer world
MINISTRY OF FOREIGN AFFAIRS OF DENMARK Danida
wellcome
SERUM INSTITUTE OF INDIA Cyrus Poonawalla Group
The Research Council of Norway

Biomedical Advanced Research and Development Authority (BARDA) | Foundation for the National Institutes of Health | National Institute of Allergy and Infectious Diseases | amfAR, The Foundation for AIDS Research | Broadway Cares/Equity Fights AIDS | Cancer Research UK | The City of New York, Economic Development Corporation | Congressionally Directed Medical Research Program (DoD) | GSK | The Hearst Foundations | Keith Haring Foundation | Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the USA and Canada)

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