



PACIFIC HEALTH SUMMIT  
SEATTLE - LONDON

*Connecting science, industry, and policy for a healthier world.*



# VACCINES:

## HARNESSING OPPORTUNITY IN THE 21ST CENTURY

A report from the Pacific Health Summit  
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Plenary I panelists



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# THRUSTING THE VACCINES FIELD SQUARELY INTO THE 21ST CENTURY

## A TURNING POINT IN SCIENTIFIC DISCOVERY: FAST-TRACKING IMMUNIZATION VICTORIES

“Vaccine science is advancing rapidly on a remarkable trajectory, providing opportunities that would have been unimaginable ten years ago,” said **Anthony Fauci**, Director, National Institute of Allergy and Infectious Diseases, U.S. National Institutes of Health. Fauci’s ‘State of the Science’ address at the 2011 Pacific Health Summit detailed the cutting-edge discoveries that have expanded today’s scientific toolkit and are primed to elevate the field of vaccinology to unprecedented heights. “Now, it is up to us to thrust this field squarely into the 21st century.”

Speaking candidly, Fauci addressed a unique gathering of strategic stakeholders—policymakers, government leaders, industry executives, renowned scientists, and global health experts—attending the seventh annual Summit

in Seattle. This potent mix of leaders from different sectors and global regions convened to discover a new understanding and appreciation of the role they each play—in collaboration with others—in the interconnected landscape at the heart of this year’s Summit theme: “Vaccines: Harnessing Opportunity in the 21st Century.”

Vaccines are widely seen as one of the most powerful, effective, and cost-effective tools in the global health arsenal, fast-tracking public health gains worldwide. Time and time again, we have witnessed vaccines’ ability to save lives and prevent debilitating disease, providing a high return on the investment they require.



*“The Summit’s most precious asset is the incredibly high concentration of people who matter.”*

**Kate Taylor**, Visiting Fellow, Nossal Institute for Global Health, University of Melbourne



Anthony Fauci



Paulo Gadelha, Sally Davies  
(left to right)

## SUMMIT BACKGROUND

The Pacific Health Summit launched in 2005 to connect science, industry, and policy for a healthier world. The annual, invitation-only Summit is widely recognized as a landmark event on the global health calendar and offers an unparalleled opportunity to engage high-level and diverse stakeholders around specific themes. Having addressed diverse topics such as maternal and newborn health, MDR-TB, malnutrition, and pandemic influenza, the Summit has a proven track record of fostering innovative partnerships and meaningful action. The Summit is co-presented by the Fred Hutchinson Cancer Research Center, Bill & Melinda Gates Foundation, Wellcome Trust, and The National Bureau of Asian Research, which serves as the Secretariat.

The last decade alone has seen tremendous strides in vaccine access. We are now at a critical tipping point, with opportunities to realize new victories in the battle against meningococcal meningitis, rotavirus, avian influenza caused by the H5N1 virus, pneumococcal disease, and cervical cancer caused by human papillomavirus (HPV), among other vaccine-preventable diseases. Meanwhile, the vaccines market—ever more dynamic with new players and promising discoveries—has flourished, growing nearly threefold since 2000. Hard-won successes, however, are tempered by ongoing challenges, and there is still much work to do. Every year, 24 million children don't have access to the vaccines they need and as a result, 2.4 million children under the age of five die annually from preventable diseases.

How can we build on ground-breaking accomplishments, such as the rollout of the MenAfriVac meningitis vaccine—which was first

introduced in December 2010 and reached 20 million people in three African countries in the first six months of 2011? How can we address key challenges such as boosting regulatory science to accelerate the pace of translating new breakthroughs into life-saving products, and how do we get them quickly to those who need them most? What other strategies will clear barriers to expanded immunization programs, as we define a vision of efficient delivery for the next generation of vaccines? How do we effectively deploy resources to provide new target groups and growing populations with more commodities and education?

This year's Summit explored each of these questions, building on a surge of momentum fostered by a series of key events and milestones: the ongoing Decade of Vaccines Collaboration, the World Health Assembly in May, and the GAVI Alliance 2011 Pledging Conference in June—which secured \$4.3 billion and a resounding vote of confidence in the power of vaccines.



*"As well all know, in order to realize the full global benefits of vaccination, it is essential to ensure that vaccines reach those in the poorest countries where the disease burden is often greatest."*

**Mark Swindell**, President, Vaccines, Pfizer Inc.





UN Photo/Eskinder Debebe

A reenergizing of the field of vaccines infused Summit discussions with optimism and confidence that much more is possible, and delegates were committed to building the networks to help make that happen. Importantly, participants acknowledged in each discussion the practical realities on the ground, speaking from diverse perspectives about the challenges that different communities face.

Tangible outcomes have already taken root. New partnerships are forming across sectors. As one example, managers of Ghana's Expanded Program on Immunization (EPI) and executives at Dimagi, an appropriate technology company, are collaborating to optimize mobile technologies for supply chains and EPI surveillance. Another development initiated prior to the Summit and continued to gain traction at the meeting. It involves a major health company, which is taking steps toward making its proprietary adjuvants—an ingredient used in vaccines to boost immune response—available to a major international vaccine research organization. This is intended to further the development of vaccines against neglected tropical diseases (NTDs) and one of many collaborations and newly forged partnerships that are gaining momentum as a result of Summit discussions. Many more examples are illustrated on the Summit website.

## STRIKING A BALANCE: OPTIMIZING A PUBLIC GOOD WITH A SUSTAINABLE BUSINESS MODEL

This year's Summit welcomed participants from 35 countries, with broad representation from the regions at the heart of the issues. Leaders ranged from Nigerian government officials and medical experts, to the Health Minister of Sindh Province, Pakistan, to a Ugandan science and health correspondent for *The East African*, to the heads of major

civil society organizations and the CEOs of multinational pharmaceutical companies. Delegations represented India's flourishing vaccine industry, China's food and drug regulatory body, Brazil's pharmaceutical manufacturers, and Cuba's state biotechnology sector, as well as many others.



*"When 1 billion people are hungry, 2 billion are poor, and 3 billion women don't have control over their lives, families, or communities worldwide, we need to think about vaccines as a tool for development, not as a vertical program where we talk about getting as many antigens to as many children as possible."*

**Benjamin Schwartz**, Senior Director for Health, CARE USA



Muhammad Pate, Sheri McCoy,  
Philip Campbell, Anuradha Gupta  
(left to right)

## ENGAGING FRONT-LINE JOURNALISTS, REACHING A BROADER AUDIENCE

Keeping with Summit tradition, this year's meeting provided a forum for frank discussions that went beyond talking points and ventured into the controversial, while consistently acknowledging the varying and nuanced priorities of different sectors and organizations. Participants challenged each other, calling for immediate action to tackle a breadth of difficult issues and to move promising ideas and initiatives toward tangible outcomes in the vaccine space:

- increase country ownership
- integrate comprehensive technology transfers
- construct a global pricing architecture
- improve trust and public confidence
- strengthen supply chain and delivery systems
- increase access to, and sharing of, adjuvants
- maximize existing product development partnerships (PDPs)

The vaccines field is rich with complexity and layered with divergent points of view. Summit delegates agreed that successful immunization efforts are the result of appropriate, effective partnerships and that all sectors must come together to manage the tension that exists between providing a public good and maintaining a sustainable business model.

“The things I learned about the pharmaceutical industry and the importance of vaccines will forever percolate in my work as a science journalist and as an individual influencing decisions about myself, my family, and my community,” said **Esther Nakkazi**, Freelance Science and Health Reporter, *The East African*.

In 2011, the Summit expanded the geographic reach of invited media participants to include the regions and countries at the core of the discussions. Five developing-country journalists, hailing from Uganda, South Africa, Kenya, and India, enriched the discussion with exceptional insights from the front-line while gaining invaluable access to key sources to inform their reporting.

The Summit sought to empower and support media delegates in their efforts to successfully communicate complex issues to a broader audience. For example, on July 1, 2011, the article “Made in China, Protected in Africa” by Mia Malan led the health section in South Africa’s *Mail & Guardian*. Drawing from participant interviews at the Summit, Malan highlighted China’s evolving role as a vaccine supplier to the developing world and the price advantages this could offer countries in Africa. Additional stories featuring key Summit speakers were published in the *Times of India* and *The East African*, and more are forthcoming.



Jean Stéphenne



Margaret Chan, Mark Walport (left to right)

# FINANCING AND PRICING A NEW FRONTIER:

## *Eliminating Barriers to Vaccine Accessibility*

“If we miss the poor, we miss the point,” said **Margaret Chan**, Director-General, World Health Organization (WHO). She urged Summit leaders to explore and address the fault lines between cutting-edge vaccine discovery and the high costs that accrue throughout the development and delivery chain.

“Our collective failure to harness the opportunity of vaccines would come at an unacceptably high price,” said **Peter Singer**, CEO, Grand Challenges Canada. “This is what is at stake over the next ten years: 6.4 million lives, \$6.2 billion in treatment costs, and \$145 billion in lost productivity.”

However, success requires resources. For that reason, innovative financing and funding mechanisms form the fulcrum of our ability to achieve a paramount public health goal: providing existing and next-generation vaccines to those who need them most.

A Summit session on financing examined today’s funding mechanisms and pricing structures to determine if they are keeping pace with a rapidly

*“If we miss the poor, we miss the point.”*

Margaret Chan, Director-General, World Health Organization

evolving and dynamic global environment. Are they effective and sustainable? Do they truly address fundamental funding challenges? **Mark Dybul**, Distinguished Visiting Scholar, O’Neill Institute for National and Global Health Law, Georgetown University, and Inaugural Global Health Fellow at the George W. Bush Institute, led the discussion, raising key points that spurred further debate throughout subsequent Summit sessions and led to a conversation about pricing that has continued beyond the June meeting.

“We absolutely have to take on the politically difficult conversations and start pushing for a global agreement on multiple tiers in pricing—no matter how complicated,” said Dybul. “We need a system that allows companies to do R&D, to understand what their market is, while allowing countries to know what the purchasing costs are going to be.”



*“The Critical Path to TB Drug Regimens collaboration, which came out of the 2009 Summit, is a model for the ways in which industry can work together with regulators and institutions to speed the development of enabling significant progress against TB.”*

Paul Stoffels, Worldwide Chairman, Pharmaceuticals, Johnson & Johnson





Peter Singer, Xiaoming Yang,  
Mark Swindell, Suresh Jadhav  
(left to right)



HRH Emir of Argungu



*“There is plenty we could do in the public sector to be a good partner to the private sector. Let’s stop saying ‘bring down the prices.’ Let’s do what the companies have said will bring down the prices. And if the private sector doesn’t step up, then we’ll have something to say.”*

**Melinda Moree**, CEO, BIO Ventures for Global Health

## AN INCLUSIVE PRICING STRUCTURE: HIDDEN IN PLAIN SIGHT?

“We need to ask ourselves: are we using the right business model?” asked Margaret Chan. “Can we deconstruct and reconstruct it and look for new cost opportunities?”

Tiered pricing was a deliberate discussion thread woven throughout the Summit. Participants overwhelmingly agreed that the widely used two-tiered pricing system, providing low-cost vaccines to low-income countries only, was inflexible and outdated. Instead, multiple tiers are required to offer prices that are commensurate with the breadth of middle-income country budgets.

Yet, while multiple tiers can provide prices that are more appropriate for middle-income country budgets, we should be wary of turning the push to drive prices down into a race to the bottom, cautioned **Olivier Charmeil**, President and CEO, sanofi pasteur. “A healthy vaccine industry is required for vaccination ... As a multi-sector network, we must reach a consensus to create effective multi-tiered pricing that is also sustainable.”

**Seth Berkley**, CEO of GAVI (then President & CEO, IAVI) suggested that tiered pricing, implemented correctly and with the support of wealthy countries, offers all parties a win-win solution. “The important point is to maximize tiering. If we can get to those models, we’ll do exactly what we want to do, which is to get the maximum number of people vaccinated at the best price and make it as profitable as possible for the company.”

## CALLS FOR COLLABORATION: IMMEDIATE ENGAGEMENT ACROSS SECTORS, REGIONS, AND ISSUES

Summit “Calls for Collaboration” provide key stakeholders with immediate entry points to join existing efforts, going beyond financial donations. Each year, the Summit Secretariat uses this format to invite participants to submit proposals for cross-sector collaboration.

This year’s Summit highlighted four Calls, two of which pertained to vaccine supply and cold chain issues. Through the Immunization Innovation Fund, Project Optimize is seeking partnership proposals for innovative solutions to address six critical areas of vaccine delivery in low and middle-income countries. Home of the Global Good program and an innovative passive cold chain device, Intellectual Ventures sought country partners for testing and feedback on the device’s contribution in realtime to vaccine delivery.

One Call spearheaded by the International Pediatric Association, American Academy of Pediatrics, and London School of Hygiene & Tropical Medicine sought partners to grow public engagement in promoting immunization. Meanwhile, Swedish Medical Center and the Pacific Northwest Diabetes Research Institute appealed for support in using mobile information systems to address type 2 diabetes, specifically in underserved populations.



William Hook, Leo Reuben,  
Guy Wollaert (left to right)

Kewen Jin

A coherent tiered pricing solution is essential, added **Yu Wang**, Director, Chinese Center for Disease Control and Prevention. “But we must push industry to produce new technology for a public health good at a suitable price.”

In the tiered pricing debate, participants also raised the point that there are several approaches to consider—such as the six-level model used by The World Bank—and that there is a need to differentiate between tandem government-based markets and private markets.

Preventing infectious disease also provides an economic development advantage that must be recognized and factored into pricing discussions, stated **Jean Stéphenne**, Chairman & President, GlaxoSmithKline Biologicals. He suggested a collaborative risk-sharing strategy—incorporating the public health system, public purchase of vaccines, and also private systems—to forge a tiered pricing system where middle-income countries agree to pay their share. “I see this as a key concept if we want to achieve sustainability of the vaccine industry and innovation.”

To get the prices they seek, **Andrew Jack**, Health and Pharmaceuticals Correspondent, *Financial Times*, suggested countries look to each other for mutually beneficial support. “Perhaps we should go beyond the national level and look at options such as pooled procurement; we might consider more middle-income countries collectively negotiating with some of the vaccine companies.”

Currently, only low-income countries have access to lower prices through GAVI, a vaccine pricing approach that does not address the needs of middle-income countries. Recognizing that a coherent vaccine pricing approach is required for both low and middle income-countries, two Summit participants are now collaborating on a multi-tiered pricing strategy, and many others remain profoundly engaged in an ongoing dialogue.

## THE DCVMN: DRIVING A HISTORIC SHIFT

The Developing Country Vaccine Manufacturers Network (DCVMN) is an alliance that aims to make a consistent supply of quality vaccines that are accessible to developing countries.

A robust delegation of DCVMN members attended the Summit, representing twelve companies and countries, including Brazil, China, Cuba, India, Indonesia, Mexico, South Africa, and Thailand. Members joined discussions with leaders of major multinational pharmaceutical companies such as GSK, Merck & Company Inc., Pfizer Inc., Sanofi, and Johnson & Johnson. More importantly, the Summit was an opportunity for each to articulate how their own R&D efforts and disease priorities figure into the vaccine establishment more broadly.

“We face a balancing act,” acknowledged **Mahima Datla**, Senior Vice President, Biological E Ltd. “By participating at the Summit, we were able to engage in critical international discussions on making lifesaving vaccines available at affordable prices for the developing world.”



*“I think GAVI should seriously consider not giving us the money, not procuring the vaccines, but helping [middle-income countries] negotiate the price down.”*

**Najwa Khuri-Bulos**, Professor,

Pediatrics and Infectious Disease & Dean of Research, Jordan University

Andrew Jack, Mark Dybul,  
Helen Evans (left to right)



*“Preventing disease is so economically important that the rhetoric should not be about the cost of a vaccine, but the cost of not having a vaccine.”*

**Lawrence Corey**, President & Director, Fred Hutchinson Cancer Research Center

## MORE “SKIN IN THE GAME”: TRANSPARENCY, EFFICIENCY, AND ACCOUNTABILITY

What if the field were to make a drastic departure from established vaccine pricing structures toward a global pricing architecture *and* reconfigure existing international finance mechanisms? What would the results look like, and what might we stand to gain?

The answer: a possible paradigm shift, prompting countries toward greater ownership, thus putting more “skin in the game,” suggested **Armin Fidler**, Lead Advisor, Health Policy and Strategy, Human Development Network, The World Bank Group.

As an example, he explained that international financing as a proportion of total national health expenditures, even in very poor countries such as Malawi and Rwanda, is astonishingly low. “Therefore, perhaps we might consider alternatives. Would GAVI and international financing be better used as a catalyst, to introduce new vaccines, to take the risk, to provide the training, capacity building, and initial investment?”

This takes us in new directions, asserted Fidler: “There is a new frontier beyond funding commodities; now countries are asking how they can bolster their capacity analysis and how to implement international best practices.” An exemplary strategic partnership that

highlights innovative financing coupled with broad cooperation was forged in August 2011, between the government of Pakistan, Japan International Cooperation Agency (JICA), and the Bill & Melinda Gates Foundation. Banding together, these three entities will step up the effort to eradicate polio.

Whichever financing and funding model proves to be correct, Summit participants returned to the trifecta of transparency, efficiency, and accountability throughout their discussions. These would multiply the resources we have today and reinforce opportunities for the future. They also agreed that innovative financing is essential to addressing underfunded R&D issues in the vaccine space, such as NTDs. Summit participants brought an innovative concept to the table: to form a product development partnership to develop and deliver vaccines against NTDs

Value for the money is a top donor priority, **Helen Evans**, Deputy CEO, GAVI (then Interim CEO, GAVI), reminded her peers. “One of the reasons why GAVI was able to attract high-level political support was because of results and transparency. Over the last six months or so, in negotiations with UNICEF, our procurement agent, we’re now making agreed prices available, which I think is a big step forward.”



# THE TRUST CHAIN

Margaret Chan, Yu Wang,  
Seth Berkley (left to right)

## STREAMLINING COMMUNICATION, PROTECTING COMMUNITIES

“There has not been a single death from measles in Ghana since 2003,” **K.O. Antwi-Agyei**, National Program Manager, Expanded Program on Immunization, Ministry of Health, Ghana, said on the final day of the 2011 Summit. By contrast, that same day, the U.S. Centers for Disease Control and Prevention (CDC) issued a sobering health advisory: the United States is backsliding on a tremendous public health achievement. Though measles was declared eliminated in the United States in 2000, this year, 156 cases were reported—the highest number since 1996.

The resurgence of a deadly but preventable disease in the United States is a poignant reminder that public trust can be quickly shaken, and gaining it back is a painstaking and complex process. Trust in vaccines is a truly global issue, not limited to any country or region. If maintaining public confidence is essential to furthering public health, how do we safeguard against misperceptions and misinformation and constructively address concerns?

Listen, engage, and understand, advised **Heidi Larson**, Senior Lecturer, Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine. “We can’t assume the reasons for distrust,” she said. As an example, she pointed to a case in Uttar Pradesh, India. Health workers presumed vaccine refusal in one area to be based on a fear of sterilization. In fact, mothers objected

to men vaccinating their children and preferred women from within the community who spoke their language.

In an era of where information moves instantaneously, misinformation can spread globally within seconds. Knowing your audience and tailoring the message to specifically address their concerns is as crucial as carefully selecting the messenger, offered **Sheri McCoy**, Vice Chairman, Executive Committee, Johnson & Johnson.

“It’s not a one-size fits all approach,” McCoy acknowledged. She highlighted a social networking maternal health project that identified HIV-infected mothers in Africa as having the greatest influence on other mothers. “Successfully communicating to these mothers requires us to reverse-engineer the process to make sure we are getting the information out.”

In Nigeria, one of the world’s four remaining polio-endemic countries, resistance to vaccination in the northern region has led to some of the lowest coverage rates for routine immunizations in the world. Reversing this trend requires a government that is accountable and proactively building trust-based relationships with traditional institutions, explained **Muhammad Pate**, Chief Executive, National Primary Health Care Development



*“The crucial importance of there being active communication between scientists and journalists was crystallized for me here.”*

**Seth Mnookin**, Journalist and Author, *The Panic Virus*

## ON-THE-GROUND PARTNERS: ENGAGING EPI MANAGERS

Individuals leading immunization efforts “on the ground” are an invaluable resource with important perspectives that can benefit the entire vaccines community. The Summit hosted several country managers of the WHO’s Expanded Program on Immunization (EPI) and other representatives operating on the front lines of health delivery service.

Delegates representing ten countries, largely from sub-Saharan Africa, South Asia, and Southeast Asia, exchanged ideas and networked among top-level policymakers, government leaders, and entrepreneurs.

“We often forget about human resources, the main role of EPI managers, and their knowledge of all aspects of vaccination,” said **Silvia Bino**, Head, Control of Infectious Diseases, Institute of Public Health, Albania. “Participating in the Summit helped us identify similarities with other successful programs, learn from their errors, and enrich immunization programs.”

*“We don’t need science and technology only; we need the social science of effective communication.”*

Muhammad Pate, Chief Executive, National Primary Health Care Development Agency, Nigeria

Agency, Nigeria. “We need to respond to the legitimate concerns of the lack of essential services that are fueling distrust in populations,” he said. Nigeria’s essential capacity-building needs, he added, must be viewed through the lens of soft infrastructure. “We don’t need science and technology only; we need the social science of effective communication.” In every patient conversation, and in messaging on vaccines more broadly,

doctors and nurses must be clear and consistent, said **Sally Davies**, Chief Medical Officer & Chief Scientific Advisor, UK Department of Health. “Our front-line nurses are very important. We must take the front-line with us; we must take our communities with us.”

Yet successful efforts to build trust differ greatly between the developed and developing world, commented **Anuradha Gupta**, Joint Secretary, Reproductive and Child Health, Ministry of Health and Family Welfare, India. “In India, 70% of the population is living in villages, and exposure to media is limited. Therefore the critical question is: who builds that trust?” In the Indian context, the auxiliary nurse midwife is the only messenger, Gupta continued, “Therefore, her skill set is so very critical.”



*“I’m asking people who have had a long history in the industry, and have seen it change, to offer constructive suggestions for how we can maintain safety and public trust in immunization but, at the same time, do away with unnecessary regulation that complicates the process, increases costs, and . . . holds back innovation.”*

**Orin Levine**, Associate Professor, Johns Hopkins University and Executive Director, International Vaccine Access Center




Jacqueline Koch



Sagheer Ahmed



UN Photo/Marie Frechon



Zulfiqar Bhutta



Peter Hotez

## INCREASING PUBLIC CONFIDENCE IN VACCINES: UNDERSTANDING THE CORE DRIVERS OF DECISIONMAKING

The 2011 Summit furthered another model for building trust, an initiative catalyzed by a first-time meeting between Heidi Larson and **Michael Watson**, Vice President, Global Immunization Policy, sanofi pasteur, at the 2010 Summit. Joining forces, they have begun to formalize a center for public decisionmaking around immunization. The center, to be housed at the London School of Hygiene & Tropical Medicine, will deploy a multi-disciplinary network of researchers to develop and pursue a collaborative research agenda to better understand and tackle issues around public confidence in, and acceptance of, vaccines, with the goal of improving public health.

Larson and Watson held a targeted session at the 2011 Summit to gather feedback from a diverse array of stakeholders. Synergies emerged between similar but less developed aspirations in other institutions, as did significant interest from the global media, and a clear enthusiasm and desire for a center of this kind.

## THE MESSENGER IS THE ALLY

Amid this discussion, a number of leaders in the room noted that an important potential ally was often overlooked: the media.

“The role of the media is to put pressure on government to get its distribution systems into place, to make sure the resources are there, to enact the right policies,” said **Mia Malan**, Lecturer & Project Manager, Rhodes University, and Health Journalist, *Mail & Guardian*, South Africa. To diffuse potential controversies, she urged government health officials and scientists “to come down to the community” and provide journalists with accurate, relevant, and timely information. “As a journalist, I cannot report on an issue like vaccines without the help of a scientist, but it’s crucial that scientists themselves understand how the media operates, how we work.”

*“As a journalist, I cannot report on an issue like vaccines without the help of a scientist, but it’s crucial that scientists themselves understand how the media operates, how we work.”*

**Mia Malan**, Lecturer & Project Manager, Rhodes University and Health Journalist, *Mail & Guardian*, South Africa

“If we want to build reservoirs of trust, we need to invest time and effort to nurture understanding. This includes bringing journalists together for long-range briefings about technology and other topics so they are primed in these areas, which could turn hot at any moment,” said **Philip Campbell**, Editor-in-Chief, *Nature*. He added that science media centers such as those in the United Kingdom, New Zealand, and several other countries offer a model to



*“Sometimes the qualifications of scientists, experts, doctors, or professors has little to do with their preparedness to give opinions, and that is not always perceived by the journalists who are seeking opinions. So we have to be much clearer when communicating what the issues are, and know who the right experts are who should be advising.”*

**David Salisbury**, Director of Immunization, UK Department of Health





Leo Reuben, Guy Wollaert, K.V. Balasubramaniam, Prashant Yadav (left to right)



Linear Productions

# THE INNOVATIVE PARTNERSHIP:

## *Thinking Big, with an End in Mind*

build on. “There is a need for continuous monitoring of information by everyone involved in immunization. To prevent a breach of trust, it is a job that really involves all of us,” stated **Dorothy Esangbedo**, President, Pediatric Association of Nigeria.

### THE PROMISE OF GLOBAL SYMMETRY

“We must avoid the unacceptable risk of allowing innovation to foster inequalities,” declared **Carlos Gadelha**, Secretary of Science, Technology, and Strategic Inputs, Ministry of Health, Brazil. To ensure equity across income strata, he urged his peers to engage in innovative partnerships, buttressed by significant investment, and—most importantly—to think big. Through large-scale initiatives, he continued, “We can induce ‘global symmetry’ to address global health needs.” He reminded Summit participants that vaccines are a key strategic product that allowed Brazil to address health, poverty, and development, while delivering tremendous economic opportunities.

Thinking big means thinking broadly across sectors and specialties and casting a broad net into the private sector—a core Summit goal. Vaccine development and production are largely channeled through public-private partnerships. With that in mind, business leaders attending the Summit represented a full spectrum of commercial products and services: The Coca-Cola Company, GE Healthcare, and UPS, among others. Together with heads of leading multinational pharmaceutical companies and global vaccine manufacturers, business executives explored how they might contribute in unexpected and multidimensional ways to quicken the pace of immunization efforts worldwide.

“Partnership innovation has to be key,” stated **Julie Gerberding**, President, Merck Vaccines, Merck & Company Inc. “As we all experiment and learn to do this better, it creates an environment of immunization that’s greater than the sum of its parts.”



*“None of these individual organizations are working on their own; it’s about collective commitments to partnership. And it’s no longer a question of donors versus recipients, but of development partners.”*

**Mark Walport**, Director, Wellcome Trust



Igor Calvet, Artur Couto, Carlos Gadelha, Paulo Gadelha (left to right)

**Guy Wollaert**, Senior Vice President & Chief Technical Officer, The Coca-Cola Company, described a multi-partner project focusing on a broad range of medical products that identified potentially far-reaching opportunities for vaccines. “Seek partnerships based on complimentary capability,” he suggested, “and test practical and appropriate ways for these partnerships to be established.”

As a result of these discussions, a multinational health company is currently in discussions with a key vaccine research organization and other partners to organize a coalition of private development partnerships around vaccines.

## VACCINES: A LEGACY OF SUMMIT RESULTS

Vaccines have figured prominently in past Summits, fostering a legacy of disease prevention. The 2007 Summit helped bring together key individuals from the Wellcome Trust and Merck & Company Inc., who harnessed complimentary organizational interests to form a groundbreaking collaboration in India: the MSD Wellcome Trust Hilleman Laboratories. The \$145 million research institute is developing vaccines to address unmet medical needs and neglected diseases in developing countries, while optimizing current vaccines for resource-limited settings.

Discussions at the 2009 Summit led to a partnership between Merck & Company Inc. and Qiagen, a molecular diagnostics company. Bringing together new HPV vaccine and DNA testing technologies—developed in isolation—enabled the two companies to expand into the world’s poorest countries, which are also facing the greatest impact from the disease.

That same year, Sanofi announced its donation of 100 million doses of influenza vaccine. This built on Margaret Chan’s 2007 Summit announcement—the WHO’s creation of a global vaccine stockpile for the H5N1 avian flu virus—which prompted a 50-million-dose seed contribution from GlaxoSmithKline.



Jacqueline Koch



Michael Watson

## RESULTS MATTER: DEMONSTRATE THE RETURN

Though companies are nimble and able to react quickly, they need guidance on where to invest and where to require results, said **James Allen**, Asia-Pacific Medical Director, Chevron Corporation. “We could benefit from better information that demonstrates the concrete return on investment in specific immunization initiatives. In the business mindset, if we can’t demonstrate that return, then our managers are going to look elsewhere.”

*“In the business mindset, if we can’t demonstrate that return, then our managers are going to look elsewhere.”*

James Allen, Asia-Pacific Medical Director, Chevron Corporation

Smart integration can help us achieve the greatest impact for every dollar invested, stated **Amie Batson**, Deputy Assistant Administrator, Global Health, U.S. Agency for International Development. “How can we strengthen overarching systems so that we are reaching a child or family with multiple interventions at once?” she asked. “Immunization, together with family planning, antenatal care, and nutrition counseling as a package, is proving to be much more efficient in terms of how you deliver services.”



*“We should consider multi-party associations for joint development of new vaccines. An example could be a joint venture between local producers in Brazil, Cuba, and Mexico to manufacture a vaccine for endemic disease or an affordable jumbo vaccine with components coming from each party.”*

**Samuel Ponce de Leon**, Director-General, Biologics and Reagents Laboratories of Mexico (BIRMEX)



# WHAT GETS MEASURED GETS DONE:

## *Immunizing Against Inefficiency*



UN Photo/Eskinder Debebe



Nabeela Ali



Michael Birt, Nigel Darby  
(left to right)

### REACHING FIVE OUT OF FIVE: SLOGANS VS. ON-THE-GROUND COMPLEXITIES

Eighty percent of the world's children have access to vaccines, which means one in five is currently beyond the reach of vaccination efforts. While imagining every fifth child as needing a vaccine is helpful in immunization advocacy efforts, it risks oversimplifying the reality of the vaccine delivery challenge, especially in low and middle-income countries. There is tremendous heterogeneity in local healthcare systems and this variation must inform national and community strategies for achieving the universal coverage that will bring the benefits of vaccines to all children, as **Christopher Elias**, President & CEO, PATH, pointed out.

“It is important to recognize that half of the world's vaccine-preventable diseases occur in five countries, with very large, complex, heterogeneous societies, he said. “We see tremendous variation in terms of coverage of vaccinations, from over 80% to less than

10% in some different parts of those same countries.” “Every third unimmunized child in the world is from India,” exclaimed **Bachi Karkaria**, Consulting Editor, *Times of India*. Forty-four percent of Indian children remain unimmunized by the age of five, which she suggested reveals skewed priorities and a lack of political will, when juxtaposed against a soaring 8% economic growth rate. “We need to ‘immunize’ our health system against inefficiency, against inadequacy, against inequity, and, most importantly, against corruption.”

Complex challenges require complex solutions. Like India, Pakistan is a polio-endemic country with considerable immunization gaps. Facing a breakdown in political leadership at the national level, **Sagheer Ahmed**, Minister of Health, Government of Sindh, Pakistan, saw the door of opportunity open unexpectedly at the provincial level. “Government



*“It’s important we strive for better metrics for immunization coverage, but we must also track the disease and the impact of these vaccines; some don’t work as well or last as long as we thought they would. Some vaccines actually work much better.”*

**Anne Schuchat**, Director, National center for Immunization and Respiratory Diseases, U.S. Centers for Disease Control and Prevention



Bachi Karkaria



Julie Gerberding  
and Plenary I panelists

*“Now we can address important core issues that have been neglected, such as immunization and vaccines, with far greater efficiency and transparency.”*

Sagheer Ahmed, Minister of Health, Government of Sindh, Pakistan

failure has led to a devolution of power, putting social and health portfolios into the hands of the provinces. Now we can address important core issues that have been neglected, such as immunization and vaccines, with far greater efficiency and transparency.”

Nabeela Ali, Chief of Party, John Snow Inc., suggested that Pakistan, like other developing countries with poorly functioning health systems, must consider priorities carefully. “When we talk of commodities, security, and vaccines availability, where we are not

## INTEGRATING IMMUNIZATION: A HOLISTIC APPROACH TO HEALTH SYSTEMS

Universal health coverage (UHC) grants a population wider access to a guaranteed set of health services while providing financial protection against catastrophic health expenditures. As the push for expanded immunization converges with the drive for health system strengthening, the Summit examined the possible synergies through the lens of UHC.

A focused session had significant representation from member countries of the Joint Learning Network, an alliance of low and middle-income countries that are implementing health financing reforms. Drawing from their diverse experiences and expertise, the workshop speakers agreed to continue the dialogue beyond the Summit to create lasting and meaningful results for the UHC movement.

“We need to look at the vaccine beyond immunology,” stated **Yot Teerawattananon**, Leader & Founder, Health Intervention and Technology Assessment Program, Ministry of Health, Thailand. “We need to link it to health for mothers and children, so they will go to their health professionals and access other effective health interventions.”



*“Rotavirus vaccines have been fabulous in the United States and middle-income countries, but they’ve only been partially or half effective in low-income countries. How do we continue the research efforts to make these more effective or to improve strategies, rather than sit on the laurels of what already exists?”*

Roger Glass, Director, Fogarty International Center, U.S. National Institutes of Health



Xiaoming Yang



Silvia Bino



Qi Shen



*“The value of vaccines is not often accounted for or communicated effectively. . . the responsibility to change the perception of value doesn’t rest with industry alone . . . [A]ffordability is a very subjective discussion.”*

**Mahima Datla**, Senior Vice President, Biological E Ltd.

even able to reach and provide services to 50% of the population, we need to look at the health system and learn to stand on our feet rather than start running after new vaccines. A functional health system is essential for the success of routine as well as introduction of new vaccines.”

## UNEXPECTED SOLUTIONS AT ACCESSIBLE PRICES

Producing a safe and effective vaccine, on average, requires 12–15 years of research and costs between \$500 million and \$1 billion. The global investment in HIV vaccine research alone, including industry and research agencies in industrialized countries, has been estimated at approximately \$500 million per year.

Behind-the-scenes technology is increasingly important for vaccine delivery, and this has put a broader range of industry players at the forefront of the vaccine space, said **Nigel Darby**, Vice President, BioTechnologies & Chief Technology Officer, Life Sciences, GE Healthcare. “The main question we hear [from partners in the developing world and emerging economies] is, ‘Can you produce technologies that allow us to manufacture vaccines more cheaply, do it with infrastructure that is less sophisticated, and create an environment where we can become more self-sufficient in vaccines?’”

But while we need new technologies and innovation, we also need to make the most of the tools we have at our disposal now. This might require constructing a

warehouse to store vaccines, getting appropriately powered refrigerators to the right settings, or simply collecting and harnessing key data.

“I believe that what gets measured gets done,” announced Margaret Chan, suggesting that we go back to the basics, such as a robust health information system, to ensure we can take greater strides forward.

Data collected in a 2004 PATH study in conjunction with the Indonesian Ministry of Health, Biofarma, and other key government agencies, prompted a complete overhaul of vaccine delivery in the tropical archipelago of Indonesia, explained **Leo Ruben**, Managing Director, PT MediBest Group. The study found that 75% of Indonesian government-purchased vaccines—\$80 million worth—had frozen and were lost. “It was a great surprise; everyone had assumed that our challenge was heat exposure. Now, freezing is extremely rare.”

What if we applied consumer products to the medical field using technology that costs \$149, asked **Craig Mundie**, Chief Research & Strategy Officer, Microsoft Corporation. While it might not find a vaccine for HIV, it could help address the shortage of 1.8 million doctors worldwide, improving data management and expediting diagnostics and effective treatment. “There are unexpected solutions to global health challenges, and I’m a big advocate of bringing the world’s engineers to bear on the problems of medicine.”





Louis Cooper, Ciro de Quadros,  
Najwa Khuri-Bulos, Roger Glass (left to right)

# FOCUSING ON THE FIRST MILE TO REACH THE LAST

## REMAPPING VACCINE SUPPLY AND COLD CHAINS

Consider the PEPFAR program in Africa, which delivered \$1 million worth of commodities a day, ensured continuous supply of antiretrovirals (ARV) to 1.2 million patients, and distributed \$860 million worth of ARVs over the life of the project.

“PEPFAR’s Supply Chain Management System is the supply chain equivalent of putting a man on the moon,” remarked Iain Barton, CEO, RTT Group Ltd.

At the Summit, an in-depth session examined the complicated web of factors that determines the success or failure of vaccine supply chain and delivery: from regulatory, packaging, and vaccine regimen standardization to expedited customs processes and robust health systems. Alongside the supply chain, there are enduring challenges to the cold chain: lack of infrastructure, access to electricity, transport, and trained human resources for stock management and equipment maintenance.

*“Focus on the first mile... The food industry has a proven model to move volumes at levels... the medical world can only dream of.”*

Iain Barton, CEO, RTT Group Ltd

“Focus on the first mile—the skills and controls—and collaborate and learn,” Barton recommended. “The food industry has a proven model to move volumes at levels of control that the medical world can only dream of.”

Technical cooperation, particularly for the development of human resources for health, and the operating environment for the delivery of vaccines are additional considerations, offered **Yasuhiro Tojo**, Deputy Director-General & Group Director, Health Group 2, Human Development Department, JICA. “Furthermore,



*“When we consider the policy and vaccine nexus, particularly in developing nations, we can’t let policymakers get away with proclaiming a 78% vaccine rate when that’s only for the first dose, and patients don’t come back for the second or third.”*

Rachel Jones, Journalism Trainer and Consultant, International Center for Journalists



Craig Mundie



in some countries, to expand immunization, considerations should be paid on security issues due to their unstable domestic circumstances.”

In India, vaccine delivery is undermined by a lack of professional stakeholder engagement, lamented **K.V. Balasubramaniam**, Managing Director, Indian Immunologicals Ltd. “If the government entered into long-term supply arrangements with qualified suppliers, who have a sense of belonging to the program and are therefore willing to commit investments, it would improve flexibility in supply response and be more cost-effective.”

What are the synergies we can find in complementary health programs, the private sector, and logistics innovations to keep step with the evolving needs of the next ten years?

**William Hook**, Vice President, Global Strategy, Healthcare Logistics, UPS, encouraged participants to take a step back and look at the whole picture of what is possible, distinguishing between emotional issues, such as project ownership, and tangible issues, such as demand planning, package design, technology, and standardization.

The session was an opportunity to share know-how across sectors. Albania’s national immunization program manager exchanged thoughts with The Coca Cola Company’s supply chain chief and UPS’s Health Sector Chief on how they could convince their executive leadership to invest in the supply chain function and effectively convince her ministers to invest in the immunization supply chain. “Such conversations alone were worth holding this workshop,” observed **Prashant Yadav**, Director, Health Care Research, The William Davidson Institute & Faculty Member, Ross School of Business and School of Public Health, University of Michigan.



HRH Emir of Argungu, Lola Dare (left to right)



Jacqueline Koch

# A NEW WORLD MARKET

## THE GROWING CONTRIBUTIONS OF EMERGING ECONOMIES AND DEVELOPING COUNTRY MANUFACTURERS

The fast-paced development of emerging global economies—including Brazil, China, India, Indonesia, South Africa, and Thailand—is also fueling a revolution in global health, particularly in the vaccines field.

China provides a prominent example, and a Summit session focused on China’s role in the vaccine field. Working with multinational pharmaceutical companies that provided essential technology transfers, China has achieved astonishing accomplishments within its borders. For instance, effective immunization underpinned by exceptional delivery systems has led to a tenfold decrease of hepatitis B in children under five years of age.

China’s global potential, however, was stymied by regulatory challenges, said **Xiaoming Yang**, President, China National Biotec Group. “China has 36 vaccine

manufacturers and is able to produce 49 vaccines; the issue was that we weren’t able to provide them to developing countries without WHO pre-qualification.”

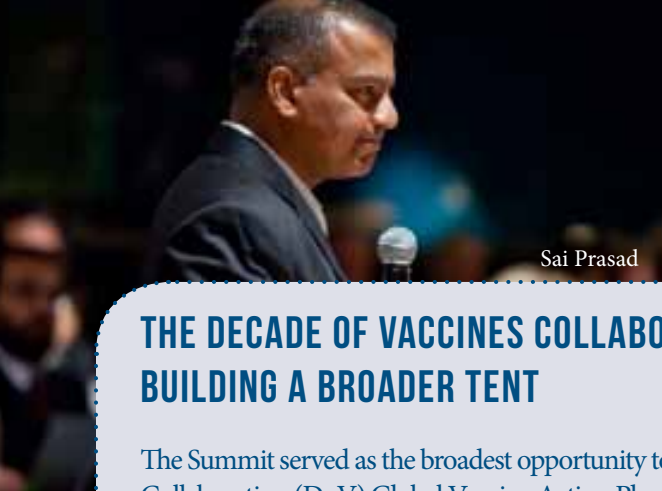
This is changing. China’s State Food and Drug Administration (SFDA) drastically changed its vaccine manufacturing regulations—specifically prohibiting the use of antibiotics, said **Qi Shen**, Director, Department of Biological Products Testing, National Institutes for Food and Drug Control, China. As a result, in March, the WHO announced that China’s SFDA now meets WHO indicators for a functional vaccine regulatory system. This will allow Chinese vaccine manufacturers to apply for WHO pre-qualification status, which is expected to drive up global vaccine production and drive down prices to unprecedented levels.



*“We created a myth in the developing world that if you introduce a vaccine, you have to introduce it with money coming from the outside. This concept of aid to introduce vaccines is a bankrupt concept. If developing countries are serious about the health of their children, they should take responsibility for getting the vaccines.”*

**Adel Mahmoud**, Professor, Woodrow Wilson School of Public and International Affairs & Department of Molecular Biology, Princeton University





Sai Prasad



Mark Feinberg,  
Lawrence Corey  
(left to right)

## THE DECADE OF VACCINES COLLABORATION: BUILDING A BROADER TENT

The Summit served as the broadest opportunity to date to garner industry input and support for the Decade of Vaccines Collaboration (DoV) Global Vaccine Action Plan, a blueprint for expanding immunization delivery over the next ten years.

“These global health initiatives are often perceived as the product of a few people around the table; we want to go well beyond that,” said **Pedro Alonso**, DoV Co-Chair, and Professor & Director, Institute for Global Health of Barcelona. A working breakfast allowed industry leaders to provide feedback on the Action Plan directly to DoV Co-Chairs and Steering Committee members. It also allowed them to address other issues alongside their peers, including innovation bottlenecks and the need for low-tech solutions.

Michael Watson suggested that, with more outreach and consultation from the DoV, industry had much to offer. “We’re good at taking research, turning it into robustly scalable products, and then putting [these] through clinical trials; we are good at managing risk.” With better cooperation, he added, “It’s a win-win-win.”

“In China, the entire vaccine industry is growing, and the quality—with WHO pre-qualification—has caught up,” said **Rino Rappuoli**, Global Head of Vaccines Research, Novartis. “I see China as a center of extensive future innovation.”

***“In China, the entire vaccine industry is growing, and the quality—with WHO pre-qualification—has caught up...”***

Rino Rappuoli, Global Head of Vaccines Research, Novartis

Yet participants also discussed the challenges around the “China price.” As China invests very significant human and financial resources in its continuing effort to meet international standards, are rock-bottom prices for new and improved vaccines feasible? The outlook is uncertain—quality, safety, and innovation are expensive. A myopic focus only on achieving the lowest prices, instead of best value, could have a negative impact on all three. In the context of meeting international regulatory standards, a number of participants, particularly those hailing from China’s manufacturing sector, noted that there is still a need for soft infrastructure, processes, and professional training to implement international procedures and management practices, integrating them into a Chinese context.



*“When we think of finance, funding, and political support, we shouldn’t be thinking only in terms of price, buying power, and distribution. We should think of what would have an integrated impact on the national health service. This way we move towards the big picture.”*

**Paulo Ernani Gadelha Vieira**, President, Oswaldo Cruz Foundation (Fiocruz)



Carlos Gadelha,  
Plenary I panelists  
(left to right)

India provides another model, as it is also a key leader in the new global market. It manufactures 34% of UNICEF's total vaccine supply and 43% of the vaccines for India's Universal Immunization Program.

**Sai Prasad**, Vice President, Business Development, Bharat Biotech, India, outlined his company's bold plan for broad access to its rotavirus vaccine candidate that is currently under development in collaboration with India's Ministry of Science and Technology. He noted that Bharat would price it at \$1 per dose, "without differentiating between middle and low-income countries."

Tackling the tiered-pricing question head-on, Prasad's announcement underscored India's ability to lead on pricing, bringing about a powerful global health shift.

**Suresh Jadhav**, Executive Director, Serum Institute of India Ltd., was also able to illustrate success in bundling competitive pricing with reliable quality products. Jadhav explained how his company helped develop and supply the meningitis A vaccine for roll-out in Burkina Faso, which immunized twelve million people aged 1–29 years old in just eleven days last December. "Just four cases of the illness were reported till June 2011, under rigorous disease surveillance," Jadhav said. "The success of this product speaks for itself."

***"UN agencies are procuring almost 80% of their vaccines from developing country manufacturers."***

Suresh Jadhav, Executive Director, Serum Institute of India Ltd.

Thanks in part to the emergence of new manufacturers, it is now more possible to effectively reach poor populations in the developing world with affordable vaccines than at any other time in history. Developing nations, alongside emerging economies, have clearly stated they no longer want to be passive players.

"Being from a research university, particularly from the developing world, we also think of ourselves as having a role in the generation of innovations," explained **Pornchai Matangkasombut**, Chairman, Thailand Center of Excellence for Life Sciences. "One often thinks that developing countries are always the recipient of scientific advances, but that is not true; I can testify to that."



***"We have to fit vaccines into our budget, and to fit our budget we must produce the vaccines ourselves."***

**Isaías Raw**, President, Council of Science and Technology, Butantan Foundation



“[The developing world’s] commitment to global health today is clear: UN agencies are procuring almost 80% of their vaccines from developing country manufacturers,” added Jadhav.

## HOW DO WE REACH THE NEXT MILESTONE?

Consider how far we’ve come.

“If we go back to January 1, 2000, there were no Millennium Development Goals. We didn’t have GAVI, PEPFAR, the Bill & Melinda Gates Foundation, or the Global Fund,” noted **Jonathan Quick**, President & CEO, Management Sciences for Health. Yet he reminded Summit participants that by 2008, nearly \$100 billion had been committed to global health, mostly for AIDS, TB, malaria, and immunization, all in just a few years. “It’s a commitment that has led to enormous global health impact.”

“With the introduction of new vaccines, and the growing vaccine pipeline, we have the potential to save many more lives. The challenge will be ensuring that the supply and logistics systems needed to get these vaccines to those who need them most are strengthened and ready for the task,” stated **Michel Zaffran**, Director, Project Optimize & Senior Advisor, Department of Immunization, Vaccines, and Biologicals, WHO.

Summit discussions sparked aspirations for novel initiatives that continue to gain momentum. One is to develop a R&D fund based on the GAVI model that will also help share risks between companies and PDPs. Another is to compile a “vaccines index” that ranks pharmaceuticals on their efforts to support immunization worldwide. In the days and weeks immediately following the Summit, participants began reporting back on new relationships forged at the meeting.





Peter Singer,  
Mark Swindell  
Suresh Jadhav  
(left to right)

On August 3, 2011, key Summit leaders from Merck & Company Inc. and the Serum Institute of India Ltd. announced they would join forces to develop and commercialize a pneumococcal conjugate vaccine (PCV) for use in emerging economies and the developing world. This collaborative-development partnership combines know-how and technology, and both companies will contribute to the development and manufacture of the new PCV vaccine, stated **Mark Feinberg**, Vice President & Chief Public Health and Science Officer, Merck Vaccines, Merck & Company Inc. “We need to develop solutions that go beyond traditional structures, models, and pathways,” Feinberg said. “While the initial discussions of this collaboration began before the Summit, the value of such innovative approaches that bring together new partners who share a common commitment to advancing global health progress was confirmed by the discussions at the Summit.”

And what is our strategy to achieve this success and reach five out of five children in the decade to come?

**Rajeev Venkayya**, Director of Vaccine Delivery at the Bill & Melinda Gates Foundation, discussed shared responsibility. “In industrialized countries, we often take vaccines for granted, as we have essentially eliminated vaccine-preventable diseases in our populations. But these diseases are still prevalent in developing countries and account for countless child deaths each year. When we fail to prioritize these vaccines in our global efforts, we deny children in these countries access to interventions that could be life-saving.”

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