# Center for Health Security

## **India–United States Track 1.5 Strategic Biosecurity Dialogue**

Report from the Ninth Dialogue Session Washington, DC, USA

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**Center for Health Security** 

## India-United States Track 1.5 Strategic Biosecurity Dialogue

#### **Report from the Ninth Dialogue Session**

Co-hosted by the Regional Centre for Biotechnology of the Department of Biotechnology in the Indian Ministry of Science and Technology and the Johns Hopkins Center for Health Security



**Center for Health Security** 



क्षेत्रीय जैव प्रौद्योगिकी केन्द्र Regional Centre for Biotechnology



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## **Executive Summary**

On May 24 and 25, 2023, the Johns Hopkins Center for Health Security ("the Center") co-hosted a dialogue ("the dialogue") with the Regional Centre for Biotechnology of the Department of Biotechnology in the Indian Ministry of Science and Technology, in Washington, DC, to discuss biosecurity issues of importance to both India and the United States. The dialogue aimed to increase knowledge of prevention and response efforts for natural, deliberate, and accidental biological threats in India and the US; share best practices and innovations; examine opportunities for partnership and collaboration; develop and deepen relationships among dialogue participants; and identify issues that should be elevated to the attention of Indian or US government officials.

The meeting convened senior thought leaders, scientists, public health practitioners, and medical experts from the United States and India. In accordance with the dialogue format, participants offered insights based on personal expertise and did not represent the government of either country in an official capacity.

The dialogue focused on a variety of health security topics—including lessons learned from COVID-19, future pandemic preparedness and response, epidemic containment and disease surveillance, emerging technologies and potential dual-use concerns, and management and development of medical countermeasures (MCMs)—and identified priorities for discussion at the next India–US Biosecurity Dialogue and for joint action by India and the US. Cross-cutting discussion points emerged during the meeting, including the need to elevate biosecurity issues for government-to-government engagement, especially in advance of an official state visit between US President Joe Biden and Indian Prime Minister Narendra Modi on June 22, 2023; work to overcome the destructive impact of misinformation and disinformation in future disease emergencies; understand biosecurity priorities through a One Health lens, breaking down the silos that separate animal, human, plant, and environmental health; ensure that biotechnology and bioscience is pursued safely and securely; and continue to learn from the COVID-19 pandemic to inform preparedness.

Participants from India included:

- Himanshu Chauhan, MBBS, MD, Joint Director and Officer In-Charge Integrated Disease Surveillance Programme, National Centre for Disease Control, Ministry of Health and Family Welfare, Government of India
- Saumitra Das, PhD, Professor, Department of Microbiology and Cell Biology, Indian Institute of Science
- Randeep Guleria, MD, Chairman, Institute of Internal Medicine and Respiratory and Sleep Medicine, Medanta Hospital
- Bandhana Katoch, JD, Executive Director, Koffman Southern Tier Incubator at Binghamton University, and Principal Advisor, IKP PRIME
- Chandrashekar Macha, PhD, Associate Vice President, Bacterial Vaccine Development and Manufacturing, Biological E. Limited

- Rakesh Mishra, PhD, Director, Tata Institute for Genetics and Society
- V. Siva Reddy, PhD, Former Chief Scientific Officer, Biosafety Support Unit, Regional Centre for Biotechnology, Government of India
- Ambassador Rakesh Sood, PhD, Foreign Policy and Strategic Affairs Expert
- Sudhanshu Vrati, PhD, Executive Director, Regional Centre for Biotechnology, NCR Biotech Science Cluster, Government of India

Participants from the United States included:

- Luciana Borio, MD, Venture Partner, ARCH Venture Partners
- Anita Cicero, JD, Deputy Director, Johns Hopkins Center for Health Security
- Gerald L. Epstein, PhD, Contributing Scholar, Johns Hopkins Center for Health Security
- John Grabenstein, PhD, President Vaccine Dynamics
- Gigi Gronvall, PhD, Senior Scholar (Principal Investigator), Johns Hopkins Center for Health Security
- Dan Hanfling, MD, Vice President, Technical Staff, In-Q-Tel
- Tom Inglesby, MD, Director, Johns Hopkins Center for Health Security
- Ambassador Ron Lehman, Counselor to the Director, Lawrence Livermore National Laboratory
- Melissa Morland, MS, Executive Director, Facilities and Operations, University of Maryland
- Aishwarya Nagar, MPH, Analyst, Johns Hopkins Center for Health Security
- David Relman, MD, Thomas C. and Joan M. Merigan Professor in Medicine, Professor of Microbiology and Immunology, Stanford University
- Sarah Schneider-Firestone, MSW, Research Program Manager, Johns Hopkins Center for Health Security
- Olivia Zetter, MPP, Strategic Advisor and Venture Partner, ARCH Venture Partners

Participants heard from guest speakers on biosecurity-related topics, including **Rebecca Hersman**, Director, Defense Threat Reduction Agency, US Department of Defense; **Brandi C. Vann**, PhD, Principal Deputy Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, US Department of Defense; **Richard Danzig**, JD, Senior Fellow, Johns Hopkins Applied Physics Laboratory and Former Secretary of the US Navy; **Megan Frisk**, PhD, Senior Advisor and Biotechnology Policy Coordinator, Office of the Special Envoy for Critical and Emerging Technology, US Department of State; Kathryn **Insley**, JD, MPP, Deputy Assistant Secretary, Nonproliferation Programs Bureau for International Security and Nonproliferation, US Department of State; and **Gary L. Disbrow**, PhD, Director of the Biomedical Advanced Research and Development Authority (BARDA), Deputy Assistant Secretary for Preparedness and Response, Administration for Strategic Preparedness and Response (ASPR), US Department of Health and Human Services. Vijayabaskar Narayanamurthy, Counsellor, Embassy of India, Washington, DC, attended the meeting as an observer. In addition, several observers from the US Department of Defense (DoD) attended the meeting: Ada A. Bacetty, PhD, Department Chief, Biological Threat Reduction Program, Defense Threat Reduction Agency; Lt Col Timothy Bucher, Division Chief, Biological Threat Reduction Program, Defense Threat Reduction Agency; Andrew Hollands, International Project Manager, Defense Threat Reduction Agency; Aaron Jay, Director, Cooperative Threat Reduction Policy, Office of the Secretary of Defense (Policy); Olivia Iannone, Advisor, Cooperative Threat Reduction, Office of the Secretary of Defense (Policy); Rick Peterson, PhD, WMD Threat Reduction Program Analyst, Office of the Secretary of Defense; Scott Vitarelli, India Country Manager, Biological Threat Reduction Program, Defense Threat Reduction Agency; Sapana Vora, PhD, Senior Policy Advisor, Countering Weapons of Mass Destruction/DoD CTR Policy, Office of the Secretary of Defense (Policy); and Amali Wijeweera, Office of Policy Coordination, Bureau of International Security and Nonproliferation, Department of State.

Participants also met at the White House during this year's dialogue, where they discussed the US National Biodefense Strategy, the US–India Initiative for Critical and Emerging Technologies, and biosecurity-related bilateral collaborations, particularly in advance of the upcoming state visit between US President Biden and Indian Prime Minister Modi. The visit was hosted by **Hillary Carter**, Deputy Senior Director for Global Health Security and Biodefense, National Security Council, and featured presentations from the following National Security Council speakers: **Anthony Renzulli**, Director for India; **Helena Fu**, Director for Technology Alliances; **Kendra Chittenden**, Director for Global Health Security; and **Kirsten Weand**, Director for Biotechnology Risk and Biological Weapons Nonproliferation.

The tenth meeting of the India–US Strategic Dialogue will be held in India in 2024, though the location and date have not yet been determined.



Delegation for India–US Strategic Dialogue on Biosecurity 2023

## Introduction

In May 2023, the Johns Hopkins Center for Health Security co-hosted an in-person strategic dialogue on biosecurity with the Regional Centre for Biotechnology of the Department of Biotechnology in the Indian Ministry of Science and Technology. The purposes of this dialogue were to increase knowledge of prevention and response efforts for natural, deliberate, and accidental biological threats in India and the United States; look for new synergies and share best practices and innovations; examine opportunities for partnership and collaboration; develop and deepen relationships among dialogue participants; and identify issues that may warrant being brought to the attention of the Indian or US government. This was the ninth meeting of the dialogue, which took place in Washington, DC.

While the dialogue began as informal engagement at the Track 2 level, it has evolved to include semi-formal engagement at the Track 1.5 level, with an increased focus on identifying opportunities for collaboration outside of the dialogue to address priority biosecurity threats and risks. The dialogue is conducted on a not-for-attribution basis, which facilitates frank and open discussion and contributes to a more complete appreciation of existing capabilities, gaps, operations, and policies in each country.

The dialogue consisted of sessions focused on national biosecurity priorities and concerns; pandemic preparedness, response, and lessons learned from COVID-19; epidemic containment, data systems, and disease surveillance; emerging technologies and dual-use concerns; management of medical countermeasures (MCMs) and opportunities to increase biosecurity through biotechnology; and future priorities for the next meeting of the India–US Biosecurity Dialogue. The 2-day dialogue included a site visit to the White House, where attendees engaged in a discussion with National Security Council officials.

**Rebecca Hersman**, Director, Defense Threat Reduction Agency, US Department of Defense, opened the dialogue, highlighting the importance of biosecurity-related conversations between India and the US. She encouraged delegations of both countries to work together to prepare for the next pandemic, leverage existing linkages between the nations and forge new ones, make innovating capabilities globally accessible, and ensure that collaboration on biosecurity does not start and end with the COVID-19 pandemic.

## **Discussion Overview**

During the 2-day dialogue, participants discussed biosecurity-related topics of importance to India and the US. The sections below summarize topic-specific findings, though a few cross-cutting discussion points emerged during the meeting:

• Elevating biosecurity for government-to-government engagement. The 2023 India–US Biosecurity Dialogue took place a month before an official state visit between US President Joe Biden and Indian Prime Minister Narendra Modi, scheduled for June 22, 2023.<sup>1</sup> That visit will touch on issues like strategic technology partnerships, defense cooperation, and broader health security. Dialogue attendees were interested in intentionally surfacing biosecurity to the governments of both countries, especially during the state visit, and elevating key issues for Track 1 government-to-government engagement. There are many biosecurity-related areas that would benefit from joint endeavors between India and the US, from surveillance to biosafety.

- Accounting for the role of misinformation and disinformation. Many participants noted that misinformation, disinformation, and infodemics during COVID-19 undermined both countries' populations' trust in public health and affected health outcomes. Attendees suggested prioritizing transparency, acknowledging uncertainty in available scientific data about emerging diseases, and accounting for value-based public dissent in communications during future disease emergencies.
- Understanding biosecurity through a One Health lens. Throughout the dialogue, participants shared examples of plant and animal pathogens that harm human health and international security. Additionally, they noted that zoonoses are a problem now more than ever before, due to the effects of climate change and population growth. Participants thought that future biosecurity discussions should include transdisciplinary experts who focus on One Health to examine areas where India and the US can work together to address these issues.
- Ensuring that biotechnology and bioscience are pursued safely and securely. Participants discussed research governance, laboratory capacity and containment, and advancing biosafety and security in the laboratory.
- Continuing to learn from the COVID-19 pandemic and plan accordingly. Lessons learned from the COVID-19 pandemic permeated all dialogue sessions. Participants drew on their professional experiences with the pandemic to reflect on how both countries can strengthen public health preparedness and response, bolster biomanufacturing capabilities, develop medical countermeasures, detect pathogens of pandemic potential early, bolster biosafety, and take other actions. These lessons need to be captured now, before knowledge of the challenges fades, and incorporated into future planning for disease emergencies.

## **Dialogue Sessions**

### **National Biosecurity Priorities and Concerns**

Geopolitical change, technological advancement, and concerns about the potential emergence of globally catastrophic biothreats have spurred a need to better understand future threats and collaboratively address them. Both India and the US need to bolster biosurveillance mechanisms, monitor biological threats through a One Health lens, strengthen bilateral communications, and create a shared strategy around norms for biosafety and high-containment research. Open, transparent, and cooperative trust-building is crucial for addressing future threats collaboratively, as is the need for both countries to harmonize their approach to biosecurity issues. Both India and the US approach biosecurity in a compartmentalized way based on academic tradition, and it is challenging to change these patterns. Participants recognized that the COVID-19 pandemic has elevated the value of advancing biosecurity; both countries should capitalize on lessons learned to spur better government-to-government collaboration and continue focusing on investing in innovative technologies and strategies to improve national biosecurity.

Two guest presentations provided additional input on this topic. Richard Danzig, JD, Senior Fellow at the Johns Hopkins Applied Physics Laboratory and Former Secretary of the US Navy, discussed perspectives and lessons observed from past biological threats and previewed future challenges. He described how both countries experienced health security successes and failures related to their approaches to SARS-CoV-2 vaccine innovation, federal pandemic response policies, and over-stressed healthcare systems. Both countries support and can help each other; for example, they support different parts of pharmaceutical supply chains, with the US leading preparation of finished pharmaceutical products and India leading provision of intermediate pharmaceutical products. Dr. Danzig suggested that supply chains challenged during the pandemic may have been further strained if China had not instituted its zero COVID policy. Finally, he highlighted how both India and the US could serve the world better in a future disease emergency by synergizing financial power and brainpower, combating vaccine nationalism, and making improvements to data-sharing. Following the presentation, participants talked about whether it helped to frame public health challenges as national security risks, fears around pathogens being weaponized for terrorism, and how both countries could strengthen health systems to make them more resilient.

Brandi C. Vann, PhD, Principal Deputy Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, US Department of State, provided an overview of the US Biodefense Posture Review, biosecurity priorities for the US Department of Defense (DoD), and overall perspectives as a senior leader in the DoD. She elaborated on the importance of biosecurity-focused bilateral relations, given India's thriving bioeconomy, innovation landscape, and mutual goal of preventing the proliferation of biothreats. Based on lessons learned from previous biothreats, eroding global norms around biosecurity, growing risks of pathogens being weaponized, and after-action reviews that have identified areas for improvement across the DoD biodefense enterprise, DoD recently conducted a Biodefense Posture Review.<sup>2,3</sup> According to Dr. Vann, the review assesses the future landscape for accidental, deliberate, and natural biothreats; pursues threat agnostic countermeasures; and supports cooperative threat reduction. The review also redefines what biothreats mean to the DoD, how the department approaches response, and how it prepares for biosecurity incidents. The review prompts the DoD to reflect internally on the role it plays in future biothreats, particularly after lessons learned from the COVID-19 pandemic. Participants initiated a follow-up discussion about how the review is situated with other US biosecurity and biodefense strategies, how Operation Warp Speed—a US government effort that supported multiple SARS-CoV-2 vaccine candidates to speed up development-balanced accelerating biomanufacturing and regulatory frameworks during

the pandemic, and opportunities for bilateral collaboration on scientific advancements among agencies.

### Pandemic Preparedness, Response, and Learning from COVID-19

Introductory remarks for this dialogue session highlighted the challenges faced by India and the US during the COVID-19 pandemic. Participants noted common challenges, including stressed healthcare systems, difficulties associated with isolating airborne outbreaks, underinvestment in research and development, negative impacts of postponing non-COVID-19 medical care, school closures that affected the training of the healthcare workforce, and others. They urged elevating and pursuing solutions related to developing strategies to maintain access to non-pandemic-related healthcare, improving data systems and interoperability, implementing hybrid response strategies that leverage telemedicine, investing in research on broad-spectrum drugs, advancing environmental surveillance through a One Health lens, improving domestic biomanufacturing, and strengthening health systems in rural settings. Participants had a lively discussion about whether biothreats should be addressed through a national security framework, partly due to the logistical successes of Operation Warp Speed. Finally, participants emphasized the importance of setting new norms for the next disease emergency, as populations of both countries will likely expect faster turn-around times for the development of diagnostic tests, vaccines, and other medical countermeasures and for the implementation of response policies.

#### **Epidemic Containment, Data Systems, and Disease Surveillance**

Participants discussed the importance of early detection of disease outbreaks and surveillance of pathogens of concern (both known and unknown), including the generation of quality data from which public health decisions may be made. Several participants advocated for strengthening environmental surveillance processes, including wastewater surveillance, to detect pathogens with outbreak potential, identify surges in cases, and respond in a localized manner. Some efforts in the US that combine wastewater surveillance with metagenomics have shown promise, especially when linked to hospital data.<sup>4</sup> Healthcare institutions can provide valuable case identification and surveillance data, and clinicians could benefit from training to identify, collect samples for, and contain suspected outbreaks. Moving forward, tertiary hospitals need to share data more quickly and link their data systems with national reporting networks, and response frameworks must deploy personnel dedicated to collecting surveillance data, so clinicians can focus on patient care.

When the COVID-19 pandemic began, India already had a routine reporting system and dedicated core staff for surveillance. The system was used to mobilize reporting units across India and harmonize multiple sources of data like genome sequencing, community-level case data, and oxygen utilization to paint a bigger picture on national and subnational levels. Participants recommended enhancing data quality by prioritizing real-time data

across all points of care, bolstering data interoperability between institutions and countries, pursuing predictive data analytics, and strengthening data integrity. To enhance data integration and interoperability, participants suggested building coalitions of hospitals, emergency management entities, public health entities, and governments. Bilaterally, this could look like Indo–US centers that can share data and practices for sequencing, sample isolation, clinician training, etc. The group engaged in discussion on other core challenges, such as data privacy and sharing, inconsistent communication about surveillance data, and the challenges of providing reliable but evolving information to the public.

## Emerging Technologies, Dual-Use Concerns, Biosafety/Biosecurity, and Deliberate Biological Threats

The discussion began with presentations from **Megan Frisk**, PhD, Senior Advisor and Biotechnology Policy Coordinator, Office of the Special Envoy for Critical and Emerging Technology, US Department of State, and **Kathryn Insley**, JD, MPP, Deputy Assistant Secretary, Nonproliferation Programs Bureau for International Security and Nonproliferation, US Department of State (DoS). They provided a high-level overview, mission, and goals of biosecurity-related work being conducted by the DoS. The department's approach to promote and protect the US bioeconomy was shaped by the 2022 Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy.<sup>5</sup> DoS policies aim to promote peace through approaches such as investing in biotechnology, enabling science-based riskproportionate regulation, and reinforcing norms around reciprocity and transparency of data; manage risks by preventing sensitive technology from falling into the wrong hands and prioritizing biosafety; and set up "rules of the road" to ensure biotechnology is used "for and not against society."

The DoS sees India as a strategic partner to address top priorities like guaranteeing that high-containment labs are safe, secure, and sustainable; investing in data-driven biosafety practices; identifying bioincidents and deliberate threats through mechanisms like the Quad's counterterrorism working group<sup>6</sup>; regulating dual-use commodities in secondary marketplaces; improving biorisk management; and enhancing capacity to respond to nonstate perpetrators of biothreats. Participants discussed the failings of the United States' patchwork approach to biosecurity and the ways in which DoS's approach to biosecurity and biotechnology dovetails with other agencies' roles. They expressed interest in using grants, formal resources, and official collaborations to support work on biotechnology advancements, biosecurity best practices, and technology transfers, as well as developing biomanufacturing and commercialization talent in India.

Dialogue participants discussed how attitudes around risks of emerging technologies and dual-use research of concern (DURC) have progressed historically. They explored how both countries have a moral obligation to understand threats that potentially increase vulnerability, the risks they pose, whether there is research that ought not to be done because of the risks, and what research is worth protecting. Participants discussed several guidance resources as potential jumping-off points for developing additional norms and "rules of the road," including the US National Science Advisory Board for Biosecurity's (NSABB) *Proposed Biosecurity Oversight Framework for the Future of Science*,<sup>7</sup> WHO's *Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research*,<sup>8</sup> India's Department of Biotechnology-mandated *Guidelines for Biosafety*,<sup>9</sup> and the Indian Biosafety Knowledge Portal.<sup>10</sup> Discussions also focused on how to increase funding and training for biosafety, for example. However, participants noted that it may be difficult to enforce and transform norms, especially for scientists in the commercialization space, and even the most well-intentioned people could circumvent regulations. One participant likened the norms change process to "having guardrails when you are zooming down the highway, but also streetlights to tell you where to go." Bilateral initiatives like the Indo-US Science and Technology Forum<sup>11</sup> can lead on how to set norms around critical and emerging technologies and biosafety.

## Management of Medical Countermeasures and Opportunities to Increase Biosecurity Through Biotechnology

Gary L. Disbrow, PhD, Director of the Biomedical Advanced Research and Development Authority (BARDA), Deputy Assistant Secretary for Preparedness and Response, ASPR, US Department of Health and Human Services (HHS), provided a spotlight on BARDA initiatives, including government-supported innovation, advanced research, development, manufacturing, and procurement of MCMs. Driven by BARDA's mandate to develop MCMs against chemical, biological, radiological, and nuclear threats, as well as infectious diseases, his team has supported end-to-end product development. He highlighted several BARDA strategies to develop MCMs during the COVID-19 pandemic and for the ongoing threat of antimicrobial resistance, including leveraging existing investments and solutions that could pivot to address emerging threats, strengthening domestic biomanufacturing capabilities, de-risking research and development for biotechnology companies, establishing accelerator networks to streamline the research-to-commercialization pipeline, and facilitating collaborations among government, academic institution, venture capitalist, and private sector stakeholders. Follow-up conversations focused on the benchmark of making safe, effective vaccines, therapeutics, and diagnostics for the next "Disease X" within 100 days of identification,<sup>12</sup> moving MCMs from research and development to manufacturing and then commercialization, analogues for BARDA around the world, and how to sustain competitive markets during emergencies.

During this dialogue, participants discussed how the landscape of MCM manufacturing and development has changed during various outbreaks, strategies for stockpiling MCMs, and considerations for mobilizing supply chains. During emergencies, it is often difficult for manufacturers to meet the demand for therapeutics and vaccines quickly because they take time to develop and manufacture. Some participants questioned whether countries should prioritize manufacturing therapeutics over vaccines. Participants suggested improving local and domestic production of MCMs and personal protective equipment in both countries, using real-time subnational case surveillance data to modify production strategies, investing in locally deployable strategies, lowering talent requirements needed to manufacture MCMs (and therefore scaling up the production workforce), and targeting pan-genotype or long-term solutions when emergencies end. Innovative manufacturing strategies are crucial for strengthening stockpiles and scaling MCM production rapidly. Participants noted that decisions around stockpiling are often made in the absence of a disease emergency, and therefore might not incorporate the logistical realities of crises and the political challenges of sharing needed tools to fight an epidemic. In the US, the Strategic National Stockpile cannot expand without also expanding its budget, and crucial questions are being asked about whether the federal government should pay for stockpiling, whether stockpiled MCMs should be stored where they are produced or moved to a central location, how to pay for and keep or discard MCMs with limited shelf lives, etc. Participants lauded the United Kingdom's approach of developing virtual stockpiles.<sup>13</sup> Participants also recommended moving from a "just in time" approach for mobilizing stockpiles to incentivizing commercial counterparts to keep supply chains "warm," which would allow the private sector to rapidly scale up MCM production during emergencies.

# Site Visit: Discussion with National Security Council Officials at the White House

Dialogue participants traveled to the White House for a site visit and engaged in a discussion with several National Security Council officials, including Hillary Carter, Deputy Senior Director for Global Health Security and Biodefense; Kirsten Weand, Director for Biotechnology Risk and Biological Weapons Nonproliferation; Anthony Renzulli, Director for India; Helena Fu, Director for Technology Alliances; and Kendra Chittenden, Director for Global Health Security. Officials shared that the outcomes of this dialogue would be relevant to an upcoming state visit between US President Biden and Indian Prime Minister Modi.<sup>1</sup> They lauded the long history of collaboration between India and the US, underscored the importance of a shared vision of a secure Indo-Pacific region, and expressed interest in collaborations related to resilient supply chains, artificial intelligence (AI), global health, biotechnology, and other strategic issues that benefit from a multifaceted global and bilateral partnership. Officials highlighted the recently launched United States-India Initiative on Critical and Emerging Technologies (iCET),<sup>14</sup> which expands strategic technology partnerships and prioritizes cooperation between governments, agencies, businesses, and academic institutions of both countries. In the future, the initiative may expand to include biosecurity, biotechnology, and bioeconomy as priorities, though it does not currently cover concrete collaborations on these topics.

Officials provided an overview of the US National Biodefense Strategy,<sup>15</sup> which explains how the US government will manage its activities to more effectively assess, prevent, prepare for, respond to, and recover from biological threats. As one official said, biosecurity "is not just nice to have, it's a need to have." They stressed the importance of advancing the bioeconomy and biotechnology through a One Health lens, transforming biosafety norms, integrating biosafety and biosecurity as standard practice, collaborating across sectors, using data-driven approaches to assess and mitigate risks, preventing pandemics more quickly through extended global health partnerships, and building high-level political awareness of biosecurity issues.

During the roundtable discussion that followed, participants shared ideas for expanding biosecurity-related bilateral collaborations. Several participants suggested surfacing action items of mutual interest at the state visit between the US and India leaders; they recommended prioritizing areas where biosecurity-related policies in India—such as the National Biotech Development Strategy<sup>16</sup>—dovetail and synergize with the US National Biodefense Strategy (eg, detecting biothreats, preventing biothreats through bilateral approaches, strengthening health systems, investing in post-pandemic recovery). Participants also suggested other collaborations, including the following actions:

- Bilateral initiatives to identify pathogens using combined surveillance, natural environment sample collection, and genome sequencing.
- Joint strategies to ensure continuous, real-time environmental surveillance and IT-enabled data sharing between both countries; ideally, surveillance could take place on a global multi-country level and account for diseases that affect plants and animals.
- Joint ventures to research and create high-quality libraries of broad-spectrum drugs, including antivirals, antibody therapies, and antimicrobials, particularly by leveraging advancements in structural biology and AI.
- Joint endorsement of internal attribution mechanisms in preparation for the next pandemic.
- Joint programs to preserve a supply chain of raw materials for vaccine development during pandemics, develop innovative vaccine platform technologies, protect intellectual property during vaccine development, and harmonize both countries' advancements in vaccine manufacturing, with an ambitious goal to create prototypes within 30 days.
- Partnerships between academic and healthcare institutions to develop new diagnostic tests, indigenous solutions, and innovations to use in healthcare facilities during outbreaks.
- Training programs to strengthen biosecurity at multiple levels, such as helping healthcare workers develop effective outbreak containment strategies or mainstreaming biorisk management training for laboratory workers.
- Investment in strengthening the cybersecurity of biosurveillance platforms and programs.



Delegation for India–US Strategic Dialogue on Biosecurity 2023 visit to the White House

### **Future Priorities for India-US Biosecurity Dialogue**

In addition to the potential collaborative projects discussed at the White House meeting, participants discussed several other key topics and opportunities for collaboration, including:

- Bilateral efforts to advance biosafety and applied biosafety research, such as developing better models for assessing biosafety and strengthening biosafety protocols through training and oversight mechanisms.
- Embedding experts in plant and animal pathogens, as well as experts who approach biosecurity through a One Health lens, in bilateral discussions and the iCET initiative.
- Potential Indo–US centers covering specific zones of surveillance interest, such as sequencing, sample isolation, or clinician training, and connecting them with hospitals, coalitions, etc.
- Promoting collaborations between health-related data analytics and forecasting efforts in the US, such as the Center for Forecasting and Outbreak Analytics at the US Centers for Disease Control and Prevention (CDC),<sup>17</sup> and emerging efforts at the National Centre for Disease Control in the Indian Ministry of Health and Family Welfare.
- Sensitizing governments of both countries to the importance of having consistent strategies, programming, and research and development on biosecurity.

The tenth meeting of the India–US Strategic Dialogue will be held in India in 2024, though the location and date have not yet been determined.

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## **Appendix A: Dialogue Participants**

## **Participants from India**

- Himanshu Chauhan, MBBS, MD, Joint Director and Officer In-Charge Integrated Disease Surveillance Programme, National Centre for Disease Control, Ministry of Health & Family Welfare, Government of India
- Saumitra Das, PhD, Professor, Department of Microbiology & Cell Biology, Indian Institute of Science
- Randeep Guleria, MD, Chairman, Institute of Internal Medicine and Respiratory and Sleep Medicine, Medanta Hospital
- Bandhana Katoch, JD, Executive Director, Koffman Southern Tier Incubator at Binghamton University, and Principal Advisor, IKP PRIME
- Chandrashekar Macha, PhD, Associate Vice President, Bacterial Vaccine Development and Manufacturing, Biological E. Limited
- Rakesh Mishra, PhD, Director, Tata Institute for Genetics and Society
- V. Siva Reddy, PhD, Former Chief Scientific Officer, Biosafety Support Unit, Regional Centre for Biotechnology, Government of India
- Ambassador Rakesh Sood, PhD, Foreign Policy and Strategic Affairs Expert
- Sudhanshu Vrati, PhD, Executive Director, Regional Centre for Biotechnology, NCR Biotech Science Cluster, Government of India

### **Participants from the United States**

- Luciana Borio, MD, Venture Partner, ARCH Venture Partners
- Anita Cicero, JD, Deputy Director, Johns Hopkins Center for Health Security
- Gerald L. Epstein, PhD, Contributing Scholar, Johns Hopkins Center for Health Security
- John Grabenstein, PhD, President Vaccine Dynamics
- Gigi Gronvall, PhD, Senior Scholar (Principal Investigator), Johns Hopkins Center for Health Security
- Dan Hanfling, MD, Vice President, Technical Staff, In-Q-Tel
- Tom Inglesby, MD, Director, Johns Hopkins Center for Health Security
- Ambassador Ron Lehman, Counselor to the Director, Lawrence Livermore National Laboratory
- Melissa Morland, MS, Executive Director, Facilities and Operations, University of Maryland
- Aishwarya Nagar, MPH, Analyst, Johns Hopkins Center for Health Security
- David Relman, MD, Thomas C. and Joan M. Merigan Professor in Medicine, Professor of Microbiology & Immunology, Stanford University

- Sarah Schneider-Firestone, MSW, Research Program Manager, Johns Hopkins Center for Health Security
- Olivia Zetter, MPP, Strategic Advisor and Venture Partner, ARCH Venture Partners

#### **Guest Speakers**

- Richard Danzig, JD, Senior Fellow Johns Hopkins Applied Physics Laboratory, Former Secretary of the US Navy
- Gary L. Disbrow, PhD, Director of the Biomedical Advanced Research and Development Authority (BARDA), Deputy Assistant Secretary for Preparedness and Response, Administration for Strategic Preparedness and Response (ASPR), US Department of Health and Human Services.
- Megan Frisk, PhD, Senior Advisor and Biotechnology Policy Coordinator, Office of the Special Envoy for Critical and Emerging Technology, US Department of State
- Kathryn Insley, JD, MPP, Deputy Assistant Secretary, Nonproliferation Programs Bureau for International Security and Nonproliferation, US Department of State
- Brandi C. Vann, PhD, Principal Deputy Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, US Department of State

#### **Observers**

- Ada A. Bacetty, PhD, Department Chief, Biological Threat Reduction Program, Defense Threat Reduction Agency, US Department of Defense
- Lt Col Timothy Bucher, Division Chief, Biological Threat Reduction Program, Defense Threat Reduction Agency, US Department of Defense
- Andrew Hollands, International Project Manager, Defense Threat Reduction Agency, US Department of Defense
- Olivia Iannone, Advisor, Cooperative Threat Reduction, Office of the Secretary of Defense (Policy), US Department of Defense
- Aaron Jay, Director, Cooperative Threat Reduction Policy, Office of the Secretary of Defense (Policy), US Department of Defense
- Vijayabaskar Narayanamurthy, Counsellor, Embassy of India, Washington DC
- Rick Peterson, PhD, WMD Threat Reduction Program Analyst, Office of the Secretary of Defense, US Department of Defense
- Scott Vitarelli, India Country Manager, Biological Threat Reduction Program, Defense Threat Reduction Agency, US Department of Defense
- Sapana Vora, PhD, Sr. Policy Advisor, Countering Weapons of Mass Destruction/ DoD CTR Policy, Office of the Secretary of Defense (Policy), US Department of Defense
- Amali Wijeweera, Office of Policy Coordination, Bureau of International Security and Nonproliferation, US Department of State

## **Appendix B. Dialogue Agenda**



**Center for Health Security** 



क्षेत्रीय जैव प्रौद्योगिकी केन्द्र Regional Centre for Biotechnology



## **India-United States Biosecurity Dialogue**

Co-Hosted by

The Johns Hopkins Center for Health Security

and the

Regional Centre for Biotechnology, Department of Biotechnology, Indian Ministry of Science and Technology

24 - 25 May 2023

The Hay-Adams Hotel Washington, DC, USA

**Meeting Room: The Hay-Adams Room** 

### Day 1 • 24 May 2023

8:45 – 9:15 Opening Session: Welcome & Meeting Goals Tom INGLESBY

Director, Johns Hopkins Center for Health Security

Sudhanshu VRATI

Executive Director, Regional Centre for Biotechnology, Department of Biotechnology, Govt. of India

Rebecca HERSMAN

Director, Defense Threat Reduction Agency, Department of Defense

#### 9:15 – 10:00 Introductions

#### 10:00 – 11:00 Dialogue Session One: National biosecurity priorities and concerns

Participants will remark on what they think are the most concerning biosecurity threats and the major efforts being made—or should be made—to address them. For this dialogue, we define "biosecurity" as the policies, programs, and actions taken to prepare for, prevent, and mitigate the effects of biological threats and events, whether they are natural, deliberate, or accidental.

Issues for Discussion:

- What do participants judge to be their country's greatest biosecurity priorities?
- How does each country determine its most important biosecurity risks?
- How are changes in biology and biotechnology creating new risks and new opportunities?
- How has COVID-19 changed the biosecurity landscape?
- Participants will also discuss what biosecurity issues, challenges, or new proposals could be elevated for consideration through government-to-government engagement. This discussion will prepare the group for its conversations in the afternoon with members of the National Security Council at the White House, where there will be opportunities to advance ideas and make recommendations for future collaborations.

#### 11:00 – 11:30 Coffee & Tea Break

#### 11:30 – 12:00 Remarks by Richard DANZIG, Senior Fellow, Johns Hopkins Applied Physics Laboratory and Former Secretary of the US Navy

*Perspectives and lessons observed from past biological threats and previews of challenges ahead* 

Q&A and Group Discussion

## 12:00 – 13:00 <u>Dialogue Session Two</u>: Pandemic preparedness, response, and learnings from COVID-19

The COVID-19 pandemic is a seminal event in global health security, and it will serve as the foundation for decades of future research, preparedness activities, and response efforts, reaching far beyond health care and public health. Over the course of the pandemic, countries implemented policies, expanded capacities, and developed new collaborations to improve their emergency responses. As we move toward the endemic stage of COVID-19 and return attention to future threats, it is critical to identify key lessons from this pandemic experience and apply them to the broad and expanding scope of health security.

#### Issues for Discussion:

- What have been the most important lessons you took away from your country's COVID-19 experience?
- What were the biggest challenges your country faced during the pandemic?
- How are India and the US changing their preparedness and response approach to address future pandemics?
- What policy and new programs has your country put in place— or will it put in place— to improve the preparedness of your healthcare system for epidemics and pandemics?
- As we prepare to respond to future infectious disease emergencies, are there new approaches or collective initiatives we can take to improve the global supply chain for PPE and medical countermeasures?

#### 13:00 – 13:15 Group photo

#### 13:15 – 14:15 Working Lunch in The Hay-Adams Room\*

During lunch, dialogue participants will continue to exchange views on lessons learned from the COVID-19 response and consider in more detail potential future collaborative activities that could improve both countries' prevention, preparedness, and response programs.

#### 14:15 – 15:30 Walk to the Eisenhower Executive Office Building at the White House and go through security

*Address*: Southwest Visitor's Gate: 17<sup>th</sup> Street and State Place, NW, Washington, DC 20005

#### 15:30 – 17:00 Discussion with National Security Council officials at the Eisenhower Executive Office Building, White House

*Location*: Room 350

Hillary CARTER

Deputy Senior Director for Global Health Security and Biodefense, United States National Security Council

#### Kirsten WEAND

Director for Biotechnology Risk and Biological Weapons Nonproliferation, United States National Security Council

Group introductions and discussion with White House officials

*Issues for Discussion*: Biosecurity priorities, and ideas for potential government-to-government engagement

17:00 – 17:30 Walk to Hotel Washington

Address: 515 15th St NW, Washington, DC 20004

- 17:30 18:30 Reception at Hotel Washington sponsored by the Center for Health Security
- 18:30 20:30 Dinner at Old Ebbitt Grill

Address: 675 15th St NW, Washington, DC 20005

### Day 2 • 25 May 2023

- 7:30 8:30 Breakfast available in The Hay-Adams Room\*
- 8:30 10:15 <u>Dialogue Session Three</u>: Epidemic Containment, Data Systems, and Disease Surveillance (breakfast provided)

Early detection and quality data are critical to the ability to rapidly identify and contain emerging outbreaks and epidemics. The COVID-19 pandemic illustrated that countries around the world—independent of geography, government, and resources—continue to struggle in establishing and maintaining disease surveillance systems and integrating them at the regional and global levels. Highly effective emergency operations for epidemic containment are also critical, and those systems were stressed when personnel managing them may not have had the training or background to do this work for prolonged periods of time over the course of COVID-19 containment efforts.

Issues for Discussion:

- What are the strengths and challenges of your country's disease surveillance systems, including the detection of novel pathogens?
- What information and data systems does your country use to track the course and evolution of a new pandemic? How is disease surveillance data integrated nationally from across the country?
- What is the public health and emergency operations approach in your country to preparing for and responding to emerging outbreaks and epidemics, including for novel pathogens?
- How does the public health and medical response operation that is responsible for disease containment interact with political and national policy leadership in your country?
- How have approaches to disease containment and disease surveillance changed since the emergence of COVID-19?

## 10:15 – 10:45 Remarks by Brandi VANN, Principal Deputy Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs

*Overview of the US Biodefense Posture Review, biosecurity priorities in the US Department of Defense, and overall perspectives as a senior leader in the Department* 

Q&A and Group Discussion

#### 10:45 – 11:15 Coffee & Tea Break

#### 11:15 – 11:45 Remarks by Megan FRISK, Senior Advisor and Biotechnology Policy Coordinator, US Department of State, and Kate INSLEY, Deputy Assistant Secretary for Nonproliferation Programs in the Bureau for International Security and Nonproliferation

*High-level overview, mission, and goals of biosecurity-related work being conducted by the Department of State* 

Q&A and Group Discussion

## 11:45 – 13:00 <u>Dialogue Session Four</u>: Emerging technologies, dual-use concerns, biosafety/ biosecurity, and deliberate biological threats

The biosafety and biosecurity risks associated with increases in advanced biological research have garnered elevated attention and scrutiny, particularly since the COVID-19 pandemic began. As a result, some countries have increased investments in developing new highcontainment laboratory capacity and other emerging technologies that have reignited concerns around dual-use research and biosafety. In addition, strong continued focus and attention are needed to mitigate deliberate biological threats.

Issues for discussion:

- How is your country's government addressing oversight and governance of dual-use research of concern (DURC), generally defined as knowledge, information, methods, products or technologies generated for peaceful and legitimate purposes that may be appropriated for non-peaceful or harmful purposes?
- What are your greatest priorities/concerns regarding biosafety and biosecurity?
- What are your country's plans, if any, to implement and operationalize the new <u>WHO Global guidance framework for the responsible use of the life sciences</u>?
- To what extent are you concerned about research intended to increase the lethality or transmissibility of pathogens in your country or other countries?
- What level of concern do you have regarding cyber-security threats in your country, particularly those related to laboratories, genomic databases, or the production of life science-related materials?
- What concerns are there in your country regarding deliberate biological threats? What programs are in place to detect or deter the development or use of biological weapons?

- What programs does your country have in place to promote the responsible use of biology and mitigate deliberate biological threats (eg, a select agent program, personnel reliability program, insider threat program, and research codes of conduct)?
- What challenges exist for the implementation of the Biological & Toxin Weapons Convention (BWC), UNSCR 1540, and other international instruments in your country?

#### 13:00 – 14:00 Working Lunch in The Hay-Adams Room\*

During lunch, dialogue participants will share their observations and reactions to the morning presentation and dialogue session with the goal of advancing ideas for potential future joint activities or initiatives.

#### 14:00 – 14:30 Remarks by Gary DISBROW, Deputy Assistant Secretary Director, Biomedical Advanced Research and Development Authority

Spotlight on HHS BARDA initiatives: government-supported innovation; advanced research, development, and manufacturing; government procurement of medical countermeasures

Q&A and Group Discussion

## 14:30 – 15:45 <u>Dialogue Session Five</u>: Management of medical countermeasures and opportunities to increase biosecurity through biotechnology

New capabilities in medical countermeasures (MCMs) research, development, and manufacturing are emerging, building on decades of advancements in biotechnology. MCMs and other biotechnological advances have the potential to help countries make major progress and to greatly improve preparedness for future epidemics and pandemics.

*Issues for Discussion:* 

- How has COVID-19 changed national approaches to developing medical countermeasures for infectious disease and pandemic threats?
- What types of technologies would you want to see your country invest more in, in order to advance biosecurity goals?
- What research and development approaches are needed to improve capabilities to make MCMs and biotechnologies even more rapidly available in future emergencies in your country?
- Does each country have a national strategy for stockpiling MCMs?
- What are new ideas for planning for better global access to medical countermeasures in future pandemics? Are new international partnerships needed?

#### 15:45 – 16:15 <u>Roundtable Discussion</u>: Future priorities for India–US Biosecurity Dialogue and closing discussion

This session will focus on next steps and future topics for this biosecurity dialogue, to be held in India in the spring of 2024. It will also invite ideas for collaboration and engagement between India and the US, both at the government-to-government level and., at the Track 1.5 level.

*Issues for Discussion:* 

- What key insights stood out to you from this dialogue?
- What topics, threats, or capabilities would you like to see included in future dialogue discussions?
- What opportunities would you like to see for collaboration outside of dialogue meetings?
- How could JHCHS or DTRA provide assistance?
- What issues should be elevated for Track 1 engagement?

#### 16:15 Dialogue adjourns

\* Food costs are considered "meals provided" and per diem will be adjusted according to the applicable regulations.

#### The Johns Hopkins Center for Health Security has supplemented DTRA support for meals using other funding sources

# Center for Health Security

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