CARNEGIE
ENDOWMENT FOR
INTERNATIONAL PEACE

WORKING PAPER

DECEMBER 2020

Biological Risks in India: Perspectives and Analysis

Shruti Sharma

Biological Risks in India: Perspectives and Analysis

Shruti Sharma

Carnegie Endowment for International Peace
Publications Department
1779 Massachusetts Avenue NW
Washington, DC 20036
P: + 1 202 483 7600
F: + 1 202 483 1840
CarnegieEndowment.org

This publication can be downloaded at no cost at CarnegieEndowment.org.

CONTENTS

ABBREVIATIONS LIST

BSL	biosafety level
BRAI	Biotechnology Regulatory Authority of India
BTPR	Biological Threats Preparedness and Response
Cas9	CRISPR associated protein 9
CDC	(U.S.) Centers for Disease Control and Prevention
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CSIR	Council of Scientific and Industrial Research
DBT	Department of Biotechnology
DIP Act	Destructive Insects and Pests Act
DLC	District Level Committee
DNA	deoxyribonucleic acid
DST	Department of Science and Technology
EDA	Epidemic Diseases Act of 1897

FCRA	Foreign Contribution Regulation Act, 2010
FSSAI	Food Safety and Standards Authority of India
GDP	gross domestic product
GEAC	Genetic Engineering Appraisal Committee
IBSC	Institutional Biosafety Committee
ICMR	Indian Council of Medical Research
IDSP	Integrated Disease Surveillance Programme
KFD	Kyasanur Forest Disease
LI Act	Livestock Importation Act
MEA	Ministry of External Affairs
MERS	Middle East respiratory syndrome
MHA	Ministry of Home Affairs
MIV	Manipal Institute of Virology
MOEFCC	Ministry of Environment, Forest, and Climate Change
MOHFW	Ministry of Health and Family Welfare
NCDC	National Centre for Disease Control
NDMA	National Disaster Management Authority
NITI Aayog	National Institute for Transforming India Aayog

NPSP	National Polio Surveillance Project
NSA	National Security Adviser
PMO	Prime Minister's Office
PPE	personal protective equipment
RCGM	Review Committee on Genetic Manipulation
RNA	ribonucleic acid
SARS	severe acute respiratory syndrome
SBCC	State Biotechnology Coordination Committee
WHO	World Health Organization
WMD	weapons of mass destruction

Summary

Infectious diseases such as COVID-19, the disease caused by the novel coronavirus; severe acute respiratory syndrome (SARS); Middle East respiratory syndrome (MERS); and the diseases caused by the Ebola, Nipah, and Zika viruses have exposed countries' susceptibility to naturally occurring biological threats. Even though scientists from multiple countries concluded that the virus responsible for the coronavirus pandemic shifted naturally from an animal source to a human host,[1] the international community should not ignore the possibility of pathogens escaping accidentally from research labs and threats of deliberate manipulation to create more dangerous bioweapons.

India is especially vulnerable to such infections because of its geographical position, large population, low healthcare spending, minimal expenditure on research that benefits public health, weak coordination between central and state health authorities, limited involvement of private actors, poor awareness of biosecurity, and the rickety state of public health infrastructure. Most recently, COVID-19 has revealed the deep fault lines in India's public health infrastructure, including a shortage of healthcare workers, lack of trained epidemiologists, scarcity of medical equipment, poor access to healthcare facilities in rural areas, and inefficient disease reporting and surveillance in most states. The pandemic should therefore be a wake-up call for India to assess gaps in its public health infrastructure and divert its resources toward the healthcare sector to prepare itself for both natural and man-made biological emergencies.

Like any country, India faces three major biological threats: naturally occurring infections in humans or animals, or agricultural infestations; infections arising from accidental release of pathogens into the environment; and possible outbreaks caused by deliberate weaponization of dangerous pathogens that affect humans, animals, or crops. These threats—either alone or together—will force India to strengthen its capacity to detect and respond to them.

In all of this, there is a further challenge to wisely manage the trade offs between regulations to reduce the risks of accidents and attacks, on the one hand, and on the other, policies that enable government, scientific researchers, and industry to develop and market beneficial applications of biotechnology. Breakthroughs in biotechnology will be necessary to treat or vaccinate people against naturally occurring diseases as well as to detect and counter potential human-made threats and their consequences. This means researchers, businesses, regulators, media platforms, nongovernmental organizations, and voters must strive to educate themselves and their audiences or constituencies about possible threats and about the socially beneficial ways to prevent and manage them.

This paper addresses these varied challenges faced by India. It is based on interviews and informal conversations with leading government officials, scientists, academicians, and private-sector experts,

as well as insights from workshops, roundtable discussions, and extensive literature review. Given India's vulnerability to infectious disease outbreaks, the goal is to provide all stakeholders and the Indian public with an understanding of the biological risks facing India and the existing policies and involvement of various agencies working to enhance safety, security, and responses to threats. The paper further provides a brief assessment of how these policies are being implemented today and the scope of enhanced and better implementation in the future. The aim is to highlight the vital roles that bioscience, technology, and industry can play to advance the well being of Indian citizens while reducing risks of natural or human-induced afflictions.

Threats and Risks

Naturally Occurring Infections

- Given India's climate conditions, the country is vulnerable to vector-borne diseases such as malaria and dengue fever, among others.
- A high-density livestock population and a poorly guarded animal-human interface make India susceptible to zoonotic infections such as avian influenza, commonly called bird flu; pig influenza, commonly called swine flu; Nipah virus disease; and coronavirus diseases, such as COVID-19.
- Poor patient adherence to antibiotic treatment, nontherapeutic use of antibiotics to promote growth in farm animals, self-medication, and illegal over-the-counter access to antibiotics makes antibiotic resistance an emerging health threat that demands immediate policy attention.

Safety Concerns

- India has multiple laboratories with different biosafety levels (BSLs) set up across the country. Although new biosafety guidelines issued by the Department of Biotechnology (DBT) mention certification and validation for the higher-standard BSL-3 and BSL-4 labs, the country lacks accredited government or private agencies to certify and validate the lower-standard BSL-2 laboratories' compliance with safety rules.
- In interviews, some scientific experts emphasized that the sudden ban on plastic in India in 2018 has made it difficult to use autoclavable plastic bags to dispose of laboratory waste. This has complicated the implementation of the proper disinfection protocol to dispose of biomedical waste, posing a serious biosafety hazard.
- Unforeseen infection of laboratory personnel or the accidental release of pathogens or other biological materials from designated laboratories, either due to negligence or poor understanding of biosafety protocols among the laboratory workers.
- Deliberate introduction of genetically engineered organisms for beneficial purposes might have unintentional harmful consequences.

Security Concerns

- Disease-causing pathogens are abundantly available in nature. Technologies needed to manipulate them are becoming more easily accessible. Actors with nefarious designs could purposefully weaponize such technologies and naturally occurring pathogens.
- India is vulnerable to zoonotic diseases. Naturally occurring zoonotic pathogens can be manipulated in the lab to enhance their virulence, transmissibility, and/or resistance to therapeutic interventions.
- Because India shares porous borders with most of its neighboring states, the possibility of cross-border infections is another major biological threat.
- In addition to manipulating pathogens that affect human health, bad actors could release naturally occurring invasive pathogens or synthetically created pathogens or pests to weaken the agricultural supply chain.

Safety and Security Regulations and Policies

To address safety and security risks, India follows two different approaches—biosafety and biosecurity. Biosafety seeks to protect humans from pathogens while biosecurity protects pathogens from humans.[2] Though these two concepts and practices reflect diverse scenarios and mitigate different risks, they complement each other. Robust implementation of biosafety protocols, in addition to reducing the risk of accidental exposure, limits risks of intentional theft or misuse.[3]

Biosafety regulations in India are defined under the 1986 Environment Protection Act, with implementation broadly distributed between the Ministry of Science and Technology and the Ministry of Environment, Forest, and Climate Change (MOEFCC). These regulations have three aims:

- To prevent biological materials from escaping designated places in laboratories
- To prevent laboratory workers from unintentional exposure
- To prevent unintended consequences when genetically modified organisms are released purposefully into the environment

Like biosafety, biosecurity regulations in India, although not clearly defined and categorized, empower different ministries or agencies that are responsible for sectors usually associated with human health, food safety, agriculture, livestock, and the environment. As no uniform definition of biosecurity exists globally, the concept differs across human, animal, and plant health sectors. Biosecurity for public health often refers to "the protection of microbiological assets from theft, loss or diversion, which could lead to the inappropriate use of these agents to cause public health harm."[4] However, because biosecurity for plant and animal health entails protecting biological resources from foreign or invasive species,[5] regulations in India are broad enough to cover four major aims:

- To prevent unauthorized or ill-conceived release of naturally occurring biological agents
- To prevent cross-border entry and movement of dangerous pests and pathogens
- To prevent theft or acquisition of sensitive research, organisms, and information for nonlegitimate use
- To prevent weaponization of pathogens by both state and nonstate actors

Implementation

Even though India has enacted laws and regulations to protect the country from biological threats, the coordination and monitoring of their implementation remains irregular.

For the first category of biological threats—diseases emerging from natural sources—India has invested in a public health infrastructure and has various laws and guidelines that drive preparedness and response to naturally occurring disease outbreaks. However, India's response to the avian influenza, Nipah virus disease, and COVID-19 has exposed the country's rickety public health infrastructure, poor disease surveillance network, inadequate coordination between ministries to prevent zoonotic infections, absence of a national policy on biological disasters, and dismal investment in scientific research. Rather than using the time between outbreaks to develop national guidelines to tackle infectious diseases, India mostly relies on ad hoc notifications and guidelines, along with World Health Organization (WHO) advisories.

For the second category of threats—diseases caused by accident—India has developed comprehensive biosafety guidelines to monitor the safety of biotechnological research. Although implementation of biosafety guidelines falls under the ambit of the Ministry of Science and Technology and MOEFCC, researchers often work in labs supported by the Indian Council of Medical Research (ICMR) and the Indian Council of Agricultural Research, which are research bodies set up under the Ministry of Health and Family Welfare (MOHFW) and the Ministry of Agriculture and Farmers' Welfare. The multiplicity of organizations operating under different ministries makes it difficult to ensure implementation of biosafety guidelines across the country. Moreover, the system often experiences poor coordination between center and state regulatory units. In addition, some experts interviewed during the project note that while scientists or researchers perform all necessary safety tests before approaching the regulatory authorities, the approval agencies, perhaps influenced by activist groups, perform additional safety tests that delay the clearance of such products.[6] Whether such additional tests are necessary or not is often disputed.

For the third category of biological threats—threats emerging from intentional sources—India has no specific biosecurity policy or legislation but has a multiplicity of regulations that address threats emerging from different sources. However, entities set up under different ministries with inadequate collaboration among them leaves India vulnerable to a variety of foreign threats. While security agencies, such as the National Security Council Secretariat, are responsible for investigating a security threat, response to an event is often coordinated by civilian ministries.[7] Because threats emerging from biological sources have a technical component, security agencies often include experts from other government departments, such as the Defence Research and Development Organisation, for their scientific inputs. Some experts, however, highlight that biosecurity discussions are mostly confined to closed policy circles and rarely involve experts from outside the government, leading to poor nationwide biosecurity awareness in India. Further, most regulations cover the export and import of pests and pathogens but do not adequately cover commercially ordered (mostly through e-commerce platforms) deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) sequences that may encode virulent genes. At present, biosecurity regulations often empower customs officials as the only authority that can check the baggage of incoming passengers. But most customs officials are inadequately trained to identify specific pests or pathogens. In addition, there seems to be no systematic assessment of vulnerabilities in the existing system nor development plans and methodologies to build a sustainable, functional, and well-equipped system to counter biothreats.

Beyond the need to prevent outbreaks caused by safety and security lapses, any system must also be able to respond to threats whether they occur through human action (and inaction) or through natural processes. Although security agencies require time to investigate if an outbreak is natural or man-made, the mitigation strategy to tackle the threat must be prepared in advance and implemented immediately after detection of an outbreak.

Major Recommendations

As the spread of infectious diseases is a long-term, continuous, and evolving threat, India may need an agency specifically responsible for preventing and managing biological threats. India could consider investing in an agency that can coordinate policy responses for any biological emergency. A full-time Office of Biological Threats Preparedness and Response (BTPR) under the National Disaster Management Authority (NDMA) is being suggested as an alternative. This paper sketched out this idea to stimulate further dialogue among interested stakeholders. This office could focus on naturally occurring diseases, threats emerging from laboratory accidents, and deliberate weaponization of diseases. Because India has numerous organizations that sometimes perform overlapping roles with limited or no coordination with each other, the office could become a nodal agency that brings together experts from different ministries, representatives from the private sector, and experts from the academic and scientific community.

Whether or not a new office is set up, it is important for India to review domestic measures needed to predict, prevent, and respond to both natural and man-made biological threats. These measures include:

- **Periodic training** of healthcare workers on nursing practices, safe handling of samples, decontamination procedures, and proper disposal of biomedical waste;
- **Strengthening cooperation** between central and state health authorities;
- **Introducing clearer and stronger incentives** for personnel to identify and report disease outbreaks among plants, animals, and humans to strengthen the disease surveillance network;
- **Aggregating data** obtained from different disease surveillance programs that collect data on plant, animal, and human health to detect outbreaks in a timely manner;
- **Developing common disease reporting standards** to harmonize data collection from all organizations reporting disease outbreaks;
- **Creating an epidemiological model** for diseases through collaboration between government, scientists, academicians, industry, epidemiologists, and data scientists;
- **Implementing capacity-building measures**, such as engaging with local donors to mobilize resources needed to ramp up public health infrastructure, increasing funding to research bodies, introducing incentives to invest in biotechnology research, and fostering collaboration between the scientific and the policy community, which should all be encouraged to strengthen India's preparedness for biological threats;
- **Conducting surprise on-site inspections** by members of the government-led Review Committee on Genetic Manipulation (RCGM), the Genetic Engineering Appraisal Committee (GEAC), and state regulatory authorities to ensure rigorous monitoring of biotechnological research;
- **Harmonization of application protocols** and introduction of standard evaluation forms for researchers applying for approvals to commercialize biotechnology-derived products;
- **Introducing mandatory certification and validation** for BSL-2 labs that sometimes work with high-risk pathogens;
- **Developing a formal biosecurity policy** that encompasses threats emerging from different sectors such as plant health, animal health, and public health to avoid any overlaps or coordination issues;
- **Conducting specific training sessions** for customs officials to identify specific pests or pathogens that might pose a risk to India's national security;
- **Introducing simulation exercises** to develop standard operating protocols that can be implemented during the time of a crisis, like inexpensive tabletop exercises that can help generate awareness among relevant agencies and can be useful for monitoring, assessing, and strengthening the capabilities of emergency policies, plans, and procedures.

Introduction

Outbreaks of life-threatening infectious diseases such as the Ebola virus disease in West Africa, the Zika virus disease in South America, severe acute respiratory syndrome (SARS) in China, and the Nipah virus disease in India are not only limited to the region but frequently put people all over the world at risk. Most recently, COVID-19, the disease caused by the novel coronavirus, originated in China in late 2019 and rapidly evolved into a global pandemic, clearly demonstrating the harm infectious diseases can cause to the world economy and health security.

Natural processes of mutation and transmission caused these threats to human society. Human beings could create similar or even more dangerous threats—by accident or on purpose. Such accidents happened, for example, in 2003 when a Singaporean researcher acquired SARS from inadvertent cross-contamination of viral samples.[8] In 2004, the accidental release of the SARS virus from a Chinese laboratory infected nine people, one of whom died.[9] In 2014, a researcher working in a lab in India was accidentally infected with buffalopox virus,[10] and in 2019 more than 3,000 brucellosis cases were detected in China due to contaminated exhaust from a brucellosis vaccine–making company.[11] Going further back in history, during World War II, Japan deliberately used pathogens to spread plague, anthrax, typhoid, cholera, and other diseases among Chinese military and civilians.[12] The United States and the Soviet Union developed major biological weapons programs during the Cold War,[13] which Russia, then part of the Soviet Union, continued illegally even after it signed the Biological Weapons Convention in 1972.[14] Yet, if societies and governments overreact and impose ill-conceived regulations to control these risks, they would defeat themselves by depriving the world of the great benefits that bioscience and technology can provide. The study of genes and their functions—genomics—enables researchers to understand the genetic causes of human, animal, and plant maladies. Synthetic biology and gene-editing tools such as the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) and CRISPR associated protein 9 (Cas9) can be used to modify genes to fix maladies and to create new functionalities—for good or ill, as discussed below. Bioscience and technology together are needed to produce vaccines that prevent the spread of infectious diseases such as COVID-19 and medicines that treat people who could not be vaccinated. New biotechnologies also promise to advance prevention and treatment of other human afflictions and to boost agricultural productivity and sustainable development.

This paper is divided into five sections. The first section describes how different stakeholders perceive and think about the possible benefits of biotechnology and the factors that could prevent these benefits from being realized. Based on interviews and informal conversations with leading government officials, scientists, academicians, and private-sector experts, as well as insights gleaned from workshops, roundtable discussions, and extensive literature review, the paper highlights India's vulnerability to three major categories of biological risks:

1. Those produced by nature (like the Ebola and Nipah viruses)
2. Those produced by human accident
3. Those produced on purpose by hostile individuals or governments

Based on these perspectives, the paper argues that societies need to create a healthy balance between innovation, commerce, and regulation to ensure safety and security. This means researchers, businesses, regulators, media platforms, nongovernmental organizations, and voters must strive to educate themselves and their audiences or constituencies about possible threats from biotechnology and about the socially beneficial ways to prevent and manage them so that this technology can be used to enhance social welfare.

Next, the paper focuses on the first category of risk, which is probably the largest biological danger if multiplying the probability of occurrence with the consequences of occurrence. And, because naturally occurring sources of infectious disease in human beings and animals will occur, even if human-made ones do not, this paper, through brief case studies, explores India's plans and capacity to detect and mitigate biothreats once they have dispersed into the larger environment and human population. Assessing the gaps in India's response to disease outbreaks, this section of the paper suggests that New Delhi must create, fund, and deploy capabilities to detect, mitigate, and eventually prevent naturally occurring outbreaks. Most, if not all, of the policies and capabilities needed to respond to natural outbreaks would be vital also in responding to biological attacks and accidents, which is an argument for prioritizing them.

The third and fourth sections elaborate on how India seeks to protect against infections arising from accidental or deliberate release of pathogens through biosafety and biosecurity regulations, respectively.

While biosafety is the protection of humans from pathogens, biosecurity is the protection of pathogens from humans.[15] Though these two concepts and practices reflect diverse scenarios and mitigate different risks, the paper argues that they share a common goal of keeping biological materials and the world safe and secure.

The final section of the paper identifies areas where stakeholders can work together and proposes a new nodal organization called the Office of Biological Threats Preparedness and Response (BTPR), operating under the National Disaster Management Authority (NDMA), to strengthen India's capacity to tackle biological threats. Whether or not the office is set up, this section proposes other recommendations to strengthen India's public health infrastructure, necessary to tackle both natural and manmade biological threats.

Biological Risks in India

Emerging technologies can provide immense and widespread public health benefits by enabling the global scientific community to improve diagnostics and treatments of diseases that afflict human beings, animals, and plants. The benefits of some methods and new biotechnologies sometimes entail risks such as the accidental spilling of pathogens from the labs or the deliberate misuse of technology to create more dangerous pathogens. Other types of research may come with risks that are commensurate to the potential large-scale benefits they could provide. For example, to evaluate the effectiveness of current and future public health interventions, scientists in the United States have re-created the Spanish flu virus, the pathogen responsible for the world's deadliest pandemic to date.[16] To develop better vaccines and cancer therapeutics, Canadian researchers have synthetically reconstructed an infectious horsepox, a close relative of smallpox.[17] Gain-of-function experiments, which increase transmissibility or virulence of pathogens, if undertaken with extreme care, can develop better vaccines by enhancing the pathogenicity of potential pandemic pathogens, such as coronaviruses, in laboratories in order to test new ways to kill or slow them.[18]

While such research promotes scientific understanding and provides tools to design medical countermeasures to reduce global disease burden, experts in India understandably worry that wide applications of dual-use technologies and decreasing barriers to access them raise safety and security concerns.

Naturally Occurring Diseases

Given India's geographical placement and history of infectious disease outbreaks, there are three major concerns that exist under this category:

1. Vulnerability to vector-borne diseases such as malaria and dengue fever
2. Susceptibility to zoonotic infections, such as COVID-19 and Nipah virus disease
3. Growing rate of antibiotic resistance

India lies within the distribution zone of disease vectors, such as *Aedes aegypti*, a mosquito that carries and transmits viruses. India is therefore prone to mosquito-borne diseases such as dengue fever, malaria, Japanese encephalitis, and chikungunya virus disease. The vulnerability to vector-borne diseases is exacerbated by its tropical climate and annual monsoon season.[19]

Additionally, several scientific and academic experts in India stress that among a myriad of different diseases, viral infections—especially the ones that jump from animals to humans, called zoonotic diseases—have the potential to cause devastation in India.[20] Scientific experts further suggest that smaller genomes, higher replication speed, and greater transmission rates make it easier for certain pathogens, especially viral pathogens, to cause infections. Moreover, the high density of livestock and the difficult-to-regulate interface between human and animal populations make India more vulnerable to contagious viral zoonotic diseases. West Nile, avian influenza, swine flu, SARS, Middle East respiratory syndrome (MERS), Ebola virus disease, Nipah virus disease, and COVID-19 are examples of such zoonotic diseases. This is compounded by the unhygienic maintenance and breeding of livestock for human consumption.

Some industry and scientific experts in India emphasize that viral infections lead to secondary bacterial infections. Increasing rates of antibiotic resistance, a subset of antimicrobial resistance, is an emerging health trend in the country.[21] Human pathogens frequently isolated from infections in patients and hospital sources have been growing more resistant to commonly used broad-spectrum antibiotics. Major contributors to this growing problem include poor patient adherence to antibiotic treatment, nontherapeutic use of antibiotics for growth promotion in farm animals, self-medication, and illegal over-the-counter access to antibiotics.

Biosafety Concerns

There are four major biosafety threats in India:

1. Unforeseen infection of laboratory personnel or the accidental release of pathogens or other biological materials from designated laboratories, either due to negligence or poor understanding of biosafety protocols
2. Lack of proper certification and validation mechanisms for biosafety level 2 (BSL-2) labs that sometimes work with dangerous biorisk group 3 pathogens
3. Improper disposal of biological waste and animals used in drug testing and clinical trials
4. Unintended consequences of the deliberate release of genetically modified organisms in the environment

Several scientific, academic, and industry experts stress that personnel in some of the laboratories might have a poor understanding of the prescribed laboratory procedures and/or may be inadequately trained to follow them. This can result in ignorant mishandling of pathogens, cross-contamination of samples, inadequate oversight in a laboratory, or uncontrolled experiments.[22]

Several scientists in India note that by improperly handling a live attenuated strain of virus that is being used to develop a vaccine, for example, laboratory personnel could unintentionally make the pathogen more virulent. This could either lead to an unforeseen infection of the personnel or their local communities, or even a pandemic.

These risks are not unique to India. In 2001 in Australia, for example, scientists hoping to render a mouse infertile instead accidentally created a lethal mousepox virus.[23] In the Soviet Union in 1979, anthrax spores were accidentally released from a Soviet military microbiology facility, causing livestock deaths and a few human fatalities.[24] Almost seventy-five scientists from the U.S. Centers for Disease Control and Prevention (CDC) were exposed to anthrax because researchers failed to kill the bacteria and accidentally shipped live strains to other CDC labs that were not equipped to handle them.[25] In another incident involving the CDC, a scientist cross-contaminated a benign strain of bird flu virus with a deadly bird flu strain, causing unintentional death of chickens, though it did not result in any human infection.[26] These episodes demonstrate why layers of safety procedures and physical protection are necessary. Reviewing some of them, a few scientific and industry experts in India highlight that the absence of mechanisms to certify that all relevant laboratories are actually implementing safety standards for facilities, personnel training, and operations might lead to similar accidents in India in the future.

Moreover, multiple laboratories with different BSLs have been set up by the network established under the Indian Council of Medical Research (ICMR) across the country to deal with pathogens relevant to public health.[27] Although a Department of Biotechnology (DBT) memorandum has introduced an application form to make certification and validation of BSL-3 and BSL-4 labs by the Review Committee on Genetic Manipulation mandatory,[28] experts in India worry about the lack of national guidelines and absence of any accredited government or private agency for the certification and validation of BSL-2 labs, which are widely distributed all over the country.[29] This is important because some of the BSL-2 labs sometimes work with biorisk group 3 pathogens, thereby raising safety concerns. Based on the objective of the laboratory, certification includes physical inspection of the facility to ensure that the building and infrastructure meet the design criteria and the basic requirements of protecting people and the environment from infectious agents. Validation, on the other hand, is necessary to review that the prescribed processes and procedures are followed within the laboratory. This includes having standard operating protocols and a training record of personnel in the laboratory. Certification and validation, according to experts, is necessary to ensure basic minimum standards are promoted and implemented to avoid unintentional exposure to high-risk pathogens.[30] Scientists also emphasize that without proper disinfection, disposal of biomedical waste, including animals used for clinical and drug trials, is another serious biosafety hazard that might have ramifications for public health.[31] Large numbers of coronavirus patients all over the world have produced garbage contaminated with bodily fluids and other infectious material. Maharashtra, a state in central India, for example, observed maximum coronavirus cases in the country, generating an average of 1,500 kilograms of coronavirus-contaminated waste per day. According to civic bodies in the state, improper segregation of waste and inadequate equipment provided to garbage collectors increased the risk of transmission.[32]

In addition to the biosafety of laboratory operations, participants in this project have also expressed concern about safety outside the laboratory. Genetically engineered organisms could be introduced for purposes such as mosquito control, agriculture, environmental remediation, biofuels, and medications. These experiments or applications, according to some experts in India, raise the possibility of unintentional interaction with naturally occurring organisms, which if not adequately addressed and monitored, could lead to unintended consequences. Despite these concerns, some scientists emphasize the importance of genetically engineered organisms in reducing India's vector-borne disease burden.[33]

Biosecurity Concerns

The four major biosecurity threats relevant to the Indian context are:

1. Intentional release of invasive pests or pathogens to disrupt India's agricultural supply chain
2. Deliberate introduction of naturally occurring infectious disease-causing organisms, such as anthrax or coronavirus, by nefarious actors or hostile states to cause human infections
3. Synthetic creation of dangerous organisms from scratch, either by using genomic information available online or acquiring information through unauthorized means for nonlegitimate use
4. Vulnerability to cross-border infections

Most experts in India acknowledge the value of biotechnology applications to improve the yield and nutritional quality of crops and to boost their resistance to diseases and drought.[34] Naturally evolving pests and plant pathogens may be extremely invasive and costly to Indian agriculture. They can reduce crop production as well as negatively influence international trade. For example, the European Union in 2014 temporarily banned the import of Alphonso mangoes and a few vegetables from India after the consignment was found to be contaminated by pests—a potential threat to the union's salad crop industry and to Indian agricultural exports.[35] Similarly, accidental introduction of blight-causing fungus from Asia led to the loss of American chestnut trees in the eastern United States.[36]

Some experts in India therefore worry that actors with nefarious intentions might deliberately release naturally occurring invasive pathogens or synthetically create pathogens or pests to target the agricultural supply chain.[37] Individuals, businesses, terrorists, or hostile states could seek to bypass or break rules for a variety of reasons. Some might seek profit from more productive crops or livestock. Terrorists could seek to create panic and distrust within the society by introducing or claiming to introduce infectious disease into livestock. An enemy state could seek to impair military responses, paralyze government functioning, and decimate the economy.

Several experts in India also worry that nefarious actors could release naturally occurring known pathogens that have the capacity to cause widespread harm, such as anthrax or coronavirus. To influence election results in the U.S. state of Oregon, the Rajneesh group deliberately contaminated salad with the naturally occurring *Salmonella* bacteria, to reduce voter turnout on election day,[38] and the *Bacillus anthracis* bacteria strain, isolated from an infected cow in Texas decades earlier, was used for the anthrax attack in 2001 that targeted prominent U.S. senators and media outlets, infecting seventeen Americans and killing five individuals.[39] These real-world examples point to the fact that the development of biological weapons does not necessarily require genetic engineering.

More sophisticated malicious actors—both inside and outside the lab—could take advantage of genomic data that is now online and new and inexpensive synthetic biology tools to engineer deadly pathogens in a lab. Even for the information that is not available publicly, these actors can compromise the information system to gain unauthorized access to confidential genomic information. Thus, as one former government official emphasized, access to a pathogen's culture is no longer a precondition to develop biological weapons.[40] Custom-made genes can now be ordered online to produce drugs, vaccines, or other disease therapies. For example, do-it-yourself biologists, a group of amateurs who conduct biotechnology research outside a formal institutional setup, teamed up online to create coronavirus test kits and vaccines.[41] Even though do-it-yourself biologists are independent researchers not linked to formal institutions, India does not have any policy to regulate them, thereby raising both safety and security concerns.[42] Moreover, synthetic biology allows actors to develop pathogens from scratch in the lab. Large strands of deoxyribonucleic acid (DNA) can be created artificially, with the cost of DNA synthesis dropping from a dollar to less than ten cents per base pair in the last decade.[43] Actors with nefarious intentions could order custom-made DNA strands online to create dangerous pathogens with enhanced virulence, transmissibility, and/or resistance to therapeutic interventions.

Individuals and groups have demonstrated intentions to get involved in such activities. A senior biodefense researcher in the United States was believed to have mailed anthrax—obtained from a government lab—in letters that killed five people and infected seventeen others in 2001.[44] A laboratory technician in the United States was charged in 1998 for stockpiling plague and anthrax and conspiring to use it as a weapon.[45] Al-Qaeda reportedly made repeated attempts to acquire biological weapons,[46] and operatives from the self-proclaimed Islamic State are known to have accessed information to weaponize pathogens.[47] It is reasonable to assume that other such cases have been intercepted by various countries' intelligence and security services without publicity.

Although advances in biosciences and technology can help contain and eradicate naturally occurring outbreaks, experts in India worry that since pathogens responsible for such infections are freely available in nature and the tools and technologies needed to manipulate them are easily accessible, developments in technology can lead to purposeful weaponization of such diseases. Not all pathogens have this versatile nature, and it requires tacit knowledge to weaponize them; for this reason, some government officials believe that it is more difficult than it might seem for an adversary to create and/or steal a bioagent with bioweapon potential and use it in devastating ways.

As pathogens do not respect national borders, some experts emphasize that they can be intentionally or unintentionally carried across borders. India shares porous borders with most of its neighboring states, so it is vulnerable and needs to secure its frontiers as much as possible and check travel and trade to prevent the proliferation of biological weapons.[48] Recently, the director general of the police in Jammu and Kashmir claimed that Pakistan is pushing coronavirus-positive militants into Kashmir to spread the disease throughout the valley.[49] Although the government in Pakistan has rebutted this claim, it indicates India's vulnerability to cross-border infections.[50]

Risks of Opportunity Costs

Discussions of biological risk naturally focus on the dangers of human action or inaction, purposeful or accidental. This is because human actions are controllable in ways that natural mutations of organisms are not. Human beings also fear losing things they already have more than they fear not gaining things in the future.[51] From the perspective of societal well-being, then, some stakeholders in India see potential risks in restricting or burdening research, development, and applications of bioscience and technology without adequate evidence that the social benefits of such restrictions outweigh both their direct and opportunity costs. The two major areas that have faced strong public resistance in India are vaccines and genetically modified food/crops.

The World Health Organization (WHO) notes that fear of vaccine side effects has led to vaccine hesitancy.[52] Although there is no organized antivaccination campaign, resistance to vaccines prevails in some parts of India, as concluded by a study that was commissioned after the reemergence of eradicated vaccine-preventable diseases such as diphtheria. The main reasons behind this growing trend are often the lack of trust in the government, fear of safety and efficacy of vaccines influenced by rumors, and poor communication regarding the benefits of vaccines.[53] For example, resistance to the polio vaccine in some parts of North India was spurred by religious suspicions that the immunization drive was part of the government's agenda to control the high birth rate among the Muslim population. Similar resistance was observed with the human papillomavirus vaccine after rumors connected the vaccination to death among girls.[54] Although dubious information is mostly spread by people with little or no scientific background, virus conspiracy theories are sometimes spurred by discredited researchers, as observed during the coronavirus pandemic.[55] Such uncorroborated rumors regarding vaccines can sometimes jeopardize public health efforts to fight vaccine-preventable infectious diseases.

Similarly, people in India are more alarmed by the possibility that modifying plant genetics will accidentally reduce harvests or raise the costs of seeds for farmers than they are by the possibility that prohibiting such modifications will deprive them of faster growth in the future.

Experts have highlighted that no restrictions exist for plants or other organisms modified through traditional techniques. They added that traditional biotechnology techniques such as selective breeding, hybridization, and fermentation have been used to modify living plants for improved yield or enhanced nutritional value. In addition to producing the desired product, these traditional breeding techniques can lead to random mutations. With improvements in knowledge about the role of individual plant genes, modern biotechnology techniques can be used to edit the specific gene to produce a desired variety, thereby reducing the possibility of off-target effects.[56]

Despite widely documented economic, health, and environmental benefits of genetically modified crops, public backlash against these varieties, irrespective of their validity, has created a difficult political atmosphere in India where stringent measures have been developed to restrict transgenic research, field trials, and commercial product release.

Some Indian experts have witnessed mixed and varied reactions from the public and the government, depending on the product in question. They believe that it is not the technology but the way the product is perceived by the public that affects whether a product receives government backing. The primary example they used to highlight this was the contrasting treatment of genetically modified cotton and brinjal. The former is a cash crop widely accepted and in use, while the latter, a food crop, is still facing resistance to its introduction to the market.[57]

To address public concerns regarding biotechnology-derived products, the Indian government adopted a multilayered regulatory system to examine the safety of biotechnology products before their commercialization. However, the hierarchical setup is often plagued by coordination issues between various bodies at different levels. Bureaucratic delays in approving products sometimes lead to regulatory uncertainties. As a result, the private sector and the venture-capitalist community limit their investment in the biotechnology sector, constricting the scope of research in India.

The Way Forward

First and foremost, it is important for India to periodically update the three categories of risks mentioned above. Once risk cataloging is complete, the next step is to identify and assess regulations that deal with each of these different categories of risk. For the first category—diseases occurring because of natural mutations—it is important to understand the functioning of India's public health infrastructure to identify gaps and limitations in the existing system. For risks emerging either from lab accidents or deliberate release, it is important to evaluate existing regulations against recent developments in biotechnology. Next, it is important to identify stakeholders that would be involved in dealing with each of these categories of risks. In addition to assessing regulations and identifying stakeholders, it is imperative for India to invest in scientific communication strategies to build a bridge between the scientific community and Indian society. This would help in fighting misinformation and would also help address public resistance to biotechnology-derived products, thereby spurring innovation.

Assessing India's Capacity to Deal with Naturally Occurring Diseases

As discussed above, biothreats can emerge from natural events, human accident, and/or malicious human action. This chapter focuses on India's capacity to tackle the first category of risk—the ones emerging from natural sources.

In case of any disease outbreak, the central government issues specific notifications and guidelines to control and monitor the disease and has in several instances set up new ad hoc response committees. Like any naturally occurring biological disaster, accidental release or intentional attack also affects a country's health infrastructure. Case studies of India's responses to naturally occurring outbreaks can foster understanding of the health infrastructure.

India's Performance in Tackling Biological Emergencies: Five Case Studies

To assess India's capacity to handle human-induced biological threats, it is important to understand India's responses to naturally occurring infections. The five case studies discussed in this section highlight India's response toward agricultural infestations, such as the recently observed locust attacks; diseases that affect animals and have not yet infected humans, such as avian influenza; and zoonotic infections that have jumped from animals to humans, such as the Kyasanur Forest Disease (KFD), Nipah virus disease, and more recently COVID-19.

How Did India Respond to Kyasanur Forest Disease?

In 1957, India adopted an interdisciplinary approach to tackle an outbreak of KFD, a tick-borne viral hemorrhagic fever. The disease, commonly called the monkey fever, primarily infects primates and spreads to humans through ticks. The Rockefeller Foundation extended financial and technical support, including laboratory facilities to investigate the disease outbreak. Scientific expertise was provided by researchers at the National Institute of Virology, a lab set up by the Rockefeller Foundation (now under the ICMR). In addition, WHO supported an ornithologist who started the Bird Migration Project under the Bombay Natural History Society, which traces the origins and transmission of KFD.[58]

Epidemiological investigation of KFD was one of the early successful examples of the multidisciplinary approach needed to tackle zoonotic infections.[59] However, no detailed studies have been carried out on any zoonotic pathogen in India, including the KFD virus, especially after the Rockefeller Foundation pulled its support in the 1970s.[60] Even though most experts in India speculate that the next pandemic may also move from animals to humans, India has developed a more reactive approach to disease outbreaks rather than developing measures to prevent such infections. Independent ministries that are responsible for agriculture, animal husbandry, environment, and public health often work in silos and do not coordinate with each other. This leads to inadequate information sharing, which results in a weak surveillance mechanism needed for timely diagnosis of zoonotic infections. It is therefore important to break the silos, develop robust coordination mechanisms for better information sharing, and develop a strong disease surveillance mechanism for early detection of diseases.

How Did India Respond to the Avian Influenza?

A high-density poultry population combined with the illegal movement of poultry and poultry products makes India vulnerable to avian influenza, a viral disease that affects both wild and domestic birds alike but very rarely infects humans. India has so far reported avian influenza, commonly called bird flu, almost every year, starting from 2005 until 2015. Fresh cases were again reported in 2020. Although state governments have been successful in minimizing human infections so far, the response strategy mostly involves the mass culling of birds, as is done in other Asian nations. This policy response, however, entails huge financial cost for farmers and the poultry industry in general, without appropriate compensation. Most of these bird flu cases are restricted to rural areas; as a consequence, the lack of awareness along with the huge financial burden on farmers sometimes lead to underreporting of cases.[61] It is therefore important to strengthen India's disease surveillance mechanism that monitors and reports diseases in animals. Early detection of diseases in animals might help contain the spread of zoonotic infections, one of the major biological threats in India.

How Did India Respond to the Nipah Virus Outbreak in Kerala?

Nipah, a zoonotic virus that moved from bats to humans, killed seventeen people in the southwestern state of Kerala in 2018. Kerala's State Surveillance Unit of the Integrated Disease Surveillance Programme (IDSP), an initiative led by the Ministry of Health and Family Welfare (MOHFW), reported the Nipah outbreak to the Central State Surveillance Unit of the IDSP. The Manipal Centre for Virus Research (now Manipal Institute of Virology [MIV]) at the Manipal Academy of Higher Education confirmed the Nipah outbreak, which was later reconfirmed by the National Institute of Virology in Pune.[62]

Following the confirmation of the outbreak, a multidisciplinary team from the National Centre for Disease Control (NCDC) was sent to Kerala to work locally with the state government to investigate and respond to the infection. The team was headed by the director of NCDC, with representatives from the National Institute of Virology; All India Institute of Medical Sciences; Ram Manohar Lohia Hospital; the Department of Animal Husbandry, Dairy, and Fisheries; and the Division of Emergency Medical Relief. This team was sent to support the local authorities to train medical personnel to detect and isolate active cases, trace their contacts, provide treatment, discard hospital waste, and safely dispose of the deceased. NCDC also activated the Strategic Health Operations Centre to monitor the outbreak and issue daily situation reports. In addition, WHO also provided support in terms of technical materials and guidance on the Nipah virus to both the MOHFW and the state health authorities. These coordinated and collaborative efforts of the central and the state government, along with WHO's technical support, led to an effective containment of the outbreak.[63]

Despite the successful containment of the outbreak, the central government determined that the lab that detected Nipah was underqualified, so it was dropped from a central list of virus research and diagnostic labs in 2019. The Ministry of Home Affairs (MHA) suspended the lab's account under the 2010 Foreign Contribution Regulation Act (FCRA), which regulates foreign donations based on national security implications, for collaborating with the U.S. CDC for its research on the Nipah virus. Some government officials noted that "the lab was being used to map the Nipah virus, which can be used to develop a vaccine, the intellectual property right of which will not be with India. Importantly, understanding how the human body reacted to the virus will also produce a more virulent form of virus for biological warfare."[64] The laboratory, however, issued a clarification, emphasizing that the CDC was only involved in training to detect Nipah and was never involved in the actual Nipah investigation. Detection of the outbreak was exclusively funded and carried out in close collaboration with the ICMR. Samples for virus isolation were transferred to the National Institute of Virology. The statement issued by the laboratory further clarified that "the research at MIV was not connected to any vaccine development and no intellectual property right was generated or transferred."[65] Given that government bodies at the central level were aware of the research, including MIV's capacity to detect Nipah, the Health Ministry's sudden allegation and withdrawal of the lab's FCRA license undermines the capacity of the lab and creates disincentives for other labs.

Not only does it undermine the potential of private labs, it also threatens prospects for global cooperation needed to tackle biothreats. Because biological threats, especially infectious diseases, are transnational in nature and cannot be tackled individually by national governments, international cooperation is both necessary and important in all facets of disease control—prevention, detection, warning, response, and the development of drugs and vaccines. While commercial considerations and debates around intellectual property are important, India's biosecurity policy should foster global cooperation to advance knowledge and strengthen infrastructure to tackle biological threats.

How Did India Respond to Locust Attacks?

Contrary to previous locust infestations that were localized to the northwestern states of Rajasthan and Gujarat, a latest locust attack that started in April 2020, much ahead of the normal July to October interval, damaged crops in the states of Gujarat, Madhya Pradesh, Maharashtra, Rajasthan, and Uttar Pradesh. Because winter crops were harvested and monsoon crops were yet to be sown, locusts in search of fodder moved deeper into India, affecting new states. Moreover, strong westerly winds from the Cyclone Amphan in the Bay of Bengal also influenced their widespread movement.[66] Pandemic-induced economic slowdown made it difficult for the Indian government to tackle the invasion in a timely manner.

Locusts are transboundary pests that damage crops and threaten food security. Repeated locust infestations in India led to the 1939 establishment of Locust Warning Organisation, which in 1946 was integrated with the Directorate of Plant Protection Quarantine and Storage under the Ministry of Agriculture and Farmers' Welfare.[67] To combat the locust invasion, the organization worked closely with the MHA, Ministry of Civil Aviation, Ministry of External Affairs (MEA), Ministry of Defence, Ministry of Communications, relevant state departments, and other pertinent stakeholders, including farmers. At an international level, the Locust Warning Organisation coordinated with the Food and Agricultural Organization, a United Nations body that performs monitoring of possible locust outbreaks and issues timely warnings.[68]

Some states noted this locust invasion as "mid-season adversity" under the government-sponsored crop insurance program known as Pradhan Mantri Fasal Bima Yojana, which processes insurance claims for farmers' losses.[69] Although part of the claim is disbursed based on a joint survey conducted by the concerned insurance company and the state government, the remaining payment depends on the result of crop-cutting experiments that map damage from locusts at a village level. However, the methodology to conduct such experiments is skewed and depends on random selection of any four fields in the village. Because locusts do not affect all fields uniformly, random sampling sometimes does injustice to farmers, thereby causing financial strain.[70] Moreover, pesticides used to limit the spread of locusts also adversely impact food crops, causing further financial troubles for farmers.[71]

Given the impact of locusts on food security and agricultural supply chain, scientists all over the world are trying to genetically engineer locusts to control their spread.[72] However, these experiments raise security concerns because the same techniques can be used to modify locusts or other insects in ways that would make it harder to control them.[73] For example, scientific experts have raised concerns around the U.S. Insect Allies program that uses insects to spread viruses to create genetically engineered crops. While the program intends to develop healthier crops, some bioethicists and scientists believe that this technology poses serious safety and security risks.[74] It is therefore important to strengthen India's capacity to prevent, detect, and respond to natural infestations to better prepare for man-made invasions.

How Is India Responding to COVID-19?

India observed its first few COVID-19 cases almost a month after Chinese authorities officially reported the coronavirus outbreak to the WHO. The first three cases were reported in Kerala from January 30 to February 3, 2020, among students who came back from Wuhan, the Chinese city where the initial outbreak took place.[75] Because health is a state subject in India, the Kerala government declared COVID-19 a state disaster as soon as it reported its third case. A multidisciplinary state response team was composed of experts in epidemiology, community medicine, infectious diseases, pediatrics, drug control, and food safety. This team was supported by other state-level teams to enhance the surveillance of the outbreak, train medical personnel, and strengthen the state's public health infrastructure. In addition to the state response team, rapid response teams were also constituted at the district level to facilitate micro-level planning.[76]

A month later, in the first week of March, India witnessed a sudden spike in the number of coronavirus cases across the country. Recognizing the severity of the situation, the Prime Minister's Office (PMO) took charge. The response was guided by a team of more than thirty health experts and scientists who worked relentlessly to fight the contagion. This team was divided into two groups—one comprising health professionals and the other consisting of researchers from the ICMR and secretaries from the DBT, the Department of Science and Technology (DST), the Council of Scientific and Industrial Research (CSIR), and the Defence Research and Development Organisation.[77] Based on their recommendations, the government imposed severe travel restrictions to limit cross-border movement of people. In addition, all states and union territories were advised to invoke section 2 of the Epidemic Diseases Act of 1897 (EDA), which allowed them to take preventive measures to contain the spread of coronavirus in their respective states.

While measures taken by most states and union territories moved in the right direction, lack of uniformity across multiple states led to complications and impediments. To overcome this, the Indian government declared COVID-19 a notified disaster under the 2005 Disaster Management Act.[78] As a result, Prime Minister Narendra Modi, who is also the chairperson of the NDMA, announced a nationwide lockdown, starting from late March through May 2020. Most states followed the central government's guidelines and directives to tackle the pandemic, but some states did not comply with the central government–issued advisories. This was caused by ambiguity in the constitutional structure, where health is classified as a state subject and disaster management, though not explicitly stated, falls under the concurrent list. While only state governments have the power to create laws for subjects falling under the state list, both central and state governments have powers over subjects mentioned in the concurrent list, with the center's decisions prevailing in case of differences. Because the central government declared COVID-19 a disaster, it gave both central and state governments the authority to draft rules and regulations to tackle the pandemic, with the central government playing an upper hand. Some states, however, argued that because health is a state subject, the states should have more flexibility in tackling the pandemic. This ambiguous nature of center-state relations complicated India's fight to contain the pandemic.[79]

Recognizing the need to ramp up domestic capacity to strengthen India's response to COVID-19, a task force was set up under DST with representatives from CSIR, DBT, DST, and ICMR; the Ministry of Electronics and Information Technology; Atal Innovation Mission; the Ministry of Micro, Small, and Medium Enterprises; Startup India; and the All India Council for Technical

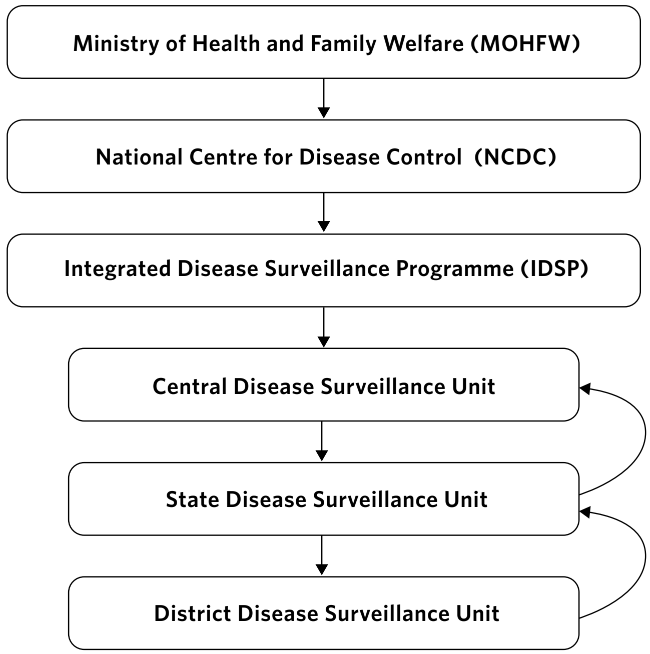
Education. This group tried to identify startups with market-ready solutions to develop affordable testing kits and to scale up manufacturing of equipment supplies such as masks, protective gear, sanitizers, ventilators, and respirators. The task force was also constituted to identify data-mapping solutions to develop an effective surveillance for coronavirus in India.[80] Taking lessons from other countries, India also developed a contact-tracing app, called Aarogya Setu, to detect, trace, and isolate people who came in contact with COVID-19 patients.

Although the government took strict measures to implement social distancing, the country did not have adequate capacity to handle the pandemic.[81] Personal protective equipment (PPE) for frontline medical workers was not easily accessible. Respirators, ventilators, and other equipment required to set up isolation wards were available in limited quantity. Diagnostic kits were also not available in sufficient quantity. In addition, the former Indian Health Secretary Preeti Sudan wrote a letter during the coronavirus pandemic stating that India needs to hire epidemiologists on a "war footing" because they are a "critical element in the effective management of the pandemics like COVID-19."[82] Hiring epidemiologists and microbiologists in the middle of the coronavirus pandemic indicates the shortage of trained personnel in India to fight the disease.[83] Moreover, an academic expert in India highlighted that most scientific institutions in India prefer to recruit personnel who have received their degrees from abroad rather than hiring people who have been trained locally and have a better understanding of the Indian scientific and administrative environment. Such hires unfortunately lack an initial vision about the crisis from an Indian perspective and take time to adjust to the local system, which creates a longer lag phase and loss of valuable time, a crucial element during health emergencies.[84]

The above case studies clearly underscore India's reactive approach toward infectious disease outbreaks. Rather than using the time between two outbreaks to develop national legislation to tackle infectious diseases, India mostly relies on ad hoc notifications and guidelines. Invoking the 2005 Disaster Management Act to tackle the COVID-19 crisis when this enactment is not geared toward handling epidemics in the first place highlights the poor state of India's preparedness in combating infectious diseases.[85]

Complicating matters further, the Modi government reconstituted the NDMA and downsized it. The vice-chairman post was downgraded from Union Cabinet Minister to Cabinet Secretary, and members' ranks were changed from Union Minister of State to Union Secretary of the Union government. According to the former vice chairman of the NDMA, this has weakened the organization, and "there will be difficulty in coordination with the states in this regard. If a Vice-Chairman of Cabinet Minister status goes to a state, he will be meeting the Chief Minister more easily than somebody of Cabinet Secretary level. These are issues with protocol also."[86]

FIGURE 1
Disease Surveillance Model in India



Gaps in the Existing Capacity to Tackle Naturally Occurring Diseases

Capabilities, like the ones discussed in the previous section for tackling threats that naturally occur, would also be required to deal with human-induced outbreaks resulting from safety or security lapses. However, India's responses to naturally occurring disease threats have exposed its poor disease surveillance network, inadequate coordination between ministries needed to prevent zoonotic infections, lack of a nationwide policy on biological disasters, rickety public health infrastructure, and minimal investment in research, all of which will be elaborated below.

State of Disease Surveillance in India

For rapid surveillance and response to disease outbreaks, the NCDC, under the Indian MOHFW, set up an IDSP. The IDSP is a decentralized surveillance system that establishes surveillance committees at the central, state, and district level (see figure 1). The state surveillance committee is set up under the secretary of health; the district surveillance committee is under the chairmanship of the district collector or district magistrate. Information is relayed from the district unit to the state unit to the central surveillance unit on a weekly basis using an IDSP portal. This weekly data gives insights on the disease trends and the seasonality of infections. In addition to these surveillance units, IDSP has also established multidisciplinary rapid response teams at the district level for early detection and containment of infectious disease outbreaks.[87]

Some public health experts in India have, however, raised serious concerns about the infrastructure and the human resource capabilities needed to accurately detect and report an outbreak. In addition to the IDSP, the Indian Health Ministry, under the National Health Mission, runs several other disease surveillance programs such as the National Vector-Borne Disease Control Programme, Revised National Tuberculosis Programme, and National Leprosy Eradication Programme.[88] Moreover, there are additional surveillance programs such as the National Polio Surveillance Project (NPSP) that run beyond the ones included under the mission. These organizations sometimes collect data for the same disease, but often not with similar standards and practice. For example, both IDSP and NPSP record data for polio incidences in India. They use differing case definitions with little or no coordination (and often bureaucratic turf battles), which leads to different disease numbers being reported under different programs.[89]

Moreover, all these surveillance programs only mandate a few institutions, mostly government affiliated, to report disease outbreaks. This makes it difficult for organizations excluded from this network to report diseases. Limited involvement of private labs and practitioners in the disease reporting network leads to severe underreporting of disease outbreaks.[90]

In addition to disease surveillance programs that gather information on human infections, India runs parallel surveillance programs that collect data for livestock diseases. The National Animal Disease Reporting System, a computerized network set up under the Department of Animal Husbandry, Dairy, and Fisheries (within the Ministry of Fisheries, Animal Husbandry, and Dairying), collects and collates animal health information at the block, district, and state level.[91] The National Animal Disease Referral Expert System is another web-based interactive livestock disease database that operates under the Indian Council of Agricultural Research, a body under the Ministry of Agriculture and Farmers' Welfare.[92]

These multiple disease surveillance programs, set up under different ministries, work in silos and sometimes collect data for the same disease with different standards. This leads to the collection of redundant data, resulting in a convoluted, uncoordinated, and ineffective disease-mapping mechanism.

Status of Policy on Biological Disasters

India's response to biological disasters, both natural and man-made, is specified under the non–legally binding guidelines for managing biological disasters, issued by the NDMA in 2008. The guidelines have clearly outlined the role of separate ministries in the wake of biological emergencies. MOHFW is responsible for handling naturally occurring biological disasters. The MHA is in charge of events arising through bioterrorism; the Ministry of Defence is responsible for events related to biological warfare; and the Ministry of Agriculture and Farmers' Welfare has been put in charge of animal health and events related to agroterrorism. In addition, the guidelines mention the role of the community, medical care professionals, public health personnel, and veterinary professionals in preventing, responding, and mitigating the impact of any biological emergency.

Although the guidelines mentioned that the EDA should be repealed and a national-level policy for biological disaster should be framed, there is still no formal legislation for biological disasters. Because of the absence of a nationwide policy, many states have developed their own public health legislations to deal with disease outbreaks.[93]

The NCDC and the Directorate General of Health Services jointly prepared a 2017 public health bill, which was introduced in the parliament as the first step toward a formal legislation. The 2017 bill, which is now lapsed, was an attempt to replace the archaic 1897 EDA. Unlike the EDA, this proposed bill clearly defined an epidemic and identified thirty-five epidemic-prone diseases and thirty-six bioterrorism agents, high-priority pathogens that pose public health risk.[94]

This bill, however, has certain issues: it is more reactive than proactive, the measures included in the bill are insufficient and lack clarity, and it does not address the balance between public health and human rights.

Even though the NDMA's 2008 guidelines for biological disasters mention preventive options such as immunization of first responders or stockpiling of medical countermeasures, the new public health bill is not comprehensive enough and does not cover any prophylactic procedures. It only specifies scientific and containment measures that must be followed once the outbreak has happened. Key themes such as disease surveillance and identification of disease hotspots, development of vaccines, establishment of fully equipped hospitals, training for medical professionals, and coordination and collaboration among scientists and the biomedical industry appear to be missing in this proposed legislation. Besides this, the bill has not addressed the human resource component needed to contain disease outbreaks. For example, training of public health professionals, epidemiologists, and other frontline workers seem to be notably absent from the bill. Moreover, it fails to address budgetary challenges needed to create a robust public health infrastructure that is capable of tackling epidemics, bioterrorism, and biological disasters.

Although the bill empowers local governments to take measures to contain various diseases, it does not clearly explain the organizational structure that will operate in case of an emergency. Even though the bill mentions both natural and man-made biological threats, it has not clarified whether the setup would be operational under the guidelines issued by the NDMA or if a new authority will be established under the newly proposed bill.

In addition, some experts emphasize that the bill violates basic human rights and gives enormous powers to medical officers to inspect any location, isolate patients, limit their movement, conduct medical investigations, and treat them irrespective of their consent.[95] To get a glimpse of what these powers might look like, consider a 2017 example where the Tamil Nadu state health department, under the Tamil Nadu Public Health Act of 1939, tried to make the measles-rubella vaccination mandatory for all children under the age of 15 without parental consent.[96] Privacy concerns were also raised during the coronavirus pandemic when the Indian government deployed the Aarogya Setu contact-tracing app, meant to detect, isolate, and treat contacts of COVID-19-patients. Anyone using any public transport had to have the app installed on their phone, although it was not mandatory to download the app otherwise. Some data experts in India raised apprehensions regarding the privacy and consent framework of the app.[97] The public health bill, if it is enacted, would need to be modified to include measures to prepare for a biological emergency and introduce provisions that balance public health and human rights.

State of Public Health Infrastructure

Even though the MOHFW in 2016 conceded that India's public expenditure on health as a percentage of gross domestic product (GDP) is far lower than countries classified as "poorest" in the world,[98] the latest financial budget has increased the expenditure only marginally from 1.5 percent to 1.6 percent of the GDP.[99] According to a few public health professionals, the Indian government's plan to increase its public health expenditure to 2.5 percent of GDP by 2025 looks disappointing when the global average will be about 6 percent.[100]

Given India's minimal investment in public health, the coronavirus pandemic exposed the bleak reality that India only has 8.5 beds and eight physicians per million people, with even lower numbers reported in rural areas.[101] Although the WHO recommends a ratio of 1 doctor to 1,000 people, a recent study showed that India only has one government doctor per 10,819 people and one nurse per 483 patients, highlighting a deficit of 600,000 doctors and almost 2 million nurses.[102]

On top of this personnel deficit, healthcare workers tested positive for coronavirus, owing to the lack of protective health supplies such as masks, gloves, and gowns. The lack of healthcare workers and shortage of PPE kits both seem to have jeopardized India's efforts to respond to the coronavirus disease. To divert all available public health resources to combat the pandemic, most hospitals in India closed their outpatient departments, thereby creating a huge problem for non-COVID-19 patients. As India has limited beds and facilities, several reports noted that patients with surgical procedures, routine checkups, and follow-up visits were deferred to avoid extra hospitalizations.[103] Some states also halted immunization and reproductive health outreach to free up community healthcare workers for COVID-19-related surveillance and contact tracing. As a senior official in the

Health Ministry reportedly noted, India, with its high disease burden, would fare best by avoiding a situation like the Democratic Republic of the Congo was in after the Ebola crisis, where more people died of tuberculosis, malaria, and measles than from Ebola.[104]

State of Expenditure on Research

India's research and development spending fluctuates between 0.7 to 0.9 percent of its GDP, much lower than other countries like Brazil (1.3 percent), Canada (1.6 percent), the United Kingdom (1.7 percent), China (2.1 percent), France (2.2 percent), the United States (2.8 percent), Germany (3 percent), Japan (3.2 percent), South Korea (4.5 percent), and Israel (4.6 percent).[105] Among various scientific departments, the Department of Health Research, set up under the MOHFW, received only seven crore rupees for the development of tools and technologies needed to combat disease outbreaks such as the new coronavirus. Furthermore, the department's apex research organization, the ICMR, which is responsible for setting up diagnostic laboratories across India, has always faced budgetary constraints. In 2016, the then director general of ICMR reported that although ICMR had asked for 10,000 crores for a five-year plan from 2012 to 2017, only 50 percent of the amount was sanctioned.[106] Similar reports highlighted that in 2020, when ICMR budgeted 2,300 crores for operations, it was allocated 1,795 crores.[107] This mismatch between demanded and allocated funds, along with minimal investment in research to set up diagnostic labs, could be one of the many factors that contributed to India's abysmally low testing numbers toward the beginning of the coronavirus pandemic. Because the research pipeline is not adequately developed, the country also struggled to ramp up domestic production of diagnostic kits. Several experts noted that this budget crunch might be detrimental to research and might impact innovation in public health.[108]

The Way Forward

Repeated outbreaks of infectious diseases along with a huge burden of noncommunicable diseases should be a warning for policymakers in India to invest more in public health, build capacity to face a biological emergency, strengthen its disease surveillance mechanism, enhance interministerial collaboration to avoid bureaucratic bottlenecks, and spend time to develop a strategy to respond to disease outbreaks (see box 1).

Assessing India's Biosafety Landscape

To deal with the second category of risks (that is, risks emerging from human accidents), India has developed a series of biosafety guidelines and related rules and adherences to monitor and address the safety of research and its applications.

BOX 1

Ways to Strengthen India's Public Health Capacity

The following are a set of recommendations for tackling diseases that emerge from natural sources:

1. Restrengthen the National Disaster Management Authority (NDMA) to reduce bureaucratic challenges and to coordinate effective prevention and response strategies needed to tackle biological emergencies.
2. Create a new nodal agency such as the Office of Biological Threats Preparedness and Response (BTPR) under the NDMA to coordinate the policy responses during biological emergencies.
3. Invest in basic healthcare, strong disease surveillance mechanisms, and public health research, as well as work with state governments to improve public health infrastructure.
4. Introduce clearer and stronger incentives for personnel to identify and report disease outbreaks among plants, animals, and humans to strengthen the disease surveillance network.
5. Aggregate data obtained from different disease surveillance programs that collect data on plant, animal, and human health to get a holistic view and to detect outbreaks in a timely manner.
6. Develop reporting standards for common diseases to harmonize data collection from all organizations reporting disease outbreaks.
7. Involve private stakeholders in the disease surveillance programs for better and more expansive outreach.
8. Create an epidemiological model for diseases that considers the geographical location, demography, socioeconomic circumstances, and environmental conditions that are associated with disease occurrence.
9. Develop public-private collaboration and identify stakeholders in advance who can ramp up the manufacturing of products and services needed during a biological emergency.
10. Enhance interministerial collaboration to detect outbreaks, especially zoonotic infections, in a timely manner.
11. Divert more money and resources to research bodies such as the Indian Council of Medical Research (ICMR) and the Indian Council of Agricultural Research.
12. Conduct simulation exercises to train, monitor, and assess the capacity of India's emergency plans, procedures, and policies.

Biosafety seeks to keep laboratory workers and the surrounding environment physically safe from any unintentional exposure to dangerous or genetically engineered organisms. Personal protection such as laboratory coveralls and PPE to avoid accidental contact with blood, body fluids, and other potentially infectious material is necessary to ensure the safety of lab workers. Facility design and training to ensure safe handling of samples is important to reduce the possibilities of unintentional release of any organism into the environment.

Biosafety regulations and practices in India generally have three aims:

1. To prevent biological materials from escaping designated places in laboratories
2. To prevent laboratory workers from unintentional exposure
3. To prevent unintended consequences when genetically modified organisms are released purposefully into the environment

Existing Regulatory Framework

India's 1989 Rules for Manufacture, Use/Import/Export, and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells (commonly called Rules 1989), notified under the 1986 Environment Protection Act, focuses on maintaining biosafety for all biotechnological experiments. These rules are supported by a series of guidelines issued by the DBT.[109] These separate guidelines take into consideration the rapid pace of biotechnological advancements and the need to strengthen oversight for those involved in biotechnology research.

Under Rules 1989, DBT created the Review Committee on Genetic Manipulation (RCGM) to monitor the safety-related aspects of ongoing research projects or activities involving hazardous organisms. The RCGM includes representatives of DBT, the ICMR, the Indian Council of Agricultural Research, the Council of Scientific and Industrial Research, and other experts in their individual capacity. RCGM may appoint subgroups to assist RCGM on matters related to risk assessment and in reviewing existing and preparing new guidelines.[110]

In 2017, RCGM consolidated all existing guidelines issued by the DBT and released a new paper titled, Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment. These guidelines prescribe containment measures for storage, growth, research, manufacture, exchange, import, and export of genetically engineered and non–genetically engineered organisms (microorganisms, animals, plants, arthropods, and aquatic organisms) and products of such organisms. It provides clarity on biosafety requirements and recommendations for facility design, biosafety equipment, PPE, good laboratory practices, and waste management.[111]

TABLE 1

Competent Authorities Under Rules 1989

Competent Authorities	Role
Recombinant DNA Advisory Committee	Advisory
Institutional Biosafety Committee (IBSC) Review Committee on Genetic Manipulation (RCGM) Genetic Engineering Appraisal Committee (GEAC)	Regulatory/Approval
State Biotechnology Coordination Committee (SBCC) District Level Committee (DLC)	Monitoring

SOURCE: Ministry of Science and Technology, Department of Biotechnology, *Regulations and Guidelines for Recombinant DNA Research and Biocontainment 2017* (New Delhi: Government of India, 2017).

Rules 1989 assigns biosafety governance to two separate ministries—the Ministry of Science and Technology and the Ministry of Environment, Forest, and Climate Change (MOEFCC). These rules apply over three different phases—pre-research, research, and commercial release. RCGM oversees the research on genetically engineered organisms and permits small-scale field trials. The Genetic Engineering Appraisal Committee (GEAC), set up under MOEFCC, monitors deliberate and commercial release of genetically engineered organisms.

Six governmental bodies advise, oversee, and in some cases, monitor the implementation of regulations produced by the Ministries of Science and Technology and of Environment, Forest, and Climate Change (see table 1).

The Recombinant DNA Advisory Committee, constituted by the DBT, takes note of all national and international biotech developments and recommends suitable and appropriate safety regulations for India in recombinant research.

Institutional Biosafety Committees (IBSCs) are constituted by all centers engaged in genetic engineering research. They are the nodal points for implementing biosafety guidelines and for interaction within institutions. Based on internal deliberations, IBSCs notify the RCGM if the host institution has enough biosafety capacity and infrastructure to safely conduct the study, without any risks.

A RCGM constitutes a team with its own members (and sometimes even external experts) who periodically monitor the safety of ongoing research projects or activities involving hazardous microorganisms, genetically engineered organisms, and their products in the areas of human and animal healthcare, agriculture, industry, and environmental management.[112]

After the RCGM recommends product safety measures based on small-scale trials and preclinical data, GEAC approves activities involving the large-scale use of hazardous microorganisms and recombinant products in research and industrial production. GEAC also examines data from clinical trials with respect to living modified organisms and grants clearances pertaining to the discharge of genetically engineered organisms from labs and hospitals into the environment.

At the state level, the State Biotechnology Coordination Committee (SBCC) inspects, investigates, and takes punitive action in case of safety violations and on-site control measures to reduce the damage, if any, due to release of genetically engineered organisms.

District Level Committees (DLCs), headed by a district collector, monitor safety regulations in installations engaged in the use of genetically modified organisms and their applications in the environment.

In addition to these authorities, RCGM and GEAC sometimes constitute committees on a case-by-case basis with experts from different disciplines drawn from public-sector institutions. For agricultural products, the Indian Council of Agricultural Research is responsible for conducting biosafety analysis.[113] Specific to medicines, the Central Drugs Standard Control Organization, headed by the Drugs Controller General of India, is responsible for approving preclinical and clinical trials, new drug applications, and the importation of drugs.[114]

Gaps in the Existing Framework

Although India has multiple authorities set up at each step to ensure safety of biotechnological research, experts in India point out that illegal cultivation of genetically modified cotton and brinjal in different pockets of the country exposes the weak implementation of biosafety guidelines and limited communication with the society.[115] GEAC approved the commercial cultivation of genetically modified cotton in the southeastern state of Andhra Pradesh, despite the absence of SBCC and DLC monitors in the state. Field trials of this cotton in most areas were carried out without prior intimation from designated state authorities. These examples reveal poor coordination between central and state regulatory bodies and weak implementation of biosafety regulations.[116] Moreover, regulatory bodies at the state level do not have a meeting schedule, which sometimes results in approval delays for private-sector developers of transgenic crops.[117]

Distrust between the scientific community and regulatory bodies is another challenge that sometimes leads to delayed approvals. While scientists or researchers perform all the necessary safety tests before approaching regulatory authorities, the regulators, perhaps influenced by activist groups, perform additional safety tests that delay the clearance of such products. Whether such additional tests are necessary or not is often disputed. This regulatory uncertainty and the slow approval process create commercial risks that often result in limited monetary support from banks, private-sector developers, angel investors, and venture capitalists. As a result, government is the sole driver of research and innovation in the country. Unfortunately, most of this government funding is exhausted before products reach the market phase. This creates a huge gap between research and commercialization of products.

In 2013, the Ministry of Science and Technology introduced to Parliament the Biotechnology Regulatory Authority of India Bill, which has now lapsed.[118] The bill mandated the creation of a Biotechnology Regulatory Authority of India (BRAI) with the head office in the National Capital Region and the capacity to set up regional offices across the country, in concurrence with the central government. This authority was proposed to replace the GEAC and the RCGM and act as an independent statutory body related to all biosafety matters. BRAI would have had the power to regulate the research, transport, import, manufacture, and use of organisms to ensure human and animal health. The bill did a commendable job in making this authority the single nodal agency for international activities, monitoring, reviewing, and analyzing national and international policies that might affect the government's priorities in relation to the modern biotechnology sector.

To promote interdepartmental cooperation for effective implementation of the regulatory system, the bill also had provisions to set up an interministerial governing board and biotechnology advisory council with representatives from the Ministries of Food Processing Industries; Agriculture and Farmers' Welfare; Animal Husbandry, Dairying, and Fisheries; Health and Family Welfare; Science and Technology, Environment, Forest, and Climate Change; Commerce and Industry; and External Affairs, along with members from scientific and research organizations. This interministerial board was to promote interministerial or departmental cooperation for the effective implementation of the regulatory system.[119]

Unlike the GEAC, which is a multidisciplinary authority responsible for approval of genetically engineered products, the BRAI was proposed to include only scientific experts. Scientists have the capacity to assess the implications of their research on both public health and the environment, but they might not be suitably trained to take policy decisions and build public trust in their decisions.[120]

The Way Forward

Biosafety infrastructure in India aims to ensure that genetically modified plants, animals, and insects would only be introduced into society after experiments have proven it safe to do so. However, coordination issues often hamper the effective and smooth functioning of this regulatory setup. It is therefore important to introduce measures that can ensure rigorous monitoring of biotechnological experiments, bridge gaps between the regulators and the scientists, build public trust, and ensure no lab accidents occur (see box 2).

BOX 2

Ways to Strengthen India's Biosafety Infrastructure

The following set of recommendations address the gaps in India's biosafety infrastructure:

1. Ensure better coordination between central and state regulatory authorities to minimize chances of illegal cultivation of transgenics. In addition to frequent regular on-site visits by regulators during large-scale field trials, surprise inspections will help in better implementation of biosafety guidelines.
2. Perform rigorous monitoring of research and the commercial cultivation of transgenic crops, but also monitor social responses and attitudes—an imperative to avoid illegal cultivation of genetically modified crops.
3. Develop a standard evaluation form for researchers to harmonize application protocols and to ensure efficiency. For transparent decisionmaking, regulators should also publish the evaluation strategy and reports.
4. Introduce mandatory certification and validation mechanisms for biosafety level-2 (BSL-2) labs that sometimes work with high-risk pathogens.
5. Monitor the implementation of protocols needed to discard biomedical waste and dispose of animals used in drug testing and clinical trials to ensure there are no biosafety lapses.
6. Initiate a mechanism that encourages reporting of accidents when they occur. Even though there have not been a significant number of lab-acquired infections in India, it is important to have a process in place to prevent such accidents. Incentives can be introduced for those who report a lab accident.
7. Conduct periodic training of laboratory personnel on the safe handling of samples, decontamination procedures, and the proper disposal of biomedical waste.
8. Broaden the proposed scope of Biotechnology Regulatory Authority of India (BRAI). If the BRAI bill is ever reintroduced into the parliament, include representatives from the scientific and academic communities as well as members from the appropriate government departments, the private sector, bioethicists, security forces, and the civil society groups that represent farmers' interests.

Assessing India's Biosecurity Landscape

For risks arising through deliberate sources, India still does not have a formal biosecurity policy, but it has numerous guidelines, laws, and rules to govern biosecurity.

Biosecurity supports governments to defend against actors that might seek to divert technology or biological material for offensive military or terrorist purposes. Terrorists are the most obvious threat here, but so are criminal networks seeking sensitive intellectual property and other data they could sell. But such actors could be abetted by people working within bioresearch institutions. This is one reason why securing a laboratory and safeguarding its assets (such as organisms, information, tools, and technologies) are of paramount importance. Institutions that harbor such facilities, researchers working there, and the governmental authorities regulating such research have a collective responsibility to prevent unregulated access.

Security regulations therefore have four aims:

1. To prevent unauthorized or ill-conceived release of naturally occurring biological agents
2. To prevent laboratory insiders from causing harm
3. To prevent theft or acquisition of sensitive research, organisms, and information for nonlegitimate use
4. To prevent weaponization of pathogens

Existing Regulatory Framework

Multiple entities work to implement the five major pieces of legislation that regulate the protection of humans, plants, animals, and the environment from disease-causing organisms in India. Together, these laws reflect differing objectives and public concerns.

First, the 2006 Food Safety and Standards Act was primarily legislated to guarantee the availability of safe and wholesome food to ensure human biosecurity in India. The act established a single-point reference system for food safety called the Food Safety and Standards Authority of India (FSSAI), which is under MOHFW. The authority formulates science-based standards for food articles and regulates their manufacture, import, storage, and distribution. FSSAI also collects data regarding the incidence and prevalence of biological risks and coordinates with central and state governments to implement crisis management procedures.[121] FSSAI is assisted by several scientific panels and a central advisory committee for its overall functioning. Though standards and regulatory frameworks are developed by FSSAI, enforcement of this legislation lies with the state governments and union territories through the state commissioner for food safety and panchayats and municipal bodies.

Second, the 1914 Destructive Insects and Pests Act (DIP Act) regulates the introduction and movement of any insect, fungus, or other pest that may be destructive to crops. The aim is to strengthen agricultural biosafety and prevent the emergence of biosecurity threats in India. Recognizing the impact of globalization and developments in biotechnology, in 2003 the Plant Quarantine (Regulation of Import into India) Order was issued under the DIP Act.[122] The order expanded the scope of the original 1914 act to include germplasm, genetically engineered organisms, and transgenic material for research and was an effort to harmonize India's regulations with international standards.[123] The new order established the Plant Quarantine Organization of India, under the Ministry of Agriculture and Farmers' Welfare, as the national plant protection organization. The central government, through the Joint Secretary in Charge of Plant Protection in the Department of Agriculture Cooperation and Family Welfare can relax conditions relating to the import of any consignment.[124] However, the import and export of plants and plant products for commercial purposes is still separately regulated under the Rules 1989 issued by the MOEFCC under the 1986 Environment Protection Act.[125]

Third, the 1898 Livestock Importation Act (LI Act), which was amended in 2001, prevents biosecurity threats associated with the import of livestock affected by infectious or contagious disorders. The act empowers customs officials at every port, airport, inland container depot, and land customs station to regulate, restrict, or prohibit the import of livestock or livestock products that pose a threat to animal or human health.[126] State governments also have the power to make rules for the detention, inspection, disinfection, or destruction of imported livestock and other items, as well as to regulate the powers and duties of the officers it may appoint.[127] In addition to the LI Act, the Ministry of Agriculture and Farmers' Welfare also coordinates the import and export of livestock and livestock-related products through animal quarantine and certification services. The MOEFCC, under the Wildlife Protection Act of 1972, is responsible for maintaining wildlife health in sanctuaries and national parks. The Department of Animal Husbandry, Dairy, and Fisheries is responsible for monitoring and coordinating the various institutions associated with animal health.[128]

Fourth, the 2009 Prevention and Control of Infectious and Contagious Diseases in Animals Act provides for the prevention, control, and eradication of infectious diseases of animals to avoid such diseases having an adverse impact on the economy of the country, to prevent interstate transmission of animal diseases, and to meet India's international obligations for export and import of animal and animal products.[129]

Fifth, India enacted the 2005 Weapons of Mass Destruction and Their Delivery Systems (Prohibition of Unlawful Activities) Act that fulfills India's commitment to the nonproliferation of weapons of mass destruction (WMD), including nuclear, chemical, and biological weapons. The act was adopted to exercise controls over the export of materials, equipment, and technologies and to prohibit unlawful activities in relation to WMD and their means of delivery. The act declares that "no person shall unlawfully manufacture, acquire, possess, develop or transport a biological or chemical weapon or their means of delivery."[130] This law was most recently in the news after India detained a ship heading to Pakistan from China that carried equipment that could be used for the development of WMD.[131]

Gaps in the Existing Framework

The fragmented nature of biosecurity regulations in India and the involvement of multiple implementation entities may have complicated the state of biosecurity in the country. This leaves India vulnerable to a variety of foreign invasions, according to experts. India has faced at least ten major invasive pest and weed infestations in the last fifteen years, including the fall armyworm that destroyed almost the entire maize crop in 2018.[132] Most recently, locust infestations during the COVID-19 pandemic impacted standing crops over northwest and central India, thereby threatening food security.[133]

Regarding the export and import of pests and pathogens, most regulations empower customs officials as the only authority that can check the baggage of incoming passengers. But most of these officials are inadequately trained to identify specific pests or pathogens. As the core committee of the Department of Agriculture, Cooperation, and Farmers' Welfare noted:

> The Destructive Insects and Pests Act, 1914 and the Livestock Importation Act, 1898 are age old legislations and are subsidiary to the Customs Act, 1962 which does not give direct powers to the quarantine officers to deport or destroy or confiscate the consignment or lodge complaints under the Indian Penal Code. Inadequate or obsolete definitions in these Acts need to be updated. Adequate provisions for regulating plants, livestock and aquatics and powers for inspecting transport vehicles and seizure and destruction of infested or infected plants and livestock or their products have to be incorporated. Punishment or penalty on the importer or custom house clearing agents or other defaulters for violation of provisions of the legislation has to be provided. Provisions for effective domestic quarantine have to be incorporated. The enabling legislation for the proposed biosecurity authority would have to be enacted.[134]

To strengthen the state of biosecurity in India, an agriculture biosecurity bill was tabled in the lower house of the parliament in 2013. The bill, which lapsed, was meant to repeal the DIP and LI Acts and to bring together animal health, plant health, living aquatic resources, and agriculturally important microorganisms. The draft proposed the creation of a national authority called the Agricultural Biosecurity Authority of India, which would have regional offices all over the country. Because it is sometimes hard to distinguish between safety and security threats, the authority, proposed to be set up under the central government, was drafted to have the mandate to regulate the import and export of plants, animals, and related products to prevent entry of pests, implement post-entry quarantine measures, conduct surveillance of pests and diseases, and regulate their interstate spread and the import of transgenic materials. The agricultural biosecurity authority was proposed to prevent the entry of quarantine pests from outside the country,[135] especially ones that can have catastrophic implications for the economy and either do not exist in India or are controlled. While the nodal agency was setup at a national level, state governments were allowed to implement control measures in case an invasive pest, pathogen, or transgenic organism enters the country. The bill proposed empowerment of quarantine officials who could deport, destroy, or confiscate the assignment or lodge complaints under the 1860 Indian Penal Code.[136]

The Way Forward

Numerous factors, such as attention to protecting biodiversity, cross-border movement of people and agricultural products (at least until the COVID-19 pandemic), recent advancements in biotechnology, and international obligations to control the import and export of quarantine pests have required updating domestic laws to govern biosecurity. New Delhi should therefore identify vulnerabilities in the existing system and put in place plans and methodologies to develop a formal biosecurity policy (see box 3).

BOX 3

Ways to Strengthen India's Biosecurity Infrastructure

1. Develop a formal biosecurity policy that consolidates threats emerging from different sectors to avoid any overlaps, confusions, or coordination issues.
2. Include provisions in the biosecurity policy that maintain a record of personnel who have access to labs with sensitive information, make it mandatory for suppliers to demand background verification and keep records of actors ordering tools and reagents online, and require audits of the labs that conduct dual-use research.
3. Address the possibility of theft and espionage occurring from cyber attacks. Given the increasing digitization of biotechnology and the transition to cloud-based storage for genomic data, any biosecurity policy should therefore establish standards that biotech companies and research labs should follow to defend their digital assets.
4. Prohibit anyone from importing, exporting, or releasing naturally produced pests and keep anyone from taking man-made pests, invasive plants, or animal diseases from the laboratory and introducing them to the environment on purpose.
5. Conduct training sessions for customs officials, who are often the first responders to any import or export of unauthorized material, on how to identify specific pests or pathogens. It is also important to empower these officials to either destroy the consignment or lodge a complaint under the Indian Penal Code.
6. Broaden the scope of the Agricultural Biosecurity Authority of India bill, if it is brought back into the parliament, to include zoonotic infections.

Recommendations

The coronavirus pandemic is a wake-up call for India to invest in public health infrastructure and develop the capacity needed to combat disease outbreaks. This section reviews some essential domestic measures needed to predict, prepare, and respond to both natural and man-made biological threats.

Proposal to Create an Office of Biological Threats Preparedness and Response

India's history of slow reforms, especially in the health and biotechnology sector, leaves it too vulnerable to dangers and too slow and inadequately resourced to realize the health and economic benefits of new biotechnologies. As highlighted in the previous sections, India faces three kinds of biological threats: diseases occurring through natural mutations, infections arising from the accidental release of pathogens into the environment, and outbreaks happening as a result of deliberate weaponization of dangerous pathogens.

Although the policies and capabilities needed to deal with natural biological disasters might differ from the ones needed to prevent accidental and deliberate outbreaks, all three have implications for India's public health infrastructure. Considering this intersection, NCDC in 2017 introduced a public health bill to manage pandemics, bioterrorism, and other biodisasters.[137] The bill, however, has since lapsed. Major reforms and reorganizations are therefore needed, along with additional resources to enhance the capacity of India's health infrastructure to tackle biological threats.

As the spread of infectious diseases is a long-term, continuous, and evolving threat, India should consider investing in an agency that can coordinate policy responses for any biological emergency. As India does not have a formal policy for biological disasters, as highlighted in the NDMA's Guidelines for Biological Disasters,[138] this new agency could fill in this gap. It should develop a pandemic preparedness and response plan and should also have the authority to propose, modify, or create necessary legislation to strengthen public health infrastructure, allocate resources needed to achieve goals, and plan for the likely impact of a public health crisis on businesses and other essential services.

Such offices exist globally and were set up to tackle global health emergencies, especially after the Ebola outbreak in 2014. For example, the German Epidemic Preparedness Team was established by the Federal Ministry for Economic Cooperation and Development and the Federal Ministry of Health in 2015.[139] The Office of Pandemics and Emerging Threats was established in the United States in 2014. This office was, however, dissolved under President Donald Trump's administration. Experts in the United States suggest that the absence of a nodal agency to coordinate pandemic preparedness and response led to a weak and fragmented response to the coronavirus pandemic.[140]

To avoid similar instances in India in the future, it is important to derive lessons from other countries and invest in an organization that tackles biological threats.

India has a high-level National Crisis Management Committee, chaired by the cabinet secretary, with union secretaries of the concerned ministries as its members. The committee convenes as soon as there is a threat to national security. Although the committee cuts through the different government ministries, it is only mandated to coordinate responses once a disaster has occurred.[141] It is therefore recommended to create a full-time high level BTPR office that would be able to manage both preparedness and response to biological threats.

Introducing such reforms will be difficult and will also face some resistance from existing players. Nevertheless, at the very least, it may be useful to provide a vision or proposal for an organization that could improve India's capacity to deal with different biological threats.

A full-time BTPR, set up under the NDMA, is one possible alternative. The NDMA, which was established under the Disaster Management Act, is the apex body that coordinates timely and effective responses to disasters. It lays down policies, plans, and guidelines for different ministries and state governments to follow. It has the capacity to mobilize funds to coordinate prevention, preparedness, and response protocols. Moreover, the Disaster Management Act establishes disaster management authorities at the national, state, and district level, which this new office could leverage for better coordination.

Because no agency specifically deals with pandemics in India, and existing agencies sometimes perform overlapping roles with limited coordination and collaboration, such an office should have experts from existing organizations that tackle disease outbreaks. The proposal of such an office should encourage relevant officials, experts, and media to debate whether and how existing agencies and capacities could be improved instead. Given that pandemics can occur through either accidental release of pathogens into the environment or deliberate weaponization of dangerous pathogens, and that preventing such occurrences is by far the most affordable and beneficial objective, the office could also involve biosafety and biosecurity experts. These experts should include members from IBSCs, the RCGM, the GEAC, border security forces, and other allied security agencies. Experts from scientific and academic backgrounds as well as from the private sector should also be included for their unique risk assessment.

To achieve these objectives, the chair of the National Crisis Management Committee could be appointed as the chairman of the Office of BTPR. The vice chairman of NDMA could be appointed as the vice chairman of this office. In addition, the office could appoint a managing director, a senior government official with relevant public health experience. The appointment could be made by a high-level committee that includes representatives from the PMO, MOHFW, the office of the

National Security Adviser (NSA), the government think tank called the National Institute for Transforming India (NITI) Aayog, and other relevant ministries. The managing director in collaboration with the administrative staff could also oversee periodic training of healthcare personnel. The managing director along with the communications team also could be in charge of organizing public awareness campaigns such as scientific conferences, virtual seminars, social media posts, and a website.

Given the cross-disciplinary nature of biothreats, an effective domestic pandemic prevention, preparedness, and response plan requires collaboration among different stakeholders. The multiplicity of institutions in India along with the practice of working in silos often makes it difficult to coordinate a policy response during an outbreak. Rather than reinventing the wheel, it is worthwhile to identify and address loopholes in the existing system. This approach might need consultation with different interest groups to aggregate existing information, debate the kind of health system India needs to tackle biological threats, mobilize resources to coordinate a policy response, increase investment in scientific research, and obtain approvals from competent authorities such as the finance ministry.[142]

The proposed Office of BTPR could therefore have six working groups with different roles and responsibilities. These working groups could draw members from existing relevant organizations or could create new posts on an as-needed basis.

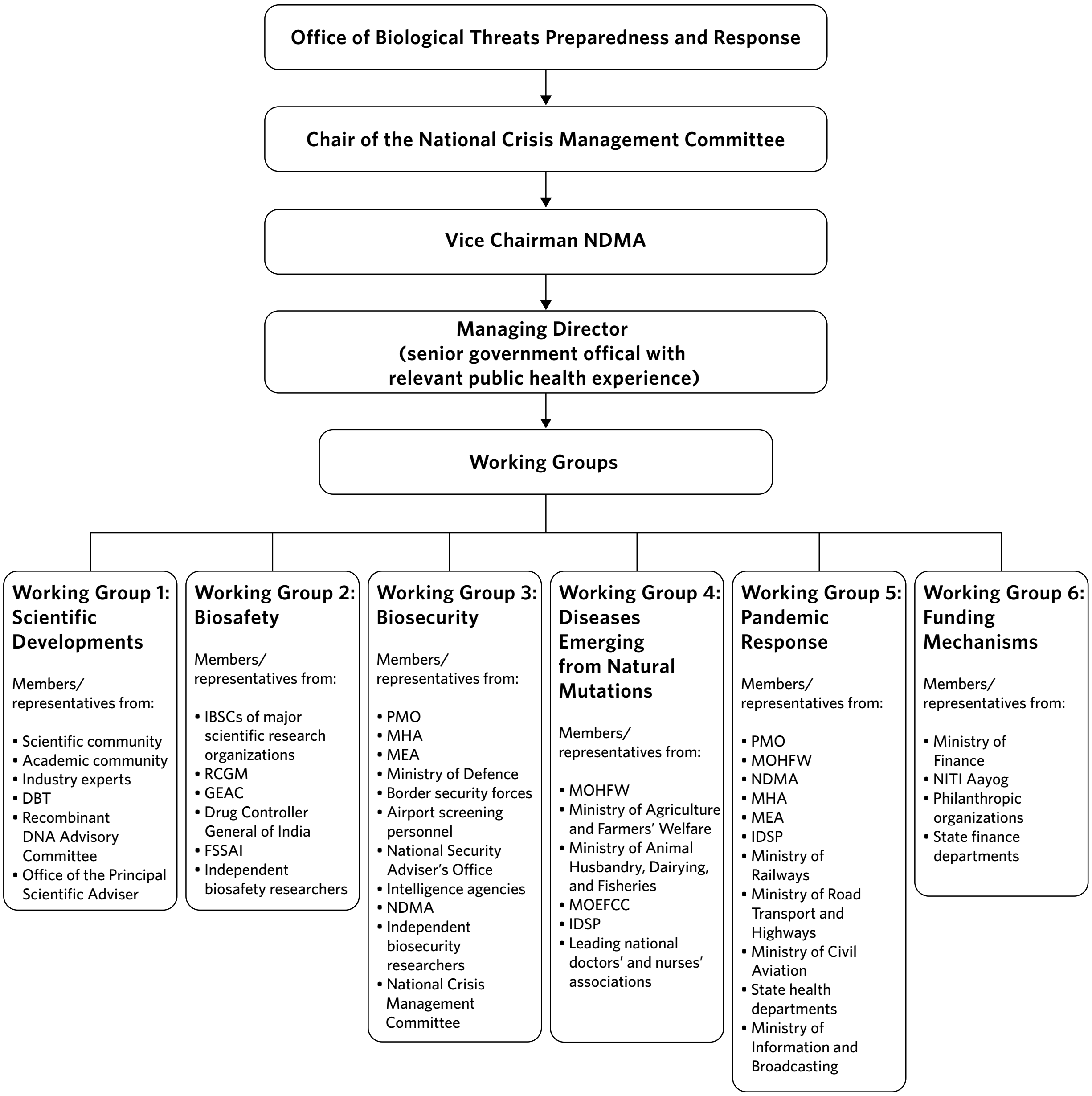
1. The first working group could focus on aggregating information on recent scientific developments. It could therefore consist of members from the scientific and academic community, industry experts, and representatives from the DBT, Department of Scientific and Industrial Research, DST, Defence Research and Development Organisation, Recombinant DNA Advisory Committee, and the Office of the Principal Scientific Adviser. This group could keep track of the latest technological developments with the foresight to visualize and mitigate the harmful effects of such technologies.
2. The second working group could assess the risk of epidemics emerging from lab accidents. India has an existing biosafety network with nodal agencies set up at institutional, district, state, and national levels. As this group aims to assess the impact of accidental release of pathogens from the labs on public health, it could leverage the existing biosafety network, such as members of the IBSCs, RCGM, GEAC, the Drug Controller General of India, FSSAI, and state biosafety authorities. In addition, it could also tap independent biosafety researchers and scientists for their unique risk assessment. This group could be responsible for conducting surprise on-site inspections, organizing periodic biosafety training for researchers, and continuously guiding scientific departments to update their biosafety practices and protocols considering the most recent technological advancements.
3. The third working group could focus on assessing the impact of biosecurity threats on India's public health. This group could include members from the PMO, the NSA's office, MHA,

MEA, the National Crisis Management Committee, and NDMA. It could also involve airport screening personnel, border security forces, intelligence agencies, representatives from scientific departments, and independent biosecurity researchers for their risk perceptions. Because biosecurity regulations empower individual ministries or agencies to respond to particular security concerns, coordination is often a challenge. This group could therefore act as an interministerial umbrella body that identifies biosecurity challenges; conducts training for border security forces, airport screening personnel, disaster management forces, and others involved as a first line of defense against cross-border infections; and coordinates with relevant authorities. This group could determine standard operating procedures that could be followed in case of a deliberate biological attack, both by state and nonstate actors.

4. The fourth working group could address scientific and social aspects of diseases emerging from natural mutations. The group could focus on the One Health approach. According to WHO, One Health could facilitate conversations between multiple sectors toward practical policy outcomes to achieve better public health, and it would be particularly helpful to address issues like "food safety, the control of zoonoses (diseases that can spread between animals and humans, such as flu, rabies and Rift Valley Fever), and combating antibiotic resistance (when bacteria change after being exposed to antibiotics and become more difficult to treat)."[143] Because One Health is a multidisciplinary approach to design and implement programs for better public health outcomes, the group could have members from the MOHFW, the Ministry of Agriculture and Farmers' Welfare, the Ministry of Animal Husbandry, Dairying, and Fisheries, MOEFCC, leading national doctors' and nurses' associations, and state health departments. This group could also closely monitor the findings of the IDSP.
5. As most of the notional working groups described so far can assess different biological risks and prepare for them, the fifth working group could be constituted to coordinate responses during an outbreak. This group could have members from the NDMA, MOHFW, PMO, MHA, MEA, Ministry of Railways, Ministry of Road Transport and Highways, Ministry of Civil Aviation, Ministry of Information and Broadcasting, and state health departments to develop standard operating procedures that need to be evoked during an outbreak. To avoid any conflicting messages, the response team could work closely with a communications team to disseminate information and other details during an outbreak.
6. For the smooth functioning of this proposed office, a sixth working group could be constituted to coordinate appropriate allocation of funds. This working group could have representatives from the Ministry of Finance, NITI Aayog, philanthropic organizations, local donors, and state finance departments. This group could allocate resources to build the capacity needed to prepare and respond to an outbreak. This group could work closely with both the MD and chairman of the organization.

FIGURE 2

Structural Organization of the Office of Biological Threats Preparedness and Response



The periodic meeting and regular check-ins of these working groups can help identify natural disease hotspots through epidemiological modeling, assess the safety and security of biotechnological research, foster interministerial and interstate cooperation to facilitate the One Health approach, strengthen the response to a disease outbreak, and allocate funds necessary to prepare and respond to pandemics (see figure 2).

These working groups, based on their performance, can also be institutionalized as permanent standing bodies that will help generate the political will needed to ensure smooth and efficient execution of strategies to contain biological threats both at the central and the state level.

Experts in India have emphasized that the time between two outbreaks should be used to strengthen a country's public health infrastructure.[144] Whether or not a new office is set up, it is important for India to review domestic measures needed to predict, prevent, and respond to both natural and man-made biological threats. Some measures are mentioned below.

Role of Public Health Workers

Public health workers, including nurses, doctors, midwives, and hospital staff, are the first responders in case of any biological outbreak. It is therefore very important to train these personnel to identify any unusual symptoms and report them to appropriate authorities. Clearer and stronger incentives to identify and report cases of infectious disease might result in better reporting of disease outbreaks.[145] Public health workers should be periodically updated on recent biological outbreaks and should have regular training on nursing practices, safe handling of samples, and decontamination procedures. Being early responders, these frontline healthcare workers should also have authority to use protective equipment, vaccines, and drugs in case of an emergency. In scenarios where vaccines are available, it is important to practice ring vaccination, an approach deployed during the Ebola outbreak in the Democratic Republic of the Congo, where contacts of suspected patients receive a vaccine shot, and also their contacts, in order to quickly contain the spread of disease.[146]

Role of Government

Although all sectors of the community should be involved in pandemic preparedness and response, the government is responsible for coordinating and communicating all efforts in the prediction, preparation, and response phase.

Prediction involves developing an effective disease surveillance model and a standardized disease reporting system with a focus on both animal and human health. It is therefore crucial to harmonize data collection tools and develop common disease reporting standards for all primary healthcare centers in India. In addition to developing domestic standards, it is important to work with international organizations to have common methods and protocols to facilitate cross-border data sharing. If nations develop common data standardization, each nation would benefit from the resultant possibility of improving international cooperation in diagnostics and development of vaccines and/or treatments.[147]

India should develop a centralized repository of standardized data to which all actors—including those in the nongovernmental sector—have incentives to provide data. This repository should contain genome sequences of pathogens and samples linked with the clinical history of patients—without any personal identifiers—to identify, diagnose, and respond to diseases. This repository can lend insights to disease epidemiology, pathogen evolution, and the trajectory of infection and help qualified laboratories perform and validate diagnoses. This information should be available on request for interested organizations, with some charges or fees if necessary.

The government should collaborate with scientists, academicians, industry, epidemiologists, and data scientists to develop epidemiological models for diseases, which could help predict the location and timing of outbreaks. Such models should consider socioeconomic circumstances, environmental conditions, and geographic terrains that are associated with disease occurrence. This model can provide adequate background information on naturally occurring diseases, which might facilitate recognition and prediction of unusual outbreaks. For early detection of disease outbreaks, a horizontal network among all primary healthcare centers can be created to communicate information on infections that manifest unusual symptoms. Training people to diagnose an infection and sequence the pathogen has proved to be quite feasible in India. However, retaining trained personnel in the absence of an outbreak remains a challenge. Continuous development of epidemiological models of diseases can create career opportunities that might help retain talent so that it is available to be deployed when needed.[148]

Preparedness for pandemics encompasses capacity building, which includes measures such as reinforcing border security to avoid cross-border infections; engaging with local donors to mobilize resources and capacities needed to ramp up public health infrastructure; increasing funding to agencies such as ICMR to strengthen lab infrastructure that can diagnose infections; fostering better coordination between central and state governments through regular dialogue and deliberation; training healthcare personnel; identifying research organizations—both public and private—that can provide scientific solutions such as developing diagnostic kits, vaccines, drugs, and other countermeasures; recognizing private players that can scale up manufacturing of medical countermeasures during an outbreak; and conducting simulation exercises to develop standard operating procedures.

Response during an outbreak requires effective disease reporting, deployment of resources, and surge manufacturing of medical countermeasures. It also entails providing reliable information on the risk, severity, and progression of the disease, as well as conveying the effectiveness of medical interventions and strategies used during the crisis.

Role of Scientists and Industry

The coronavirus pandemic generated a great deal of collaboration among scientists, the private sector, and policymakers. As scientists and the private sector offered solutions to combat the pandemic, the government also exhibited flexibility to fund and support those solutions. It is therefore imperative for India to continue this collaboration not only during a public health crisis but even later, to develop a research pipeline that can be relied on in wake of an emergency.

India should develop a robust and effective technology ecosystem—from scientific innovation to commercialization—to detect, understand, and respond to both natural and deliberate outbreaks. Advancements in genome sequencing, synthetic biology, big data, and machine learning offer opportunities to researchers who can provide scientific understanding to develop vaccines, drugs, and other countermeasures for pathogens. Manufacturing medical countermeasures can then be scaled up by industry experts. Given India's high vulnerability to viral zoonotic diseases, the country should divert its focus to developing broad-spectrum antivirals, compounds that work against a broad range of viral pathogens. Such solutions were found relevant during the COVID-19 pandemic when an antiviral known to be effective against Ebola and influenza was considered a potential candidate against the novel coronavirus.[149]

In addition, although developing vaccines for flu in advance is difficult, it is important to create a pipeline for vaccine development so that it can be generated rapidly in case there is an outbreak. For all existing vaccines, India should set aside funds to stockpile vaccines for rapid response to emergency outbreaks. In cases where no existing vaccines are available, it is important to identify representatives from the scientific and academic community and the private sector who can be consulted for the development of vaccines and other therapies during a novel disease outbreak. Given the extent of globalization, many experts argue that "an outbreak anywhere is an outbreak everywhere."[150] Therefore, in addition to strengthening the domestic capacity to manufacture vaccines, it is important to promote international cooperation to minimize duplication of research. Global collaboration can also facilitate equitable distribution of vaccines once they are deemed safe and effective.

Role of Simulation Exercises

Simulation exercises can help train, monitor, assess, and strengthen the capabilities of emergency policies, plans, and procedures. These tabletop exercises can ensure the development, update, and implementation of preparedness and response capacities and can be used as a training tool for participants to identify any unusual symptoms and report it to appropriate authorities. The 2005 International Health Regulations recommended such exercises to test countries' risk communication and capacity at least every two years.[151] These low-cost, high-impact exercises not only help develop emergency procedures and protocols but also raise awareness in the media and among the public. As part of these exercises, stakeholders from government, industry, the scientific community, and academia should be involved to discuss a simulated or fictional scenario. These exercises can serve as a platform to clarify roles and responsibilities and identify additional threat and mitigation measures. Public healthcare workers should also be involved and updated on recent biological outbreaks and should have regular training on nursing practices, safe handling of samples, and decontamination procedures. A predetermined plan of action can facilitate quick implementation of the standard operating procedures, by all related personnel, without awaiting directions from the concerned ministry.

Conclusion

To summarize, this paper highlights that India faces three major biological threats: first, diseases caused by natural mutations in humans, plants, and animals; second, infections arising from human accidents; and third, possible outbreaks occurring due to deliberate weaponization of dangerous pathogens that affect humans, animals, or crops.

For the first category of biological threats, the paper explored India's response to five different disease outbreaks to examine its capacity to respond to naturally occurring infections. The case studies revealed that rather than using the time between the two outbreaks to develop strategies to prepare and plan for infectious diseases, most of the bodies set up under the Indian government are designed to coordinate responses once a disaster has occurred. Hence, most responses are based on ad hoc notifications and committees, which are set up on an emergency basis and are dissolved once the outbreak is over. This leaves the country vulnerable to repeated disease outbreaks, with limited capacity to tackle them.

On the second category of biological risks, India has a comprehensive set of biosafety guidelines that have been issued by the Department of Biotechnology. Although implementation of biosafety guidelines falls under the ambit of the Ministry of Science and Technology and MOEFCC, researchers often work in labs supported by the ICMR and the Indian Council of Agricultural Research, which are research bodies set up under the MOHFW and the Ministry of Agriculture and Farmers' Welfare. This multiplicity of actors creates confusion. Moreover, the regulatory process is not transparent and is influenced by activist groups, which often delays the approval of biotechnology-derived products.

Specific to the third category of risks, neither does India have a biosecurity policy, nor does it have a dedicated organization that deals with deliberate risks emerging from biotechnology. In the absence of a formal biosecurity policy, India has multiple entities that work to implement legislations that regulate the protection of humans, plants, animals, and the environment from disease-causing organisms in India. Together these laws reflect differing objectives and public concerns. The fragmented nature of biosecurity regulation in India and the involvement of multiple implementation entities has complicated the state of biosecurity in the country.

Recognizing these gaps in India's capacity to tackle biological threats, the paper has proposed the creation of an office of BTPR, under the NDMA, that would be able to manage preparedness and coordinate response for both natural and man-made biological threats. Whether or not the office is set up, the paper suggests strategies that can be followed to review domestic measures needed to predict, prevent, and respond to biological threats.

Appendix

Personal Engagements in India

1. Anu **Acharya**, *founder and chief executive officer, Mapmygenome*
2. Vibha **Ahuja**, *chief general manager, Biotech Consortium India Limited*
3. Anand **Anandkumar**, *chief executive officer and managing director, Bugworks*
4. Bhaskar **Balakrishnan**, *science diplomacy fellow, Research and Information System for Developing Countries, and former ambassador of India*
5. Samir **Brahmachari**, *director general, Council of Scientific and Industrial Research*
6. Debojyoti **Chakraborty**, *senior scientist, Genome Editing, Stem Cells, and Organoid Biology, Institute of Genomics and Integrative Biology*
7. Vijay **Chandru**, *cofounder and director, Strand Life Sciences*
8. Archana **Chugh**, *associate professor, Indian Institute of Technology Delhi*
9. Saurabh **Dalal**, *consultant, National Disaster Management Authority*
10. Shaibal **Dasgupta**, *group leader, Tata Institute for Genetics and Society*
11. Pawan K. **Dhar**, *professor and dean, School of Biotechnology, Jawaharlal Nehru University*
12. B. M. **Gandhi**, *chief executive officer, Neo Biomed Services, and former adviser, Department of Biotechnology, Ministry of Science and Technology*
13. Pranay **Goel**, *associate professor, Indian Institute of Science, Education, and Research*
14. Seyed E. **Hasnain**, *vice chancellor, Jamia Hamdard*
15. Rohan **Kamat**, *cofounder and chief executive officer, Viravecs Labs*
16. Gagandeep **Kang**, *executive director, Translational Health Science and Technology Institute*
17. Satyajeet **Khare**, *assistant professor, Symbiosis School of Biological Sciences, Symbiosis International University*
18. Murali **Krishna**, *joint director, Ministry of Environment, Forest, and Climate Change*
19. Ajey **Lele**, *senior fellow, Institute for Defence Studies and Analyses*
20. Arindam **Maitra**, *associate professor, National Institute of Biomedical Genomics*
21. Shekhar C **Mande**, *director, National Centre for Cell Science*
22. Satyajit **Mayor**, *director, National Centre for Biological Sciences*
23. Shambhavi **Naik**, *research fellow, The Takshashila Institution*
24. Indira **Nath**, *former head, Department of Biotechnology, All India Institute of Medical Sciences*
25. Abhijit **Poddar**, *scientist, Biosafety Support Unit, Department of Biotechnology, Ministry of Science and Technology*
26. Anu **Raghunathan**, *senior scientist, National Chemical Laboratory*
27. Vinay Kumar **Rale**, *director, Symbiosis School of Biological Sciences, Symbiosis International University*

28. S. R. **Rao**, *former senior adviser, Department of Biotechnology, Ministry of Science and Technology*
29. Taslimarif **Saiyed**, *chief executive officer and director, Centre for Cellular and Molecular Platforms*
30. Sunil **Saroj**, *associate professor, Symbiosis School of Biological Sciences, Symbiosis International University*
31. A. K. **Singh**, *director general of life sciences, Defence Research and Development Organization*
32. Krishna Ravi **Srinivas**, *consultant, Research and Information System for Developing Countries*
33. Narayan **Suresh**, *chief operating officer, Association of Biotechnology Led Enterprises*
34. Geetanjali **Tomar**, *professor, Institute of Bioinformatics and Biotechnology, Pune University*
35. K. **VijayRaghavan**, *principal scientific adviser, Government of India*

Events

1. Workshop on "Tackling Coronavirus: Prevention, Surveillance, and Response"

Date: March 4, 2020

Objective: The workshop was organized to examine the source of the coronavirus infection, evaluate its relationship with other preexisting coronaviruses, assess its potential to become a pandemic, and discuss India's capacity to prepare and respond to such infections.

List of Participants

Facilitators: G **Arunkumar**, *director, Manipal Institute of Virology*
Shahid **Jameel**, *chief executive officer, Wellcome Trust/DBT India Alliance*
Gautam **Menon**, *professor, Physics and Biology, Ashoka University*

Moderators: Chitra **Pattabiraman**, *fellow, National Institute of Mental Health and Neurosciences*
Shruti **Sharma**, *research analyst, Technology and International Affairs, Carnegie Endowment for International Peace*

2. Closed-Door Discussion on "India's Pandemic Preparedness and Response: Role of Scientists and Industry Experts"

Date: December 6, 2019

Objective: Outbreaks of life-threatening infectious diseases such as Ebola in West Africa, Zika in South America, avian influenza in China, and Nipah virus disease in India are occurring with increasing frequency. These emerging and reemerging infections and their potential to spread across borders pose serious threats to public health and development. Responding to such threats necessitates identifying emerging health trends, conducting surveillance, diagnosing infections, and providing treatment for patients. This roundtable convened scientists and industry experts to identify how preparedness and response to pandemics can be improved, including the capabilities that industry and the research community can offer to help governments tackle adverse biological events.

List of Participants

Chair: Gagandeep **Kang**, *executive director, Translational Health Science and Technology Institute*

Participants: Frederik **Kristensen**, *deputy chief executive officer, Coalition for Epidemic Preparedness Innovations*
Dipankar **Nandi**, *professor, Department of Biochemistry, Indian Institute of Science*
Binay **Panda**, *chief officer and head, Ganit Laboratory*
Chitra **Pattabiraman**, *fellow, National Institute of Mental Health and Neurosciences*
George **Perkovich**, *vice president for studies, Carnegie Endowment for International Peace*
S. R. **Rao**, *former senior adviser, Department of Biotechnology, Ministry of Science and Technology*
Amrita **Sekhar**, *consultant, Translational Health Science and Technology Institute*
Varsha **Shridhar**, *director and cofounder, Molecular Solutions Care Health*
Rakesh **Sood**, *distinguished fellow, Observer Research Foundation*
Varadharajan **Sundaramurthy**, *group leader, National Centre for Biological Sciences*
Shashank **Tripathi**, *assistant professor, Centre for Infectious Disease Research, and intermediate fellow, Wellcome Trust/DBT India Alliance, Indian Institute of Science*

3. Student Workshop on "Biotechnology: Innovation and Regulation"

Date: December 4, 2019

Objective: India has begun leveraging the power of biotechnology—for health, medicine, or agriculture. Complementary advances in physics, chemistry, and computational and material sciences have furthered the horizons of biotechnology research today. This session aimed at understanding the applications of biotechnology in the agriculture and healthcare sectors as well as the regulatory challenges they pose in India.

List of Participants

Facilitator: Rohan **Kamat**, *head of the Discovery Group at Immuneel Therapeutics*

Participants: Kashif **Ahmed**, *assistant professor, CMR Institute of Technology*
Amruth **Anand**, *student, Law (BBA LLB Hons.), School of Law, Christ University*

V. **Anandi**, *professor, Ramaiah Institute of Technology*
Balesh B **Basu**, *student, PES University*
Neeladri **Chowdhury**, *research assistant, Centre for Cellular and Molecular Platform*
Sahithya **G**, student, *Biotechnology Skill Enhancement Program, Dayananda Sagar College of Engineering*
Jeenu **Gilson**, *PG diploma, Plant Genetic Engineering, Dayananda Sagar College of Engineering*
Anjali R **Gowda**, *PG diploma, Plant Genetic Engineering, Dayananda Sagar College of Engineering*
Anton Swaminathan **Iyer**, *research scholar, National Centre for Biological Sciences*
Anusha **Jahagirdar**, *postdoctoral fellow, Institute for Stem Cell and Regenerative Medicine*
Anjali **Jaiswal**, *PG diploma, Dayananda Sagar College of Engineering*
Shilpa **Joshi**, *associate biomodeling scientist*
Supreetha **K**, *assistant professor, Dayananda Sagar College of Engineering*
Jayashree **Kamaraddi**, *M.Tech (biotechnology), RV College of Engineering*
Madhan **Kumar M**, *PhD scholar, Indian Institute of Science*
Khushbu **Kumari**, *research fellow, Centre for Innovation, Intellectual Property, and Competition (CIIPC), National Law University, Delhi*
Shivanand **Kumbar**, *Biotechnology Skill Enhancement Program, Dayananda Sagar College of Engineering*
K Preksha **Machaiya**, *BE (biotechnology), Sir M Visvesvaraya Institute of Technology*
Sanjukta **Mukherjee**, *NCBS-Campus Fellow, National Centre for Biological Sciences–Tata Institute of Fundamental Research*
Venkatesh H **N**, *PhD (microbiology), Bangalore University*
Akshay **Narayan**, *PG diploma, Plant Genetic Engineering, Dayananda Sagar College of Engineering*
Rajeswari **Narayanappa**, *Dayananda Sagar Institutions*
Shambhawi **Singh**, *Student, RVCE Bangalore*
Gowri **Srinivasa**, *professor, Computer Science and Engineering, PES University*
Kruthika, *assistant professor, Acharya institute of technology*
Yashika, *BE (biotechnology), Sir M Visvesvaraya Institute of Technology*

4. Workshop on "Gene Editing in India: The Technology and Its Governance"
Date: July 25, 2019

Objective: In November 2018, the Chinese scientist He Jiankui claimed to have created genetically altered babies, making them resistant to the HIV virus. This news sparked a fierce global debate on the benefits and perils of gene editing. What does gene editing entail, and what about the technology polarizes the scientific community? How should the use and abuse of gene editing be governed, both domestically and globally?

List of Participants

Facilitators: Vijay **Chandru**, *cofounder and director, Strand Life Sciences*
S. R. **Rao**, *former senior adviser, Department of Biotechnology, Ministry of Science and Technology*

Moderators: Rakesh **Sood**, *distinguished fellow, Observer Research Foundation*
Shruti **Sharma**, *research analyst, Technology and International Affairs, Carnegie Endowment for International Peace*

5. Student Workshop on "Biotechnology Research: Balancing Safety and Innovation"

Date: December 17, 2018

Objective: Understand how students are perceiving biological threats, getting them engaged in dynamic discussion about the benefits and risks of biotechnology.

List of Participants

Facilitator: Taslimarif **Saiyed**, *chief executive officer and director, Centre for Cellular and Molecular Platforms*

Participants: Anushree **A**, *MSc (biotechnology), MS Ramaiah College of Arts, Science, and Commerce*
Vainavi **Alva**, *BE (biotechnology), Ramaiah Institute of Technology*
Yashika **B B**, *BE (biotechnology), Sir M Visvesvaraya Institute of Technology*
Megha **Balachandra**, *BE (biotechnology), Ramaiah Institute of Technology*
Sarayu **Beri**, *PhD research scholar, National Centre for Biological Sciences*
Sohini **Dutta**, *MSc (biotechnology), Ramaiah College of Arts, Science, and Commerce*
V. **Heera**, *student, Dayananda Sagar College of Engineering*
Ankita **Jha**, *student, MS Ramaiah Institute of Technology*
Padmashree **K**, *MSc (biotechnology), Ramaiah College of Arts, Science, and Commerce*
Gaurav **Kansagara**, *graduate student, Institute for Stem Cell and Regenerative Medicine*
Santhoshi **L**, *BE (biotechnology), Ramaiah Institute of Technology*
K Preksha **Machaiya**, *BE (biotechnology), Sir M Visvesvaraya Institute of Technology*
Joseph **Mathew K**, *PhD research scholar, National Centre for Biological Sciences*
Sai **Manoz. L**, *PhD research scholar, Institute for Stem Cell and Regenerative Medicine*
Rohan **Menon**, *research intern, Institute for Stem Cell and Regenerative Medicine*

Biswajit **Mohapatra**, *M.Tech (biotechnology), RV College of Engineering*
Anushka **N**, *MSc (biotechnology), Ramaiah College of Arts, Science, and Commerce*
Harini **N**, *MS Ramaiah Institute of Technology*
Manikanta **Prabu**, *student, BBA LLB, School of Law, Christ University*
Aahana N **Prakash**, *BE (biotechnology), Ramaiah Institute of Technology*
Pooja M. **Raju**, *BE (biotechnology), Ramaiah Institute of Technology*
Kritika **Shankar**, *BA LLB (Hons.), School of Law, Christ University*
Naela Azhar **Sharief**, *BE (biotechnology), MS Ramaiah Institute of Technology*
Adithi **Sundaresh**, *BE (biotechnology), Ramaiah Institute of Technology*

6. Closed-Door Discussion on "Safety, Security, and Promise of Bioengineering"

Date: December 19, 2018

Objective: Convene Indian scientists, government officials, and industry leaders to discuss relevant questions on biotechnology opportunities and risks.

List of Participants

Chair: George **Perkovich**, *vice president for studies, Carnegie Endowment for International Peace*

Participants:
Anirudh **Burman**, *senior research analyst, Carnegie India*
Vijay **Chandru**, *chairman and managing director, Strand Life Sciences*
Shaibal **Dasgupta**, *group leader, Tata Institute for Genetics and Society*
Rohan **Kamat**, *cofounder and chief executive officer, Viravecs Labs*
Rahul **Matthan**, *partner, Trilegal*
Shambhavi **Naik**, *research fellow, Takshashila Institution*
Binay **Panda**, *chief officer and head, Ganit Laboratory*
Jahnavi **Phalkey**, *founding director, Science Gallery Bengaluru*
Srinath **Raghavan**, *senior fellow, Carnegie India*
Anu **Raghunathan**, *senior scientist, National Chemical Laboratory*
Ramaswamy **S**, *professor, Institute of Stem Cell Biology and Regenerative Medicine*
Amrita **Sekhar**, *consultant, Translational Health Science and Research Institute*
Rakesh **Sood**, *senior fellow, Observer Research Foundation*
Narayan **Suresh**, *chief operating officer, Association of Biotechnology Led Enterprises*
Shrikumar **Suryanarayan**, *chairman and cofounder, Sea6 Energy*

7. Closed-Door Discussion on "Challenges of Minimizing Risks of New Biotechnologies"
Date: February 12, 2018

Objective: India is at the forefront of countries racing to achieve the profound benefits that new biotechnologies, including gene editing, can bring. The discussion explored how different sectors in India perceive biotechnology risks and various national and international strategies for managing them.

List of Participants

Speaker: George **Perkovich**, *vice president for studies, Carnegie Endowment for International Peace*

Chair: Ananth **Padmanabhan**, *former fellow, Carnegie India*

Participants:
Vibha **Ahuja**, *chief general manager, Biotech Consortium India Limited*
J. K. **Bansal**, *former member***,** *National Disaster Management Authority*
Saurabh **Dalal**, *consultant, National Disaster Management Authority*
Ajey **Lele**, *senior fellow, Institute for Defence Studies and Analyses*
Amit **Kumar**, *research associate, Research and Information System for Developing Countries*
Bratati **Mukhopadhyay**, *senior program officer, Translational Health Science and Technology Institute*
Indira **Nath**, *founder and former head, Department of Biotechnology, All India Institute of Medical Sciences*
Rajeswari **Rajagopalan**, *senior fellow and head, Nuclear and Space Policy Initiative, Observer Research Organization*
Kanica **Rakhra**, *consultant*, *Disarmament and International Security Affairs Division***,** *Ministry of External Affairs*
Dinakar M. **Salunke**, *director, International Centre for Genetic Engineering and Biology*
Sheel Kant **Sharma**, *honorary distinguished fellow, Centre for Air Power Studies*
Rakesh **Sood**, *distinguished fellow, Observer Research Foundation*

About the Author

Shruti Sharma is a research analyst with the Technology and International Affairs Program at the Carnegie Endowment for International Peace. She works primarily on the safety, security, and ethical implications of emerging biotechnologies. While at Carnegie India, Shruti has coauthored a paper on "Modern Biotechnology and India's Governance Imperatives." She has published in leading Indian newspapers, portals, and magazines. She holds a master's degree in biotechnology from Amity Institute of Biotechnology in Noida, India.

Acknowledgments

The author acknowledges financial support from the Open Philanthropy Project for the research that led to this paper. The author is extremely grateful to George Perkovich and Kate Charlet for their support throughout the project. The author would like to extend her gratitude to the project's interviewers and contributors for their insights, feedback, and suggestions. The author would also like to thank Sharanya Rajiv, Rhea Menon, Shreyas Shende, Anirudh Burman, Ananth Padmanabhan, Alok Kumar, Rudra Chaudhuri, Michael Nelson, Ronit Langer, C. Raja Mohan, and the Carnegie communications team for their help and input.

Notes

1 Jayashree Nandi, "COVID-19 not created in lab, has natural origins, say scientists," *Hindustan Times,* March 19, 2020, https://www.hindustantimes.com/india-news/covid-19-not-created-in-lab-has-natural-origins-say-scientists/story-E0XTs8fvHnEULaeaSrTzVL.html.

2 National Research Council (U.S.) Committee on Laboratory Security and Personnel Reliability Assurance Systems for Laboratories Conducting Research on Biological Select Agents and Toxins, *Responsible Research with Biological Select Agents and Toxins* (Washington, DC: National Academies Press, 2009), 1, introduction, https://www.ncbi.nlm.nih.gov/books/NBK44953/.

3 *Biorisk Management: Laboratory Biosecurity Guidance* (Geneva: World Health Organization, September 2006), https://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf.

4 *Laboratory Biosafety Manual* (Geneva: World Health Organization, 2004), https://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf?ua=1.

5 "Biosafety and Biosecurity," Implementation Support Unit, Biological Weapons Convention, Geneva, accessed August 19, 2020, https://www.unog.ch/80256EDD006B8954/(httpAssets)/46BE0B4ACED5F0E0C125747B004F447E/%24file/biosafety%2Bbackground%2Bpaper%2B-%2Badvanced%2Bcopy.pdf.

6 "Indian Biotech's Tough Regulatory Encounter," *Livemint*, June 27, 2013, https://www.livemint.com/Opinion/3Q95JCwHoWk2Ii4S6ESFpI/Indian-biotechs-tough-regulatory-encounter.html. Insights derived from a series of roundtables with the author. For more information on the roundtables, see the appendix.

7 *National Disaster Management Plan* (New Delhi: National Disaster Management Authority, Government of India, 2019), https://ndma.gov.in/images/policyplan/dmplan/ndmp-2019.pdf.

8 "SARS Case in Singapore Linked to Accidental Laboratory Contamination: Severe Acute Respiratory Syndrome (SARS) in Singapore–Update 2," press release, World Health Organization, September 24, 2003, https://www.who.int/csr/don/2003_09_24/en/.

9 Jane Parry, "Breaches of Safety Regulations Are Probable Cause of Recent SARS Outbreak, WHO Says," *BMJ* 328 (2004): 1222, doi:10.1136/bmj.328.7450.1222-b.

10 T. Riyesh et al., "Laboratory-Acquired Buffalopox Virus infection, India," *Emerging Infectious Diseases*, February 2014, http://dx.doi.org/10.3201/eid2002.130358.

11 "What is Brucellosis bacterial disease in China," *Indian Express,* September 27, 2020, https://indianexpress.com/article/explained/explained-what-is-brucellosis-the-disease-that-has-infected-thousands-in-china-6602697/.

12 Jeanne Gullemin, *Hidden Atrocities: Japanese Germ Warfare and American Obstruction of Justice at the Tokyo Trial* (New York: Columbia University Press, 2017); Jonathan Watts, "Japan Guilty of Germ Warfare Against Thousands of Chinese," *Guardian*, August 28, 2002, https://www.theguardian.com/world/2002/aug/28/artsandhumanities.japan; Nicholas D. Kristof, "Unmasking Horror—A Special Report: Japan Confronting Gruesome War Atrocity," *New York Times*, March 17, 1995, https://www.nytimes.com/1995/03/17/world/unmasking-horror-a-special-report-japan-confronting-gruesome-war-atrocity.html; Philip Oltermann, "Nazi Scientists Planned to Use Mosquitoes as Biological Weapon," *Guardian*, February 14, 2014, https://www.theguardian.com/world/2014/feb/14/nazi-scientists-mosquitoes-biological-weapon.

13 Jeanne Guillemin, "Scientists and the History of Biological Weapons: A Brief Historical Overview of the Development of Biological Weapons in the Twentieth Century," *EMBO Reports* 7, no. S1 (2006): S45–49, doi: 10.1038/sj.embor.7400689.

14 Jenni Rissanen, "The Biological Weapons Convention," Nuclear Threat Initiative, March 1, 2003, https://www.nti.org/analysis/articles/biological-weapons-convention/.

15 National Research Council (U.S.) Committee, *Responsible Research with Biological Select Agents and Toxins*, 2009, 1, introduction.

16 Centers for Disease Control and Prevention, "Reconstruction of the 1918 Influenza Pandemic Virus," accessed February 11, 2020, https://www.cdc.gov/flu/about/qa/1918flupandemic.htm.

17 Diane DiEuliis, Kavita Berger, and Gigi Gronvall, "Biosecurity Implications for the Synthesis of Horsepox, an Orthopoxvirus," *Health Security* 15, no. 6 (2017): https://wmdcenter.ndu.edu/Portals/97/Documents/Publications/Articles/Biosecurity_Implications_for_the_Synthesis_of_Horsepox.pdf?ver=2017-11-03-102542-867.

18 Arturo Casadevall and Michael J. Imperiale, "Risks and Benefits of Gain-of-Function Experiments with Pathogens of Pandemic Potential, Such as Influenza Virus: A Call for a Science-Based Discussion," *mBio* 5, no. 4 (Aug 2014): e01730–14, https://mbio.asm.org/content/5/4/e01730-14.

19 Chau Bui, Padma Narasimhan, and Raina Maclntyre, "Infectious Disease Outbreaks in India-Challenges and Opportunities," School of Public Health and Community Medicine, UNSW Sydney, October 13, 2016, https://sphcm.med.unsw.edu.au/infectious-diseases-blog/infectious-disease-outbreaks-india-challenges-and-opportunities.

20 Insights derived from a closed-door roundtable on "India's Pandemic Preparedness and Response: Role of Scientists and Industry Experts" with representatives from the scientific, industry, and academic community along with a few former government officials, organized as part of the Global Technology Summit in Bengaluru, December 2019.

21 Neelam Taneja and Megha Sharma, "Antimicrobial Resistance in the Environment: The Indian Scenario," *Indian Journal of Medical Research* 149, no. 2 (2019): 119–128, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6563737.

22 Personal interviews with members from the scientific, academic, and industry community conducted by the author during the project. Interviews occurred between April 2018 and December 2019.

23 William J. Broad, "Australian Create a Deadly Mouse Virus," *New York Times*, January 23, 2001, https://www.nytimes.com/2001/01/23/world/australians-create-a-deadly-mouse-virus.html?auth=login-email.

24 Stefan Riedel, "Biological Warfare and Bioterrorism: A Historical Review," *Baylor University Medical Center Proceedings* 17, no. 4 (2004): 400–406, doi:10.1080/08998280.2004.11928002. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1200679/. See also Kai Kupferschmidt, "Anthrax Genome Reveals Secrets About a Soviet Bioweapons Accident," *Science*, August 16, 2016, https://www.sciencemag.org/news/2016/08/anthrax-genome-reveals-secrets-about-soviet-bioweapons-accident.

25 Sabrina Tavernise and Donald G. McNeil Jr., "C.D.C. Details Anthrax Scare for Scientists at Facilities," *New York Times*, June 19, 2014, https://www.nytimes.com/2014/06/20/health/up-to-75-cdc-scientists-may-have-been-exposed-to-anthrax.html.

26 Alison Young, "Sloppy Practices by CDC Scientist Cited in Lab Mishap," *USA Today*, August 15, 2014, https://www.usatoday.com/story/news/nation/2014/08/15/cdc-lab-mistake-avian-influenza-h5n1-strain/13110271/.

27 Devendra T. Mourya et al., "Establishment of Biosafety Level-3 (BSL-3) Laboratory: Important Criteria to Consider While Designing, Constructing, Commissioning, and Operating the Facility in Indian Setting," *Indian Journal of Medical Research* 140, no. 2 (2014): 171–183, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4216491/.

28 Ministry of Science and Technology, Department of Biotechnology, *Regulations and Guidelines for Recombinant DNA Research and Biocontainment 2017* (New Delhi: Government of India, 2017), http://dbtindia.gov.in/sites/default/files/uploadfiles/Regulations_%26_Guidelines_for_Reocminant_DNA_Research_and_Biocontainment%2C2017.pdf.

29 Personal interviews with former government officials, scientific, academic, and industry experts conducted by the author during the project. Interviews occurred between April 2018 and December 2019.

30 D. T. Mourya, P. D. Yadav, A. Khare, and A. H. Khan, "Certification and Validation of Biosafety Level-2 and Biosafety Level-3 Laboratories in Indian Settings and Common Issues," *Indian Journal of Medical Research* 146 (2017): 459–467, http://www.ijmr.org.in/article.asp?issn=0971-5916;year=2017;volume=146;issue=4;spage=459;epage=467;aulast=Mourya.

31 Scientist in a government laboratory in conversation with the author, August 2018.

32 Badri Chatterjee, "50% of COVID-19 Waste Disposed of Unsafely, Says Mumbai Civic Body," *Hindustan Times*, April 8, 2020, https://www.hindustantimes.com/cities/50-of-covid-19-waste-disposed-of-unsafely-says-mumbai-civic-body/story-MH8KHKIhg8rs5q5DoefHfM.html.

33 Personal interviews conducted by the author with leading genome engineering scientists, April 2019.

34 Personal interviews conducted by the author with members from the scientific and academic community during the project, April 2019.

35 Antonia Molloy, "Alphonso Mangoes: EU Lifts Ban on Indian Mango Imports," *Independent*, January 20, 2015, https://www.independent.co.uk/news/business/news/alphonso-mangoes-eu-lifts-ban-on-indian-mango-imports-9990412.html.

36 John J. Ewel et al., "Deliberate Introductions of Species: Research Needs: Benefits Can Be Reaped, but Risks Are High," *BioScience* 49, no. 8 (August 1999): 619–630, https://doi.org/10.2307/1313438.

37 Personal interviews conducted by the author with former military officials and a few independent policy researchers during the project in May 2018 and April 2019.

38 Thomas J. Torok et al., "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars," *Journal of American Medical Association* 278, no. 5 (1997): https://www.cdc.gov/phlp/docs/forensic_epidemiology/Additional%20Materials/Articles/Torok%20et%20al.pdf; Scott Keyes, "A Strange but True Tale of Voter Fraud and Bioterrorism," *The Atlantic,* June 10, 2014, https://www.theatlantic.com/politics/archive/2014/06/a-strange-but-true-tale-of-voter-fraud-and-bioterrorism/372445/.

39 Gigi Kwik Gronvall, *Synthetic Biology: Safety, Security, and Promise* (Baltimore: Health Security Press, 2016), 33.

40 Author interview with a former government expert who spoke on condition of anonymity, New Delhi, July 1, 2019.

41 Andrew Lappworth, "From Coronavirus Tests to Open-Source Insulin and Beyond, 'Biohackers' Are Showing the Power of DIY Science," *The Conversation*, May 11, 2020, https://theconversation.com/from-coronavirus-tests-to-open-source-insulin-and-beyond-biohackers-are-showing-the-power-of-diy-science-138019; Kari Paul, "Biohackers Team Up Online to Help Develop Coronavirus Solutions," *Guardian*, March 18, 2020, https://www.theguardian.com/world/2020/mar/18/biohacking-online-forums-coronavirus-vaccines-testing; Kristen V. Brown, "This Biohacker Is Making a DIY Covid Vaccine, and He Is in a Hurry," *The Print*, June 25, 2020, https://theprint.in/india/this-biohacker-is-making-a-diy-covid-vaccine-and-he-is-in-a-hurry/448750/.

42 Gregory D. Koblentz, "Biosecurity Reconsidered: Calibrating Biological Threats and Responses," *International Security* 34, no. 4 (2010): 96–132, www.jstor.org/stable/40784563; Brown, "This Biohacker Is Making a DIY Covid Vaccine," June 25, 2020.

43 Nell Greenfieldboyce, "As Made-to-Order DNA Gets Cheaper, Keeping It Out of the Wrong Hands Gets Harder," *NPR*, September 24, 2019, https://www.npr.org/sections/health-shots/2019/09/24/762834987/as-made-to-order-dna-gets-cheaper-keeping-it-out-of-the-wrong-hands-gets-harder.

44 "Scientists Question U.S. Anthrax Attack Evidence," *Reuters*, February 16, 2011, https://www.reuters.com/article/us-usa-anthrax-idUSTRE71E5L620110215; Stephen Engelberg, "New Evidence Adds Doubt to FBI's Case Against Anthrax Suspect," *Propublica*, October 10, 2011, https://www.propublica.org/article/new-evidence-disputes-case-against-bruce-e-ivins; Willem Marx, "COVID-19 Has Shown U.S., U.K. Are Vulnerable to Biological Terrorism, Experts Say," *NBC News*, May 18, 2020, https://www.nbcnews.com/politics/national-security/experts-covid-19-has-shown-u-s-u-k-are-n1207776.

45 Tasha L. Pravecek, "Lest We Forget: A Critical Analysis of Bioterrorist Incidents, National Exercises, and U.S. Prevention, Response, and Recovery Strategies," *The Counterproliferation Papers*, Future Warfare Series no. 50 (2011): https://media.defense.gov/2019/Apr/11/2002115514/-1/-1/0/50LESTWEFORGET.PDF.

46 Michael R. Gordon, "A Nation Challenged: Weapons; U.S. Says It Found Qaeda Lab Being Built to Produce Anthrax," *New York Times*, March 23, 2002, https://www.nytimes.com/2002/03/23/world/nation-challenged-weapons-us-says-it-found-qaeda-lab-being-built-produce-anthrax.html.

47 Andrew Griffin, "Isis Laptop Reveals Terror Group 'Wants to Turn Bubonic Plague into a Weapon of War," *Independent*, August 31, 2014, https://www.independent.co.uk/news/world/middle-east/seized-isis-laptop-reveals-wmd-plans-9702030.html.

48 Insights derived from a closed-door roundtable discussion on "Challenges of Minimizing Risks of New Biotechnologies" with former and serving government officials, leading scientists, and policy researchers in Delhi, February 2018.

49 "Pakistan Pushing Coronavirus-Infected Militants into Kashmir: J&K DGP," *The Hindu*, April 23, 2020, https://www.thehindu.com/news/national/pakistan-pushing-coronavirus-infected-militants-into-kashmir-jk-dgp/article31412728.ece.

50 "Pakistan Pushing COVID-19 People into PoK': Indian Army's Claim Angers Islamabad," *The Week*, April 15, 2020, https://www.theweek.in/news/world/2020/04/15/pakistan-pushing-covid-19-people-into-pok-indian-army-claim-angers-islamabad.html.

51 Daniel Kahneman and Amos Tversky, "Prospect Theory: An Analysis of Decision Under Risk," *Econometrica* 47, no. 2 (1979): 263–292, https://www.jstor.org/stable/1914185?origin=JSTOR-pdf&seq=1.

52 World Health Organization defines vaccine hesitancy as delay in acceptance or refusal of vaccines, despite availability of vaccine services. See Robb Butler, "Vaccine Hesitancy: What It Means and What We Need to Know in Order to Tackle It," World Health Organization, accessed May 7, 2020, https://www.who.int/immunization/research/forums_and_initiatives/1_RButler_VH_Threat_Child_Health_gvirf16.pdf?ua=1.

53 Madhurima Shukla, "Growing Fear About Vaccination (Including in India) Is Bringing Back Eradicated Diseases," *Scroll.in*, March 30, 2019, https://scroll.in/article/916368/growing-fear-about-vaccination-including-in-india-is-bringing-back-eradicated-diseases.

54 Sanchita Sharma, "Vaccines Saves Lives, Ignorance Jeopardizes Them," *Hindustan Times*, February 10, 2019, hindustantimes.com/fitness/vaccines-saves-lives-ignorance-jeopardises-them/story-YygCYbOEDZS45AxZZfvZHJ.html.

55 Josh Rottenberg, "Meet the Ojai Dad Who Made the Most Notorious Piece of Coronavirus Disinformation Yet," *Los Angeles Times*, May 13, 2020, https://www.latimes.com/entertainment-arts/movies/story/2020-05-13/plandemic-coronavirus-documentary-director-mikki-willis-mikovits; Jason Wilson, "Plandemic: How the Debunked Movie by Discredited Researcher Judy Mikovits Went Viral," *Guardian*, May 14, 2020, https://www.theguardian.com/commentisfree/2020/may/14/plandemic-movie-discredited-dr-doctor-judy-mikovits-how-debunked-conspiracy-theory-film-went-viral.

56 Insights derived from a student workshop on "Biotechnology: Innovation and Regulation," organized during the Global Technology Summit in Bengaluru, December 2019.

57 Insights derived from a closed-door roundtable discussion on "Challenges of Minimizing Risks of New Biotechnologies," February 2018.

58 Nithyanand Rao, "The Seven-Decade Transnational Hunt for the Origins of the Kyasanur Forest Disease," *Science: The Wire*, November 19, 2016, https://science.thewire.in/health/kyasanur-kfd-rajagopalan-boshell/.

59 Abi T. Vanak and Mridula Mary Paul, "The Time Is Right for OneHealth Science," *The Hindu*, March 14, 2020, https://www.thehindu.com/sci-tech/science/the-time-is-right-for-onehealth-science/article31069639.ece.

60 Nithyanand Rao, "The Seven-Decade Transnational Hunt for the Origins of the Kyasanur Forest Disease," *Science: The Wire*, November 19, 2016, https://science.thewire.in/health/kyasanur-kfd-rajagopalan-boshell/.

61 Sridhar Srikantiah, "Mass Culling for Avian Influenza: Rational Strategy or Needless Destruction?" *Indian Journal of Medical Ethics* 5, no. 2 (2008): https://ijme.in/articles/mass-culling-for-avian-influenza-rational-strategy-or-needless-destruction/?galley=html; "Bird Flu Cases Add to the Woes of Poultry

Rearers," *The Hindu*, March 18, 2020, https://www.thehindu.com/news/cities/bangalore/bird-flu-cases-add-to-the-woes-of-poultry-rearers/article31093908.ece.

62 R. Sadanadan et al., "Towards Global Health Security: Response to the May 2018 Nipah Virus Outbreak Linked to *Pteropus* Bats in Kerala, India," *BMJ Global Health* 3 (2018): e001086, doi:10.1136/bmjgh-2018-001086.

63 "Nipah Virus–India: Emergencies Preparedness, Response," World Health Organization, August 7, 2018, https://www.who.int/csr/don/07-august-2018-nipah-virus-india/en/.

64 Sudhi Ranjan Sen, "MHA Cancels Manipal Varsity FCRA License over 'Unauthorized Research," *Hindustan Times*, February 23, 2020, https://www.hindustantimes.com/india-news/mha-cancels-manipal-varsity-fcra-license-over-unauthorised-research/story-M9I6VJEYm5OB25Wl3oobkN.html.

65 Sudhi Ranjan Sen, "MHA Cancels Manipal Varsity FCRA License over 'Unauthorized Research,'" *Hindustan Times*, February 23, 2020, https://www.hindustantimes.com/india-news/mha-cancels-manipal-varsity-fcra-license-over-unauthorised-research/story-M9I6VJEYm5OB25Wl3oobkN.html; Priyanka Pulla, "As Paranoia Goes Viral in Govt Health Circles, Testing Labs Face the Heat," *The Wire*, February 10, 2020, https://thewire.in/health/manipal-virus-research-national-institute-virology-health-ministry-icmr-nipah-virus-bsl-4-bioweapon; Chetana Belagere, "Manipal Academy of Higher Education Denies ICMR's Charges over Nipah Research," *New Indian Express*, February 14, 2020, https://www.newindianexpress.com/cities/bengaluru/2020/feb/14/manipal-academy-of-higher-education-denies-icmrs-charges-over-nipah-research-2103097.html.

66 Sandhya Ramesh and Samyak Pandey, "Why the Worst Locust Attack in Decades Has Invaded North India," *The Prin*t, May 29, 2020, https://theprint.in/science/why-the-worst-locust-attack-in-decades-has-invaded-north-india/431257/; Jacob Koshy, "The Hindu Explains: Why Is the Locust Surge Posing a Threat to Agriculture In India," *The Hindu*, May 31, 2020, https://www.thehindu.com/sci-tech/agriculture/the-hindu-explains-why-is-the-locust-surge-posing-a-threat-to-agriculture-in-india/article31712573.ece.

67 "Fact Check: How India controls desert locusts Rajasthan and Gujarat," *Indian Express,* July 11, 2019, https://indianexpress.com/article/explained/how-india-controls-dessert-locusts-rajasthan-and-gujarat-5824435/.

68 Ministry of Agriculture and Farmers' Welfare, "Contingency Plan for Desert Locust Invasions, Outbreaks, and Upsurges," June 2019, http://ppqs.gov.in/sites/default/files/contingency_plan_0.pdf.

69 Ministry of Agriculture and Farmers Welfare, "Lok Sabha Unstarred Question No. 3709," March 17, 2020, http://164.100.24.220/loksabhaquestions/annex/173/AU3709.pdf.

70 Kabir Agarwal and Shruti Jain, "Climate Change Brings the Worst Locust Attack in Decades to India," *The Wire*, May 26, 2020, https://thewire.in/agriculture/locust-attack-india-jaipur-climate-change.

71 Pallavi Das and Vineet K Giri, "How Colonial India Fought Locust Attacks—and What We Could Learn from Those Tactics," *Scroll.in*, May 30, 2020, https://scroll.in/article/963306/how-colonial-india-fought-locust-attacks-and-what-we-could-learn-from-those-tactics.

72 Isobel Ronai and Brian Lovett, "An Argument for Gene Drive Technology to Genetically Engineer Population of Insects Like Mosquitoes and Locusts," *The Conversation*, July 14, 2020, https://theconversation.com/an-argument-for-gene-drive-technology-to-genetically-control-populations-of-insects-like-mosquitoes-and-locusts-127415; Joseph Opoku Gakpo, "Scientists Call for Innovation in Fight Against Destructive Locust Pests," Cornell Alliance for Science, February 6, 2020, https://

allianceforscience.cornell.edu/blog/2020/02/scientists-call-for-innovation-in-fight-against-destructive-locust-pests/; Marlene Cimons, "Controlling Destructive Locusts by Manipulating Their Genetics," *Phys.org*, July 12, 2013, https://phys.org/news/2013-07-destructive-locusts-genetics.html.

73 Ramesh Davesar, "Is Biological Warfare Raising Its Ugly Head?" *Pioneer*, March 7, 2020, https://www.dailypioneer.com/2020/columnists/is-biological-warfare-raising-its-ugly-head-.html.

74 Matt Reynolds, "The US Military Is Hacking Insects with Virus DNA, Raising Fears of Dangerous New Bioweapons," *Wired*, October 4, 2018, https://www.wired.co.uk/article/darpa-insect-allies-crop-editing; Josh Gabbatiss, "U.S. Military Plan to Spread Viruses Using Insects Could Create 'New Class Of Biological Weapon,' Scientists Warn," *Independent*, October 4, 2018, https://www.independent.co.uk/news/science/us-military-plan-biological-weapons-insect-allies-virus-crop-darpa-a8568996.html.

75 "Three confirmed cases of Coronavirus in India, all from Kerala," *Economic Times,* February 3, 2020, https://economictimes.indiatimes.com/news/politics-and-nation/student-from-kerala-is-indias-first-coronavirus-patient/articleshow/73763438.cms?from=mdr.

76 Nileena MS, "How the Kerala Government Is Shaping and Implementing Its COVID-19 Response," *Caravan*, March 28, 2020, https://caravanmagazine.in/health/covid-19-coronavirus-kerala-vijayan-shailaja-healthcare-system.

77 Sanya Dhingra and Swagata Yadavar, "This Is the Team Advising PM Modi in India's Battle Against Coronavirus," *The Print*, March 27, 2020, https://theprint.in/india/governance/this-is-the-team-advising-pm-modi-in-indias-battle-against-coronavirus/388607/.

78 Government of India, Ministry of Home Affairs, Order No. 40-3/2020-DM-I(A), March 24, 2020, http://pibphoto.nic.in/documents/rlink/2020/mar/p202032401.pdf.

79 Kevin James, "COVID-19 and the Need for Clear Centre-State Roles," Vidhi Centre for Legal Policy, April 3, 2020, https://vidhilegalpolicy.in/blog/covid-19-and-the-need-for-clear-centre-state-roles.

80 "Covid-19: Task Force to Map Technologies to Fund Nearly Market-Ready Solutions," *Economic Times*, March 27, 2020, https://economictimes.indiatimes.com/small-biz/startups/newsbuzz/covid-19-task-force-to-map-of-technologies-to-fund-nearly-market-ready-solutions/articleshow/74839708.cms?from=mdr.

81 Benjamin Mueller and Jane Bradley, "England's 'World Beating' System to Track the Virus Is Anything But," *New York Times*, June 17, 2020, https://www.nytimes.com/2020/06/17/world/europe/uk-contact-tracing-coronavirus.html?referringSource=articleShare.

82 Anoo Bhuyan, "India Tries to Hire 227 Epidemiologists in the Middle of COVID-19 Pandemic," *IndiaSpend*, April 20, 2020, https://www.indiaspend.com/india-tries-to-hire-227-epidemiologists-in-the-middle-of-covid-19-pandemic/.

83 T. V. Padma, "In India, Microbiologists Are Suddenly in Demand. Where Were They Until Now," *Science: The Wire*, April 10, 2020, https://science.thewire.in/the-sciences/coronavirus-microbiology-virology-basic-research-funding-icmr/.

84 Personal interview with a leading academician in Pune, July 2018.

85 Subhradipta Sarkar and Archana Sarma, "Disaster Management Act, 2005: A Disaster in Waiting?" *Economic and Political Weekly* 41, no. 35 (2006): 3760–3763, https://www.jstor.org/stable/4418643?seq=1; "What COVID-19 Teaches India About Disaster Management," *Economic and Political Weekly: EPW Engage*, April 2, 2020, https://www.epw.in/engage/article/what-covid-19-teaches-india-about-disaster.

86 Press Trust of India, "Centre Gradually Weakening NDMA: Former Vice-Chairman M Shashidhar Reddy," *News18*, June 22, 2015, https://www.news18.com/news/india/centre-gradually-weakening-ndma-former-vice-chairman-m-shashidhar-reddy-1009972.html; Press Trust of India, "Govt Downgrades Post of NDMA, Vice-Chairman, Members," *Business Standard*, September 19, 2014, https://www.business-standard.com/article/pti-stories/govt-downgrades-posts-of-ndma-vice-chairman-members-114091900956_1.html.

87 Integrated Disease Surveillance Programme, "About IDSP," accessed April 2, 2020, https://idsp.nic.in/index4.php?lang=1&level=0&linkid=313&lid=1592.

88 National Health Mission: Ministry of Health and Family Welfare, "Communicable Disease Control Programme," accessed June 4, 2020, https://nhm.gov.in/index1.php?lang=1&level=1&sublinkid=1056&lid=616.

89 Insights derived from a closed-door roundtable on "India's Pandemic Preparedness and Response: Role of Scientists and Industry Experts," December 2019.

90 Eva Pilot et al., "Towards Sustainable Public Health Surveillance in India: Using Routinely Collected Electronic Emergency Medical Service Data for Early Warning of Infectious Diseases," *Sustainability* 9 (2017): doi:10.3390/su9040604.

91 National Animal Disease Reporting System, Ministry of Fisheries, Animal Husbandry, and Dairying, accessed July 16, 2020, https://nadrsapps.gov.in/.

92 NADRES: Redefining Livestock Disease Forewarning, Indian Council of Agricultural Research, accessed July 16, 2020, https://nivedi.res.in/Nadres_v2/aboutnadres.php.

93 *National Disaster Management Guidelines—Management of Biological Disasters* (New Delhi: National Disaster Management Authority, Government of India, July 2008).

94 Public Health (Prevention, Control and Management of Epidemics, Bioterrorism and Disasters) Bill, 2017, No. T-18014/3/2004/PH, Ministry of Health and Family Welfare, February 13, 2017, https://www.prsindia.org/uploads/media/draft/Draft%20PHPCM%20of%20Epidemics,%20Bio-Terrorism%20and%20Disasters%20Bill,%202017.pdf.

95 Menaka Rao, "A New Bill on Public Health Emergencies Allows for Dubious Restrictions of Citizens' Liberties," *Scroll.in*, March 31, 2017, https://scroll.in/pulse/833283/a-new-bill-on-public-health-emergencies-allows-for-dubious-restrictions-of-citizens-liberties.

96 Pushpa Narayan, "Tamil Nadu Likely to Make Measles-Rubella Vaccination Mandatory," *Times of India*, February 28, 2017, https://timesofindia.indiatimes.com/city/chennai/tamil-nadu-likely-to-make-measles-rubella-vaccination-mandatory/articleshow/57393147.cms.

97 Venkat Ananth, "Aarogya Setu's Not All That Healthy for a Person's Privacy," *Economic Times*, April 15, 2020, https://economictimes.indiatimes.com/tech/software/aarogya-setus-not-all-that-healthy-for-a-persons-privacy/articleshow/75112687.cms?from=mdr; Binayak Dasgupta, "Protection or Threat? Experts Say Aarogya Setu Poses National Security Risk," *Hindustan Times*, May 23, 2020, https://www.hindustantimes.com/india-news/aarogya-setu-protection-or-threat/story-QmpSP3H60ohkLV3l5ywhBI.html.

98 Sumi Sukanya Dutta, "India's Public Expenditure on Health Less than Lower Income Countries: Government Data," *New Indian Express*, November 1, 2019, https://www.newindianexpress.com/nation/2019/nov/01/indias-public-expenditure-on-health-less-than-lower-income-countries-government-data-2055553.html.

99 Viswanath Pilla, "Economic Survey 2020: Expenditure on Healthcare Continues to Be Flat," *Moneycontrol*, January 31, 2020, https://www.moneycontrol.com/news/economy/policy/economic-survey-2020-expenditure-on-healthcare-continues-to-be-flat-4888481.html.

100 Sumi Sukanya Dutta, "India's Public Expenditure on Health Less Than Lower Income Countries: Government Data," *New Indian Express*, November 1, 2019, https://www.newindianexpress.com/nation/2019/nov/01/indias-public-expenditure-on-health-less-than-lower-income-countries-government-data-2055553.html.

101 Puja Mehra, "India's Economy Needs Big Dose of Healthcare Spending," *Livemint*, April 8, 2020, https://www.livemint.com/news/india/india-s-economy-needs-big-dose-of-health-spending-11586365603651.html; "Study Reveals Rural India Gets Only 1/3rd of Hospital Beds," *The Hindu*, July 19, 2013, https://www.thehindu.com/sci-tech/health/study-reveals-rural-india-gets-only-13rd-of-hospital-beds/article4931844.ece.

102 "India Facing Shortage of 600,000 Doctors, 2 Million Nurses: Study," *Economic Times*, April 14, 2019, https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/india-facing-shortage-of-600000-doctors-2-million-nurses-study/articleshow/68875822.cms?from=mdr; Vidya S Sharma, "Politics Trump Health in India's COVID-19 Calamity," *EastAsiaForum*, May 2, 2020, https://www.eastasiaforum.org/2020/05/02/politics-trump-health-in-indias-covid-19-calamity/.

103 Pratyush Singh, "Non-COVID-19 Patients Are Paying the Price of India's Efforts Against the Coronavirus," *Science: The Wire*, May 3, 2020, https://science.thewire.in/health/healthcare-non-coronavirus-patients/; Archana Shukla, "Rural India and COVID-19: Pregnant Women Risk Long Travel in Search of Safe Hospital," *CNBC TV18*, May 2, 2020, https://www.cnbctv18.com/healthcare/rural-india-and-covid-19-pregnant-women-risk-long-travel-in-search-of-safe-hospital-5826661.htm.

104 Sanchita Sharma, "Need to Reboot Health Care System to Also Focus on Non-Covid Patients," *Hindustan Times*, May 4, 2020, https://www.hindustantimes.com/india-news/need-to-reboot-health-care-system-to-also-focus-on-non-covid-patients/story-a3caJQjm2BplVsvl3vkt8J.html.

105 Goutam Das, "At 0.7% of GDP, India's R&D Expenditure in Science Is Less Than BRIC Nations," *Business Today*, November 22, 2019, https://www.businesstoday.in/current/world/india-gdp-randd-expenditure-in-science-is-less-than-bric-nations/story/390874.html; Ananth Padmanabhan and Shruti Sharma, "A Larger R&D Budget Won't Secure a Quantum Leap for Innovation in India," *The Wire*, January 27, 2017, https://thewire.in/economy/a-higher-rd-budget-wont-secure-a-quantum-leap-for-innovation-in-india.

106 Kundan Pandey, "Lack of Funding for Top Health Research Body," *DownToEarth*, January 15, 2016, https://www.downtoearth.org.in/news/governance/apex-research-body-for-health-suffers-lack-of-funding-52459.

107 Yatish Yadav, "Coronavirus Outbreak: India's Miniscule Health Budget Hampers Development of Tools Necessary to Deal with Pandemics Like COVID-19," *Firstpost*, March 20, 2020, https://www.firstpost.com/india/coronavirus-outbreak-indias-minuscule-health-budget-hampers-development-of-tools-necessary-to-deal-with-pandemics-like-covid-19-8171811.html.

108 "Increase Funds to ICMR for Robust Research: Panel," *Economic Times*, March 11, 2018, https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/increase-funds-to-icmr-for

-robust-research-panel/articleshow/63256415.cms?from=mdr; Padma, "In India, Microbiologists Are Suddenly in Demand," April 10, 2020.

109 The guidelines issued by the DBT are as follows: Recombinant DNA Safety Guidelines (1990), Revised Guidelines for Safety in Biotechnology (1994), and Revised Guidelines for Research in Transgenic Plants (1998).

110 "Committees," RCGM Secretariat, Department of Biotechnology, Ministry of Science and Technology, accessed May 21, 2020, https://ibkp.dbtindia.gov.in/Content/Commitee?AspxAutoDetectCookie Support=1.

111 Ministry of Science and Technology, Department of Biotechnology, *Regulations and Guidelines for Recombinant DNA Research and Biocontainment 2017* (New Delhi: Government of India, 2017), accessed January 31, 2020, https://rcb.res.in/upload/Biosafety_Guidelines.pdf.

112 "Committees," RCGM Secretariat, Department of Biotechnology, accessed May 21, 2020.

113 B. M. Gandhi, "Biosafety, Biosecurity, and Code of Ethics," Society for the Study of Peace and Conflict Research Paper, January 2015, http://www.uop.edu.pk/ocontents/Lec%20no%201(6).pdf.

114 Ananth Padmanabhan, Shashank Reddy, and Shruti Sharma, *Modern Biotechnology and India's Governance Imperatives*, Carnegie India, October 2017, https://carnegieindia.org/2017/10/02/modern-biotechnology-and-india-s-governance-imperatives-pub-73253.

115 Vishwa Mohan, "HTBt Cotton Grown Illegally in 3 States," *Times of India*, July 3, 2019, https://timesofindia.indiatimes.com/india/67-cases-of-illegal-cultivation-of-transgenic-cotton-being-probed-in-three-states-since-2017-govt-tells-lok-sabha/articleshow/70046340.cms; Colin Todhunter, "Bt Brinjal Illegally Growing in India: Who Is Really Pulling the Strings?," *Counterpunch*, April 29, 2019, https://www.counterpunch.org/2019/04/29/bt-brinjal-illegally-growing-in-india-who-is-really-pulling-the-strings/; Meena Menon, "India Must Adopt Stricter Regulation of Genetically Engineered Crops, or Face Biosecurity Breach," *Firstpost*, June 5, 2019, https://www.firstpost.com/india/india-must-adopt-stricter-regulation-of-genetically-engineered-crops-or-face-biosecurity-breach-6754951.html.

116 Lianchawii, "Biosafety in India: Rethinking GMO Regulation," *Economic and Political Weekly* 40, no. 39 (2005): 4284–4289, https://www.jstor.org/stable/pdf/4417202.pdf?refreqid=excelsior%3A8840bbdec81c4797af3ed3637ab36635.

117 Aarti Gupta, "Governing Biosafety in India: The Relevance of the Cartagena Protocol, Belfer Center for Science and International Affairs," Discussion Paper 2000-24, Environment and Natural Resources Program, Kennedy School of Government, Harvard University, 2000, http://www.columbia.edu/cu/genie/pdf/GoverningBiosafe.pdf.

118 Biotechnology Regulatory Authority of India Bill, 2013, Bill No. 57 of 2013, as Introduced in the Lok Sabha, accessed April 15, 2020, https://www.prsindia.org/sites/default/files/bill_files/Biotechnology_Regulatory_Authority_of_India_Bill.pdf.

119 Biotechnology Regulatory Authority of India Bill.

120 D. Kiruthika, "A Critical Analysis of the Biotechnology Regulatory Authority of India Bill, 2013," *Academike*, November 13, 2015, https://www.lawctopus.com/academike/biotechnology-regulatory-authority-bill-2013/.

121 Food Safety and Standards Act, 2006, accessed May 28, 2019, https://indiacode.nic.in/bitstream/123456789/7800/1/200634_food_safety_and_standards_act%2C_2006.pdf.

122 "Online Plant Quarantine Services Launched: Delivery of Services to Become More Efficient and Transparent," press release, Ministry of Agriculture and Family Welfare, January 24, 2011, http://pib.nic.in/newsite/PrintRelease.aspx?relid=69294.

123 Amand Shah, "The Plant Quarantine Order in India," Ministry of Agriculture, Government of India, accessed April 10, 2020, http://www.fao.org/3/y5968e/y5968e0f.htm.

124 Plant Quarantine (Regulation of Import into India) Order, 2003, Ministry of Agriculture, November 18, 2003, https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115121925276_PlantQuarantine_order_2003.pdf.

125 Daniele Manzella and Jessica Vapnek, "Development of an Analytical Tool to Assess Biosecurity Legislation," Food and Agricultural Organization (FAO) Legislative Study, 2007, http://www.fao.org/3/a-a1453e.pdf.

126 Ministry of Law, Justice, and Company Affairs, "Livestock Importation (Amendment) Act, 2001," *Gazette of India*, August 29, 2001, http://dadf.gov.in/sites/default/filess/gazetteofindia29august2008%20%20%202.pdf.

127 Livestock Importation Act, 1898, Act 9 of 1898, August 12, 1898, http://dadf.gov.in/sites/default/filess/actno9of1898%20%201.pdf.

128 Roopa Madhav and Adil Hasan Khan, "India Country Study," Biosafety Report, accessed May 28, 2019, http://elrs.in/content/biosafety_report.pdf.

129 Prevention and Control of Infectious and Contagious Diseases in Animals Act, 2009, Ministry of Law and Justice, March 20, 2009, http://dahd.nic.in/sites/default/filess/Gazette_20-03-09.pdf09.pdf.

130 Weapons of Mass Destruction and Their Delivery Systems (Prohibition of Unlawful Activities) Act, 2005, No. 21 of 2005, June 6, 2005, https://www.mea.gov.in/Uploads/PublicationDocs/148_The-Weapons-Mass-destruction-And-Delivery-Systems-Act-2005.pdf.

131 Shishir Gupta, "DRDO Confirms Chinese Ship India Stopped Was Carrying Nuclear-Capable Equipment to Pakistan," *The Print*, March 4, 2020, https://theprint.in/india/drdo-confirms-chinese-ship-india-stopped-was-carrying-nuclear-capable-equipment-to-pakistan/375184/.

132 Jitendra, "Why India Is Vulnerable to Attacks by Alien Species," *DownToEarth*, August 20, 2019, https://www.downtoearth.org.in/news/agriculture/why-india-is-vulnerable-to-attacks-by-alien-species-66189; G Ram Mohan, "Fall Armyworm Attack Low Maize Yield Reduces Cattle Feed," *DownToEarth*, March 25, 2019, https://www.downtoearth.org.in/news/agriculture/fall-armyworm-attack-low-maize-yield-reduces-cattle-feed-63700.

133 "Locust Attack in India," *The Hindu*, June 2, 2020, https://www.thehindu.com/sci-tech/agriculture/locust-attack-in-india/article31729025.ece; Shoba Suri, "Amid COVID-19 Crisis, Locust Upsurge Threatens Food Security," *News18*, May 26, 2020, https://www.news18.com/news/opinion/amid-covid-19-crisis-locust-upsurge-threatens-food-security-2637841.html.

134 "Importing Plants into India: Processes and Challenges," Obhan and Associates, June 13, 2017, https://www.lexology.com/library/detail.aspx?g=4f57e779-3e2d-4bc5-903d-21db04bd8cf1.

135 Food and Agriculture Organization, "Glossary of Phytosanitary Terms," accessed April 28, 2020, http://www.fao.org/3/w3587e/w3587e01.htm.
136 Agricultural Biosecurity Bill, 2013, Bill No. 31 of 2013, as Introduced in the Lok Sabha, accessed April 15, 2020, https://www.prsindia.org/sites/default/files/bill_files/Agricultural_Biosecurity_Bill%2C_2013.pdf.
137 Public Health (Prevention, Control and Management of Epidemics, Bioterrorism and Disasters) Bill, 2017, No. T-18014/3/2004/PH, Ministry of Health and Family Welfare, February 13, 2017, https://www.prsindia.org/uploads/media/draft/Draft%20PHPCM%20of%20Epidemics,%20Bio-Terrorism%20and%20Disasters%20Bill,%202017.pdf.
138 *National Disaster Management Guidelines*, July 2008.
139 "German Epidemic Preparedness Team (SEEG): Working Against Epidemics," Deutsche Gesellschaft für Internationale Zusammenarbeit, accessed July 26, 2020, https://www.giz.de/en/worldwide/40435.html.
140 *National Disaster Management Guidelines*, July 2008.
141 Beth Cameron, "I Ran the White House Pandemic Office. Trump Closed It," *Washington Post*, March 13, 2020, https://www.washingtonpost.com/outlook/nsc-pandemic-office-trump-closed/2020/03/13/a70de09c-6491-11ea-acca-80c22bbee96f_story.html.
142 K. Sujatha Rao, "Governance: Impacting the Health System," in *Do We Care? India's Health System* (New Delhi: Oxford University Press India, 2017), 120–121.
143 "One Health," press release, World Health Organization, September 21, 2017, https://www.who.int/news-room/q-a-detail/one-health.
144 Insights derived from a workshop on "Tackling Coronavirus: Prevention, Surveillance, and Response," with representatives from the government and academic community along with health practitioners in Delhi, March 2020.
145 Insights derived from a closed-door roundtable on "India's Pandemic Preparedness and Response: Role of Scientists and Industry Experts," December 2019.
146 Seth Berkley, "Why the Work to Contain Future Ebola Outbreaks Must Continue," *Telegraph*, July 24, 2018, https://www.telegraph.co.uk/news/2018/07/24/ebola-outbreak-work-contain-potential-pandemics-must-continue/.
147 Insights derived from a closed-door roundtable on "India's Pandemic Preparedness and Response: Role of Scientists and Industry Experts," December 2019.
148 Insights derived from a closed-door roundtable on "India's Pandemic Preparedness and Response: Role of Scientists and Industry Experts," December 2019.
149 R. Prasad, "Broad-Spectrum Antiviral Inhibits Novel Coronavirus," *The Hindu*, May 2, 2020, https://www.thehindu.com/sci-tech/science/broad-spectrum-antiviral-inhibits-novel-coronavirus/article31489418.ece.
150 James M. Dorsey, "An Outbreak Anywhere Is an Outbreak Everywhere," *Modern Diplomacy*, May 12, 2020, https://moderndiplomacy.eu/2020/05/12/an-outbreak-anywhere-is-an-outbreak-everywhere/; Tom Frieden, "CDC Director: A Disease Outbreak Anywhere Is a Risk Everywhere," *CNN*, September 20, 2013, https://edition.cnn.com/2013/09/20/health/disease-outbreak-risk-frieden/index.html.
151 "Risk Communication Simulation Exercises," World Health Organization, accessed August 19, 2020, https://www.who.int/emergencies/risk-communications/simulation-exercises.

CARNEGIE
ENDOWMENT FOR
INTERNATIONAL PEACE

1779 Massachusetts Avenue NW | Washington, DC 20036 | P: + 1 202 483 7600

CarnegieEndowment.org