

# Introduction

In late 2015, health officials in Brazil reported the appearance and rapid spread of a mosquito-borne pathogen, the Zika virus. The spread of the virus was tentatively linked to an apparent epidemic of a rare and devastating birth defect, microcephaly, and to an upsurge in the number of cases of the neurological disorder Guillain-Barré. Although Zika was not a novel virus, it had never before been linked to such severe outcomes. By February 2016, the virus had infected more than a million Brazilians, and several thousand cases of infant microcephaly had been reported. Infectious disease experts hypothesized that the virus had traveled with tourists to Brazil from French Polynesia two years earlier and feared that the upcoming summer Olympics in Rio de Janeiro would be a likely setting for further global circulation. As the virus was detected in other Latin American countries, some public health officials recommended that women of childbearing age delay pregnancy during the outbreak. The U.S. Centers for Disease Control and Prevention (CDC) issued an advisory suggesting that pregnant women avoid travel to affected areas.

Researchers from North America and Europe hurried to the region of the epidemic to investigate its characteristics. How many cases were there? Could Zika be definitively linked to the cases of microcephaly? The

prevention of further transmission would be a challenge, authorities warned. It would be difficult to extinguish the virus through control of its host because the species of mosquito that carried it thrived in crowded urban settings with poor infrastructures of water provision and drainage. And it would be at least a year before researchers could test a potential vaccine against the virus. As the North American summer approached, U.S. health officials became increasingly concerned that the disease would affect populations in southern regions of the country. In the face of mounting worries, the U.S. Food and Drug Administration approved experimental trials of a genetically modified mosquito in Florida, and the CDC released funds to state and local health agencies to support Zika preparedness efforts.

Global health authorities also moved to intervene. On February 1, the Director-General of the World Health Organization (WHO) declared the Zika outbreak a “public health emergency of international concern” (PHEIC). With this announcement, the organization sought to galvanize “a coordinated international response to minimize the threat in affected countries and reduce the risk of further international spread.”<sup>1</sup> The act of classifying the situation as a global health emergency indicated both the potential for disaster and the urgency of immediate response.<sup>2</sup> But the official declaration of emergency also did something else: it brought the Zika virus into a technical and administrative relationship with a range of other public health threats. The category of PHEIC, according to WHO, not only encompassed infectious disease outbreaks but could also include incidents of food contamination, toxic chemical releases, or nuclear accidents.<sup>3</sup> Although unique in many respects, the Zika virus now also conformed to a class of event that had come to prominence among scientists, health authorities, and security officials over the prior decade.

The emergency declaration was a way of assimilating the specific event into a more general form, making it comprehensible and potentially manageable.<sup>4</sup> Through the act of classification, Zika was brought into a preexisting governance framework, the International Health Regulations (IHR), which provided health authorities with guideposts for technical and administrative action. The first such action was the establishment of an Emergency Committee comprising infectious disease experts whose task was to advise the WHO director-general on how to manage the outbreak.

The committee's initial recommendations included enhanced surveillance for cases of microcephaly in areas of Zika transmission, precautionary measures to prevent infection, increased research into the etiology of microcephaly, and ongoing discussions with the drug industry and regulatory agencies on vaccine development.

The declaration of a global health emergency, then, did not point to an extralegal state of exception but was rather a technocratic classification designed to integrate the outbreak of a novel disease into a preexisting regulatory framework.<sup>5</sup> The IHR framework envisioned a dangerous new world of potentially catastrophic outbreaks and bound its signatories to provisions for detecting and intervening in such outbreaks. However, although the regulations served as the ligature for the strategy WHO called "global public health security in the 21st century," their actual operation rested on a twentieth-century paradigm of international health in which nation-states remained the site of authority and responsibility while WHO played a role of administrative coordination and technical norm-making.<sup>6</sup> As we will see, the ability of the framework to govern the actions of states in the name of a global space of public health security was highly constrained.

It is with the declaration of a "public health emergency of international concern" that the regulatory capacity of the IHR framework is put to the test. Although the regulations provide criteria for determining whether a specific event should be considered a global health emergency, the effort to galvanize intensive global response through the declaration of a PHEIC has proven politically fraught. Tensions have arisen around questions such as the following: which diseases should be prioritized as potential emergencies? What obligations do wealthy countries have to poor ones at the advent of an emergency? And to what extent does the declaration of an emergency authorize international health officials to regulate the actions of nation-states? In April 2009, WHO made the very first such emergency declaration shortly after the appearance of a novel strain of influenza with the potential to cause a pandemic. When the pandemic strain proved milder than initially feared, the organization faced sharp criticism from some quarters for its proactive response. Five years later, the question of when to declare a health emergency was at the center of another controversy, as the Ebola epidemic raged out of control in West

Africa: in this case, WHO was widely accused of having failed to react in time to the severe threat posed by the outbreak.

With this backdrop in mind, the members of the newly established Emergency Committee charged with Zika response contributed a commentary in *The Lancet* early in 2016 to address the question, “Why is this situation a PHEIC?” The commentary began by listing the legal criteria that a given situation must meet to be considered an official global health emergency: it must constitute a health risk to other countries through international spread; it must require a coordinated response because it is unexpected, serious, or unusual; and it must have implications beyond the affected country that require immediate action.<sup>7</sup> But this list of criteria did not quite address the question that had been posed: what exactly made the situation an emergency? The committee members noted that they had been asked how their decision to declare the Zika epidemic a global health emergency related to deliberations by a different Emergency Committee, two years earlier, over the classification of the outbreak of Ebola in West Africa. “The answer to us is clear,” they wrote. The 2014 Ebola epidemic had been classified as a PHEIC “because of what science knew about the Ebola from many years of research during outbreaks in the past.” In contrast, the current PHEIC had been declared “because of what is not known about the current increase in reported clusters of microcephaly and other disorders, and how this might relate to concurrent Zika outbreaks.” In the first case, the emergency declaration was a result of knowledge; in the second case, it was due to ignorance. Given the state of non-knowledge concerning Zika, the emergency declaration was a call for an intensive scientific mobilization, in particular to understand the relation between the spread of the mosquito-borne pathogen and the upsurge in reported cases of microcephaly.

The explicit goal of the International Health Regulations is to minimize the global spread of an infectious disease and at the same time to discourage countries from imposing unnecessary trade and travel restrictions in response to outbreaks. The regulations were revised in 2005 in response to a newly articulated problem: an apparent surge in the appearance of “emerging diseases” such as hemorrhagic fevers, West Nile virus, pandemic influenza, and extensively drug-resistant tuberculosis (XDR-TB). In the wake of the 2002 SARS (severe acute respiratory syndrome) out-

break, a number of health authorities argued that the existing international health regulations were insufficient to manage this new kind of threat. Emerging diseases had several features in common: they were caused either by previously unknown pathogens or by novel mutations of existing pathogens; their emergence and spread was difficult to predict or prevent; they were difficult or impossible to contain or to treat; and their appearance carried the portent of global catastrophe if not quickly contained.

Another feature shared by these diseases was the explanation of why they were emerging: specialists argued that the increasingly frequent appearance of novel pathogens was the result of radical transformations in the relationship between humans and their environments. These changes included the disturbance of previously isolated ecosystems, increasing population density in urban slums, the rapid global circulation of people, the industrialization of food and agricultural production systems, and the overuse of antibiotics in clinics and livestock facilities. More generally, according to this diagnosis, intensifying modernization processes had generated novel threats that traditional public health measures, from sanitation engineering to mass vaccination, were incapable of managing. As infectious disease specialists and public health authorities looked toward a future horizon of ever-emergent pathogenic threats, they saw a fragile world characterized by interdependence and vulnerability.

If the category of emerging disease seemed self-evident by early 2016, it is important to underline its relatively recent invention. Beginning in the late 1980s and early 1990s, in the midst of the HIV/AIDS pandemic—which unsettled the mid-twentieth-century assumption that infectious disease was on the decline—a group of microbiologists and infectious disease epidemiologists argued that AIDS was a harbinger of many more, as-yet-unknown diseases to come. By the time of the appearance and spread of Zika virus two and a half decades later, international health authorities had sketched, and begun to implement, a diagram for the governance of such diseases, known as “global public health security.”<sup>8</sup> This diagram brought together a number of techniques of surveillance and response, such as: internet based disease reporting tools that transcended national systems of case reporting, regional laboratories capable of rapidly analyzing biological samples, stockpiles of vaccines and antimicrobial drugs, incentives to

develop new medical countermeasures, and emergency operations centers to coordinate response among disparate agencies. The diagram also included political and administrative measures such as decision tools to guide authorities in selecting which events constitute a global health emergency and injunctions against the imposition of economically damaging travel and trade restrictions.

The objective of global health security is to detect and contain the outbreak of a novel pathogen before it can spread to become a global catastrophe. But the various technical and administrative measures gathered together as part of this diagram should not be understood simply as direct responses to a growing number of emerging disease outbreaks; rather, these measures function to constitute a given situation as an emergency, one that requires an urgent and rapid collective response. In other words, it is not the inherent characteristics of a given disease outbreak but rather the classificatory schema as it combines with the techniques and politics of global health security that makes the event a candidate to become an official emergency. As a result, there is often a lack of fit between the characteristics of a disease event and the systems that are mobilized to respond to it. This is well illustrated by the international response to the early stages of the 2014 Ebola epidemic—or rather, the initial lack of such response. Crucially, for several months as the epidemic spread in West Africa, the event was not officially classified as a PHEIC and was, more broadly, ignored by the international community, with the exception of medical humanitarian organizations. The reasons for this delay remain a topic of debate, but arguably, at its early stages the outbreak did not fit international health officials' administrative criteria for the declaration of an emergency. At the time, many infectious disease specialists considered Ebola to be a highly dangerous but locally manageable disease and one that was unlikely to lead to a catastrophic and widespread epidemic.

As this dire failure of response demonstrates, global health security is better seen as a schema or a plan than as a set of effectively functioning mechanisms that can successfully manage any outbreak of emerging disease. Indeed, the rapid declaration by WHO of a global health emergency in the case of Zika can be understood at least in part as a reaction to widespread denunciation of the organization for its slow response to the Ebola epidemic. And in turn, the slow response to Ebola was likely related to

criticism for an overly intensive response to swine flu in 2009. With each outbreak of a dangerous new pathogen, then, gaps in the putative global health security system become apparent and calls for reform gain purchase.

This book tells the story of how the fragile and still-uncertain machinery of global health security was cobbled together over a two-decade period, beginning in the early 1990s. It is neither a heroic account of visionary planning by enlightened health authorities, nor a sinister story of the securitization of disease by an ever-expansive governmental apparatus. Rather, it is a story of the assemblage of disparate elements—adapted from fields such as civil defense, emergency management, and international public health—by well-meaning experts and officials and of response failures that have typically led, in turn, to reforms that seek to strengthen or refocus the apparatus.<sup>9</sup> The analysis centers on the ways that authorities—whether public health officials, national security experts, life scientists, or other privileged observers—conceptualize and act on an encroaching future of disease emergence. This uncertain future can be taken up and made into an object of present intervention according to multiple rationalities: as an object of probabilistic calculation, as a specter that must be avoided through precautionary intervention, or as a potential catastrophe that cannot be evaded but can only be prepared for.<sup>10</sup> In the chapters that follow, we see how these various logics come into tension or combine in response to actual and anticipated disease emergencies.

The book builds conceptually on work in the field of historical ontology, which asks how taken-for-granted objects of existence—whether the economy, the psyche, or the population—are brought into being through contingent and often-overlooked historical processes. Such entities, as Ian Hacking argues, “do not exist in any recognizable form until they are objects of scientific study.”<sup>11</sup> Expert knowledge not only describes its objects of interest, then; it also helps to constitute them. In this case, the technical and administrative category of global health emergency is a product not only of the forms of human-ecological interaction through which new pathogens emerge, but also of the scientific frameworks and governmental practices that seek to know and manage these pathogens. From this perspective, the invention of a concept, such as “emerging infectious disease,” is a significant event not because it marks the discovery of

what had hitherto been unknown, but because it helps bring a new kind of entity into being.

This book tracks the unstable consolidation of global health security through a series of recent episodes and follows the controversies and criticisms these episodes have provoked. Such disputes are productive sites for inquiry into the tacit assumptions that guide the everyday work of experts in fields like epidemiology, virology, and public health policy.<sup>12</sup> It is not, then, a story about a generalized cultural discourse or social imaginary. Rather, it tracks the “serious speech acts” made by authorities in settings of contestation; these statements may come from published articles, official inquiries, public testimony, or journalistic reports.<sup>13</sup> The cases illustrate distinctions in the tacit regimes of knowledge and intervention that experts bring to bear to address situations of urgency and uncertainty, distinctions that become most apparent at moments of public disagreement.

Chapter 1 serves as a prelude to the investigation of global health emergencies, looking into the history of preparedness as a style of reasoning and a set of governmental techniques for approaching uncertain threats. The chapter introduces a key distinction between two ways of thinking about and intervening into a dangerous future. A potential threat can be taken up first as a regularly occurring event whose probability can be calculated based on known patterns of historical incidence and that can be managed through the distribution of risk. Alternatively, it can be understood and managed as an unprecedented but potentially catastrophic event whose consequences can only be managed by using methods of imaginative enactment that enable planners to mitigate vulnerabilities.

The chapter draws on the argument made by historians of statistics that, in the nineteenth century, the accumulation of detailed knowledge about European populations by government bureaucracies made it possible to envision the probable future using new calculative techniques.<sup>14</sup> It asks, in turn: how do contemporary authorities seek to manage potential future dangers, such as an ecological catastrophe or a devastating pandemic, whose probability cannot be statistically calculated and whose potential consequences outstrip the capacities of existing prevention and mitigation measures? To address this question, the chapter turns to the history of civil defense and emergency management. Beginning in the 1960s, the new field of emergency management adapted a number of



techniques that had been invented to prepare for nuclear attack, such as scenario-based planning, early warning systems, and medical supply stockpiling, and repurposed them to address a range of other potential emergencies such as natural disasters, ecological accidents, and terrorist attacks. In recent years, the techniques and the thought-style of emergency management have been incorporated into significant policy framework documents such as the *National Preparedness Guidance* and the *National Critical Infrastructure Protection Plan*, and they have structured governmental response to a range of events from Hurricane Katrina to the 2009 swine flu pandemic.

Chapter 2 investigates how these techniques of emergency management were assimilated into the field of public health in the United States, beginning with approaches to the threat of bioterrorism in the 1990s. This process involved the composition of a new object of knowledge and intervention for public health: no longer, or not only, the population but also the infrastructure that underpins response to health emergencies; this includes disease surveillance, stockpiles of countermeasures and methods of rapid distribution, hospital surge capacity, and crisis communications systems. This story is framed through the historical juxtaposition of two responses to the onset of a potential influenza pandemic: first, the 1976 swine flu outbreak; second, the specter of avian influenza in 2005. Whereas in 1976, government officials understood and managed a potential pandemic mainly in terms of the available public health framework of prevention, three decades later, a new regime of public health preparedness had been put in place to address the avian influenza threat.

This shift was the result of a broader transformation: health authorities now conceptualized a future outbreak of a new or reemerging infectious disease as a potentially catastrophic event whose consequences could be mapped in advance using techniques of imaginative enactment such as the scenario-based exercise. This approach was adopted as part of U.S. health and security policy beginning in the mid-1990s, as the specter of emerging disease merged with post-Cold War concerns about bioterrorism to become a generic biological threat. Through the analysis of a 2001 exercise that simulated a smallpox attack, the chapter shows how public health and security were brought together in response to this newly constituted threat.

Chapter 3 examines how public health preparedness was extended as a global strategy in relation to the threat of emerging disease, beginning in the early 2000s. It focuses on the development of the revised International Health Regulations, adopted in 2005 as part of the WHO strategy of “global public health security.” The chapter develops an analytic distinction between two regimes for governing global health problems: global health security and humanitarian biomedicine. If global health security focuses on protecting nation-states, especially in the advanced industrial world, from the social and economic threat posed by emerging diseases, humanitarian biomedicine emphasizes the need to save all lives, regardless of political boundaries, from treatable but deadly maladies such as malaria, tuberculosis, and HIV/AIDS.

To illustrate this distinction, the chapter examines tensions that arose as the WHO sought to operationalize its global disease surveillance and response capacity to manage the threat of an avian influenza pandemic. Beginning in 2007, Indonesian health officials refused to share samples of highly pathogenic avian influenza H5N1 with WHO’s global influenza surveillance network on the grounds of equity in access to the benefits of virus sharing. Specifically, they sought guarantees that the population would have access to vaccines that had been developed using virus strains found in Indonesian flu patients. Critics of this position argued that in claiming sovereignty over these influenza strains and excluding them from the global surveillance network, the Indonesian government was threatening global health security.

Chapter 4 explores the problem of how to sustain vigilance, among officials and the public, for an event that may or may not occur. It looks in particular at the decision instruments that guide emergency intervention at the outset of an epidemic. Such instruments are designed to focus global attention on the appearance of a novel biological threat, but at the same time they raise new questions: what is a global health emergency? Who is charged with governing such events, and what does such governance imply? These questions were at the center of a 2009 controversy in Europe over the WHO’s decision to declare H1N1 swine flu to be a full-blown pandemic, which set in motion mass vaccination campaigns in western Europe and North America.

The chapter introduces the concept of the “sentinel device” to examine the alert system that is at the heart of global health security. Sentinel

devices are designed to detect the onset of an otherwise invisible or imperceptible threat; but to trigger intervention, they must be linked to larger systems of response. Although the controversy around the H1N1 pandemic was cast in terms of an ethical debate over possible conflicts of interest within WHO's emergency committee, the chapter shows that it is better understood as a conflict between two distinct ways of understanding and managing public health threats—an approach that must justify action through the statistical calculation of risk versus one that requires vigilant attention to the ongoing possibility of surprise.

Chapter 5 examines the tension between risk assessment as a standard tool for regulatory decision on the one hand, and the demand for preparedness for a catastrophic disease outbreak on the other. It focuses on an unintended consequence of government support for basic virology research as part of pandemic preparedness: the laboratory creation of the very threat that such support is designed to address. The chapter looks at the 2012 controversy over scientists' use of genetic manipulation techniques to create a humanly transmissible strain of H5N1 avian influenza. This research was supported by the National Institutes of Health and was carried out by university-based influenza virologists as part of the U.S. government's pandemic preparedness initiative.

The debate among scientists and regulators over how and whether to regulate such "gain-of-function" experiments demonstrates the problems involved in seeking to quantitatively assess the risk posed by an emerging disease: whereas the regulatory guidelines developed to govern scientific research on pathogenic threats are based on the framework of technical risk assessment, the threat of the emergence of a humanly transmissible strain of H5N1 eludes such calculation. The chapter shows how actors on each side of the debate justify their claims using the idiom of risk assessment and how each group insists on the validity of its calculation. In the end, the debate escapes resolution precisely because of the difficulty of assimilating the risk of either a deadly mutation in nature or a catastrophic accident in a laboratory within the technical framework of risk assessment.

In the final chapter, the book investigates the intense public criticism faced by WHO in the aftermath of the 2014 Ebola epidemic. These denunciations focused in particular on the organization's late declaration of a global health emergency. The chapter suggests that the slow international

response to the early stages of the epidemic was at least partly the result of a transformation in the meaning of Ebola. From the perspective of global health governance, the significance of the disease shifted between the late 1980s, when the problem of emerging infectious disease was first articulated, and early 2014, when the epidemic in West Africa began. Whereas in the earlier period, Ebola was paradigmatic of the potentially catastrophic outbreak of a novel pathogen, by 2014 many experts saw the disease as a dangerous but relatively manageable affliction that typically struck marginal, rural populations. In other words, it had become a disease that could be contained through the organizations and techniques of humanitarian biomedicine rather than those of global health security.

This contrast between two visions of the same disease helps explain why, at the initial stages of the 2014 Ebola epidemic, WHO and other public health authorities did not expect the outbreak to turn into a global health catastrophe—and thus did not invoke the decision instrument designed to galvanize intensive global response. The failure of global health security to manage the Ebola crisis led to widespread criticism and calls for reform. The demand was for more and better preparedness, in anticipation of the next emergency. As we can see from these various instances, preparedness has come to be a taken-for-granted norm of government. Indeed, a failure to be prepared for a foreseeable event—if the event occurs—can prove to be politically disastrous, as the aftermath of Hurricane Katrina demonstrated.

Gradually, over the course of two and a half decades, a new assemblage for understanding and intervening in global health problems has been cobbled together. This book explores the condition of its formation, as well as its possibilities and limitations as new disease emergencies continue to arise. The book seeks neither to warn its readers that we must become more prepared for future health disasters nor to criticize governments and health authorities for anticipating the wrong things. Rather, it asks: how did we come to be “unprepared” for future disease emergencies? By this question, I do not mean to suggest that we were once well prepared and are now less so, but instead to pose the question: how did the norm of preparedness come to structure expert thought and action concerning the future of infectious disease?