

The Independence of National Focal Points Under the International Health Regulations (2005)

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As the world grapples with the response to the COVID-19 pandemic, all eyes are now on the People's Republic of China: when did the national government know the atypical pneumonia cases indicated a novel coronavirus? How long did the national government delay the reporting of those cases to the World Health Organization and the rest of the international community? While these are key questions, they overlook the structure of China's legal relationship with the world's most important infectious disease control treaty, the International Health Regulations (2005). Under that treaty, China delegated information gathering and reporting to its provinces which were in turn supposed to notify China's National Focal Point—the body responsible for communicating potentially emergency infectious disease events to the World Health Organization and the rest of the international community. This was not the first time that National Focal Points failed: they also did so with MERS-CoV, Ebola, and H1N1. While National Focal Points are the backbone of the International Health Regulations, little is actually known about them. This Article situates the most important empirical study of National Focal Points to date—funded by the World Health Organization and conducted by the authors, a clinician and a legal scholar—to understand why they fail. The answer is that they are not independent—they must communicate information that can be economically damaging, they coordinate with other ministries that do not understand their purpose, and they almost never have an independent budget. If the International Health Regulations are to protect the world from future pandemics, reform must start with the independence of these crucial points of information gathering and communication.

INTRODUCTION

As the world's most extensive mass vaccination campaign unfolds and societies begin to return to “normal” after more than a year since the COVID-19 pandemic began, global focus has returned to the pathogen's origins, missed opportunities to contain its spread, and the responsibility for massive losses of life and livelihood attributable to it.¹ From its early stages,

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1. See, e.g., Javier C. Hernández, *The Test a Deadly Coronavirus Outbreak Poses to China's Leadership*, N.Y. TIMES (Jan. 21, 2020), <https://www.nytimes.com/2020/01/21/world/asia/china-coronavirus-wuhan.html> [<https://perma.cc/2C7A-83KC>] (“The response by the Chinese leadership, which has come under intensifying criticism that it has been slow to acknowledge the severity of the outbreak, came as fatalities from the disease tripled to at least nine. Infections surged from 200 to 440, and global financial markets were

critics have focused on two alleged culprits: the People's Republic of China ("PRC") and the World Health Organization ("WHO").² The former is accused of deliberately or negligently concealing the identification of a novel and deadly pathogen and obstructing early efforts to contain it within the PRC's territory, and spreading misinformation to divert blame from its failures.³ The latter is alleged to have failed in its responsibilities by first recommending, then later withdrawing, measures that would have restricted travel to China.⁴ According to the WHO, the PRC alerted it to novel pneumonia cases on December 31, 2019. The WHO revised its reports in April to clarify that its own office had received notice about those cases from ProMED,⁵ and received information from the PRC government only after two requests.⁶

rattled by the possibility of a pandemic emanating from the world's most populous country during the Lunar New Year.").

2. See, e.g., Marc A. Thiessen, Opinion, *The Election is Over. Can We Finally Blame China for the Pandemic?*, WASH. POST (Dec. 8, 2020), <https://www.washingtonpost.com/opinions/2020/12/08/election-is-over-can-we-finally-blame-china-pandemic/> [<https://perma.cc/YGM6-347M>] ("Chinese officials knew in December that the SARS-CoV-2 virus was capable of human-to-human transmission because medical personnel were getting sick, but as late as Jan. 15, the head of the Chinese Center for Disease Control and Prevention assured the world that 'the risk of human-to-human transmission is low.' If the regime had taken action as soon as human-to-human transmission was detected, it might have prevented a worldwide pandemic. Instead, Chinese officials deliberately covered up the outbreak, punished doctors who tried to warn the public, intentionally lied to the world about the danger the virus posed, and proactively impeded the U.S. and international response."); Amy Maxmen, *Why Did the World's Pandemic Warning System Fail When COVID Hit?*, NATURE (Jan. 23, 2021), <https://www.nature.com/articles/d41586-021-00162-4> [<https://perma.cc/9EHT-SQXY>] ("The World Health Organization (WHO) sounded its highest alarm on 30 January 2020 – a declaration called a 'public health emergency of international concern', or PHEIC, signaling that a pandemic might be imminent. Few countries heeded the WHO's call for testing, tracing and social distancing to curb the coronavirus. By mid-March, it had spread around the world. Now, health officials and researchers are evaluating why the organization's warning system failed and how to overhaul it."); Selam Gebrekidan et al., *In Hunt for Virus Source, W.H.O. Let China Take Charge*, N.Y. TIMES (Nov. 2, 2020), <https://www.nytimes.com/2020/11/02/world/who-china-coronavirus.html> [<https://perma.cc/DKE3-3S98>]. Early on, Australia, joined by several other states, called for an independent investigation into the virus's origin, and those calls have gained momentum. See Jason Scott et al., *EU Backs Independent Probe into Origins of Coronavirus*, BLOOMBERG (May 5, 2020), <https://www.bloomberg.com/news/articles/2020-05-05/eu-to-propose-investigation-into-virus-origins-australia-says> [<https://perma.cc/47Q8-BVXL>] ("Australian Prime Minister Scott Morrison told reporters in Canberra that he has written to all Group of 20 leaders this week in his bid to create support for the investigation into how the virus started and spread. Australia's previous calls for the probe have raised the ire of China, its largest trading partner. In the U.S., President Donald Trump has accused Beijing of deliberately mishandling an outbreak that has killed more than 4,600 Chinese citizens to damage him politically and promised a "conclusive" report on the virus's origins.").

3. See Joshua Kurlantzick, *How China Ramped Up Disinformation Efforts During the Pandemic*, COUNCIL ON FOREIGN RELS. (Sept. 10, 2020), <https://www.cfr.org/in-brief/how-china-ramped-disinformation-efforts-during-pandemic> [<https://perma.cc/3NB2-HPZU>].

4. See Stephanie Nebehay, *WHO Chief Says Widespread Travel Bans Not Needed to Beat China Virus*, REUTERS (Feb. 3, 2020), <https://www.reuters.com/article/us-china-health-who/who-chief-says-widespread-travel-bans-not-needed-to-beat-china-virus-idUSKBN1ZX1H3> [<https://perma.cc/XL5G-8WMT>].

5. ProMED is a web service used to identify unusual health events related to emerging and re-emerging infectious diseases. *About ProMED*, PROMED, <https://promedmail.org/about-promed/> [<https://perma.cc/JQ5K-XT6M>].

6. Agence France-Presse, *WHO Revises Coronavirus Timeline to Clarify Its China Office Raised Alert, not Authorities*, S. CHINA MORNING POST (July 4, 2020), <https://www.scmp.com/news/china/science/article/>

Despite the accusations and indirect evidence of deceit, the explanation as to the PRC's conduct also may lie within the structure of China's relationship with the international treaty that obligated it to report what it knew about the pathogen that caused the disease eventually known as COVID-19 in the first place: the International Health Regulations ("IHR") (2005). Under default norms of international law, governments are not generally required to alert other countries about events that occur within their legally recognized territory unless a treaty or customary international law provides otherwise.⁷ The terms of the IHR (2005) require states parties to designate National Focal Points ("NFPs"): offices typically located within health ministries that must send, on behalf of the state party concerned, information concerning potential public health emergencies of international concern and "disseminat[e] information to, and consolidat[e] input from, relevant sectors of the administration."⁸ NFPs are intended to communicate information to the WHO; the WHO is then meant to mobilize the global community if there is a public health emergency of international concern; and the WHO and the state party are then supposed to work together to address the threat.⁹

China had declared upon joining the treaty that while its Ministry of Health would serve as its NFP, "local health administrative authorities are the health authorities responsible for the implementation of the IHR in their respective jurisdictions."¹⁰ When atypical cases of pneumonia arose in Wuhan—the early warning signs of a COVID-19 pandemic—hospitals "deferred to local health officials who, over a political aversion to sharing bad news, withheld information about cases from the national reporting system—keeping Beijing in the dark and delaying the response."¹¹ In other words, China's NFP system failed.

It was not the first time the IHR's NFP system had failed. Nor even the second. In 2014, NFPs in Guinea and Sierra Leone failed to detect and timely report the spread of Ebola cases within their territories. In both countries, other ministries—particularly Ministries of Finance—pressured the NFPs over concerns that announcement of an Ebola outbreak would threaten

3091820/who-revises-coronavirus-timeline-clarify-its-china-office-raised [https://perma.cc/VN2H-LNTC] ("The World Health Organisation was alerted by its own office in China, and not by Chinese authorities, to the first cases in the early stages of the coronavirus pandemic, according to an updated account from the UN health body.")

7. See, e.g., Montevideo Convention on the Rights and Duties of States art. 3, Dec. 26, 1933, 1936 U.N.T.S. 25.

8. International Health Regulations (2005) art. 4, May 23, 2005, WHA58.3 [hereinafter IHR (2005)].

9. See Lawrence O. Gostin & Rebecca Katz, *The International Health Regulations: The Governing Framework for Global Health Security*, 94 MILBANK Q. 264, (2016).

10. IHR (2005), *supra* note 8, app. 2, 62–63.

11. Steven Lee Myers & Chris Buckley, *China Created a Fail-Safe System to Track Contagions. It Failed.*, N.Y. TIMES (Dec. 22, 2020), <http://www.nytimes.com/2020/03/29/world/asia/coronavirus-china.html> [https://perma.cc/6A9E-TUUQ].

foreign direct investment and trade.¹² In 2012, Saudi Arabia sought to control all data and information about MERS-CoV, limiting the content of communications between its NFP—the Ministry of Health—and the WHO.¹³

Despite the critical role of NFPs in the functioning of the IHR (2005), and the widespread acknowledgment that they have not generally worked as intended, little is actually known about them. NFPs must be designated by states parties and their contact details provided to the WHO, but this information is not made generally available to researchers. National Focal Point contact information may be available on the websites of ministries of health or through the WHO's regional offices, but even if the contact information is available, unsolicited and even solicited communications may go unanswered. Some National Focal Point offices may agree to joint reviews or other programming with the WHO, but this is not necessarily frequent or published.¹⁴ In a 2018 review article, researchers found only thirty-three articles from fifty-one countries discussing the communications capacity of states parties under the IHR (2005).¹⁵

The purpose of this Article is to fill this gap in the literature. In collaboration with WHO officials, we developed inclusion criteria and a purposive sample of NFPs in Africa, Asia, Europe, South and North America in order to understand and evaluate NFPs' self-reported ability to perform their mandated functions; identify examples of good practices (enablers to compliance); determine difficulties faced (barriers to compliance); identify major lessons learned from previous experiences; and inform opportunities for increased and tailored NFP support by the global community generally and WHO specifically.

We conducted a qualitative study consisting of semi-structured interviews with NFPs. The interview protocol consisted of open-ended questions regarding NFP experiences and perceptions regarding the implementation of the NFP functions under the IHR. Perceived barriers and facilitators to implementation were explored, as were participants' views on what NFPs need to fulfill their functions.

Our most important finding was that NFPs lack the independence to fulfill their obligations under the IHR. NFPs lack the ability to gather in-

12. See Emma Ross et al., *Sierra Leone's Response to the Ebola Outbreak: Management Strategies and Key Responder Experiences*, CHATHAM HOUSE (2017), <https://www.chathamhouse.org/sites/default/files/publications/research/2017-03-31-sierra-leone-ebola-ross-welch-angelides-final.pdf> [<https://perma.cc/FRK2-QELV>]; see also World Health Org., *Implementation of the International Health Regulations (2005): Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response*, U.N. Doc. A69/21 (May 13, 2016).

13. See Sam Halabi et al., *The Effect of Proprietary and Attribution Claims on Data Sharing During Infectious Disease Emergencies*, 23 J. HEALTH CARE L. & POL'Y 203, 205–07 (2020).

14. See Joseph F. Wamala et al., *Assessment of Core Capacities for the International Health Regulations (IHR(2005)) – Uganda*, 2009, 10 BMC PUB. HEALTH S9 (2010).

15. Amitabh B. Suthar et al., *Lessons Learnt from Implementation of the International Health Regulations: A Systematic Review*, 96 BULL. WORLD HEALTH ORG. 110 (2018).

formation across ministries, must seek approval from other ministries before reporting notifiable events under the IHR, suffer from legal ambiguities or absence of statutory or regulatory authorization for their work, and are often critically underfunded. While some other barriers included high staff turnover, overlapping responsibilities, and unfamiliarity with available training tools, the number of responses emphasized the inability of NFPs to independently perform their functions.

As COVID-19 is the latest and by far most severe infectious disease emergency to test the IHR (2005) and calls for its reform gather, the role of NFPs will be core focal points of any review efforts. Indeed, a new pandemic treaty has been proposed to replace or coordinate with the IHR (2005).¹⁶ Understanding crucial communication points and shortcomings under the most expansive infectious disease response international legal instrument will be essential to such a treaty's success. Given their importance in sovereign decisions about control of information and resources, NFPs cannot continue to serve as the crucial information nexus between a state party, WHO, and the international community while being, in reality, significantly limited in power and resources by their governments. This Article outlines the features that must be installed to make NFPs more effective and to better prepare the world for the next pandemic.

Part I provides the background to the development of the International Health Regulations (2005), especially the infectious disease emergency that unfolded with SARS-CoV-1 in 2002. Part II outlines the role of National Focal Points in the IHR (2005) scheme and explains how some representative NFPs function. Part III identifies how NFPs have functioned, or not, through three global public health emergencies: H1N1, Ebola, and MERS-CoV. Part IV provides the methods and findings of our NFP study. Part V uses those findings to recommend changes to the International Health Regulations (2005) which are almost certain to be revised given the failure of the treaty since its inception. Part VI provides a brief conclusion.

I. THE BACKGROUND TO THE INTERNATIONAL HEALTH REGULATIONS (2005)

People and governments hide their diseases for good reasons. For people, diagnoses with chronic or infectious illnesses can lead to discrimination, stigma, and ostracization, in some cases to the point of dehumanization and subjection to physical violence.¹⁷ For governments, the consequences are

16. David M. Herszenhorn, *Charles Michel Proposes 'International Pandemic Treaty'*, POLITICO (Nov. 12, 2020), <https://www.politico.eu/article/charles-michel-proposes-international-pandemic-treaty/> [https://perma.cc/P3SZ-J8GH].

17. Rachel A. Smith & David Hughes, *Infectious Disease Stigmas: Maladaptive in Modern Society*, 65 COMM'N STUD. 132, 133–34 (2014) (“[S]tigmas follow one principle: Humans will generate stigmas for and stigmatize people who present a threat to effective group functioning. For ID stigmas, the disgrace is being infected with a contagious disease.”); Don C. Des Jarlais et al., *Stigmatization of Newly*

proportionately greater. An outbreak of infectious disease may critically endanger exports, foreign investment, and even political legitimacy necessary for regime survival.¹⁸ Consider, for example, when SARS was reported in Hong Kong in 2003:

Precautionary measures were applied, with WHO recommending that people postpone travel to Hong Kong and other areas where outbreaks were occurring and contract tracing was not linking cases. Airport arrivals in Hong Kong in May, 2003 fell by 68% and hotel occupancy by 78% compared with the same period 1 year earlier. Similar negative effects were also reported in Singapore, Vietnam, Taiwan, China, and elsewhere in Asia, contributing to an estimated short-term loss of US\$30 billion.¹⁹

For individuals, protection against discrimination is one of the primary rationales for health privacy laws, but those laws often provide for mandated reporting of diseases that may require local, regional, or national attention.²⁰ For governments, the similar problem is not so easily solved. Hiding outbreaks has been common and the threats to global public health have been severe.²¹

Over the course of the late 1990s and early 2000s, infectious disease threats to global security proliferated, as did efforts to hide or obfuscate them.²² The resurgence of cholera in South America, plague in India, and

Emerging Infectious Diseases: AIDS and SARS, 96 AM. J. PUB. HEALTH 561, 563 (2006) (“There are several strong similarities between AIDS and SARS from a psychological perspective, suggesting that they may serve as a model for stigmatizing attitudes toward serious emerging infectious diseases in general.”).

18. Peter Ndebock Fonkwo, *Pricing Infectious Disease: The Economic and Health Implications of Infectious Diseases*, 9 EMBO REPORTS S13 (2008); Elizabeth Asiedu et al., *The Impact of HIV/AIDS on Foreign Direct Investment: Evidence from Sub-Saharan Africa*, 2 J. AFR. TRADE 1 (2015); Nita Madhav et al., *Pandemics: Risks, Impacts, and Mitigation*, in DISEASE CONTROL PRIORITIES: IMPROVING HEALTH AND REDUCING POVERTY 315 (Dean T. Jamison et al. eds., 2017).

19. David L. Heymann et al., *SARS legacy: outbreak reporting is expected and respected*, 381 LANCET 779, 779 (2013).

20. See, e.g., Sandra Roush et al., *Mandatory Reporting of Diseases and Conditions by Health Care Professionals and Laboratories*, 281 JAMA 164, 168 (1999) (“Several factors may affect whether a disease or condition on the list for national surveillance is reportable within a specific state or territory at any given time. . . . Time needed to enact a requirement, available resources, and competing public health priorities each affect a state’s list of reportable diseases and conditions.”); Gérard Krause et al., *Notifiable Disease Surveillance and Practicing Physicians*, 11 EMERGING INFECTIOUS DISEASES 442, 442 (2005) (“In most countries, notifiable disease surveillance systems rely on mandatory reporting of cases by physicians and laboratories.”).

21. See *infra* Part IV; see also Jason A. Tetro, *From Hidden Outbreaks to Epidemic Emergencies: The Threat Associated with Neglecting Emerging Pathogens*, 21 MICROBES & INFECTION 4 (2018); David Bishop, *Lessons from SARS: Why the WHO Must Provide Greater Economic Incentives for Countries to Comply with International Health Regulations*, 36 GEO. J. INT’L L. 1173 (2005).

22. NAT’L INTEL. COUNCIL, NIE 99-17D, THE GLOBAL INFECTIOUS DISEASE THREAT AND ITS IMPLICATIONS FOR THE UNITED STATES 5 (2000) (“New and reemerging infectious diseases will pose a rising global health threat and will complicate US and global security over the next 20 years.”); David E. Bloom & Daniel Cadarette, *Infectious Disease Threats in the Twenty-First Century: Strengthening the Global Response*, 10 FRONTIERS IMMUNOLOGY 1, 3 (2019) (“While rapid transmission of resistant pathogens is unlikely to occur in the same way it may with pandemic threats, the proliferation of superbugs is making

Ebola in Africa, as well as the emergence of HIV as a global pandemic, encouraged global unity in the belief that an international agreement was needed to address local infectious disease outbreaks that increasingly poured over borders.²³ As international trade and travel accelerated, multiplying the risks that local outbreaks would rapidly spread, the need for such an agreement was recognized at the highest levels of international law-making.²⁴ In January 2000, the U.N. Security Council recognized for the first time an infectious disease, HIV/AIDS, as an international peace and security matter. The precursor to the Security Council debate in 2000 was a U.S. National Intelligence assessment of the security threat posed by infectious diseases, which singled out HIV/AIDS as the gravest such peril. The National Intelligence Council report emphasized potential ramifications on international stability: “the persistent infectious disease burden is likely to aggravate and in some cases, may even provoke economic decay, social fragmentation and political destabilization of the hardest hit countries in the developing world.”²⁵

As it happened, there was an international agreement in place, only it was narrow in scope and limited in effect. The International Health Regulations (1969) covered only six diseases (cholera, plague, yellow fever, smallpox, relapsing fever, and typhus) and its mechanisms for reporting and response were minimal.²⁶ The World Health Assembly, the body comprised of all member states that oversees the WHO, adopted resolutions charging the WHO Director-General with identifying new responses to emerging and re-emerging infectious diseases as early as 1995.²⁷ However, half a decade of negotiations did little to advance the agenda at either the WHO or the United Nations.

In late 2002, informal reports arose about an epidemic of atypical pneumonia in China’s Guangdong Province.²⁸ On February 11, 2003, a regional health office in China reported to the press there were over 100 cases of a

the world an increasingly risky place.”); see *infra* Part IV (describing efforts to obfuscate disease outbreaks in the context of SARS-1 and Ebola-West Africa 2014).

23. See, e.g., Sam Halabi et al., *International Institutions and Ebola Response: Learning from the 2017 Outbreak in the Democratic Republic of Congo*, 64 ST. LOUIS U. L.J. 91, 94 (2019).

24. DAVID A. RELMAN ET AL., *Travel, Conflict, Trade, and Disease*, in *INFECTIOUS DISEASE MOVEMENT IN A BORDERLESS WORLD* 88 (2010).

25. NAT’L INTEL. COUNCIL, *supra* note 22, at 9.

26. See *Strengthening Health Security by Implementing the International Health Regulations (2005): The International Health Regulations (1969)*, WORLD HEALTH ORG., <https://www.paho.org/en/node/78897> [<https://perma.cc/33RB-54ET>]; see also Sam F. Halabi, *Multipolarity, Intellectual Property, and the Internationalization of Public Health Law*, 35 MICH. J. INT’L L. 715, 723–24 (2014).

27. World Health Org. Res. WHA48/1995/REC/1, Forty-Eighth World Health Assembly (May 1–12, 1995).

28. Rui-Heng Xu et al., *Epidemiologic Clues to SARS Origin in China*, 10 EMERGING INFECTIOUS DISEASES 1030, 1030 (2004) (“On March 12, 2003, the World Health Organization (WHO) issued a global alert about cases of atypical pneumonia in Guangdong Province and Hong Kong Special Administrative Region, China, and in Vietnam.”); Zixue Tai & Tao Sun, *The Rumouring of SARS During the 2003 Epidemic in China*, 33 SOCIO. HEALTH & ILLNESS 677, 680 (2011) (“The outbreak of the lethal virus in Guangdong in early 2003 prompted a site investigation by an expert team comprising officials from the

novel pneumonia emerging while the Chinese Ministry of Health reported the outbreak contained.²⁹ On February 21, a doctor who had treated infected patients in Guangdong developed symptoms while in Hong Kong.³⁰ The pathogen spread to sixteen other guests at the hotel, who then spread it across the globe. Outbreaks were reported in Toronto, Singapore, and Hanoi. Within four months, there were around 8,500 cases and 800 deaths.³¹

The WHO obtained samples of the virus in early March, and identified it as a novel coronavirus, SARS-CoV-1 (SARS). The WHO labeled it a global health threat.³² According to Fiona Fleck:

China's failure to admit the true extent of the SARS outbreak drew severe criticism from governments and from WHO's Director-General Gro Harlem Brundtland. China has been hardest hit to date (24 June), with 5327 cases and 348 deaths reported from throughout the mainland. Beijing and Guangdong were the most severely affected, with 4033 of these cases and 250 of the deaths.

But it took two months — after explosive SARS outbreaks in Hong Kong, Singapore, Hanoi and Toronto, and the spread of exported cases to every continent — for China, under mounting international pressure, to allow WHO epidemiologists to enter Guangdong province on 3 April to assess the situation there and determine that the outbreak of atypical pneumonia was indeed SARS.

On 18 April, China warned officials not to 'withhold any information or delay its release'. Two days later, Beijing's health minister and mayor were sacked, and the authorities eventually admitted that there were hundreds more cases in Beijing than previously reported.³³

Because SARS was not a notifiable disease under the International Health Regulations as they then existed, China had no legal obligation to report cases to the WHO, and the WHO had no legal authority to require information from China in response to unofficial reports.³⁴

provincial government and the national Ministry of Health, which concluded on 21 January that the infection was atypical pneumonia and recommended measures of prevention and treatment.”)

29. David L. Heymann, *The International Response to the Outbreak of SARS in 2003*, 359 PHIL. TRANSACTIONS ROYAL SOC'Y LONDON B 1127 (2004).

30. Yanzhong Huang, *The SARS Epidemic and Its Aftermath in China: A Political Perspective*, in LEARNING FROM SARS: PREPARING FOR THE NEXT DISEASE OUTBREAK 116 (Stacey Knobler et al. eds., 2004).

31. Fiona Fleck, *How SARS Changed the World in Less than Six Months*, 81 BULL. WORLD HEALTH ORG. 625 (2003).

32. Heymann, *supra* note 29.

33. Fleck, *supra* note 31, at 626.

34. Christian Kreuder-Sonnen, *China vs the WHO: A Behavioural Norm Conflict in the SARS Crisis*, 95 INT'L AFFS. 535, 544 (2019).

By July 5 . . . , WHO was able to declare that “all known chains of person-to-person transmission of the SARS coronavirus” had been broken. (footnote omitted) Whether SARS would have become endemic in people or in an animal reservoir without this determined global health response will never be known. One clear lesson that emerged from the outbreak, however, was that inadequate surveillance and response capacity in one country can endanger not only its population, but also global public health security.³⁵

The experience with SARS facilitated the 2005 revisions of the IHR.³⁶

The IHR (2005) was revised to encompass the detection and prevention of all infectious diseases.³⁷ Their scope was expanded to include “any event that may constitute a public health emergency of international concern.”³⁸

The Regulations now encompass public health risks whatever their origin or source (Article 1.1), including: (1) naturally occurring infectious diseases, whether of known or unknown etiological origin; (2) the potential international spread of non-communicable diseases caused by chemical or radiological agents in products moving in international commerce; and (3) suspected intentional or accidental releases of biological, chemical, or radiological substances.³⁹

Acknowledging the importance of communication and cooperation to successful detection and prevention of communicable diseases, states parties

35. Heymann et al., *supra* note 19, at 780.

36. David P. Fidler, *Revision of the World Health Organization's International Health Regulations*, 8 ASIL INSIGHTS (2004), <https://www.asil.org/insights/volume/8/issue/8/revision-world-health-organizations-international-health-regulations> [https://perma.cc/3MQ4-FENU]; Rebecca Katz & Julie Fischer, *The Revised International Health Regulations: A Framework for Global Pandemic Response*, 3 GLOB. HEALTH GOVERNANCE 1, 2 (2010).

37. The stated purpose is to “prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.” IHR (2005), *supra* note 8, Foreword, 1; *see also id.* at 2 (“By not limiting the application of the IHR (2005) to specific diseases, it is intended that the Regulations will maintain their relevance and applicability for many years to come even in the face of the continued evolution of diseases and of the factors determining their emergence and transmission. The provisions in the IHR (2005) also update and revise many of the technical and other regulatory functions, including certificates applicable to international travel and transport, and requirements for international ports, airports and ground crossings.”).

38. Kathleen J. Choi, *A Journey of a Thousand Leagues: From Quarantine to International Health Regulations and Beyond*, 29 U. PA. J. INT'L L. 989, 1015 (2008) (“The new IHR’s requirement that state parties notify WHO of any event that may constitute a public health emergency of international concern in its territory is significantly broader than the old IHR’s duty to report cases of only three specific infectious diseases.”).

39. David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34 J.L. MED. & ETHICS 85, 86–87.

are obligated to “develop the means to detect, report, and respond to public health emergencies.”⁴⁰ They must establish an NFP⁴¹ for communication to and from WHO.⁴² States parties must inform the WHO within twenty-four hours of an assessment of any event that could be considered a public health emergency of international concern.⁴³

The revised IHR also authorizes the WHO to draw information about potential public health emergencies from non-governmental organizations.⁴⁴ Those organizations are able to provide a check on state control of information, especially in situations where a state is resistant to reporting information regarding a potential emergency. Médecins Sans Frontières (Doctors Without Borders) and the International Federation of Red Cross and Red Crescent Societies, for example, have been able to investigate and provide information about an emergency where a government may be unable to report it itself, or unwilling to risk the harm in reporting it.⁴⁵

The IHR (2005) became effective in 2007 and now govern the reporting of diseases with the potential to become public health emergencies of international concern (“PHEIC”).⁴⁶ The purpose for this expansion was to better “prevent, protect against, control and provide a public health response to the international spread of disease” while minimizing burdens on civil liberties, international trade, and travel.⁴⁷ The previous regulations aimed to control the spread of disease at ports of entry, an approach inherited from 19th century treaties but supported by little or no epidemiological evidence.⁴⁸ The revised IHR (2005) were intended to place detection and reporting at the center of global infectious disease emergency preparedness.⁴⁹

40. IHR 2005, *supra* note 8, arts. 5, 13; annex 1.

41. The NFP is a “national centre, established or designated by each State Party” and “must be accessible at all times . . . for IHR (2005)-related communications with WHO.” *International Health Regulations (2005): Toolkit for Implementation in National Legislation*, WORLD HEALTH ORG. 1, 7 (2009).

42. IHR (2005), *supra* note 8, art. 4.

43. *Id.* art. 6; World Health Org., *Pandemic Influenza Preparedness and Response: A WHO Guidance Document* (2009) (“Under the IHR (2005), a number of reporting requirements obligate states parties to promptly inform WHO of cases or events involving a range of diseases and public health risks. These include the obligation to notify WHO of all cases of ‘human influenza caused by a new subtype’ in their territories within 24 hours of assessment in accordance with the case definition established by WHO for this specific purpose.”).

44. IHR (2005), *supra* note 8, art. 9 (“WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring.”).

45. See Médecins Sans Frontières, *Pushed to the Limit and Beyond: A Year into the Largest Ever Ebola Outbreak*, DOCTORS WITHOUT BORDERS (Mar. 23, 2015).

46. Arielle Silver, *Obstacles to Complying with the World Health Organization’s 2005 International Health Regulations*, 26 WIS. INT’L L.J. 229, 232 (2008).

47. IHR (2005), *supra* note 8, Foreword, 1.

48. NORMAN HOWARD-JONES, *THE SCIENTIFIC BACKGROUND OF THE INTERNATIONAL SANITARY CONFERENCES, 1851–1938* (1975).

49. Julie E. Fischer, *The International Health Regulations (2005): Surveillance and Response in an Era of Globalization*, STIMSON CTR. (2011).

II. THE ROLE OF NATIONAL FOCAL POINTS UNDER THE INTERNATIONAL HEALTH REGULATIONS (2005)

A. *The Duties of National Focal Points*

NFPs are designed to operate as the central point of contact for a state party to the WHO. These focal points are expected to be institutions that operate continuously to communicate information about outbreaks. Article 4 of the IHR lays out the expectations of NFPs, providing in full:

1. Each State Party shall designate or establish a National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.

2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:

(a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 [notification] to 12 [public health emergencies of international concern]; and

(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.

3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.

4. States Parties shall provide WHO with contact details of their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details

of National IHR Focal Points it receives pursuant to this Article.⁵⁰

NFPs are designed to operate as the central point of contact for a state party to the WHO.⁵¹ These focal points are expected to be institutions that operate continuously to communicate information about outbreaks. In the treaty text, NFPs are impliedly legally authorized to gather the information they need from other national bureaucracies and their internal health systems, including localized cases of covered diseases communicated to state and national operations. The IHR require these contact points to update and keep their systems current, as well as to annually confirm their compliance. Yet, while the IHR outline the NFP requirement and list the responsibilities of NFPs, there is little in terms of how they are organized, where in the government they sit, how they are legally authorized or funded internally, or which further roles they might play.⁵²

Annex 1 of the IHR (2005) lists the “core capacities” that each country must meet with respect to “surveillance, reporting, notification, verification, response and collaboration,” all of which are relevant under Article 4 for reportable information from the NFP.⁵³ Annex 1 has caused considerable dispute between parties to the treaty because meeting core capacity obligations is costly. Indeed, low- and middle-income countries have repeatedly emphasized that compliance with the IHR (2005) core capacities is dependent on financial and other support from high income countries.⁵⁴

Annex 2 provides a decision instrument for each NFP to use when determining whether to report events that may constitute a public health emergency of international concern.⁵⁵ The Annex 2 instrument emphasizes the importance of reporting any virus, known or unknown, if it poses a risk of spreading internationally with a severe public health impact. The instrument is transparent and detailed; thus, NFPs theoretically should have little problem determining whether a public health risk should be reported. The NFP is expected to report any events related to this possible public health

50. IHR (2005), *supra* note 8, art. 4.

51. Frederick M. Burkle, Jr. et al., *An Authority for Crisis Coordination and Accountability*, 379 ELSEVIER PUB. HEALTH EMERGENCY COLLECTION 2223, 2224 (2011) (“Additionally, National Focal Points should be identified to ensure a two-way channel of communication between WHO and its 194 member states, and countries are required to establish surveillance capacities and to share information relevant to public health risks.”).

52. IHR (2005), *supra* note 8.

53. *Id.* annex 1.

54. Hans Kluge et al., *Strengthening Global Health Security by Embedding the International Health Regulations Requirements into National Health Systems*, 3 BMJ GLOB. HEALTH 1 (2018); David P. Fidler, *From International Sanitary Conventions to Global Health Security: The New International Health Regulations*, 4 CHINESE J. INT’L L. 325 (2005); Commission on Social Determinants of Health, *Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health*, WORLD HEALTH ORG. 372-74 (2008), <https://www.who.int/publications/i/item/WHO-IER-CSDH-08.1>.

55. See World Health Org., *WHO Guidance for the Use of Annex 2 of the International Health Regulations (2005)*, WHO/HSE/IHR/2010.4 (2008).

emergency as well as any of the nation's responses to address the threat.⁵⁶ After notification, NFPs are obligated to continue to communicate with the WHO.⁵⁷ This communication includes "case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; . . . [NFPs are also directed to] report, when necessary, the difficulties faced and support needed in responding to" the threat.⁵⁸ NFPs are encouraged to communicate with the WHO even if an outbreak does not meet the standards of an international public emergency.⁵⁹

B. *Structural Heterogeneity of NFPs*

As identified in Part I, comprehensive analysis of NFP structure and behavior is scant in the published literature. The greatest sources of information about NFPs are reports summarizing meetings convened by the WHO, typically by region (that is, African Region, Region of the Americas, South-East Asia Region, European Region, Eastern Mediterranean Region, and Western Pacific Region). Occasionally, these reports provide significant detail, as did one following a meeting of the Americas in 2017.⁶⁰ More typically, the summaries are brief.⁶¹ Additionally, studies available about NFP structures are undertaken in partnership with the WHO, and do not necessarily cover most or even a significant minority of states parties to the IHR (2005).⁶²

To accomplish their functions under Article 4 of the IHR (2005), NFPs are constantly receiving, analyzing, and evaluating information from a host

56. See IHR (2005), *supra* note 8, annex 2, 43 (providing flowchart decision-making for reportable events); see also Michael G. Baker & David P. Fidler, *Global Public Health Surveillance Under New International Health Regulations*, 12 EMERGING INFECTIOUS DISEASES 1058, 1060 (2006) ("The focal point is designed to facilitate rapid sharing of surveillance information because it is responsible for communicating with the WHO IHR contact points and disseminating information within the state party (article 4.2). By linking national IHR focal points through WHO, IHR 2005 establishes a global network that improves the real-time flow of surveillance information from the local to the global level and also between state parties (article 4.4).").

57. IHR (2005), *supra* note 8, art. 6.

58. *Id.*

59. See *id.* art. 8.

60. WHO, *International Health Regulations (2005) National Focal Points Regional Meeting: 28-30 November 2017, Miami, United States of America* 13 (Dec. 2018), <https://www.paho.org/en/file/69752/download?token=6fFMzqnf>.

61. Press Release, WHO, *Annual Meeting for National Focal Points (NFP) for the International Health Regulations (IHR) from Eastern and Southern European States, Hillerød (Copenhagen), Denmark, 16–18 June 2008*, <https://www.euro.who.int/en/media-centre/events/events/2008/06/annual-meeting-for-national-focal-points-nfp-for-the-international-health-regulations-ihr-from-eastern-and-southern-european-states> [https://perma.cc/278W-PDKY].

62. See e.g., Thomas Haustein et al., *Should this event be notified to the World Health Organization? Reliability of the international health regulations notification assessment process*, 89 BULL. WORLD HEALTH ORG. 296 (2011); (analyzing NFP's use of the Annex 2 decision instrument only); Aranka Anema et al. *Descriptive review and evaluation of the functioning of the International Health Regulations (IHR) Annex 2*, 8 GLOBAL HEALTH. 2012 (same).

of sources within their state.⁶³ Even with substantial resources and personnel, however, the structure of an NFP matters a great deal with respect to its effectiveness. However, the resources and personnel that may be dedicated to surveillance, analysis, and reporting correspond to the relative size and wealth of the country.

For small, well-resourced countries, fulfilling these functions may be straightforward. For example, Grenada's NFP receives and analyzes data from the environmental health department, veterinarians, nurses, doctors, customs departments, food inspectors, the agricultural department, and its military.⁶⁴

However, the lack of resources has exacerbated NFPs' struggle. In some circumstances, the NFP is a single individual and there is no feasible way to cover all functions technically charged to the NFP under the IHR (2005).⁶⁵ In some sub-Saharan and low-income southeast Asian countries, the NFP may be two or three individuals with various responsibilities around the Ministry of Health and its subsidiary departments.⁶⁶

Even in large, wealthy countries, internal legal structures may erect barriers to compliance.⁶⁷ In the United States, for example, the responsibility of ensuring compliance with the IHR (2005) has been assigned to the Department of Health and Human Service's Assistant Secretary for Preparedness and Response (ASPR).⁶⁸ The primary responsibility of ASPR is ensuring the safety of Americans by preparing effective responses to emergencies.⁶⁹

The U.S. NFP is comprised of the Division of International Health Security, "which provides policy and procedural oversight for all IHR obligations (both core and expanded NFP functions)"; ASPR, which "provides overall leadership and serves as the approval authority for all official IHR communications"; and the HHS Secretary's Operations Center ("SOC") managed by the ASPR Office of Emergency Management, "which provides 24/7/365 situational awareness and communications nationally and internationally in close coordination with operation centers of other federal departments and agencies."⁷⁰ However, reporting PHEICs is not necessarily straightforward under the U.S. NFP structure:

63. WHO, *supra* note 60, at 13.

64. *Id.* at 11–12.

65. Kumanan Wilson & Sam Halabi, Studies for the Assessment of World Health Organization Support Needed by National IHR Focal Points, (Jan. 28, 2020) (unpublished study) (report on file with authors).

66. This was revealed through study interviews.

67. See Eric Mack, *The World Health Organization's New International Health Regulations: Incursion on State Sovereignty and Ill-Fated Response to Global Health Issues*, 7 CHINESE J. INT'L L. 365, 370 (2006).

68. U.S., Dep't of Health & Hum. Servs., *The U.S. International Health Regulations National Focal Point*, PUB. HEALTH EMERGENCY (Feb. 15, 2017), <https://www.phe.gov/about/OPP/dihs/Pages/ihr-nfp.aspx> [<https://perma.cc/4C7L-TEAX>].

69. *Id.*

70. *Id.*

Official reporting of potential PHEICS requires technical event/risk assessments from U.S. government departments and agencies, like the CDC, U.S. Food and Drug Administration, U.S. Department of Defense, U.S. Department of Agriculture, U.S. Department of the Interior, and others, WHO notification assessment using Annex 2 of the IHR, as well as official interagency clearance, and approval from the ASPR. In the United States, individual federal departments and agencies maintain their own internal structures and policies for interagency coordination related to public health surveillance, detection, and assessment of potential events, and communication of those events to the NFP. Federal agencies also have ongoing health security collaborations with U.S. state governments and other subnational health departments, non-governmental agencies in the United States, and governmental and non-governmental organizations outside of the United States, including the WHO.⁷¹

The Centers for Disease Control and Prevention, for example, has agreed not to release information until it has consulted with federal agencies in order to protect national security.⁷² The United States' NFP, therefore, is a mix of agencies and authorities, the view of which may delay or prevent necessary reporting.

Canada's NFP sits within the Public Health Agency of Canada ("PHAC"), in the Agency's Health Security Infrastructure Branch and the Center for Emergency Preparedness and Response.⁷³ Canada utilizes what it calls a "single window approach."⁷⁴ The NFP is designed to run through one phone number and one email address, which facilitates coordination, as it is the official contact channel with the WHO about IHR (2005) obligations.

Some countries effectively "outsource" their NFP functions. In Poland, the NFP is located in the National Institute for Public Health (NIPH).⁷⁵ NIPH provides comprehensive surveillance services to the Polish Ministry of Health, analyzes potential outbreaks, and generates daily reports for the Ministry of Health to comply with its IHR obligations.⁷⁶ The Department of International Cooperation is focused on ensuring Poland's compliance

71. *Id.*; see also *United States of America: Partner in Global Health*, WORLD HEALTH ORG., <https://www.who.int/about/planning-finance-and-accountability/financing-campaign/us-impact> [https://perma.cc/N34E-LMHF].

72. Mack, *supra* note 67, at 370.

73. WHO, *supra* note 60, at 42.

74. *Id.* at 42–43.

75. Paulina Maria Nowicka et al., *Review of Measles-Related Events Recorded by the National IHR Focal Point in Poland in the Years 2016 - 2018*, 73 PRZEGL EPIDEMIOLOG 3 (2019).

76. *Poland: WHO National Counterpart and National Technical Focal Points*, WHO EUROPE, <http://www.euro.who.int/en/countries/poland/who-national-counterpart-and-national-technical-focal-points> [https://perma.cc/T6VQ-LQKP]; Roman Topór-Madry et al., *Poland*, in ORGANIZATION AND FINANCING OF PUBLIC HEALTH SERVICES IN EUROPE: COUNTRY REPORTS (Bernd Rechel et al. eds., 2018).

with several different international health treaties and maintaining an international health care presence.⁷⁷

NFPs are therefore of heterogenous structure, their resources are frequently minimal, and their relationships to other ministries may be harmonious, complex, antagonistic, or, at any given time, combinations of these. The next Part will discuss how NFPs have performed in light of these characteristics and constraints.

III. NFP PERFORMANCE, 2009-2020

A. *Background: Infectious Disease Communication before H1N1*

Government practices of hiding or obfuscating disease outbreaks for international political purposes have a long history. Consider, for example, the strain of influenza (often called the Spanish Influenza) that spread through Europe and America during World War I. That strain was unique in that it seemed to affect healthy people more than the elderly or frail.⁷⁸ That virus targeted the healthiest because it turned the immune system of the human body against itself. So, the more robust the immune system, the more likely adverse outcomes for the one infected.⁷⁹ This flu spread into the battlefield, infecting barracks of soldiers. When it was first discovered, those nations at war did little to publicize it, or make the details about the disease known. Death tolls were hidden, and rates of infection were not published.⁸⁰

However, Spain was not involved in the war, and thus the press there published details about the virus. The Spanish press covered the virus and the number of dead. Soon, Spain had reported more dead than anywhere else, because they were willing to publish real numbers.⁸¹ As a result, the pandemic was named after Spain in order to take light and blame away from the countries fighting each other.⁸²

Countries at war when the influenza spread in the late 1910s sought to evade the consequences that could come from widespread knowledge of struggles with the pandemic (such as perceived weakness in wartime). Consider, for example, the United States' approach:

77. *Int'l Coop. Off.*, MINISTRY OF HEALTH DEP'T OF INT'L COOP., <https://www.gov.pl/web/zdrowie/departament-wspolpracymiedzynarodowej> (last accessed Nov. 20, 2021).

78. Robert Kessler, *Outbreak: Lies and Misinformation*, ECOHEALTH ALLIANCE (2018), <https://www.ecohealthalliance.org/2018/05/outbreak-lies-and-misinformation> [<https://perma.cc/L35D-Y4HN>].

79. *Id.*

80. *Id.* ("And so then it is unsurprising that, as Americans were dying by the thousands, public health officials continually lied about the scope and severity of what was going on.")

81. *Id.* ("As the disease spread throughout the trenches of the European battlefield, belligerent nations' governments went to great lengths to conceal its severity, so as not to lower morale. In neutral Spain, however, the press was free to report as it pleased and did so especially when the nation's King Alfonso XII became gravely ill, leading to the assumption that the flu had originated in Spain.")

82. *Id.* ("In fact, even the pandemic's vernacular name, the Spanish flu, is based on mistaken assumption.")

Under the auspices of maintaining wartime morale, President Woodrow Wilson signed the Sedition Act in 1918. Under threat of 20 years' imprisonment, the law made it illegal to "utter, print, write, or publish any disloyal, profane, scurrilous, or abusive language about the form of government of the United States."

It was an era in which the government felt absolutely comfortable lying to its citizens.

"Truth and falsehood are arbitrary terms," Arthur Bullard, a former student of President Wilson's wrote at the time. "The force of an idea lies in its inspirational value. It matters very little whether it is true or false."

And so, then it is unsurprising that, as Americans were dying by the thousands, public health officials continually lied about the scope and severity of what was going on. The media fell right in line. An October 15, 1918 headline in the *Philadelphia Inquirer* read "Scientific Nursing Halting Epidemic." In that week alone, 4,597 people in Philadelphia died of flu-related illnesses. On September 20, the *Arkansas Gazette* wrote: "Spanish influenza is plain la grippe – same old fever and chills." The next month, Arkansas confirmed it had 1,800 cases and issued a statewide quarantine.⁸³

This was precisely the problem that the IHR (2005) was meant to address generally, and NFPs specifically. The first test, H1N1 in 2009-10, appeared to show that the IHR (2005) held promise. Subsequent public health emergencies, however, have largely shown NFP weakness.

B. H1N1, 2009-10

In February of 2009, the earliest case of what was later widely described as pandemic H1N1 presented in Mexico.⁸⁴ By mid-March, the Mexican government had noticed a larger-than-average number of cases of flu-like illnesses, and by April, advanced surveillance detected the outbreak in a small village in Veracruz.⁸⁵ PAHO, the WHO region for the Americas, received notice about the increase in media attention on flu illnesses in Mexico, and contacted the NFP for more information regarding the situation.⁸⁶ At that

83. *Id.*

84. Sam Halabi, *Obstacles to pH1N1 Vaccine Availability: The Complex Contracting Relationship between Vaccine Manufacturers, WHO, Donor and Beneficiary Governments*, in *THE PUBLIC HEALTH RESPONSE TO H1N1: A SYSTEMS PERSPECTIVE 2003-04* (Michael A. Stoto & Melissa A. Higdon eds., 2015).

85. Sami Al Hajjar & Kenneth McIntosh, *The First Influenza Pandemic of the 21st Century*, 30 *ANNALS SAUDI MED.* 1, 4 (2010).

86. Rebecca Katz, *Use of Revised International Health Regulations during Influenza A (H1N1) Epidemic*, 2009, 15 *EMERGING INFECTIOUS DISEASES* 1165, 1166 (2009).

point, the Mexican NFP assessed the situation and decided there may be a public health emergency of international concern.⁸⁷ On April 18, the U.S. NFP identified and reported two cases in California,⁸⁸ and they were confirmed to be genetically identical to the Mexican strains.⁸⁹ By April 25, the WHO Director-General had declared a Public Health Emergency of International Concern.⁹⁰ Over the next year, 214 countries, regions, and territories reported confirmed cases and about 200 million people contracted the virus, resulting in around 18,500 deaths.⁹¹ A year later, in August of 2010, the WHO declared the world was moving into a post-pandemic period.⁹²

The H1N1 pandemic served as a test of the IHR (2005). Mexico and the United States' willingness to report and confirm the presence of the virus served as a demonstration of the possibilities of the IHR (2005). The Mexico and U.S. NFPs communicated rapidly and accurately. Countries also shared resources in fighting the virus, such as samples and data. The international response to the outbreak under the regulations was, by and large, a success.⁹³

But there were also failures—and they resurrected the ghost of recrimination and economic sanction for revealing disease outbreaks to the international community. The IHR (2005) was meant to mobilize global response to infectious disease threats that might cross borders while preserving international traffic, trade, and civil liberties. Although the WHO did not recommend travel restrictions as part of the protective measures against H1N1, several member states recommended against travel to North America.⁹⁴ Because the virus originated in swine operations, H1N1 was commonly referred to as “swine flu,” resulting in the mass slaughter of farmed hogs.⁹⁵

The post-H1N1 reaction informed international attitudes toward the IHR (2005) generally and the role of NFPs specifically. The SARS outbreak that prompted the 2005 revisions was tiny compared to the H1N1 pandemic (8,000 cases versus 200 million). Yet, after the WHO declared the post-pandemic period, H1N1 was regarded as “mild” and the WHO was perceived as having overreacted, especially since the declaration of a pan-

87. 2009 H1N1 Influenza Pandemic - WHO Recommendations for the Post-Pandemic Period, PAN AMERICAN HEALTH ORG., https://www.paho.org/hq/index.php?option=com_content&view=article&id=3328:2009-h1n1-influenza-pandemic-who-recommendations-for-the-post-pandemic-period&Itemid=569&lang=en [<https://perma.cc/VG8T-T9FW>].

88. *The 2009 H1N1 Pandemic: Summary Highlights, April 2009–April 2010*, CTRS. FOR DISEASE CONTROL AND PREVENTION (June 16, 2010), <https://www.cdc.gov/h1n1flu/cdcresponse.htm> [<https://perma.cc/VG8T-T9FW>].

89. Halabi, *supra* note 84.

90. Katz, *supra* note 86, at 1167.

91. *Pandemic Influenza A (H1N1)*, WORLD HEALTH ORG. 2 (Mar. 3, 2011).

92. *H1N1 in Post-Pandemic Period*, WORLD HEALTH ORG. (Aug. 10, 2010), <https://www.who.int/news/item/10-08-2010-h1n1-in-post-pandemic-period> [<https://perma.cc/7665-ZGWW>].

93. Fischer, *supra* note 49, at 31.

94. Ana L.P. Mateus et al., *Effectiveness of Travel Restrictions in the Rapid Containment of Human Influenza: A Systematic Review*, 92 BULL. WORLD HEALTH ORG. 868, 868 (2014).

95. Nadim Audi, *Calling Pigs in Flu Fight, Egypt Angers Herders and Dismays U.N.*, N.Y. TIMES (Apr. 30, 2009), <https://www.nytimes.com/2009/05/01/health/01egypt.html> [<https://perma.cc/VB63-RS5Z>].

demically triggered lucrative provisions in pharmaceutical companies' contracts with governments.⁹⁶ Influenza had caused recurrent pandemics over time, and vaccines would become available as soon as five months after the strain was isolated.⁹⁵ SARS, on the other hand, was unknown; there existed no antivirals or vaccines to combat it.⁹⁷ Indeed, Mexico, having done all that it was supposed to do under the IHR (2005) and more, experienced difficulty even obtaining the vaccine.⁹⁸ The perception was that the IHR (2005), especially its core capacities, were too costly for mainly low- and middle-income countries, and that rapid reporting by NFPs would adversely affect economic interests with no corresponding benefit in international assistance or access to medicines or vaccines.⁹⁹

C. *MERS-CoV Saudi Arabia 2012*

In September of 2012, Dr. Ali Mohamed Zaki reported the isolation of a novel betacoronavirus on ProMED, the internet infectious disease alert system run by the International Society for Infectious Diseases.¹⁰⁰ The patient, a 60-year-old male from Saudi Arabia presenting with pneumonia-like symptoms died from an unknown viral infection in June 2012.¹⁰¹ Later dubbed the Middle East Respiratory Syndrome Coronavirus (MERS-CoV),¹⁰² this emerging infectious disease became responsible for more than 2,200 laboratory-confirmed infections in people from 27 countries, and close to 800 deaths.¹⁰³ The vast majority of these cases have been recorded in Saudi Arabia, however MERS-CoV is considered a severe emerging disease with the potential to cause a major global health emergency.¹⁰⁴

The timing of the outbreak threatened important Saudi national interests, in particular the integrity and expectations surrounding the Hajj, the annual pilgrimage to Mecca. In 2012, the Hajj occurred between October 23 and 28. "There is evidence that the Saudi National Focal Point had been alerted

96. Halabi, *supra* note 84, at 211; Peter Doshi, *The Elusive Definition of Pandemic Influenza*, 89 BULL. WORLD HEALTH ORG. 532 (2011) (describing the controversy around WHO's declaration of an influenza pandemic in 2009).

97. Halabi, *supra* note 84.

98. Richard Knox, *WHO Resolves Impasse over Sharing of Flu Viruses, Access to Medicines*, NPR (Apr. 18, 2011), <https://www.npr.org/sections/health-shots/2011/04/18/135519592/who-resolves-impasse-over-sharing-of-flu-viruses-access-to-vaccines> [https://perma.cc/WNZ7-PDVU].

99. See Kumanan Wilson et al., *The International Health Regulations (2005), the Threat of Populism and the COVID-19 Pandemic*, 16 GLOBALIZATION & HEALTH (2020).

100. Ali Mohamed Zaki, *Novel Coronavirus - Saudi Arabia: Human Isolate*, ProMED (Sept. 20, 2012).

101. Ali Mohamed Zaki et al., *Isolation of a Novel Coronavirus from a Man with Pneumonia in Saudi Arabia*, 367 NEW ENGLAND J. MED. 1814, 1815–16 (2012).

102. Raoul J. de Groot et al., *Middle East Respiratory Syndrome Coronavirus (MERS-CoV): Announcement of the Coronavirus Study Group*, 87 J. VIROLOGY 7790, 7791 (2013).

103. *Epidemic and Pandemic-Prone Diseases: MERS Situation Update, June 2018*, WHO REG'L OFF. FOR THE E. MEDITERRANEAN (2018), <http://www.emro.who.int/pandemic-epidemic-diseases/mers-cov/mers-situation-update-june-2018.html> [https://perma.cc/LBB3-4FW2].

104. Halabi et al., *supra* note 13, at 206; *2018 Annual Review of Diseases Prioritized under the Research and Development Blueprint*, WHO GENEVA 1, 9 (Feb. 7, 2018), <http://www.who.int/emergencies/diseases/2018prioritization-report.pdf?ua=1> [https://perma.cc/L67W-6Y2U].

to outbreaks of an unknown pathogen prior to the 20 September ProMED post, but did not report it to the WHO for fear that it would disrupt the upcoming Hajj which attracts more than one million pilgrims annually.”¹⁰⁵

Aside from reporting the novel coronavirus to WHO, the Saudi NFP did not report, as Article 6 of the IHR (2005) requires, “laboratory results” and “conditions affecting the spread of the disease.”¹⁰⁶ The Saudi Deputy Minister of Health exercised an extensive level of control over biological samples and epidemiological data.¹⁰⁷ The Saudi government claimed proprietary rights to the virus and resulting research upon it, hindering information sharing.¹⁰⁸

Health experts present during the crisis expressed frustration with the Saudi Ministry of Health for not meeting expectations of transparent and timely data sharing in the early stages of the outbreak.¹⁰⁹ This complaint was expressed in media coverage at the time, as well as in the scientific literature.¹¹⁰ “The criticisms ranged from accusations of what might be considered passive forms of neglect (mistakes or delays) to allegations of more egregious data handling practices, including deliberately withholding data and information that could have been made available earlier and destroying of virus samples and data.”¹¹¹

Similarly, during the MERS-CoV outbreak, the Saudi government was resistant to releasing information, and cracked down on reporters within its own country who reported on the matter. In 2011, a royal decree amending press freedoms in Saudi Arabia criminalized any criticism of Saudi senior religious figures and government officials.¹¹² “Furthermore, in 2012, all daily newspapers in Saudi Arabia were ‘controlled by individuals affiliated

105. GEORGETOWN UNIV. MEDICAL CENTER: CENTER FOR GLOBAL HEALTH SCIENCE AND SECURITY, MERS-CoV DATA SHARING CASE STUDY REPORT 4 (2018) (“Multiple interviewees noted the timing of the outbreak in relation to the annual Hajj, the sacred Islamic pilgrimage to Mecca, which in 2012 occurred between 23 and 28 October. These interviewees speculated that the Saudi government had been alerted to outbreaks of an unknown pathogen prior to the 20 September ProMED-mail post but did not report it to the WHO for fear that it would disrupt the upcoming Hajj which attracts more than one million pilgrims annually.”).

106. IHR (2005), *supra* note 8, art. 6.

107. Helen Branswell, *MERS’s Best Friend is Ignorance, So It’s Time to Wise Up*, NEW HUMANITARIAN (June 16, 2015), <http://www.thenewhumanitarian.org/analysis/2015/06/16/mers-s-best-friend-ignorance-so-it-s-time-wise> [https://perma.cc/9WNW-R7FZ].

108. See Helen Branswell, *Saudi Silence on Deadly MERS Virus Outbreak Frustrates World Health Experts*, SCI. AM. (June 7, 2013), <http://www.scientificamerican.com/article/saudi-silence-on-deadly-mers-virus-outbreak-frustrates-world-health-experts/> [https://perma.cc/R272-Z949].

109. See Scott J.N. McNabb et al., *Triumphs, Trials, and Tribulations of the Global Response to MERS Coronavirus*, 2 LANCET RESPIRATORY MED. 436 (2014).

110. See, e.g., David P. Fidler, *Who Owns MERS? The Intellectual Property Controversy Surrounding the Latest Pandemic*, FOREIGN AFFS. (June 6, 2013), <https://www.foreignaffairs.com/articles/saudi-arabia/2013-06-06/who-owns-mers> [https://perma.cc/5PGV-ELYI]; Jeremy Youde, *MERS and Global Health Governance*, 70 INT’L J. 119, 133 (2014).

111. GEORGETOWN UNIV. MEDICAL CENTER: CENTER FOR GLOBAL HEALTH SCIENCE AND SECURITY, *supra* note 105.

112. *Saudi Arabia - Freedom of the Press 2012*, FREEDOM HOUSE (2012).

with the royal family' and broadcast media stations were under government control."¹¹³

The absence of trustworthy information from official sources and the lack of a free press in Saudi Arabia created an increased dependence on informal channels of information, including personal and professional contacts and social media. "News stories from Saudi media outlets in the early days of the outbreak were often verbatim reproductions of official government press releases."¹¹⁴ Saudi Arabia was not alone in manipulating the information about MERS-CoV that could be released. In 2015, South Korea also refused to release the names of hospitals which had patients infected with MERS-CoV in an effort to reduce panic.¹¹⁵

D. *Ebola Virus Disease West Africa 2014-16*

On December 6, 2013, near the Guinean village of Meliandou, Emile Ouamouno died after four days of suffering from vomiting and fever.¹¹⁶ The cause of the small boy's infection is unknown, although he is now widely considered to be the index case for the outbreak of Ebola hemorrhagic fever (Ebola Virus Disease ("EVD")). Within a month, the child's sister, mother, and grandmother died after experiencing similar symptoms.¹¹⁷ The funeral for the latter was attended by a midwife who passed the disease to relatives, and to a health care worker who treated her.¹¹⁸ That health care worker was treated at a hospital in Macenta, about 80 kilometers (50 miles) east. A doctor who treated her contracted Ebola. The doctor then passed it to his brothers in Kissidougou, 133 kilometers (83 miles) away.¹¹⁹ The transmission of the virus went largely undetected by Guinean health officials, who suffered many of the resource constraints typical of many NFPs described above.¹²⁰

The outbreak of EVD originated in Guinea, between December 2013 and March 2014, and spread rapidly in the eastern regions of Sierra Leone and

113. Halabi et al., *supra* note 13, at 213–14.

114. Georgetown Univ., *supra* note 105, at 7.

115. Ji-hye Shin, *Korea Mulling Disclosure of MERS-Affected Hospitals*, KOREA HERALD (June 2, 2015), <http://www.koreaherald.com/view.php?ud=20150602001071> [<https://perma.cc/Z76U-WP79>]; Kyungwoo Kim & Kyujin Jung, *Dynamics of Interorganizational Public Health Emergency Management Networks: Following the 2015 MERS Response in South Korea*, 30 ASIA PACIFIC J. PUB. HEALTH 207, 208 (2018).

116. Halabi et al., *supra* note 13, at 1; Michelle Roberts, *First Ebola Boy Likely Infected by Playing in Bat Tree*, BBC (Dec. 30, 2014), <https://www.bbc.com/news/health-30632453> [<https://perma.cc/5U8A-PLCX>].

117. GEORGETOWN UNIV. MEDICAL CENTER: CENTER FOR GLOBAL HEALTH SCIENCE AND SECURITY, DATA SHARING DURING THE WEST AFRICA EBOLA PUBLIC HEALTH EMERGENCY: CASE STUDY REPORT 1,1 (2018).

118. Holly Yan & Esprit Smith, *Ebola: Who is Patient Zero? Disease Traced Back to 2-Year-Old in Guinea*, CNN (Jan. 21, 2015), <https://www.cnn.com/2014/10/28/health/ebola-patient-zero/index.html> [<https://perma.cc/MF8Y-RL3L>].

119. *Id.*

120. Mohamed F. Jalloh et al., *Assessments of Ebola Knowledge, Attitudes and Practices in Forécariah, Guinea, and Kambia, Sierra Leone, July – August 2015*, 372 PHIL. TRANSACTIONS ROYAL SOC'Y B (2017).

then in North Central Liberia, before it reached Nzérékoré in Guinea.¹²¹ Between December 2013 and April 10, 2016, a total of 28,616 suspected, probable, and confirmed cases of EVD were reported.¹²² A total of 11,310 deaths were attributed to the outbreak.¹²³ The largest numbers of cases and deaths occurred in Guinea, Liberia, and Sierra Leone, but thirty-six cases were reported from Italy, Mali, Nigeria, Senegal, Spain, the United Kingdom, and the United States.¹²⁴

The 2014–16 Ebola public health emergency differed from H1N1 and MERS-CoV, with respect to both the role of NFPs and the role of the WHO. Unlike in dealing with North America and H1N1 or with Saudi Arabia and MERS-CoV, the WHO maintained a significant presence in Guinea, Liberia, and Sierra Leone, as they had among the world's weakest health systems and were dependent upon external institutions and organizations for much of their routine health care needs.¹²⁵

Although the WHO released official case definitions of confirmed, probable, and suspected Ebola cases, different countries adopted different testing strategies, thereby limiting the opportunity for inter-country comparison. The Government of Sierra Leone used only laboratory-confirmed cases in its preliminary response analyses. In Guinea, deceased individuals were not tested for Ebola, meaning these individuals were never classified as confirmed cases, unlike in Liberia and Sierra Leone. In Liberia, “ministries [including port, airport, finance, health, and environment,] local governments, clinicians, nongovernmental organizations, suppliers, and donors” all collected data related to identifying cases and taking immediate action, but there was “no information sharing” because there was no centralized authority or resource to coordinate this.¹²⁶ Even within the data collected, inconsistencies limited usefulness. “Dates recorded on a case document might have referred ambiguously to when data was collected, submitted, or edited.”¹²⁷

Between March and July of 2014, the Guinea and Sierra Leone NFPs sought to decrease the perception that there was a crisis, and insisted that the WHO work with them to do so.¹²⁸ A retrospective study by Chatham House noted that the “WHO was not playing an independent role, and that no one in authority wanted to admit to [Sierra Leone] President Koroma how bad the situation was.”¹²⁹ The health minister play[ed] down the sever-

121. WHO Ebola Response Team, *After Ebola in West Africa - Unpredictable Risks, Preventable Epidemics*, 375 NEW ENGLAND J. MED. 587, 588 (2016).

122. *Id.* at 587.

123. *Id.*

124. *Id.*

125. *See id.* at 588.

126. Leon Schreiber, CHASING AN EPIDEMIC: COORDINATING LIBERIA'S RESPONSE TO EBOLA, 2014–15, 3 (2017).

127. GEORGETOWN UNIV. MEDICAL CENTER: CENTER FOR GLOBAL HEALTH SCIENCE AND SECURITY, *supra* note 117, at 7.

128. Médecins Sans Frontières, *supra* note 45.

129. Ross et al., *supra* note 12.

ity of the outbreak and the ministry's inability to cope with it.¹³⁰ "British participants in the response said that by late July they had decided that information coming out of the Sierra Leone Ministry of Health and Sanitation had to be ignored."¹³¹ This sentiment was confirmed by other logistics, humanitarian, and aid representatives.¹³²

Between March and August 2014, when the WHO Director-General declared a public health emergency of international concern, Médecins Sans Frontières (Doctors without Borders) repeatedly endeavored to alert first the government of Guinea and then the government of Sierra Leone about the severity of the epidemic. In response, Médecins Sans Frontières faced several accusations that it was stirring a panic in order to raise donations.¹³³ In a January 2015 report, the WHO Ebola Interim Assessment Panel acknowledged that "problems with information flow within WHO[] and difficult negotiations with countries" explained much of the failure to respond as robustly as it should have, and those problems and negotiations involved desires primarily by Guinea and Sierra Leone to control or delay the messaging about a health emergency.¹³⁴ "Ministries overseeing both the economy and finance in Sierra Leone were concerned about what closing the borders would mean to the post-conflict improvements in Sierra Leone's economic outlook, which were promising in early 2014."¹³⁵

In short, the Guinea and Sierra Leone NFPs were viewed as 1) insufficiently capable of detecting Ebola cases when they emerged and 2) unable or unwilling to effectively communicate with the WHO as the International Health Regulations (2005) required.

IV. THE NATIONAL FOCAL POINT STUDY

A. *The Study Background*

The IHR Review Committee on the Role of the IHR in the Ebola Outbreak and Response found at its third intersessional meeting in December 2015 that many NFPs lack the authority, capacity, training and resources to effectively carry out their mandate regarding urgent, event-based communi-

130. *Id.* at 8.

131. *Id.* at 22 ("MOHS wouldn't share data with the NERC, but they would share it with the WHO. We would only get the top-level data from MOHS, but not the granularity that was needed. WHO would publish its data. That had a material effect on the credibility of our data; people didn't trust the data coming out of the NERC and the President was asking DFID and AGI for data.")

132. *Id.* (citing the various agencies that also did not trust information coming from the Sierra Leone Ministry of Health).

133. Médecins Sans Frontières, *supra* note 45 ("On 10 May, Guinean media reported the president of Guinea complaining that MSF was spreading panic in order to raise funds.")

134. World Health Org., *Ebola Interim Assessment Panel*, 4, U.N. Doc. A68/25, annex (May 8, 2015).

135. GEORGETOWN UNIV. MEDICAL CENTER: CENTER FOR GLOBAL HEALTH SCIENCE AND SECURITY, *supra* note 117, at 16.

cations as stated in Article 4 of the IHR.¹³⁶ This third intersessional meeting also observed that there was limited knowledge by high-level officials of the role of NFPs.¹³⁷ The Review Committee concluded that one of the key impediments to IHR implementation remains the insufficient levels of capacity and authority of NFPs.¹³⁸ Similarly, the first intersessional meeting noted that “there are indications that NFPs are not yet a timely source of initial, early information on events” and that “notification appears to have a high threshold in some countries.”¹³⁹ Despite the widespread establishment of NFPs and states parties’ acceptance of the IHR, results of studies suggest there are important barriers to the notification of events to the WHO.¹⁴⁰

In light of these shortcomings, the Review Committee on the Role of the IHR in the Ebola Outbreak recommended that NFPs should be centers “with sufficient staff with experience, expertise, and seniority, and should be supported with the required resources (administrative, logistical, and financial) to carry out all of their mandatory communication functions—as well as any other functions assigned by the State Party.”¹⁴¹ In addition, the Committee emphasized that “NFPs must be positioned to ensure they have sufficient authority and governmental mandates to access the most senior government officials in health and other sectors, to access information sources across the health sector (at all levels) and in the many other sectors that are critical for effective compliance by the state party with its IHR obligations.”¹⁴²

Given the critical role of the NFPs in ensuring the effectiveness of the IHR, this study sought to evaluate the experiences of NFPs in fulfilling their functions, including the identification of both good practices and challenges reported by NFPs in implementing Article 4 of the IHR.

B. Study Design and Methodology

We developed interviews consisting of open-ended questions regarding NFPs’ experiences and perceptions regarding their functions under the

136. World Health Organization, *supra* note 12, at 23 (“Informants from States Parties and WHO regional offices and headquarters consistently reported that many NFPs lack the authority, capacity, training and resources to effectively carry out their mandate as stated in Article 4.”).

137. *Id.* at 51.

138. WHO, IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005): REPORT OF THE REVIEW COMMITTEE ON SECOND EXTENSIONS FOR ESTABLISHING NATIONAL PUBLIC HEALTH CAPACITIES AND ON IHR IMPLEMENTATION 4 (2015).

139. WHO, IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005): REPORT OF THE REVIEW COMMITTEE ON THE FUNCTIONING OF THE INTERNATIONAL HEALTH REGULATIONS (2005) IN RELATION TO PANDEMIC (H1N1) 2009 70 (2011).

140. See, e.g., Thomas Hausteine et al., *Should This Event Be Notified to the World Health Organization? Reliability of the International Health Regulations Notification Assessment Process*, 89 BULL. WORLD HEALTH ORG. 296, 302 (2011); Aranka Anema et al., *Descriptive Review and Evaluation of the Functioning of the International Health Regulations (IHR) Annex 2*, 8 GLOBALIZATION & HEALTH 1 (Jan. 10, 2012).

141. See WHO, *supra* note 12, at 12.

142. *Id.* at 67.

IHR.¹⁴³ Perceived barriers and facilitators to implementation were explored, as were participants' views for how NFPs in low- and middle-income countries can be better supported. By using a qualitative methodology, the researchers were able to explore a wide breadth of themes and explore each of these themes in detail.

In collaboration with the WHO officials, we developed a sample of countries in Africa, Asia, Europe, South and North America.¹⁴⁴ In developing the preliminary list, between three and ten NFPs from each of the WHO regional groupings (Africa, Europe, Americas, Southeast Asia, Eastern Mediterranean, and Western Pacific) were selected, remaining mindful throughout of regional geographical representation within each grouping (for example, attempting to ensure representation from eastern, western, and southern states within the African region). The preliminary sample of each grouping was highly dependent on both the geopolitical stability and the gross domestic product ("GDP") per capita and weighted towards fragile and low-income countries.

These indicators are likely to have a significant impact on a state's ability to fully implement the IHR. We also sought to identify states frequently affected by conditions that will more likely lead to the use of the Annex 2 decision instrument because they have demonstrated the potential to cause serious public health impact and to spread rapidly internationally.¹⁴⁵ In this regard, we focused on states particularly affected by viral hemorrhagic fevers. We also prioritized countries affected by the recent Ebola outbreaks given the interest in the effectiveness of the IHR in helping to identify and manage these outbreaks.

Each interview was audio-recorded, and later transcribed verbatim, in order to ensure the accuracy and integrity of data collected. The transcripts indicate the position of the interviewee, date, time, and duration of the interview only. Information identifying the name of the participant was omitted from the interview transcript. Participants were given the opportunity to either agree or disagree with being contacted for follow-up questions. Following transcription, participants were allocated numerical identifiers in order to ensure the confidentiality of their responses. Participants were given the option of having any direct quotes used in the publications resulting from this study attributed to them, or presented anonymously with identifying information omitted or paraphrased to conceal their identity.

A total of twenty-five interviews were conducted between May and September 2019. Study participants described a number of challenges in carrying out their duties as NFPs and reporting public health events of

143. See Corinne Packer et al., *A Survey of International Health Regulations National Focal Points Experiences in Carrying Out Their Functions*, 17 *GLOBALIZATION & HEALTH* 2, 3 (2021).

144. *Id.* at 1.

145. *Id.* at 10.

significance.¹⁴⁶ Their responses are grouped into five categories. These are summarized in the order of most to least frequently referenced. Solutions proposed by the participants follow.

Further data collection was accomplished through an online survey.¹⁴⁷ The survey collected a broad range of quantifiable (objective and numerical) indicators regarding how NFPs perceived their ability to perform their job under the IHR.¹⁴⁸ Questions were developed from the themes that emerged from the qualitative interviews.¹⁴⁹ In order to facilitate quantitative analysis of findings, this questionnaire included questions that prompt participants for a dichotomous (Yes/No) answer, or an answer that can be measured on a scale (for example, always, sometimes, never; never agreed, agreed, always agreed, etc.).¹⁵⁰ Apart from quantitative analysis, the survey was also designed to facilitate some open-ended questions to obtain a deeper insight regarding guidance documents and tools. Participants were also given a choice to share any informative material that they had produced, and which could be used for future references. The online questionnaire was administered to the NFPs of all IHR states parties that expressed their willingness to participate and for whom email addresses were available.¹⁵¹ The online questionnaire was administered to the representatives of NFPs individually in their respective language of communication based on the WHO's six official languages (Arabic, English, French, Spanish, Russian, and Chinese) via a secured internet-based system. Inclusion for the quantitative survey was additionally dependent on availability of personnel of NFPs to complete the survey. One staff member from each NFP (chosen by the NFPs themselves) was to be responsible for completing the survey on behalf of the NFP, but the survey could be completed as a group if the NFP staff members feel that this will more accurately convey their perspectives.¹⁵² Each state party was only able to submit one completed survey.¹⁵³

The quality of data collected was ensured by several methods in the qualitative and quantitative studies.¹⁵⁴ In the qualitative study, quality was assured through the use of multiple research team members reviewing the results to confirm the accuracy of the themes identified; by having the interviews conducted by more than one individual; through objective transcrip-

146. *Id.* at 10–13.

147. *Id.* at 2.

148. *Id.*

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.* at 3.

153. *Id.* at 4.

154. Initially, we used a qualitative research software, to code and sort the qualitative data collected. Coding is an interpretive technique that both organizes data and provides a means of introducing interpretations of it into quantitative methods. Coding of data allowed researchers to identify salient common themes across the sample, as well as to detect variation in responses. It was additionally important to inform the development and design of the quantitative survey after conducting the interview.

tion of audio-taped interviews; and by coding and classifying data. In the survey, by relying on an automated online survey tool, we eliminated the possibility of human error that may arise in transferring respondents' answers from hand-written hard copies to a computer program. We stripped all data of identifiers, enabling objective statistical analysis.

1. *The Qualitative Interview*

A total of twenty-five interviews were conducted between May and September 2019.¹⁵⁵ Study participants described a number of challenges in carrying out their duties as NFPs and reporting public health events of significance. Their responses fell broadly into five categories, discussed in descending order of importance: intersectoral relationships, technology, legal authorizations, budget limitations, and human resources.¹⁵⁶

a. Intersectoral Relationships

The majority of countries (twenty-two out of twenty-five) represented in interviews have situated their NFPs within their ministries mandated to govern public health; essentially, within their 'ministries of health.'¹⁵⁷ Only three have located their NFPs elsewhere: one within its Ministry of Human Resources, and two within institutes contracted externally by their governments to carry out the tasks of NFPs, with direct lines of contact to their ministries of health.¹⁵⁸ None reported NFPs to be located across multiple ministries. Over half of those interviewed (thirteen of twenty-five) raised the importance of 'intersectoral collaboration'; that is, collaborative and coordinated communications and efforts across government departments and ministries in the event of public health incidents of concern to NFPs.¹⁵⁹ Five of these reported successful collaborations between the government ministries which should be immediately involved in the process of identifying a public health incident. For instance:

The health sector, namely, our department, and our colleagues, are approaching all the other governmental sectors, other ministries, other bodies and institutions that are connected or relevant in terms of health, such as all the hospitals, laboratories, civil defense . . . We are following the private sector, health private sector providers. We are also dealing with our colleagues in the Ministry of Municipality and the Environment for all those issues connected to zoonotic diseases, you know, the animal-human inter-

155. Packer et al., *supra* note 143, at 2.

156. *Id.* at 6–8.

157. *Id.* at 3.

158. Wilson & Halabi, *supra* note 65.

159. Packer et al., *supra* note 143, at 7.

face . . . We are also very well connected with the ports inventory . . . air and sea and land (Respondent F).¹⁶⁰

Another described the smooth functioning of intersectoral collaboration:

[In terms of] bringing on board the relevant actors at the national [level], whether at the level of the Ministry of Health or the other actors—the other line ministries in human health, environmental health, environment or even the cabinet at the level of the President—there are no major issues. (Respondent D).¹⁶¹

A good measure of successful intersectoral collaboration is the amount of time it typically takes from the start of a notification assessment to the authorization of release of the actual notification (if an event is indeed deemed notifiable).¹⁶² Only three respondents reported notifications issued within twenty-four hours, with the larger majority reporting within twenty-four to forty-eight hours, and three others requiring two to seven days.¹⁶³

Challenges exist in intersectoral collaboration. These challenges manifested themselves in different ways. Some involved questions of capacities and competencies across sectors:

We don't have good enough intersectoral coordination. For example, we don't know all the details of the IHR competencies which are part of other sectors outside of the health sector . . . We don't know the details, for example, of the capacity of the veterinarians at border crossings. We partly know the capacities of sanitary inspection, but not all—not in detail. (Respondent T).¹⁶⁴

Others pointed to the lack of knowledge and appreciation of the IHRs by colleagues in other relevant ministries and their own roles in seeing them implemented.¹⁶⁵ As described by two participants:

Because those who are within the health sector are really colleagues, they understand, you know, the needs, and we see them regularly, we communicate with them regularly. The others are really far away, sometimes the focal point will be changed, departments will be, you know, reformed or changed, the follow-up—and sometimes, I would say the feeling or the perception of those departments, about the importance of IHR is not as good as our department or our ministry. (Respondent F).

160. *Id.*

161. Wilson & Halabi, *supra* note 65.

162. *Id.* at 12.

163. *Id.*

164. *Id.*

165. *Id.*

The main limitation we have . . . comes from the fact that the IHRs are not well known by directors at high levels in the different sectors and the technical personnel in these sectors (for example, safety, animal health, environments, among others). (Respondent S).¹⁶⁶

The underlying source of this challenge to intersectoral collaboration seems to stem from difficulties in communication between departments of concern, for example, customs, animal health, agriculture, transportation, trade, tourism, and military.¹⁶⁷ These can be categorized into three distinct issues.

First, the absence of protocols for communicating concerns for potential public health events and the need for data between ministries:

There needs to be a formal and regular mechanism for communication . . . For example, the animal health do not provide us regular information on the influenza situation in the animal population. We do not provide on a regular basis, and the information on the seasonal influenza, but in humans. And beyond us, it's even more murky. (Respondent J).¹⁶⁸

Second, the inadequacy of speedy responses from the colleagues in other ministries, likely owing to their lack of appreciation of the importance of their roles and responses in implementing the IHR (2005):

I don't feel that they have enough knowledge. Even though we've had a series of meetings, we now have cross multidisciplinary and cross sectoral . . . we need them to be trained in International Health Regulations. We need policymakers to step up to the level of acknowledging their requirements and responsibilities. (Respondent L).¹⁶⁹

Third, the sheer lack of knowledge by NFPs of contact details of their counterparts in ministries outside of the health ministry:

I am comfortable as far as access to my own ministry or decision makers in my ministry . . . but when it deals with people in other ministries, in other institutions . . . I would have to kind of explore who are the people that I can call and through whom I can reach the highest-level decision makers. (Respondent J).¹⁷⁰

166. *Id.*

167. *Id.*

168. *Id.*

169. *Id.*

170. *Id.*

b. Technology

Nearly half of countries (ten out of twenty-five) indicated they need technical support from the WHO to fulfil their NFP duties. Requests were for assistance in upgrading outdated equipment and information technology systems. Others expressed frustrations about the challenges of accessing required technology in rural and remote areas to share information on potential outbreaks: “Sometimes physicians and nurses working in remote areas” cannot access computers and “they forget to report the case” (Respondent M).¹⁷¹ Even if they wished “to share information [about a case] in a very remote state, they may not necessarily be online for some reason or another—either the Internet is off or is not working all week” (Respondent D).¹⁷² Two countries indicated they did not have adequate national public laboratories for diagnosis of diseases to confirm potential viral emergencies and requested the (largely financial) assistance of the WHO to set them. (Respondents D, F).¹⁷³ Another felt it needed technical support from the WHO to raise awareness in the event of a potential outbreak. (Respondent M).¹⁷⁴

One NFP focal point lamented the disappearance of a system set up by the WHO, in use some five years ago. (Respondent F).¹⁷⁵ This system was described as being able to identify what kinds of infections needed to be reported and alert countries automatically when notifications were necessary. Another raised the need to improve (or develop new), early warning systems, particularly in the event of infectious disease outbreaks during mass gatherings, as well as comprehensive surveillance systems:

We need some support in terms of an integrated surveillance system, from farm to fork, which is basically the one health approach. . . [including] food production, agriculture . . . and the human animal environment . . . [We need] some help to master it, to fill the gaps that we have . . . We have very fast, exponential expansion of our food and animal production, and we need to ensure that they are properly monitored, and they are safe . . . free from any contamination. (Respondent F).¹⁷⁶

Doubling up on the concern for improved intersectoral collaboration, this same NFP officer also called for technical support by the WHO “to assess our capabilities and capacity to . . . detect, respond to and manage chemical and radiological events. Because these are . . . shared with other ministries, it’s not pure health. . . [they involve] shared responsibilities between other

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.*

176. *Id.*

major ministerial players in the country.” (Respondent F).¹⁷⁷ Another participant suggested the WHO itself should conduct randomized blind research on biological threats. (Respondent H).¹⁷⁸

c. Legal Authorization

NFPs experienced difficulty in ensuring compliance of the IHR (2005) and declaring notifications expeditiously. Approximately one-third of NFPs (eight of twenty-five) interviewed indicated that a lack of legal authority or clear governance procedures impacted upon their ability to report events to the WHO in a timely fashion. These difficulties presented themselves in three forms:

i. Approval from Other Ministries

Respondents discussed challenges with having to get sign off from other ministries before reporting:

I have no legal authority on any other sector, so most of my work is considered personal connections between other sector[s] and other ministries in the government. But until now, I don't have this legal authority to [obtain] verification from other ministries or other sector[s] . . . Sometimes, I have to convince them . . . (Respondent R).¹⁷⁹

Even in cases where respondents indicated their countries had legislation in place to enforce IHRs, problems arose when they needed to get data or approvals from ministries and sectors outside of their own ministry. The animal health sector was cited a number of times as a challenge as was civil aviation (for ports of entry). One respondent explained:

The biggest challenge we face is a lack of clear-cut legal authority . . . It is quite a struggle for us trying to establish very good coordination with the civil aviation authorities. They do not understand that it is an essential part of their responsibilities as part of international civilization community [sic]. And same [sic] when it comes to information sharing. (Respondent J).¹⁸⁰

One country has a unique situation in that the NFP and its functions are out-sourced, contracted to a domestic, academic center.¹⁸¹ While no difficulties were cited in transferring information rapidly to the appropriate governmental departments, it was pointed out that the center's contract is renewed on an annual basis so there is some risk in a break in continuity of coverage:

177. *Id.*

178. *Id.*

179. *Id.*

180. *Id.*

181. *Id.*

“Once the contract is signed, we are kind of secure for a year. But . . . it is a short period in a way. So we always have to fight a little bit in advance.” (Respondent H).¹⁸²

The burdensome process of obtaining clearance from different ministries was reported to cause delays (in one case up to four weeks) in reporting events to the WHO.¹⁸³

ii. The Influence of Politics and Money

Political assessments were reported to cause hesitation in reporting events.¹⁸⁴ As one participant summed it up, “emergencies are always political” and result in “difficulty to obtain clearance to report events to [the] WHO” (Respondent N). Another described the fear of declaring an emergency to be the effect it might have on the movement of people in and out of the country. Others pointed the finger at trade and commerce: “When commercial interests are involved, or when they think it will bring an adverse impact on tourism, on industry or other things, then it gets a bit complicated.” (Respondent J).¹⁸⁵

Participants acknowledged that these challenges are entirely a result of their own governance structures and internal hierarchies but they still requested assistance from the WHO to enhance accountability and transparency among all concerned sectors. The WHO could consider exploring whether countries have in place sufficient governance structures—Memoranda of Understanding (“MOUs”), inter-ministerial agreements, enabling legislation, conditional funding—that may facilitate IHR compliance; providing guidance on how to address challenges relating to competing interests within a country, as a form of capacity building; and, easing fears by addressing IHR compliance with Director-General and Expert Committee recommendations.

d. Budget Limitations

Just over one fifth (six of twenty-five) of respondents said they do not have sufficient monetary resources to carry out their IHR obligations. The few among them who described this shortage said they were unable to send teams out to assess potential outbreaks or had insufficient resources for laboratory testing. Respondents asked that the WHO convince policymakers in their countries that their IHR obligations require providing NFPs with dedicated resources.

182. *Id.*

183. *Id.*

184. *Id.*

185. *Id.*

e. Human Resources

Five of twenty-five respondents indicated issues related to human resources, especially training, as barriers to fulfilling their functions. A well-trained NFP and staff are vital to the successful implementation of the IHR.¹⁸⁶ As one respondent explained: “Training has assisted with IHR compliance . . . The impact has been enormous. I’ve seen the proportion of reports, proportion of notification have increased over the years” (Respondent L).¹⁸⁷

Study participants were asked when they had last issued a notification of a public health event using Annex 2 of the IHR.¹⁸⁸ All but three responded. The majority (thirteen of twenty-five) had issued a notification within the last two years, and an additional few had done so within the last five years. Five of twenty-five respondents had never issued a notification, and thus had never used the reporting mechanism under Annex 2.¹⁸⁹ Three of these offered as reason that they had not been in their position for long.¹⁹⁰

The low frequency of notifications issued explains to some extent the concerns of NFPs regarding their training; while all study participants indicated they were familiar with the IHR and their duties as NFPs, many reported gaps in knowledge which better and fresh training (beyond online training tools) could provide.

A common complaint from NFPs was that they and their staff had not received any or sufficient training when newly placed in the NFP office. Five countries indicated they need more training to do a good job as NFPs: “We are trying to do things by learning—sometimes with setbacks. Sometimes . . . we need to be retrained.” (Respondent M).¹⁹¹ Staff turnover was one of the challenges which resulted in inadequate training: “The NFP, as you know, is an institution, not a person, and as people change, they do not come with prior knowledge of IHR.” (Respondent J).¹⁹² Another country described their “biggest issue is with [staff] turnover, which does tend to be high,” adding that their small team relies heavily on individuals knowing what they are doing. (Respondent V).¹⁹³ Some described an absence of any form of mandatory training upon starting the job as a major hurdle.

Respondents recommended a dedicated program from the WHO for training new NFPs on how to roll out activities in their countries; training of trainers, so that someone within the country is able to train new, onboarding staff; fellowships for in-depth training, for example, at regional

186. Packer et al., *supra* note 143, at 2.

187. Wilson & Halabi, *supra* note 65.

188. *Id.*

189. *Id.* at 7.

190. *Id.*

191. *Id.*

192. *Id.*

193. *Id.*

WHO offices; and additional funding to train staff. NFPs reported training on the IHR for the NFP would be beneficial:

My biggest challenge is that even within my own health system, and within my own division, a lot of people do not know, what really IHR is and what are the responsibilities of the IHR NFP and we do not do a very good job of raising awareness about it . . . I would have to admit that even in my own team, I talk with people and they all have their own different ideas of IHR and what are the responsibilities of an IHR NFP. (Respondent J).¹⁹⁴

Respondents also were unanimous in their opinion that, since the IHR requires a holistic approach to human and animal health, IHR training should be provided beyond the NFP office and the ministry of health. It requires the participation and buy-in of multiple key line ministries, such as those responsible for animal health, agriculture, the environment, sanitation, transportation (air and shipping), tourism, military, and more. For other respondents, it is the professionals required for the timely detection of suspected infections—statisticians, epidemiologists, and virologists, for example—who lack sufficient training to ensure compliance with the IHR.

Four respondents indicated that they had some difficulty in determining whether an infectious disease event qualified as a notifiable event: “I would like . . . a clear list of the infectious diseases that need to be reported. Then I would like the definition that describes potential limitation of passengers and freight . . . As the cases become more frequent, when does it become an epidemic?” (Respondent C).¹⁹⁵

These respondents requested more assistance from the WHO in making the determination as to whether an event was a public health emergency worthy of notification in accordance with the IHR, or merely an event requiring information sharing.¹⁹⁶ Consultation with the WHO during the determination process would help in this regard. Assistance from the WHO was also requested following the notification of an event to the WHO, namely: assistance in response (for example, by providing expert technical guidance and by the WHO assessing the effectiveness of on-site controls) and a WHO task force responsible for oversight of the implementation of the IHR during emergency responses.¹⁹⁷

2. *The Quantitative Survey*

A total of 113 questionnaires were completed and coded. Similar trends as observed in the interviews manifested across the wider surveys. The majority (79%) of countries participating in the survey have their NFP offices located

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

within their Ministry of Health.¹⁹⁸ The remainder have them placed in related ministries (such as the Ministry of Social Affairs), or national institutes or centers of health or disease control.¹⁹⁹ Fifty-nine percent of the individuals heading NFPs have held this position for five years or more, with two-thirds of this group in place for over eight years.²⁰⁰ By contrast, nearly one in ten NFPs are relatively new to the role, having held the position for under one year.²⁰¹

While the survey results demonstrate that NFPs are secure in their knowledge and understanding of the IHR (2005), when it comes to the tasks expected of them and their communications with the WHO, they are less certain of the knowledge and collaboration of key colleagues in other ministries.²⁰² “In order to carry out its functions and submit reports to the WHO quickly, the NFP depends on input from other ministries and agencies in related areas of government outside of health; smooth collaboration is key.”²⁰³ Over half of respondents feel that “most” or “all” of the other ministries and agencies with responsibilities relevant to the implementation of the IHR understand the role of the NFP.²⁰⁴ However, while over half of respondents believe colleagues in these other relevant sectors know how and when to engage with NFPs, a considerable number of them (44%) believe that only some, a few, or none do.²⁰⁵

Survey participants were also asked whether procedures and structures were in place for timely communication between the NFP and relevant sectors at the national level.²⁰⁶ More than one in ten did not believe this to be the case. This same concern was reflected by the affirmation of nearly 10% of respondents that their NFPs did not have access to the necessary ministries and decision-makers, including senior management.²⁰⁷ Over one third (37%) reported that clearance from these other sectors is required before an event can be notified to the WHO.²⁰⁸

The results show that respondents believe “concern about how the WHO will use the information that is reported to them (for example, dissemination to other countries)” is most likely to impact their timely notification of a public health event to the WHO (58%).²⁰⁹ “Uncertainty over how to report an event” followed at a close second at 53%.²¹⁰ States parties were

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.*

202. *Id.* at 7.

203. *Id.*

204. Packer et al., *supra* note 143, at 3.

205. *Id.* at 5.

206. *Id.* at 3.

207. *Id.* at 8–9.

208. *Id.* at 3.

209. *Id.* at 5.

210. *Id.*

clearly concerned about the potential damage a public health event might bear on their image (40%) and their tourism or trade (33%) and were therefore concerned about the confidentiality of reports to the WHO (45%).²¹¹ Less impactful on the timely release of notifications, yet by no means insignificant, were internal issues such as the lack of the NFP's authority to do so (41%), political challenges (41%), and insufficient financial (34%), human (31%), and surveillance/detection (31%) resources to do so.²¹²

a. Limits to the Independence of NFPs

NFPs experienced difficulty in ensuring compliance of the IHR (2005) and declaring notifications expeditiously. Approximately 62% of NFPs surveyed indicated that a lack of legal authority or clear governance procedures impacted upon their ability to report events to the WHO in a timely fashion.²¹³ Similarly, precisely 60% of respondents indicated that a "lack of NFP authority" impeded reporting to WHO.²¹⁴ Approximately 59% indicated that "political challenges" served as a barrier to reporting.²¹⁵

Financially, nearly 65% of NFPs reported that "insufficient financial resources" impacted their ability to timely notify WHO of information relevant to the determination of a public health emergency of international concern.²¹⁶

Narratives from the qualitative survey bring detail to some of these numbers. Respondents discussed challenges with having to get sign off from other ministries before reporting. Even in cases where respondents indicated their countries had legislation in place to enforce the IHR (2005), problems arose when they needed to get data or approvals from ministries and sectors outside of their own ministry.²¹⁷ The animal health sector was cited a number of times as a challenge as were airports.²¹⁸ One respondent explained:

One country has a unique situation in that the NFP and its functions are outsourced, contracted to a domestic, academic centre. While no difficulties were cited in transferring information rapidly to the appropriate governmental departments, it was pointed out that the centre's contract is renewed on an annual basis so there is some risk in a break in continuity of coverage: "Once the contract is signed, we are kind of secure for a year. But . . . it is a short period in a way. So, we always have to fight a little bit in advance." (Respondent H).²¹⁹

211. *Id.*

212. *Id.*

213. Wilson & Halabi, *supra* note 65, at 34.

214. *Id.* at 31.

215. *Id.* at 30.

216. *Id.* at 33.

217. Packer et al., *supra* note 143, at 7.

218. *Id.*

219. *Id.*

The burdensome process of obtaining clearance from different ministries was reported to cause delays (in one case up to four weeks) in reporting events to the WHO.²²⁰

Political assessments were reported to cause hesitation in reporting events.²²¹ As one participant summarized, “emergencies are always political” and result in “difficulty to obtain clearance to report events to WHO.” (Respondent N).²²² Another described the fear of declaring an emergency to be the effect it might have on the movement of people in and out of the country.²²³ Others pointed the finger at trade and commerce: “When commercial interests are involved, or when they think it will bring an adverse impact on tourism, on industry or other things, then it gets a bit complicated.” (Respondent J).²²⁴ As long as countries worry about trade and travel restrictions or other adverse effects of early reporting, they will continue to require high-level approvals from sectors with competing interests. These high-level approvals hamstringing a focal point’s ability to quickly and effectively report any potential health emergencies.

b. Study Conclusions

The majority of NFP Offices are within ministries of health and are headed by individuals who have held their positions for five years or more, reflecting sound knowledge and familiarity with the IHR and the required procedures for notification of public health events.²²⁵

While respondents affirmed that NFPs are secure in their knowledge and understanding of the IHRs, the tasks expected of them, and their communications with the WHO, they were less certain of the knowledge and collaboration of key colleagues in other ministries.²²⁶ Survey results demonstrate that a fair number of colleagues in these related sectors have an insufficient understanding of the role of NFPs or knowledge of how and when to engage with NFPs.²²⁷

About 10% of states parties lack the procedures and structures to promote timely communication between the NFP and stakeholders in the relevant sectors at the national level.²²⁸ Unsurprisingly, nearly the same number of respondents claim their NFPs did not have access to the necessary ministries and decision-makers.²²⁹ All of these factors can jeopardize the timeliness of information shared and the expeditious reporting of public health

220. *Id.*

221. *Id.*

222. Wilson & Halabi, *supra* note 65.

223. *Id.*

224. *Id.*

225. *Id.* at 3.

226. *Id.* at 7.C.

227. *Id.*

228. *Id.*

229. *Id.*

events to the WHO;²³⁰ indeed, well over one third of NFPs cannot proceed to issue a notification to the WHO without first receiving clearance from decision-makers in these other sectors.²³¹

The most significant observation in the study was the need for and challenges inherent in obtaining intersectoral approval. This was repeatedly stated and elaborated upon in the interviews and further supported by the response to the surveys.²³² For a variety of reasons for an event to be reported it would potentially require several departments to review and approve. This would include ensuring accuracy of description of the event and likely allow a department to assess any impact of a notification. These departments are often not familiar with the IHR and its obligations.²³³

3. *Strengths and Weaknesses of the Study*

In evaluating the results of this study, it is important to recognize the strengths and limitations of qualitative studies. The primary purpose of qualitative research is to be explorative and to gain a more in-depth understanding of an issue than would occur with a quantitative analysis. From a qualitative study one can potentially infer strength and breadth of concepts but cannot quantify these. The latter is primarily due to the fact that the sampling is purposeful and cascading, and that the interview guide also necessarily evolves as the study progresses. The subsequent survey that is informed by these interviews will be better suited to quantifying the responses although it cannot ascertain strength of belief. Combining the qualitative with the quantitative results will provide a more complete picture than either individually.

It is also important to recognize another limitation in a study of this type, specifically the risk of social desirability bias (attempting to provide responses that are perceived as acceptable to the interviewee). There is also the risk that the respondents may be uncomfortable fully disclosing issues that may be viewed as portraying themselves or their state in a bad light—in particular as this project has been supported by the WHO.

Our study has important strengths and limitations. The primary strength is that this is the most comprehensive assessment of NFP experience with the IHR (2005). Our response rate to the interview portion was good (at twenty-five representative NFPs) and to the survey was very good at 121 NFP representatives answering the 56-question survey; 105 in full, and an additional 16 in part. Collaboration with the WHO head office and regional offices facilitated our response rate. WHO and regional office input also guided our interview and survey design to ensure we were answering questions that were important to policymakers.

230. Packer et al., *supra* note 143, at 7.

231. *Id.*

232. *Id.*

233. *Id.*

The conduct of both qualitative interviews and a quantitative survey permitted a form of triangulation. The interviews provided an in-depth knowledge and understanding of NFP experience—permitting elaboration and context. The surveys provided a broader sample and ability to determine the generalizability of the findings of the interviews.

Another important limitation of this study is the potential for bias in responders versus non-responders to both the interviews and the surveys. In particular, the potential for systematic differences between these two populations relating to their views on the IHR could distort the results (that is, those who were not favorable to the WHO or the IHR may have chosen not to participate). We also noted a regional discrepancy in responses—with an absence of, in particular, interviews with representatives from the WHO Region for Africa (“AFRO”) region. This is particularly important as one of the motivations for this study was the Ebola outbreak which affected the AFRO region.

V. THE INDEPENDENCE OF NATIONAL FOCAL POINTS AND THE REFORM OF THE IHR (2005)

The COVID-19 pandemic has renewed calls for the review and reform of the International Health Regulations (2005) generally, and the role of National Focal Points specifically.²³⁴ NFPs are critical to the implementation of the IHR as they have core responsibilities for several functions including the communications aspects of the Regulations, both within their countries and internationally. In the wake of the emergency, some governments recommended tying health development assessment to an external assessment of current health risks.²³⁵ Global stakeholders are now discussing the formation of a “pandemic treaty,” with no clear detail on its relationship with the IHR (2005).²³⁶

Our study identified a number of important challenges that NFPs face in fulfilling their functions under the IHR (2005). The most prominent challenge involves two different problems with intersectoral collaboration within national governments: (1) difficulties that NFPs experience in obtaining information from, and sharing information with, other parts of the national government in connection with implementing the IHR and (2) the

234. See Jaemin Lee, *IHR 2005 in the Coronavirus Pandemic: A Need for a New Instrument to Overcome Fragmentation?*, 24 AM. SOC’Y INT’L L. (2020), <https://www.asil.org/insights/volume/24/issue/16/ihr-2005-coronavirus-pandemic-need-new-instrument-overcome-fragmentation> [https://perma.cc/6GTJ-BNJJ].

235. Daniel Stowell & Richard Garfield, *How Can We Strengthen the Joint External Evaluation?*, 6 BMJ GLOB. HEALTH (2021).

236. Svet Lustig Vijay, *WHO Proposes New “Pandemic Treaty” to Tighten Global Monitoring and Enforcement of Disease Outbreak Response*, HEALTH POL’Y WATCH (Jan. 20, 2021), <https://healthpolicy-watch.news/who-proposes-new-pandemic-treaty-to-tighten-global-monitoring-and-enforcement-of-disease-outbreak-response/> [https://perma.cc/LG2D-AXUG].

national-level requirement for NFPs to obtain approval from other government authorities before notifying the WHO of serious disease events. Also, the survey and study highlight concerns that NFPs do not have sufficient material and human resources to carry out their functions under the IHR. Importantly, while progress appears to have occurred, many of these same issues have been identified in previous reviews of the IHR.

Potential reforms of NFPs involve relatively achievable alternatives that fit within the existing framework, and changes that will involve greater forfeiture of sovereignty and therefore more protracted negotiation. This is even more so if the IHR (2005) is enveloped within a pandemic treaty.

A. *Soft Reforms*

1. *Technical Assistance for Core Capacities*

Over the intermediate term, the WHO should emphasize the importance of states parties meeting Annex 1 core capacity requirements. This could assist NFPs in obtaining material support to carry out their functions. The WHO also could share best practices for NFPs to address three identified governance challenges: how to execute functions in the absence of the NFP's (and by extension the ministry of health's) legal authority over other sectors; strategies to expedite obtaining approval from other ministries and approaches to address competing political and economic considerations that could impact reporting of public health events. Participants acknowledged that these challenges are a result of their own governance structures and internal hierarchies, but they still requested assistance from the WHO on how to navigate these issues. Suggestions for WHO support included technical reviews of governance structures and sharing individual NFPs' approaches to governance (such as MOUs, inter-ministerial agreements, and enabling legislation) and the perceived success of these approaches in facilitating NFPs' ability to execute their functions.

2. *Training non-Ministry of Health Stakeholders*

Similarly, given the frequency with which NFPs identified intersectoral misunderstanding, the WHO might also adapt training modules for other ministries. This was identified as a major factor that could potentially delay reporting. It is possible that political or economic considerations could impact the sign-off but the impression from the interviewees was that there was, in general, a lack of familiarity of the IHR in these ministries. These modules might be a simple fact sheet about the IHR or a rapid learning module as well as WHO guidance on how to work with other ministries to ensure proper understanding of the states parties requirements under the IHR.

3. *Creating a Community of NFPs*

As noted in Part IV, *supra*, one of the few sources of publicly available information about NFPs is reports or summaries from regional meetings typically convened by the WHO on a regional basis.²³⁷ On those occasions, NFPs have the opportunity to identify and assess common problems, including those related to intersectoral relationships analyzed above. Several NFPs support the participation of NFPs in a collaborative NFP network, which may be accomplished with relatively modest financial investment.

B. *Fundamental Reforms*

More fundamentally, the International Health Regulations (2005) could adopt reforms at the nexus of country-level reporting, measures aimed at requiring NFP independence as a function of participating in the treaty. These measures would potentially intrude deeply into otherwise sovereign concerns like how national ministries of health are funded, administered, and empowered, but they have precedent in some of the regimes that work in the field of other international security threats.²³⁸

The WHO could provide further support to intersectoral collaboration challenges. This includes helping to build IHR knowledge and capacity in ministries outside of health so that states parties are better able to implement the IHR. To do so, the WHO could collect and share best practices for intersectoral communication and collaboration on establishing communication protocols between ministries. Additionally, the WHO could also share best practices on raising awareness across sectors of the importance of according NFPs authority when notifications of public health events must be approved and issued. The WHO approach in addressing these specific issues must carefully navigate issues around state sovereignty.

1. *Verification*

“Verification” is the process that one or more countries use to assess whether another country is complying with an international agreement.²³⁹ No treaty relies on any one provision as the basis for successful monitoring and verification. “A verifiable treaty contains an interlocking web of constraints and provisions designed to deter cheating, to make cheating more

237. See Suthar et al., *supra* note 15; see also Herszenhorn, *supra* note 16.

238. For example, GAVI, as part of financial support for LMIC procurement of vaccines, requires ministries of finance and ministries of health to develop plans for financing after GAVI support ends. Helen Saxenian et al., *4 Things Ministers of Finance Need to Know About Immunization in GAVI Transitioning Countries, Learning Network for Countries in Transition* (Jan. 17, 2019), <https://lnct.global/blog/blog-4-things-ministers-of-finance-need-to-know-about-immunization-in-gavi-transitioning-countries/> [<https://perma.cc/65W5-ZLZT>].

239. See Richard A. Scribner et al., *THE VERIFICATION CHALLENGE: PROBLEMS AND PROMISE OF STRATEGIC NUCLEAR ARMS CONTROL VERIFICATION* 24–25 (1985).

complicated and more expensive, or to make its detection more timely.”²⁴⁰ The text of the IHR (2005) allows the WHO to consider “other reports” but requires the WHO to consult with the state party before taking action on “other reports.” Articles 9 through 11 of the IHR (2005) are specific to the ability of the WHO to consider reports other than notifications from or consultations with the notifying state party.

Article 9 – Other Reports

WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring . . .

Article 10 – Verification

WHO may, when justified by the magnitude of the public health risk, share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned . . .

When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures . . .

In the context of COVID-19, Taiwan reported to the WHO that its doctors had heard from mainland colleagues that medical staff were becoming ill after treating patients diagnosed with atypical cases of pneumonia—a sign of human-to-human transmission. Taiwanese officials further stated that they reported this to both the WHO and Chinese health authorities on December 31, 2019.

Yet Articles 9 and 10 are, by virtue of the negotiation process leading to the conclusion of the IHR (2005), deferential to the state party’s interest about how “other reports” may affect that State’s interests. Although the IHR (2005) endeavor to balance public health protection with individual liberties, international travel and trade, reporting events that may lead to

240. AMY WOOLF, CONG. RSCH. SERV., R41201, MONITORING AND VERIFICATION IN ARMS CONTROL 3 (2011).

the declaration of a public health emergency of international concern inevitably carries adverse economic effects for the state party making those reports.²⁴¹

National Focal Points could be required by the treaty to have the permanent or regular presence of the WHO or other qualified non-citizen participants as members of the NFP. This would clear the communication pathway between the state party and the WHO as well as provide technical assistance for gathering information from relevant ministries. Regular verification by international organizational third parties has long been a feature of arms control regimes like the Strategic Arms Reduction Treaty (“START”) between the United States and the Russian Federation and the multilateral Joint Comprehensive Plan of Action that was aimed at controlling the use of nuclear material in Iran.²⁴²

2. *Mandated Joint External Evaluations*

In 2014, approximately sixty countries and dozens of international organizations, foundations, and businesses formed the Global Health Security Agenda (“GHS”).²⁴³ The formation of the GHS coincided with the emergence of the Ebola outbreak in Guinea, Liberia, and Sierra Leone, which lasted through 2016 and claimed over 11,000 lives.²⁴⁴ Its formation marked the international community’s acknowledgment that infectious disease and biosecurity threats were fundamentally tied, and integrated into its partnership not only the WHO, the UN Food and Agriculture Organization (“FAO”), and the International Organization for Animal Health (“OIE”) but also security-oriented international organizations like the International Criminal Police Organization (“Interpol”).²⁴⁵ According to the GHS, the fight against COVID-19 has been significantly enhanced by “national plans supported by the International Health Regulations and Joint External Evaluations [which] are guiding action and providing resources for decision making, prioritisation, and actions.”²⁴⁶

The Joint External Evaluation (“JEE”) process is a “voluntary, collaborative, multisectoral process” that assesses countries’ capacities to identify the

241. See Barbara J. von Tigerstrom et al., *The International Health Regulations (2005) and the Re-Establishment of International Travel amidst the COVID-19 Pandemic*, 27 J. TRAVEL MED. 1, 1–4 (2020).

242. See generally CONG. RSCH. SERV., R41219, THE NEW START TREATY: CENTRAL LIMITS & KEY PROVISIONS (2021); International Atomic Energy Agency, *Verification and Monitoring in Iran*, <https://www.iaea.org/newscenter/focus/iran> [<https://perma.cc/AP67-ZH3Q>].

243. *The U.S. Government Engagement in Global Health: A Primer*, KAISER FAM. FOUND. (Feb. 5, 2019), <https://www.kff.org/global-health-policy/report/the-u-s-government-engagement-in-global-health-a-primer/view/print/> [<https://perma.cc/8DKG-LA4B>].

244. Sam Halabi et al., *supra* note 13, at 203.

245. *About the GHS*, GLOBAL HEALTH SECURITY AGENDA, <https://ghsagenda.org/home/about-the-ghsa/> [<https://perma.cc/5SZS-GE9U>].

246. *COVID-19 Chair’s Statement: What Is the Role of GHS2024 in This Pandemic?*, GLOBAL HEALTH SECURITY AGENDA (Mar. 17, 2020), <https://ghsagenda.org/2020/03/17/covid-19-chairs-statement-what-is-the-role-of-ghsa2024-in-this-pandemic/> [<https://perma.cc/89ZZ-6WY5>].

most critical gaps within their human and animal health systems, in order to prioritize opportunities for enhanced preparedness and response.²⁴⁷ The JEE “bring[s] together national representatives from key sectors, including human and animal health, agriculture, wildlife, finance, defense, security, environment, communication, disaster management board, transportation, customs, civil aviation, universities or institutes, and political leadership.”²⁴⁸ The JEE exercise identifies whether a country has adopted laws specific to the International Health Regulations, maintains surveillance systems for animal health, and monitors the use of antibiotics and signals for the emergence of antimicrobial resistance.²⁴⁹

The establishment and capacity of NFPs is a crucial inquiry under the JEE. One fundamental reform of the IHR (2005) with respect to NFPs could be the mandated review of its personnel, surveillance capacity, and financial support through the JEE process.

3. *Mandated NFP Training*

Adequate training bolsters compliance. Numerous NFPs reported that they and their staff did not receive any, or had insufficient, training when newly placed in the NFP office; twenty percent of those interviewed went so far as to say they needed more training to carry out their job adequately.²⁵⁰ Staff turn-over with poor hand-over was cited most often as the reason, although others cited a lack of experience in reporting notifiable events to the WHO owing to the low frequency of threats. NFPs in our study suggested the WHO require states parties to report change-over in NFP personnel and enforce a form of mandatory training for newly appointed NFPs upon starting their position, including awareness of the WHO’s comprehensive NFP Guide and online tools.²⁵¹

4. *A Pandemic Treaty*

In November 2020, Charles Michel, President of the European Council, began circulating the idea of an “international pandemic treaty” at the Paris Peace Forum.²⁵² In December 2020, Michel met with Tedros Adhanom Ghebreyesus (who goes by Tedros), the Director General of the WHO, to

247. *Strengthening Health Security by Implementing the International Health Regulations (2005): Joint External Evaluations*, WORLD HEALTH ORG. (2005), <https://www.euro.who.int/en/health-topics/health-emergencies/international-health-regulations/misc-from-old-ihr/monitoring-and-evaluation/joint-external-evaluation> [<https://perma.cc/EVA6-CQQT>].

248. Nirmal Kandel et al., *Joint External Evaluation Process: Bringing Multiple Sectors Together for Global Health Security*, 5 LANCET 857, 857 (2017).

249. See generally WHO, *International Health Regulations (2005): Country Implementation Guide: Voluntary Joint External Evaluation* (2017).

250. See *supra* section V.B.1.e. and accompanying notes.

251. *Id.*

252. See Herszenhorn, *supra* note 16.

discuss the treaty.²⁵³ In January 2021, Tedros endorsed the EU's international pandemic treaty proposal "as a way to guarantee countries' political commitment to fighting future disease outbreaks."²⁵⁴ He expressed the WHO's support of such a treaty, saying "[i]t will give the IHR [International Health Regulations] the political dimension" it needs.²⁵⁵

Tedros's endorsement occurred at the 148th session of the Executive Board on the coronavirus disease outbreak in Geneva, Switzerland.²⁵⁶ He advocated for the treaty's potential to guarantee political commitment of member states.²⁵⁷ So far, it is not clear what traction the pandemic treaty idea has, nor what its components might be. Regardless, it will necessarily involve communication between governments, and very likely communication between governments and the WHO. If that is true, then this study will have even more relevance as treaty provisions seek to improve upon the failings of the IHR (2005).

CONCLUSION

In this study, we conducted a detailed assessment of the National Focal Points experience in executing the NFP functions of the IHR (2005). Our study consisted of twenty-five qualitative interviews and 113 fully completed interviews. While our analysis was conducted just prior to the COVID-19 pandemic, it will be particularly important to determine if any of our identified barriers played a role in the global response to the pandemic. In particular, questions have arisen about whether reporting was timely and comprehensive amongst states parties. If this is the case, it would be important to determine the role of the barriers we identified to NFPs' ability to execute their functions may have played. We expect comprehensive approaches to strengthening and supporting NFPs as well as raising awareness of the IHR across all aspects of government to emerge as priorities for reform. If the world's most important infectious disease control treaty is to effectively address current and future pandemics, the most important sources of information must be free to gather evidence and report it candidly to the rest of the international community. If the IHR (2005) is replaced by a pandemic treaty, the critical role of evidence gathering and communication will be nevertheless just as central.

253. Stephanie Nebehay, *WHO Chief Welcomes EU Proposal for Pandemic Preparedness Treaty*, REUTERS (Jan. 20, 2021), <https://www.reuters.com/article/us-health-coronavirus-who-treaty/who-chief-welcomes-eu-proposal-for-pandemic-preparedness-treaty-idUSKBN29P1CI> [<https://perma.cc/2W9U-DAQL>].

254. *Id.*

255. Vijay, *supra* note 236.

256. Nebehay, *supra* note 253.

257. *Id.*

