

# Global Health Security: Closing the Gaps in Responding to Infectious Disease Emergencies

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*Rising concerns about the human, political, and economic costs of emerging infectious disease threats and deliberate epidemics have highlighted the important connection between global public health and security. This realization has led security communities, particularly in the U.S., to seek ways to bolster the international health response to public health emergencies as a means of protecting national security. While there have been important recent efforts to strengthen international response to infectious disease threats, there are areas that deserve more attention from both the health and security communities. In this article, we describe two important gaps in international frameworks that govern the response to global public health threats which can negatively affect the security of states: (1) despite attempts to strengthen international rules for responding to public health emergencies, there continues to be strong disincentives for states to report disease outbreaks; and (2) systems for detecting and responding to outbreaks of infectious diseases are hindered by a lack of standards of practice for sharing biological samples and specimens. To address these gaps in global governance of infectious disease threats, additional incentives are needed for states to report disease outbreaks to the international community; there should be greater enforcement of countries' international health obligations; and both political and scientific communities should develop workable practice standards for sharing biological samples of all types.*

## INTRODUCTION

The anthrax attacks of 2001, the rapid global spread of severe acute respiratory syndrome (SARS) in 2003, the 2009 influenza A (H1N1) pandemic, and the recent *E. coli* O104 (STEC O104:H4) outbreak in Germany have all demonstrated the considerable human, political, and economic costs that result from outbreaks of infectious disease. Such outbreaks have increased global political concerns about emerging infectious disease threats and deliberate epidemics, and have highlighted the important connection between global public health and security.<sup>1</sup>

This realization has led security communities, particularly in the U.S., to seek ways to bolster the international health response to public health emergencies as a means of protecting national security. While much discussion about global health security has been appropriately focused on such issues as increasing public health surveillance to detect early emergence of disease or the appropriate safety and biosecurity measures for laboratory work, there are additional areas that deserve more attention by both health and security communities. In this article, we describe two important gaps in the international frameworks that govern the response to global public health threats that can negatively affect the security of states: (1) despite attempts to strengthen international rules for responding to public health emergencies, there continues to be strong disincentives for states to report disease outbreaks; and (2)

existing systems for detecting and responding to outbreaks of infectious diseases are hindered by a lack of international standards of practice for sharing biological samples and specimens. This article will describe these problems, explore why they are important to global health security, describe progress in addressing them, and propose additional mechanisms for resolving them.

### **EXISTING FRAMEWORKS FOR GLOBAL HEALTH SEEN AS AN OPPORTUNITY TO STRENGTHEN SECURITY**

In recent years, the U.S. national security community has expressed interest in supporting international efforts that promote global health, such as the International Health Regulations (IHRs). In 2009, the U.S. National Security Council declared that as part of the National Strategy for Countering Biological Threats the U.S. government would “work with partner countries and regions to assist in their efforts to comply with the World Health Organization’s (WHO) International Health Regulations (IHR).”<sup>2</sup> Evidence of this intention to support the IHRs can be found in the activities of other U.S. agencies. The U.S. Department of Defense, which works at 500 sites with partners in 75 countries to strengthen emerging infectious disease surveillance, noted in 2010 that, in going forward, the IHRs will serve as a framework to guide these activities.<sup>3</sup> In 2009, the U.S. Department of State also hosted two conferences meant to “highlight the interrelationship” between the IHRs and the Biological Weapons Convention.<sup>4</sup>

#### *Strengthening Global Health and Security through the IHRs*

The International Health Regulations (IHRs) are a legal framework that articulates how nations should respond to international disease threats, and are intended to limit the international spread of disease while ensuring minimum interference with trade and travel. They were first adopted by the 22<sup>nd</sup> World Health Assembly in 1969, but their history extends further back to discussions in an international sanitary conference in 1851.<sup>5</sup> The latest revision of the IHRs took place in 2005, partially in response to the 2003 SARS outbreak and the global perception that China’s lack of communication worsened the epidemic.

The core goal of these regulations has remained constant through the revisions: Article 2 of the revised International Health Regulations (2005) stipulates that the 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* [emphasis added].”<sup>6</sup> The revised IHRs encourage countries to use necessary measures to control the spread of diseases, but actively discourage the use of measures for which scientific evidence is lacking. This is meant to prevent countries from taking politically expedient measures at the expense of another country’s economy.

Several provisions of the revised IHRs have piqued the interest of both the public health and security communities.<sup>7</sup> First, the IHRs aim to improve nations’ capacities to detect and report outbreaks. Signatories to the IHRs must, within 5 years after the regulations enter into force, develop and maintain the capacity to detect and report any infectious disease outbreaks or other public health conditions that have the potential to spread beyond their borders — so-called “public health emergencies of international

concern,” or PHEIC.<sup>8</sup> The IHRs also call upon states parties to help resource-constrained countries build capacity to detect, report, and respond to PHEICs.

By employing a broad definition of what constitutes a PHEIC, the IHRs aim to increase the speed with which any significant outbreak — whether naturally-caused or deliberate — is detected and reported, which is of interest to both security and public health communities alike. Article 9 of the revised IHRs stipulates that, “States Parties shall, as far as practicable, *inform WHO within 24 hours of receipt of evidence* [emphasis added] a public health risk identified outside their territory that may cause international disease spread as manifested by exported or imported: human cases; vectors carrying infection or contamination; or goods that are contaminated.”<sup>9</sup> Previously, nations only needed to report a short, defined list of disease events to WHO, such as cholera or plague. However, in broadening the definition of a reportable event, the IHRs require that nations report a range of known and yet-to-emerge global public health disease threats, including pathogens that may be used in a bioterrorist attack.

By requiring countries to develop the medical and public health capacities to respond to outbreaks, the IHRs may also help reduce the consequences of an attack. Medical and public health communities are likely to be the first to respond regardless of whether an infectious disease event is natural or deliberate. The important role of the medical and public health as first responders was observed both in the salmonella outbreak deliberately caused by the Rajneesh cult in 1984<sup>10</sup> and the 2001 Amerithrax attack. In these two events, medical and public health communities helped to reduce the morbidity and mortality by providing medical care to sick patients, investigating the cause of the outbreak, and distributing medical countermeasures. Such medical and public health interventions that are aimed at treating the sick and protecting the well can be instrumental in reducing the scope of the outbreak and limiting the success of an attack.<sup>11</sup>

Another important security provision of the IHRs is the authority it grants to WHO to consider and act on unofficial reports of disease. In 2003, unofficial reports of a severe, contagious respiratory illness circulated for months before SARS was officially recognized by any government.<sup>12</sup> Yet, the WHO was not able to publicly comment or respond to the reports until it received official notice from the affected countries. Adding to WHO’s increased authorities are new resources for getting information: there are more systems available to provide situational awareness of global outbreaks. The Global Public Health Intelligence Network (GPHIN), originally developed by the Public Health Agency of Canada and used by governments and NGO’s worldwide,<sup>13</sup> and Project Argus, used by a variety of United States government agencies,<sup>14</sup> are two examples of systems that scan global news for evidence of outbreaks. The increase in event-based surveillance systems presents more public health intelligence for WHO and other public health officials to utilize, and may increase the speed that outbreaks are recognized, particularly in areas where traditional disease surveillance systems are not well developed.

Security communities have increasingly recognized the relevance of the IHRs to their goals of protecting the political, economic, and military well-being of nations, and have begun work to support and strengthen IHR implementation.<sup>15</sup> For example, the Biological Weapons Convention relies on confidence-building measures, such as declaration of maximum containment facilities and vaccine manufacturers, to increase transparency about the biological weapons capabilities of member states. Some have

argued that countries' compliance with the International Health Regulations may serve as yet another confidence building measure.<sup>16</sup>

### *Limits to Using the IHRs to Strengthen Security*

The intertwining of health and security in the context of the IHRs is not universally embraced. The process to revise the IHRs faced a deadlock in 2005 when several countries opposed having any explicit reference to a deliberate release of a toxic or infectious agent.<sup>17</sup> The negotiations continued after such references were dropped, and it was agreed that deliberate biological events would be implicitly covered through a broad definition of "disease" that makes no reference to its source.

This compromise highlights a potential shortcoming of the IHRs for security: less concern about the source of the outbreak. The focus of the IHRs is on controlling the disease where it is occurring, and not necessarily identifying the source of the outbreak. From a public health standpoint, this distinction is largely irrelevant, and historically, outbreaks are rarely conclusively determined. For example, the 1918 influenza pandemic was called the "Spanish flu" and was thought to originate there, or somewhere else in Europe, but it now appears — though it is still debated — that the virus originated on a farm in Kansas.<sup>18</sup> When the origin of an outbreak is identified, it is often after an enormous amount of data is collected and analyzed, which takes time. While the source of a disease may not be as important for informing public health action, it is of fundamental concern for the security community. The speed of detection of a disease outbreak may serve to eliminate this distinction, however.

Another potential security challenge is that in spite of being able to rely on unofficial sources of disease information, the WHO is still limited in how it can intervene when a country does not report. No entity, including the WHO, can verify the character of an outbreak until a sufficient body of evidence is amassed, and wrongly accusing a country of not reporting has political consequences. The WHO will likely act conservatively, favoring a wait and see approach, so as not to wrongfully accuse a member nation. Recent criticism directed at the WHO that it overstated the threat of the 2009 H1N1 pandemic may force the WHO to take an even more conservative stance in the future.<sup>19</sup> The next outbreak could escalate before the WHO is politically able to use their IHR authorities.

No matter how carefully worded, a treaty is only effective if there is adherence to its stipulations. Though security communities increasingly look to the IHRs to ensure that to detect an outbreak and limit its effect, it is important to note that during international public health crises, not all countries have chosen to respond to infectious disease outbreaks in ways that are consistent with the premises of the International Health Regulations. Rather, while there may be agreement in principle that member nations should restrict responses to only those measures that are deemed by the WHO to likely be effective, early experience with the revised IHRs indicate that when faced with the threat of disease originating in other countries, member nations may resort to protectionist tactics, such as trade and travel restrictions. These actions may be politically beneficial for the nation's populace, but would produce no public health benefits and weaken the IHR regime. To combat these tendencies new incentives need to be created to strengthen implementation of the IHRs by encouraging countries to adhere to WHO guidance during crises for the betterment of both health and security.

**GAP #1: DESPITE REQUIREMENTS, FEW INCENTIVES FOR COUNTRIES TO REPORT DISEASE**

From the perspective of a nation, there are few incentives for reporting the presence of a disease to the international community. This political decision is often not made (or made in a timely manner) because of clear disincentives — significant drops in tourism and trade, closings of borders and other measures that the IHRs are supposed to prevent, and other negative economic effects. The challenge to overcome these disincentives to reporting needs to be met head-on by the international community. While all disincentives to reporting cannot be erased, it may be possible to incentivize reporting through increased enforcement of the IHRs, or tying the willingness to report to the access and benefit sharing of medical countermeasures and public health assistance.

Right now, much of the burden of global surveillance largely falls on developing countries, where trained personnel, diagnostic laboratories, and funding required to support surveillance are at a premium. Yet without robust surveillance, these countries fall prey to “inaccurate reports and rumors [which] can rapidly lead to social disruption nationally and unwarranted panic internationally.”<sup>20</sup> Inflammatory news travels faster than accurate diagnoses can be made, especially without a robust surveillance infrastructure.

The ongoing *E. coli* O104 (STEC O104:H4) outbreak, which has to-date sickened more than 2,900 people, most of whom reside in Germany, serves as a current example of both the difficulties and consequences of diagnosing an outbreak.<sup>21</sup> In first announcing the outbreak, German health officials initially suspected that the cause of the outbreak might be linked to cucumbers imported from Spain.<sup>22</sup> Though that diagnosis has since been retracted<sup>23</sup> and though no source of contaminated produce has been confirmed, Russia and Lebanon responded to these reports by banning all produce imports from the European Union.<sup>24</sup>

*Penalties for Reporting Disease Outbreaks: The Cautionary Examples of Plague in India and Cholera in Peru*

Two infectious disease events — the Peru cholera epidemic of 1991 and the plague outbreak that was suspected to have occurred in India in 1994 — serve as cautionary tales for countries that are thinking about whether and when to report an outbreak. While both of these events predate the 2005 revision of the IHRs, they highlight the consequences that countries can face when they decide to openly report outbreaks of infectious disease outbreaks, particularly when non-affected countries take measures that are not science-based.

Although a fundamental premise of the revised IHRs is that effective response to global public health emergencies is aided by early detection and reporting of events, it can be very difficult for countries to know whether to declare that a public health event of international concern (PHEIC) is occurring. Although the IHRs provide a loose algorithm to help in determining whether an event constitutes a “PHEIC,” it is not clear-cut in all cases how to apply this algorithm, and decisions made along these lines are

often complicated by the high degree of uncertainty that tends to accompany an outbreak at its onset.<sup>25</sup>

The situation that occurred in India in 1994 illustrates such challenges. In September 1994, a handful of cases of illness and deaths occurred in the poor sections of Surat, Gujarat. The identification of a rod-shaped bacilli led to initial projections that the causative agent was *Yersinia pestis* (plague). Although laboratory confirmation of the etiologic agent was not immediately available, government officials decided to be extra cautious. India declared that the deaths may be a plague outbreak and employed a broad case definition to identify additional cases.<sup>26</sup>

In reaction to these reports, as many as 500,000 people fled Surat. Schools were closed and other governments instituted quarantines, fumigated cargo at all ports to kill rodents, cancelled flights to and from India, restricted the importation of food and other goods, and issued travel warnings.<sup>27</sup> Indian citizens living in other countries received additional scrutiny. Flight cancellations led to greater than \$30M dollars in tourist trade losses, with total losses in the billions.<sup>28</sup> All of these measures were implemented in spite of WHO requests that no travel or trade restrictions be imposed.

Ultimately, the causative agent of plague was never isolated from a patient, and many believe that health officials' handling of the outbreak may have been a mistake. Invoking plague as a possible cause of the deaths occurring in Surat led to "widespread panic, worldwide apprehension, and severe economic losses for India."<sup>29</sup> The Center for Disease Control and Prevention (CDC) and WHO concluded the response to the outbreak was excessive and unnecessary.<sup>30</sup>

India's plague situation illustrates the difficulty of reporting events before there is scientific confirmation of their cause. But even when countries have confirmation that a serious outbreak is occurring, there is still the chance that other nations will overreact and employ measures that defy international guidance. This was the case in a 1991 cholera outbreak that began in Peru and ultimately spread throughout South America, causing over a million cases and close to 10,000 deaths. Although the health effects of the epidemic were considerable, measures taken by nations to prevent the importation of the disease were not rooted in science, and exacerbated the effects of the epidemic. Despite clear evidence of the ineffectiveness of foodstuff export restrictions (as cholera bacteria do not survive cooking and drying) and immigration restrictions, many countries implemented these measures in defiance of international health and trade guidance. The European Community banned all the importation of all goods from Peru and Bolivia, Chile, Argentina, and Ecuador banned Peruvian food imports. Some countries, including the U.S., went beyond WHO recommendations, and required all food products from Peru to be tested. Argentina suspended an international soccer match as a result of the outbreak. In the end, it is estimated that the tourist industry lost \$150M. Moreover, some Peruvian travelers were barred from Europe. For Peru the economic losses on trade alone were estimated at more than \$770M.<sup>31</sup>

### *Countries Penalized When Others Ignored WHO Guidance During the H1N1 (2009) Pandemic*

The 2009 influenza A (H1N1) pandemic represented one of the first global tests of the revised IHRs. During the pandemic, the international community "generally adhered to the IHR (2005), supported WHO recommendations, and participated in

unprecedented levels of information sharing.”<sup>32</sup> However, as Katz and Fischer have comprehensively detailed, there were some notable exceptions to this general state of international cooperation.<sup>33</sup> Judging by the rapid pace influenza cases were appearing, the WHO made it clear that no practical measures existed that would prevent the disease from being spread from country to country.<sup>34</sup> Consequently, the WHO recommended that countries not ban imports, close borders, or restrict travelers to contain the outbreak at national borders.

The WHO’s position that such measures would be ineffective was informed by science and experience. Historically, closing airports and detaining travelers at borders has not been effective in preventing disease importation. In weighing evidence from multiple countries’ experiences with SARS, a WHO expert group concluded that screening and detaining travelers at international borders had “little documented effect on detecting SARS cases.”<sup>35</sup> Furthermore, in a historical analysis of previous influenza pandemics, another WHO expert concluded that “screening and quarantining entering travelers at international borders did not substantially delay virus introduction in past pandemics...and will likely be even less effective in the modern era.”<sup>36</sup>

Despite these recommendations, countries pursued these measures during the 2009 H1N1 pandemic, even after WHO issued guidance to the contrary. Around the world, a number of countries restricted flights to or from North America<sup>30</sup> in defiance of WHO guidance.<sup>37</sup> China<sup>38</sup> and Singapore<sup>39</sup> quarantined Mexicans and other North Americans traveling to those countries regardless of H1N1 exposure. Fever screens were also employed in 2009 for H1N1 at 22 international airports in countries such as China, India, and others, despite WHO judgment that such measures would hinder trade and travel without compensatory public health benefit.<sup>40</sup> The WHO based this recommendation on the grounds that fever screens did not work well to control SARS<sup>41</sup> and on evidence that suggested they would not work well to control influenza.<sup>42</sup> In addition, some countries banned pork from the affected countries in spite of a joint statement by the WHO, United Nations Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE), and the World Trade Organization (WTO), which stated that pork and pork products could not transmit H1N1 influenza.<sup>43</sup>

## **GAP #2: LACK OF STANDARDS AND PRACTICE FOR SAMPLE SHARING**

The emergence of diseases such as SARS and the 2009 H1N1 influenza highlighted the important role that disease surveillance can play in detecting outbreaks and understanding how to respond. Experiences with both of these events underscored that recognition of outbreaks, management of epidemics, and development of countermeasures can depend heavily on having access to highly specific surveillance information that is typically obtained from testing of clinical specimens. In both of these events, health authorities noticed that unusual patterns of illness had been occurring among individuals for weeks to months, but it was not until a laboratory test was applied to clinical isolates that health authorities were able to understand that a novel virus of pandemic potential was in their midst.<sup>44</sup> Such events have led to a greater emphasis within governments on improving laboratory and diagnostic capacity in order to improve global biosurveillance for infectious diseases.<sup>45</sup>

Biological samples (such as from patients or sick animals) are routinely collected for research and for epidemiological surveillance. In many cases the samples must be

shipped to laboratories far away from where they were collected for analysis and research. In the case of influenza, samples are collected in order to assess how the virus is evolving in the wild, as well as vaccine development: influenza vaccine development requires access to the naturally circulating strain that the vaccine will protect against.

Though access and sharing of biological samples and specimens is critical for surveillance and vaccine development, recent outbreaks provide some warning about the extent to which countries will continue to share clinical isolates during public health emergencies. Nations have proposed that there exists a right to *benefit* from sharing samples, such as to have access to vaccine or to vaccine profits, and in the absence of this benefit, have withheld critical samples from analysis. Impediments in the ability to share samples has global health security implications, as delays in disease detection could lead to increased numbers of cases, delays in the manufacturing of medical countermeasures, and greater uncertainty of the source of the outbreak.

### *Conflicts in Sample Sharing during H5N1 avian flu*

In 2007, Indonesian officials learned that an Australian pharmaceutical company developed an H5N1 vaccine based on a sample that was originally isolated in Indonesia.<sup>46</sup> The officials believed that those samples would be developed into vaccines that Indonesia — a nation clearly affected by flu — could not afford. Worse, the vaccine companies could potentially patent the sample. Indonesia pulled out of the Global Influenza Surveillance Network (GISN) in protest.<sup>47</sup>

No international framework currently exists that requires countries to share clinical samples or biological specimens during a public health emergency.<sup>48</sup> WHO promised to address the vaccine inequities in availability in exchange for a resumption of sample sharing. They promised to increase global vaccine production capabilities, explore short term responses like national stockpiling of vaccine/drugs, and to guarantee that if a vaccine company were to set aside a percentage of the vaccine that resulted from the samples, WHO would purchase it.<sup>49</sup> The World Health Assembly Resolution WHA60.28 called for action to promote the “transparent, fair and equitable sharing of the benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies” while maintaining “timely sharing of viruses and specimens.”<sup>50</sup> After 4 contentious years of negotiations, there has finally been a breakthrough: an agreement has been reached that would govern influenza virus sharing for all WHO countries, and obligate the sharing of vaccines, diagnostic kits and other public health benefits.<sup>51</sup>

The agreement states that influenza vaccine, diagnostic, and pharmaceutical manufacturers who participate in the WHO global influenza surveillance and response system will contribute to WHO “for improving global pandemic influenza preparedness and response” up to 50 percent of the running costs of the program, about \$56m, commencing in 2012. It also puts into place “Standard Material Transfer Agreements” to contractually identify the terms for sharing and for providing benefits. This addresses member nations’ concerns about influenza samples being used for profit by a limited number of countries and pharmaceutical companies. The agreement is a landmark, and while there have been some criticisms that the amount of the financial contributions is small, that not enough of the obligations is on developed countries, and companies are

mandatory, it is likely to pass at the WHA meeting in May, 2011.<sup>52</sup> This agreement could become a model for the sharing of samples of other pathogens.

In their battle for access to benefits from sharing samples, Indonesia also invoked the UN Convention on Biological Diversity (CBD, 1992).<sup>53</sup> The Indonesian government claimed that it was an act of ‘biopiracy’ under the Convention for pharmaceutical companies to profit from Indonesian samples.<sup>54</sup> The CBD endorses “access and benefit sharing” in article 15.7, and pathogens are included, but adding clarifying language was contentious. The recent Nagoya Protocol to the CBD is somewhat vague, stating that [States] “Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.” The next steps for the protocol will be a series of meetings to discuss how to implement fair and equitable sharing, perhaps with the creation of a specific fund.<sup>55</sup>

### *The future of (non-influenza) sample sharing is not clear*

The problem of sample sharing is not likely to go away soon, even with additional reflection on the Nagoya protocol and the WHO draft agreement for influenza virus sharing. The extent to which the WHO agreement may set a standard for access to benefits in exchange sharing non-influenza samples is also not clear.

In addition, the problem of sample sharing is likely to expand as biological samples and personal genetic information becomes even more economically important. The CBD does not extend to human samples, but this could be challenged, or another mechanism could be employed to assert the rights of those whose personal biological samples lead to profit for others. In the US, there are no legal restrictions on what can be done with a person’s biological samples that are left (for example, after a surgical procedure), and most of these samples have no commercial value whatsoever. Historically, samples which have had value have not yielded any benefits to the surviving family members of the patient. Yet as awareness increases, this practice may be challenged not only on the national level, but by individuals as well. In all such cases, pharmaceutical companies and researchers will argue that monetary incentives are required to invest in surveillance, and patenting and vaccine profits will fund the research to make new vaccines. Experts worry that compensating patients will lead to patients insisting on unrealistic financial arrangements or will hinder the benefits of that research for most people.<sup>56</sup>

### **RECOMMENDATIONS FOR FILLING THE GAPS**

The gaps in global health security referenced in this article have been seen in recent pandemics of influenza, in SARS, and are likely to be seen in future epidemics. While there have been efforts to address them, more attention is needed for resolving issues prior to an emergency, when these issues could cause delays in detecting cases or treating people. Neither of these gaps will be filled by one organization, such as WHO, but require a variety of governmental and nongovernmental actors to take the following aspirations as priorities:

**1) Reduce disincentives for countries to report disease by promoting science-based measures to controlling outbreaks (and by discouraging unnecessary restrictions for trade and travel).**

The IHRs are an important framework for health security, but the current approaches to IHR implementation are insufficient to ensure that member states comply with its guidance and reporting requirements, and to promote science-based responses to disease outbreaks.

First, there should be consequences for countries that choose politically expedient measures such as travel restrictions and trade barriers that are not supported by WHO guidance. There are IHR mechanisms that have not and are not likely to be used, including a dispute mechanism within the IHRs and a possibility of revoking World Health Assembly membership.<sup>57</sup> However, countries that violate WHO guidance could be strongly condemned by other IHR treaty members, and diplomatic and other channels can be used to prevent unnecessary restriction of trade and travel.

By specifically aiming to keep trade lines open if there is no impact on controlling disease, the IHRs keep the costs of compliance down by eliminating unnecessary penalties for those countries that report. It is important for all member nations to avoid the creation of “loser” nations — an unfair situation that puts future compliance in doubt, and which may exacerbate negative public health consequences. In addition, international governmental organizations, such as the World Health Organization, FAO, OIE, World Trade Organization (WTO), and others, should work to discourage protectionist policies, by speaking out against national actions to control disease that are not consistent with consensus recommendations. During the 2009 influenza A (H1N1) pandemic, the WTO and the WHO issued a joint statement that stressed to member states that there was “no justification...for the imposition of trade measures on the importation of pigs or their products.”<sup>58</sup> These and other organizations should continue to use their authority to criticize protectionist measures, as preventing the unnecessary restriction of trade and travel is important for ensuring implementation of the IHRs. Such measures will do little to stop the spread of disease, but send a strong message to countries that reporting outbreaks may result in strong penalties.

Countries should further use their political capital to encourage fellow member states to implement only science-based response measures and to discourage those that do not. This problem should also be worked on from the bottom-up. Health officials must work to convince their political leaders that response to disease outbreaks must be scientifically defensible. While protectionist policies may score political gains, they rarely serve to limit the spread of disease and may ultimately reduce security, by discouraging affected nations from reporting disease outbreaks early. Experience with past outbreaks has shown that in the midst of global outbreak, political leaders may be quick to try to close borders and look for other ways of keep the disease out, countries would fare better if they focused instead on implementing community-based measures that might slow the spread of the disease and lessen its impact.<sup>59</sup> Such advice may be particularly difficult to impart when the political stakes associated with responding to an outbreak are high, such as during a biological attack, but promoting science-based medical and public health interventions will be even more critical in that event, as such measures have the greatest likelihood of reducing the impact of an attack.

When possible, countries and international governmental organizations should seek to create incentives that can overcome hesitations to report cases of disease. In the 1990's, following Saudi Arabia's decision to deny entry to individuals from countries that were experiencing meningitis outbreaks, reported rates of meningitis sharply declined, which suggested that many countries were withholding evidence of cases for fear that their citizens would be barred from the Muslim Hajj. After an outbreak of meningitis that resulted in 250,000 cases and 25,000 deaths, the WHO established the International Consultative Group (ICG) in 1997 to provide meningococcal vaccines to all African countries that provided epidemiological information on the meningitis cases. This appears to have been a strong incentive for countries to resume reporting of meningitis cases.<sup>60</sup>

Although there have been recent efforts to create an international stockpile of vaccines to help countries that report outbreaks of other diseases, such as influenza and smallpox, these stockpiles are often virtual — i.e. made up of vaccines that have been pledged by other countries. Questions remain about how these stockpiles would be distributed and utilized in an emergency.<sup>61</sup> For example, during the influenza A (H1N1) pandemic of 2009, although a number of countries had pledged to donate the vaccine to the WHO, many countries delayed their contribution of the vaccine until global shortages in H1N1 vaccine production, which occurred well into the pandemic. In order for vaccine stockpiles to serve as incentives for countries to report outbreaks, there must be dedicated, actual, vaccine stockpiles and detailed plans for distribution of these countermeasures to the countries that need them, or specific funds that are available, not just promised, for purchasing countermeasures in an emergency.

In addition to conditioning access to vaccine stockpiles on whether or not a country is providing adequate epidemiological information, other “benefit sharing” incentives can be developed for disease reporting. For example, ensuring that those countries that report outbreaks will receive the technical assistance and medical expertise necessary to resolve the outbreak may encourage earlier reporting. Currently, a country that reports a PHEIC can request technical and other assistance from the WHO in responding to the event. WHO's ability to provide assistance during previous outbreaks has been limited by needing to raise funds to deploy staff to the affected area.<sup>62</sup> The international community should continue to support such efforts, ensuring that organizations, like the WHO, have the resources they need to aid in response. The international community could also consider compensation mechanisms for countries that incur losses as a result of reporting outbreaks to facilitate timely global response to health security threats, with funds set aside for that purpose.

## **2. Create mechanisms for sharing biological samples during outbreaks.**

The decision to report disease to the international community is essentially a political decision — cases will occur and will, presumably, be treated by health professionals regardless of whether the international alarm is raised. However, biological sample and specimen sharing is a technical *requirement*, a necessity for laboratory scientists to be able to confirm the causative agent of disease, to examine the way a particular virus is evolving, to develop medical countermeasures, and even to further characterize the pathogen in basic research. While ‘benefit sharing’ measures

such as receiving priority access to vaccines may encourage countries to report disease, it will likely require more involvement of technical professionals, and their technical agreements on use, to ensure that biological samples are appropriately shared in a timely manner during outbreaks. There are a myriad of concerns that need to be worked out, such as: how samples should be collected, where should they be sent, adherence to shipping regulations, and data ownership. Ideally, such terms should be worked out in advance of an emergency.<sup>63</sup>

Although there have been some important developments on the sample sharing issue — the WHO draft agreement on sharing of influenza samples and the Convention on Biological Diversity nascent framework — neither of these efforts fully address the many decisions that need to be made regarding the sharing of all pathogen. Therefore, it is likely that sample sharing will continue to be an episodic issue with other pathogens, in future outbreaks. Given the importance of this issue to international security, the need for further discussion about sample exchange could be discussed by the Biological Weapons Convention, as well, with a session devoted to “Expert Group” analysis. That group could provide an opportunity to communicate the technical imperatives of sample sharing to a non-technical audience.

As sample sharing is a necessity for biological research, scientific, and infectious disease societies should become involved in exploring the problems in sharing and workable solutions for emergencies, for surveillance, and for basic research. After Indonesia’s successful campaign to tie access to vaccines and public health assistance to sharing samples, the political dimension of sample sharing may never go away. However, technical standards of practice among scientists may make politicizing this activity less fruitful.

## CONCLUSION

The efficiency of the international public health response, and nations’ adherence to evidence-based methods for controlling disease is important to global health and global health security. While security communities, particularly in the U.S., have tied security goals to the IHRs, other forums such as the BWC, WTO, and technical audiences need to be continuously engaged and pursued to make progress. A concerted effort by health and security communities will be required to create incentives for nations to report disease outbreaks to the international community, to explore mechanisms to provide greater enforcement of the IHR obligations and evidence-based disease control, and to develop workable standards and guidance for the scientific and public health communities to share all types of biological samples.

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