Global Health Security in an Era of Explosive Pandemic Potential

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Lawrence O. Gostin* & Ana S. Ayala**

INTRODUCTION

The world is becoming increasingly vulnerable to infectious diseases, creating a serious threat to global health security that we must address before it becomes unmanageable. In the past two decades alone, a series of global health crises have emerged, ranging from Severe Acute Respiratory Syndrome (SARS) and its phylogenetic cousin Middle East Respiratory Syndrome (MERS) to highly pathogenic human influenza A (H5N1), pandemic influenza A (H1N1), and Ebola virus disease. Currently, emerging threats with pandemic potential include the ongoing Zika virus epidemic in the Americas, yellow fever in Angola, and continuing human outbreaks of influenza A (H7N9) and A (H5N6) in China. The human and economic toll of potentially explosive pandemics will only increase unless we significantly reinforce the global health system.

With an ever-growing population and, consequently, greater food production and animal-human interaction, the probability of zoonotic transmission has increased. Moreover, globalization and urbanization have facilitated the risks of contagion. Climate change threatens to alter the geographic areas of disease vulnerability, such as greater risks of mosquito-borne diseases (e.g., dengue, Zika, yellow fever), and ongoing zoonotic transmission.

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1. K. E. Jones et al., Global Trends in Emerging Infectious Diseases, 451 NATURE 990, 990 (2008).
malaria, yellow fever, and Zika) in northern latitudes. Such drivers allow microbial pathogens to become a rising threat, especially as these pathogens have the capacity to genetically evolve rapidly and adapt to new ecological niches.

Pathogens’ ability to change and adapt also poses another major threat. Resistant microorganisms (bacteria, fungi, viruses and parasites) can withstand attack by antimicrobial drugs, such as antibiotics and antivirals, so that standard treatments become ineffective, thereby increasing the risk of transmission of drug-resistant strains.5 Major endemic diseases, such as malaria, tuberculosis, and HIV/AIDS, are becoming increasingly resistant to known medications.6 Common hospital-acquired infections are also becoming resistant to treatment, including bloodstream and urinary tract infections and ventilation-associated pneumonia.7 Methicillin-resistant Staphylococcus aureus (MRSA) is a bacterium that is highly resistant to the most common antibiotics. The expansive growth in antimicrobial resistant organisms is due primarily to animal husbandry practices administering antibiotics prophylactically,8 physicians prescribing antibiotics unnecessarily,9 patients who fail to take the full course of their medications,10 and falsified or substandard medications that contain subtherapeutic doses of the active pharmaceutical ingredient.11

Despite these growing threats, our ability to counter infectious diseases continues to be grossly inadequate. Recent outbreaks have caught the global community off-guard, revealing deficiencies in almost all levels of global defenses against potential pandemics. For the Ebola epidemic in West Africa, disease surveillance was poor and local health systems were overwhelmed. Proper diagnostics, therapeutics, vaccines, and protective equipment were lack-


10. See also Michael, supra note 9.

11. See INST. OF MED., Countering the Problem of Substandard and Falsified Drugs (2013). See also Lawrence O. Gostin, Gillian J. Buckley & Patrick W. Kelley, Stemming the Global Trade in Falsified and Substandard Medicines, 309 JAMA 1693 (2013).
Leadership at all levels was subpar, and international response was uncoordinated and slow. Although the outbreak was eventually contained, many lives could have been saved with timely and effective preparation, detection, and response. In other words, three of the poorest countries in the world experienced a public health and economic tragedy from a disease that was preventable—but the global community turned its back.

Recent outbreaks have also demonstrated the public health and moral failures of the global community. During the H1N1 influenza pandemic in 2009, vaccines did not immediately reach those in need, but went primarily to wealthy countries that had preexisting contracts with manufacturing companies, even though their populations were at relatively lower risk. During the Ebola epidemic, the world cast a blind eye to the unfolding crisis despite the dire need for an immediate response in countries with desperately weak and fragile health and political systems. While the response to the Zika virus epidemic has been more timely, governments and international organizations have largely neglected the most vulnerable populations, namely pregnant women and the poor who are disproportionately affected and lack proper access to health services and commodities. In Latin American countries that have called on women to delay pregnancies, poor women have limited access to health services, are likely to live in rural areas with no running water, and have few reproductive rights. As a yellow fever outbreak fanned through Angola in early 2016, the world’s vaccine supplies became badly depleted. Again, the world’s response was muted as vaccine supplies dwindled, and vaccine technology remains highly antiquated.

With this backdrop, it will become apparent that pandemics pose a significant risk to security, economic stability, and development. The Commission on a Global Health Risk Framework (CGHRF)—one of four global commissions established in the aftermath of the Ebola epidemic—estimated annualized expected losses from pandemics at $60 billion per year. This amounts to $6 trillion in the 21st century, which is most likely a highly conservative estimate. What makes these data chilling is that these are expected economic losses, not speculative. Scientists cannot tell us which epidemics will strike, but they can

12. See S. Halabi, Obstacles to pH1N1 Vaccine Availability: The Complex Contracting Relationship between Vaccine Manufacturers, WHO, Donor and Beneficiary Governments, in THE PUBLIC HEALTH RESPONSE TO 2009 H1N1 203, 204 (M. Soto & M. Higdon eds., 2015). See also David P. Fidler, Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1, 7 PLoS MED. GLOBAL HEALTH DIPL. SERIES 1, 1 (2010).


predict with assuredness that disastrous infectious disease threats will materialize, based on historical trends and currently circulating pathogens. Yet, despite the certainty and magnitude of the threat, the global community has significantly underestimated and underinvested in avoidance of pandemic threats. CGHRF recommended an annual incremental investment of $4.5 billion – 65 cents per person – to strengthen global preparedness. This modest investment, and probably more would be needed, would provide a major security dividend.

Beyond the health and economic consequences, major outbreaks can cause political and social disruption. As a result of the Ebola crisis, schools closed for several months, the number of orphans grew, gender-based violence increased, food became scarce, and health workers died in droves in Guinea, Liberia, and Sierra Leone. The Zika virus epidemic has also caused social disruption as women of child-bearing age delay pregnancies; those already pregnant live in trepidation for the health and vitality of their infants; and a greater number of children are born with permanent cognitive impairments requiring lifelong health care and face a shorter life expectancy.

We cannot wait or continue with the status quo, in which we pay attention to infectious disease threats only when they are at their peak and then are complacent and remain vulnerable until the next major outbreak. To reinforce and sustain international focus, funding, and action, it is crucial that pandemics rise to the level of “high politics,” becoming standing agenda items for political actors in critical forums such as the G7, G20, and the United Nations. The World Health Organization (WHO) needs to become the global health leader envisaged in its constitution, but that it has rarely achieved.

In this article, we make the case for fundamental reform of the international system to safeguard global health security. We build on the action agenda offered by four international commissions formed in the wake of the Ebola epidemic (Table 1). The World Health Assembly (WHA) also formed a Review Committee on the International Health Regulations (IHR) (2005), which sets out the legal framework for global health security. Our own action agenda includes resilient national health systems with strong public health infrastructure, an empowered World Health Organization within a cohesive and determined United Nations system, and a robust and coordinated research and development (R&D) strategy. These domains encompass major challenges and changes at all levels. If our action plan were adopted, it would safeguard the global population far better against infectious disease threats. It would reap dividends in security, development, and productivity. But first, what is the business case for realistically assessing and investing in epidemic preparedness?

16. Id. at vi.
I. THE BUSINESS CASE FOR EPIDEMIC PREPAREDNESS: REVERSING THE PATTERN OF UNDERESTIMATION AND UNDERINVESTMENT

Pandemics can shatter human lives, health, and productivity on a scale comparable to the effects of wars, natural disasters, and financial crises.\textsuperscript{17} CGHRF modeling, as we indicated earlier, conservatively predicted annualized expected losses from pandemics at $60 billion per year or $6 trillion this century.\textsuperscript{18} The CGHRF model, however, included only direct economic costs. The National Bureau of Economic Research conducted a more inclusive examination of annual expected losses, concluding that they could reach $490 billion, a major blow to economic growth and stability.\textsuperscript{19} Earlier, the World Bank modeled the economic impact of a single catastrophic infectious disease event comparable to the 1918 influenza pandemic. The Bank’s model predicted a 5 percent loss in global gross domestic product (GDP), or approximately $3 trillion.\textsuperscript{20}

Although the Bank and others have projected economic losses from epidemics, multilateral organizations – including the Bank itself, the International Monetary Fund (IMF), and the Organization of Economic Cooperation and Development (OECD) – rarely incorporate infectious disease vulnerability into their official assessments of economic growth and stability. Similarly, private sector analysts, such as ratings agencies and investment banks, fail to calculate economic losses from epidemics. The failure of macroeconomic forecasting to take account of pandemic risks partly explains why governments significantly underestimate those risks and underinvest in preparedness and response.

In the aftermath of the Ebola commissions, however, economists have proposed clearer data inputs for capturing pandemic risks with the aim of spurring greater investment.\textsuperscript{21} The argument for far greater investments in epidemic preparedness and response is compelling: Given the health, economic, and political costs, pandemics should be understood as an urgent matter of national and global security, rather than simply a health event to manage after the fact.\textsuperscript{22}

A. Historical Experiences with Recent Epidemics

Clearly, economic models are often inexact, but they offer a sense of the expected losses. Actual historical experiences reinforce the judgment that epidemics incur vast human, social, political, and economic costs. An unanticipated

\begin{footnotesize}
\begin{enumerate}
\item[18.] See Comm’\textsuperscript{n} on a Global Health Risk Framework for the Future, \textit{supra note} 15.
\item[21.] See Comm’\textsuperscript{n} on a Global Health Risk Framework for the Future, \textit{supra note} 15.
\item[22.] See generally Comm’\textsuperscript{n} on a Global Health Risk Framework for the Future, \textit{supra note} 15.
\end{enumerate}
\end{footnotesize}
surge in health care costs is a major part of the problem. Not only does the health system have to treat patients suffering from the disease, but it also has to care for the worried well, who often flood clinics and hospitals during epidemics. If health care workers—physicians, nurses, and community health workers—become ill or die, it also places a major strain on scarce human resources.

Yet when an epidemic strikes, the disease itself does not account for most of the economic losses. Most of the economic burden is caused by consumer reactions, labor shortages, and cascading failures in economic and financial sectors. Epidemics also cause major overreactions by governments and the private sector, such as restrictions on trade and travel. During Ebola, for example, not only did many governments restrict travel to and from the affected countries, but the airline industry also suspended flights.23 What follow are a few illustrations of the human and economic costs of recent epidemics.

The HIV/AIDS pandemic has resulted in more than 35 million deaths since the late 1960s.24 Most deaths have occurred among women and men in their prime productive years, robbing countries of a generation of parents, teachers, health workers, and scientists.25 There is a broad consensus that HIV/AIDS has significantly dampened economic growth in sub-Saharan Africa.26 Africa has only recently begun to recover from the long economic stagnation caused by the pandemic thanks to a massive global campaign to expand access to antiretroviral treatment.

The 2002/03 Severe Acute Respiratory Syndrome (SARS) outbreak killed 774 and infected more than 8,000 people in only eight months.27 But even the short duration of the outbreak resulted in economic losses of more than $40 billion,28 with most of the economic losses in the countries hardest hit, such as


Scientists are most concerned about airborne pathogens that are easily transmissible person-to-person, such as a novel influenza virus. The 2009 Influenza A (H1N1) was such a virus, which rapidly circumnavigated the globe. But humanity was lucky because it turned out not to be highly pathogenic. Still, CDC estimated that up to 575,400 people perished worldwide in a single year from the H1N1 pandemic. The death toll disproportionately impacted poor people in Southeast Asia and Africa, where access to prevention and treatment resources is limited. Healthcare costs were significant even in high-income countries. From April 12, 2009, to April 10, 2010, approximately 60.8 million H1N1 cases, 274,304 hospitalizations, and 12,469 deaths occurred in the United States. Many governments also banned the import of pigs and pig products from countries with circulating H1N1, particularly from North America, where the pandemic originated — in clear violation of international standards set by the UN Food and Agriculture Organization/World Organization for Animal Health/WHO. While short-termed as a result of the government’s fiscal and marketing strategies, Mexico experienced a $27 million economic loss of pork products for Mexico, most of which took place at the peak of the pandemic.

Although the Ebola epidemic took fewer lives than HIV/AIDS or H1N1, its impact on poor West African countries was just as alarming, taking more than 11,000 lives and infecting more than 24,000 people. The three countries most affected by the 2014 Ebola outbreak — namely, Guinea, Sierra Leone, and...

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Liberia – lost an estimated $2.2 billion,\textsuperscript{35} representing an aggregated cumulative loss of approximately 10 percent in their gross domestic product.\textsuperscript{36} Like AIDS, Ebola took a disproportionate toll on young people, which resulted in major disruptions in basic services such as education and health care.\textsuperscript{37}

The Middle East Respiratory Syndrome coronavirus (MERS-CoV) started in Saudi Arabia, but 27 countries have reported MERS-CoV cases since September 2012.\textsuperscript{38} In 2015, the Republic of Korea experienced the greatest MERS-CoV outbreak outside of Saudi Arabia. Tourism plummeted by 40-60%, which triggered the South Korean government to launch a $19 billion fiscal stimulus plan.\textsuperscript{39}

Currently, with the Zika virus epidemic, initial estimates of the short-term economic impact in the Latin American and the Caribbean region are around $3.5 billion, based on the tenuous assumption that a swift and coordinated response is sustained.\textsuperscript{40} However, many Latin American and Caribbean countries are highly dependent on tourism, which could suffer more significant economic disruptions, especially if the virus is not promptly contained.

There are also serious other risks created by epidemics that can have significant economic repercussions. As recognized by the U.N. Security Council in

\begin{itemize}
\item \textsuperscript{36} \textit{The World Bank Group}, The Economic Impact of the 2014 Ebola Epidemic: Short and Medium Term Estimates for West Africa, 2-3 (Oct. 27, 2014).
\item \textsuperscript{39} Alastair Gale, South Korea MERS Outbreak is Over, Government Says, WALL ST. J. (July 27, 2015), http://www.wsj.com/articles/south-korea-mers-outbreak-is-over-government-says-1438052856.
\end{itemize}
Resolution 2177 in the aftermath of the Ebola crisis, and as further discussed in Part III below, these public health emergencies can undermine national and international security and political stability, leading to “civil unrest, social tensions and a deterioration of the political and security climate.”\(^{41}\) They can also mean a loss of personnel required for the military and maintaining the country’s infrastructure, among many others.\(^{42}\)

Given these numbers and concerns, greater investment in pandemic preparedness worldwide becomes a sound economic solution. The economic investment in preparing for the next infectious disease outbreak pales in comparison to threats that governments take far more seriously, as evidenced by political discourse and expenditures on, say, terrorism, migration, or the fiscal health of the financial industry.\(^{43}\) The historic and projected costs discussed above help validate our claim that there is a major disconnect between investments in preparedness and the actual humanitarian and economic harms of epidemics. The need to rethink economic and political priorities is dire and the opportunity is ripe.

**B. A Peace Dividend**

To close the investment gap, the CGHRF proposed an annual incremental “peace dividend” of $4.5 billion – 65 cents per person – to strengthen global preparedness.\(^{44}\) The dividend would be aimed at strengthening health systems, as well as financing national and global emergency response and research and development.\(^{45}\) Yet, despite the evidence of harm and the CGHRF’s modest proposal for an incremental risk in investment, few national or global actors have offered serious funding. WHO member states have not even fully funded the meager $100 million emergency contingency fund approved in 2016.\(^{46}\) There is no plan for sustainable replenishment of the fund.

The World Bank’s Pandemic Epidemic Facility (PEF) is the only significant initiative for a sustainable financing mechanism, but the PEF has major flaws, and does not come close to the peace dividend required. The PEF provides funding “for response efforts to help prevent rare, high-severity disease outbreaks from becoming more deadly and costly pandemics.”\(^{47}\) The Facility is

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41. S.C. Res. 2177 (Sept. 18, 2014).
44. See *id.* at vi.
45. *Id.* at 17.
reserved for low-income countries with weaker health systems, as they are at a higher risk of experiencing infectious disease outbreaks. Additionally, the PEF is limited to “infectious diseases most likely to cause major epidemics, including new Orthomyxoviruses (new influenza pandemic virus A, B and C), Coronaviridae (SARS, MERS), Filoviridae (Ebola, Marburg) and other zoonotic diseases (Crimean–Congo, Rift Valley, Lassa fever).”

These criteria entirely leave out middle-income countries likely to be at the epicenter of future epidemics, such as Brazil, China, and India. It also does not address major circulating threats, such as Zika and yellow fever. Funding under the PEF is capped at $500 million for three years. Even with all these deficiencies, what is striking is that there is no long-term plan for sustainable replenishment of the PEF.

At the same time, the PEF is based on the antiquated idea that responding to an epidemic is more important than preventing it. What is needed, as we argue in the next part, is outbreak prevention by building strong and resilient health systems. Health system capacity is by far a better investment. But building horizontal capacities through national health systems is a far-off aspiration, with governments apparently unwilling to fund them.

II. NATIONAL HEALTH SYSTEMS: THE FOUNDATION OF SECURITY

The WHO Constitution explicitly recognizes that “[t]he health of all people is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States. The achievement of any State in the promotion and protection of health is of value to all.” With globalization drawing us closer in time and space, what happens in one corner of the globe can affect what happens in another, often rapidly. Building a resilient health system, therefore, benefits not only the country itself, but also people in the region and globally. The International Health Regulations (see below) is an international treaty that requires all States Parties to meet core health system capacities, but very few have complied. The Ebola epidemic of 2014 exposed the world’s vulnerabilities due to impoverished health systems in three small West African countries.

Strong national health systems require well-trained and sufficient numbers of health care workers to meet the full range of health needs during routine times as well as surge capacity to deal with emergencies. The Ebola crisis decimated already fragile health systems in the affected countries, drastically undermining the population’s access to services. It was not simply that patients infected with the Ebola virus overwhelmed the system. It also meant that the health system was unable to cope with routine health care needs. The progress made in maternal/child health and malaria in Ebola-affected countries was significantly

48. The World Bank Group, supra note 47.
undermined as already decaying health systems became overwhelmed. Health care workers in Liberia and Sierra Leone have described the Ebola crisis as a “symptom” of a dysfunctional health system rather than the singular problem.\(^5^0\)

With respect to maternal health, pregnant women who went to hospitals to deliver their babies risked contracting Ebola as health care workers in maternity wards also needed to treat Ebola patients. Women who were afraid of exposing themselves to the virus at the hospital and opted to stay at home or seek help in small clinics also risked dying from classic complications, such as hemorrhages and infections.\(^5^1\) As it was, prior to the outbreak, Guinea, Sierra Leone, and Liberia suffered from some of the highest rates of maternal mortality in the world – for every one hundred women in Sierra Leone, one died during pregnancy or at childbirth.\(^5^2\) As a country that already struggled with maternal mortality and a limited health workforce, the situation in Liberia during the crisis was described as “the gravest threat since war.”\(^5^3\)

Underlying the struggle of managing the spread of Ebola and its impact on patients suffering from other health conditions were people’s distrust of the health care system and fear of resorting to hospitals for treatment. WHO’s Global Malaria Program, for example, reported a 90 percent drop in out-patient attendance in all hospitals that remained open during the crisis,\(^5^4\) which markedly diminished the country’s ability to monitor Ebola and other infectious diseases as well as to meet routine health needs.

There was also a deep cultural aspect to Ebola, for which health and funeral workers were not prepared. Touching and washing the dead were rituals deeply embedded in the communities’ culture. But that burial practice became a major spreader of infection. At the time of death, individuals reach their peak viral loads, so bodily contact became perilous.

There was even skepticism about whether the Ebola virus existed and conspiracy theories circulated claiming that the virus was a biological weapon used by the U.S. military for population control.\(^5^5\) In Guinea, a mob of residents in a village attacked and killed eight government officials and journalists who had...
come to raise awareness about Ebola.\textsuperscript{56} Likewise, the personal protective equipment used by health care workers, which resembles a space suit, created fear and distrust, making it more difficult to implement public health measures.

With rampant distrust of government and the health system, it became clear that community participation was a critical part of a successful response. The WHO belatedly began to use anthropologists, community health workers, and civil society organizations to build public trust.

\textbf{A. The International Health Regulations (2005): A Failure to Implement the Legal Framework for Global Health Security}

WHO holds the critical responsibility of “managing the global regime for the control of the international spread of disease.”\textsuperscript{57} Following the rise of global health threats in the 1990s, WHO led a decade-long process of substantially revising the 1969 International Health Regulations (IHR).\textsuperscript{58} Most importantly, the 2005 revision expanded the regulations’ scope beyond a few historic diseases (cholera, plague, and yellow fever) to cover the full range of global health threats “irrespective of their origin or source.”\textsuperscript{59} The IHR (2005) established a stronger legal framework for bolstering global health security and international cooperation. It is an international treaty, legally binding on States Parties.\textsuperscript{60} Their aim was to “prevent the international spread of disease”\textsuperscript{61} with robust surveillance and response obligations. Under the WHO Constitution, the IHR is binding on all WHO Member States, unless they “affirmatively opt out within a specific period of time.”\textsuperscript{62} Having entered into force in June 2007, there are 196 countries bound by the IHR to date—all WHO members, plus Lichtenstein and the Holy See.\textsuperscript{63} But while the IHR is binding legally, in practice States Parties have widely disregarded their requirements.

The IHR seeks to prevent or respond rapidly to a global health emergency, called a “public health emergency of international concern” (PHEIC), defined as...
“an extraordinary event which is determined . . . (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated response.”64 States Parties are bound to meet a set of standards, known as “minimum core capacity requirements,” aimed at averting and responding to a PHEIC.65 Although the IHR is designed to build and maintain capacities to detect, assess, report, and respond to a potential PHEIC,66 the core capacity obligation also indirectly strengthens national public health systems and, ultimately, the global health risk framework. The minimum core capacities include: national legislation, policy, and financing; nation-level coordination among relevant sectors and communications with international IHR coordinating bodies; surveillance; response; preparedness; risk communication; human resources; laboratory services; surveillance and response capabilities at points of entry; and mechanisms to detect and respond to zoonotic, food safety, chemical, and radionuclear events. However, despite these being deemed the minimum expected from a country, a significant number of States Parties have failed to meet these standards. Only 64 of 196 States Parties have reported meeting their minimum core capacities.67 As these data are self-assessed and reported (see below), the number of governments which have actually met the requirement may be even lower.

To ensure a working infrastructure for rapid surveillance and response, States Parties are required to establish a “National Focal Point” in charge of monitoring compliance and implementation of the IHR, while maintaining regular communications with WHO, which includes immediately notifying WHO of potential PHEICs.68 Annex 2 of the instrument provides an algorithm that specifies diseases that are automatically notifiable and those that require a more complex decision-making process before reporting. In turn, WHO is responsible for determining what amounts to a PHEIC using both official and unofficial communications.69 The IHR (2005) for the first time authorizes WHO to use unofficial data sources (e.g., media and internet), but the agency must seek to verify the information with the relevant States Parties.70

Under the IHR, WHO’s Director-General bears “sole authority” not only to convene an emergency committee to elicit advice from its members, but also to officially declare a PHEIC.71 Here, it is worth underscoring that by virtue of convening an emergency committee, the Director-General does not have to

64. See IHR, supra note 57, art. 1.
65. Id. at arts. 1, 12.
66. Id. at Annex I.
68. See IHR, supra note 57, at art. 6.
69. Id. at arts. 7-10.
70. See id. at arts. 9-10. Accord, WHO, Ten Things You Need to Do to Implement the IHR, http://www.who.int/ihr/about/10things/en/.
declare a PHEIC; rather the Director-General retains unfettered discretion to call emergency committee meetings when necessary and to declare a PHEIC. For instance, while the emergency committee was convened 10 times to review data on the Middle East respiratory syndrome (MERS), the Director-General has not declared a PHEIC.\(^\text{72}\)

In determining whether to declare a PHEIC, the Director-General must consider “information provided by the State Party involved; the decision instrument contained in Annex 2; the advice of the Emergency Committee; scientific principles [and] evidence and other relevant information; an assessment of the risk to human health, the risk of international spread of disease, and the risk of interference with international traffic.”\(^\text{73}\) Upon the Director-General’s declaration of a PHEIC, she is required to issue temporary non-binding recommendations guiding States Parties on the health measures that they should take.\(^\text{74}\)

According to a 61st World Health Assembly (2008),\(^\text{75}\) States Parties and WHO’s Secretariat are required to conduct self-assessments of their progress in meeting their core capacity obligations under the instrument. However, most States Parties did not meet the 2012 reporting requirement, and WHO granted all 81 requests for extensions until 2016. Only 64 States Parties reported meeting the minimum core capacities, and 48 failed to respond, which amounts to a 30% rate of compliance.\(^\text{76}\) Absent a rigorous independent evaluation, national self-assessments are intrinsically problematic in determining the factual status of a country’s level of epidemic preparedness.

States Parties often resist independent evaluations due to concerns about sovereignty and national interests. Consequently, building a process of external evaluation requires “creative incentives, technical and financial support, and transparency.”\(^\text{77}\) In an attempt to address the problems underlying self-assessments, WHO established a Joint External Evaluation Tool in February 2016 to assess IHR capacities every five years. The Tool includes participation of national and international subject-matter experts in reviewing countries’ self-reported data. The process also entails country evaluation visits and in-

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\(^{73}\) See IHR, supra note 57, at art. 12(4).

\(^{74}\) Id. at art. 15.


depth discussions on self-reported data.\textsuperscript{78} Furthermore, the assessment results will be made publicly available to convey the extent to which each capacity has been implemented.\textsuperscript{79} However, there are critical flaws with the mechanism, including the fact that country participation is voluntary.\textsuperscript{80} Also, given the low level of compliance with the IHR, WHO would be better served to require these assessments more frequently and integrate community-level stakeholder participation.

Part of the creative incentive system to encourage governments to participate in independent assessments\textsuperscript{81} and meet the minimum core capacities could involve linking them to financial assistance provided by global or regional financing mechanisms, such as the World Bank, regional development banks, and the International Monetary Fund (IMF). The IMF, for example, could incorporate IHR minimum core obligations into its macroeconomic stability evaluations. Likewise, the World Bank’s Pandemic Emergency Facility and regional development banks could also provide funding contingent upon state compliance with the IHR.\textsuperscript{82}

Lower-income states have argued that lack of financing has been partly responsible for failing to meet minimum core capacities. Consequently, the IMF and the World Bank (among others) could also play a fundamental role in providing the necessary financial support. WHO and these entities could together devise a sustainable financial plan that would ensure reciprocal contributions at both the national and international levels.

\textbf{B. The Global Health Security Agenda}

Given the insufficient progress made in IHR (2005) implementation since 2007, many countries have now looked to the Global Health Security Agenda (GHSA) as a possible alternative route to strengthening health systems and achieving global health security. What started as a U.S.-led diplomatic initiative is now a partnership of close to 50 countries, international organizations (including WHO), and civil society organizations formally launched on February 13, 2014, and with more than $1 billion in funding. It seeks to “accelerate progress toward a world safe and secure from infectious disease threats,” and it works to “promote global health security as an international priority.”\textsuperscript{83} Aiming to fill the gaps left by past and current IHR implementation, the GHSA complements and fosters capacity building and other relevant global health security frameworks.

\begin{itemize}
\item \textsuperscript{79} See id. at 2.
\item \textsuperscript{80} See id.
\item \textsuperscript{82} Gostin et al., supra note 77, at 4.
\end{itemize}
Importantly, it focuses on better tracking and measuring progress\textsuperscript{84} to ensure that states are able to prevent, detect, and respond to global health security threats. To do so, the GHSA consists of eleven “Action Packages” (or priority technical areas),\textsuperscript{85} each of which “includes a five-year target, an indicator (or indicators) by which to measure progress, and lists of baseline assessment, planning, monitoring, and evaluation activities to support successful implementation.”\textsuperscript{86}

The partnership is led by a steering group composed of ten countries, and it features an \textit{external} assessment mechanism to measure countries’ compliance with the GHSA. Under the GHSA, member countries may lead or join one or more action packages, and their commitments are reviewed on a regular basis, with the GHSA Steering Group underscoring the country’s gaps and next steps for implementation. Member countries are also invited to assist one another in meeting GHSA goals and targets and collaborate with member international organizations, including WHO.\textsuperscript{87} This is in stark contrast to the IHR’s self-assessment system, which, as discussed above, has proven unsuccessful in properly measuring countries’ level of preparedness.

While somewhat limited by the lack of international legitimacy enjoyed by WHO, the GHSA stands as a key opportunity to bolster IHR (2005) implementation. It not only expressly mentions IHR implementation as one of its goals, but it also directly addresses some of the critical gaps and inadequacies inherent in the Regulations. The GHSA, with its broader scope and greater financial support, can help strengthen health systems in dire need and better prepare countries for public health threats and emergencies that IHR minimum core capacities are unable to cover.

\textbf{C. Universal Health Coverage and the Sustainable Development Goals}

The growing international commitment to Universal Health Coverage (UHC) can bring about major benefits for global health security. Strong health systems are deeply embedded in the concept of UHC. Managing infectious disease outbreaks, for example, requires effective and resilient primary care and public health systems. Therefore, integrating global health security into UHC discourse (and vice versa) to increase political will in investing in strengthening health systems is critical. In December 2012, the UN General Assembly adopted a

\begin{itemize}
\item \textsuperscript{85} \textit{See id.} Action Packages: Prevent 1: Antimicrobial Resistance; Prevent 2: Zoonotic Disease; Prevent 3: Biosafety and Biosecurity; Prevent 4: Immunization; Detect 1: National Laboratory System; Detect 2 & 3: Real-Time Surveillance; Detect 4: Reporting; Detect 5: Workforce Development; Respond 1: Emergency Operations Centers; Respond 2: Linking Public Health with Law and Multi-sectoral Rapid Response; and Respond 3: Medical Countermeasures and Personnel Deployment Action Package.
\item \textsuperscript{86} CDC, \textit{supra} note 83.
\item \textsuperscript{87} \textit{See supra} note 84.
\end{itemize}
resolution" that not only pressed governments to “urgently and significantly scale up efforts to accelerate the transition towards universal access to affordable and quality health-care services,” but also expressly recognized “the importance of universal coverage in national health systems...to provide access to health services for all, in particular for the poorest segments of the population.”

Moreover, the UN General Assembly drew an important link between UHC and health security by expressly including infectious disease outbreaks as a major target. In fact, the United Nations Sustainable Development Goal 3 (good health and wellbeing) has UHC as a major target, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. What makes SDGs particularly relevant to global health security is their emphasis on health equity, as marginalized and vulnerable populations are often most affected by infectious disease outbreaks.

Ultimately, what recent public health crises have demonstrated is that national health systems play a crucial role in ensuring health security at the national and global levels. Losing sight of this critical link is dangerous.

III. WHO AS THE GLOBAL HEALTH LEADER

While a country’s ability to detect and respond to epidemics is a critical part of containing infectious disease outbreaks, so is a well-functioning global health system led by a strong, efficient, and well-funded institutional leader. Infectious diseases know no borders and can quickly jump from one host to another (animal to human), from one country to another, and from one region to a global threat. An effective global response requires a multi-sectoral approach that extends beyond human health into agriculture, trade, commerce, transportation, and the environment. As the chief international health institution with legal authority, WHO is well placed to lead global coordination across sectors that includes “managing logistics, deploying medical teams and equipment, and mobilizing humanitarian assistance” at the international level. Almost every country in the world is a WHO member. However, the emergence of other international actors in the public and private spheres – such as the Bill & Melinda Gates Foundation, GAVI Alliance, and the Global Fund to Fight HIV/AIDS, TB and Malaria – coupled with WHO’s deficient performance and

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91. Gostin, Mundaca-Shah & Kelley, supra note 81, at 1451.
decision-making during international crises have led the international community to question the organization’s ability to lead global health security. Since the IHR (2005) entered into force in 2007, the Director-General has declared four PHEICs: H1N1 influenza pandemic in 2009; polio in 2014 as a response to the rise of polio cases in Afghanistan, Pakistan, and Nigeria that threatened eradication efforts; Ebola in 2014; and the clusters of Zika and microcephaly and other neurological diseases in 2016. Each global health emergency has fueled skepticism over WHO’s ability to lead. During the H1N1 pandemic, WHO faced criticism for over-reacting and fanning public fear. European countries were particularly skeptical over the recommended widespread vaccination campaign, accusing the Organization and pharmaceutical companies of unnecessarily raising fears about what turned out to be a “mild flu” and “false pandemic.” But at other times WHO has been criticized for not declaring a PHEIC. For example, the Director-General has never declared an emergency for MERS, which has affected more than 25 countries and caused a major outbreak in the Republic of Korea.

The Ebola epidemic in particular unmasked major deficiencies in WHO’s ability to respond rapidly and effectively. Following the first cross-border transmission of the Ebola virus in West Africa, the WHO waited four-and-a-half months before declaring the Ebola outbreak a PHEIC. Although the Regional Office of Africa (AFRO) had issued urgent messages to WHO headquarters expressing concerns over the gravity of the Ebola outbreak, the calls for action “either . . . did not reach senior leaders or senior leaders did not recognize their significance.” According to Medicines Sans Frontières, “there was little sharing of information between countries, with officials relying on the WHO to act as liaison between them. It was not until July that new leadership was brought into the WHO country offices and a regional operations centre was established in Conakry [(Guinea’s capital)] to oversee technical and operational support to the affected countries.”

Taken aback by WHO’s inability to respond to the Ebola crisis and exposing the absence of a rapid decision-making culture within the institution, global health commissions have expressed disillusionment and have linked the organization’s failure to act decisively to the thousands of lives
In the aftermath of the Ebola crisis, on July 21, 2015, WHO established an Advisory Group on Reform of WHO’s Work in Outbreaks and Emergencies with Health and Humanitarian Consequences (Advisory Group), which was tasked with providing guidance to WHO on potential emergency reforms. Chaired by UN Special Envoy on Ebola David Nabarro, the Advisory Group issued two reports that underscored WHO as the international body expected to provide “leadership, support and expertise when public health is threatened by outbreaks and emergencies,” but also declared that it clearly lacked the necessary technical operational capabilities to fulfill this mandate. The Advisory Group stressed that WHO’s mandate of managing outbreaks and emergencies “must be reflected in every aspect of the Organization – its planning and budgeting of WHO, the capabilities of its staff and the focus of its governing bodies.” After all, according to the Advisory Group, “this mandate is at the heart of WHO’s identity.”

The Nabarro committee provided recommendations to enable the Organization to fulfill its constitutional mandate. Recognizing that providing technical assistance during emergencies is a fundamental part of WHO’s mandate, the Advisory Group urged the Director-General to establish a “Programme for Outbreaks and Emergencies” (Programme) that would include an “Emergencies Operations” unit to ensure sufficient technical operational capabilities. The Programme was launched in March 2016, with the aim of establishing “cross-organizational standards and rapid decision-making in health emergency operations.” Headed by an Executive Director (who reports to the Director-General), such a program functions quasi independently from WHO, requiring “enhanced capabilities, standardized procedures for operations, dedicated business processes, and predictable financing.” Moreover, it is intended to rely on “one budget and workforce (reporting to the Executive Director), one line of managerial authority, consistent procedures for supporting operations across [WHO], specially designed processes for managing human resources, finances, procurement and logistics, and one set of performance benchmarks to be

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100. Id. at Exec. Summary, ¶ 1.

101. Id. at ¶ 2.


applied across the organization."\textsuperscript{104} Upon its launch, the Member States’ delegates agreed to a budget of $494 million for 2016–2017.\textsuperscript{105} Despite progress, however, WHO’s new program lacks a sustainable funding source and governance that is independent of the Secretariat.

Nevertheless, the launch of the program was a significant advance in addressing a major weakness revealed during the Ebola crisis: insufficient emergency response staff and scarce financial resources. Prior to the outbreak, WHO underwent a half-billion budget cut, resulting in a drastic re-structuring of the Organization and loss of leading staff in the Organization’s response unit.\textsuperscript{106} The unit was reduced by two-thirds and cut staff included epidemic control experts and anthropologists.\textsuperscript{107} AFRO reduced the number of emergency response specialists from 12 to 3.\textsuperscript{108} The shortage of emergency responders and anthropologists who could have helped bridge cultural differences with the affected communities had serious repercussions.

The forced personnel cuts resulted from the deep financial crisis WHO has been facing for decades. The financing mechanisms to fund WHO operations creates substantial obstacles to ensuring its functioning. WHO relies on voluntary contributions from its Member States and outside groups such as the Gates Foundation. Discretionary contributions comprise approximately 80 percent of its budget.\textsuperscript{109} With Member States’ unwillingness to provide the necessary funding and most of WHO’s funds earmarked, the Organization has struggled to live up to its mandate and stay afloat as the global health authority. As a result, mobilizing funds during public health crises has proven a particular challenge with grave consequences.\textsuperscript{110}

Additionally, WHO engagement with civil society is problematic and undermines the Organization’s legitimacy as the leader and promoter of health equity. Civil society organizations are required to enter into “official relations” with WHO—a formal process devised under WHO’s Constitution to allow the organization to officially collaborate with NGOs in carrying out its work. To do

\textsuperscript{104} Id.
\textsuperscript{108} Id.
so, they must be “international in membership and/or scope,” a requirement that especially disadvantages grassroots organizations from low- and middle-income countries.\textsuperscript{111} Where a civil society organization enters “official relations,” these organizations still struggle to have their voices heard. As the Director-General observed in 2013, “no proactive, structured means [exist] through which WHO can seek the views of relevant non-governmental organizations.”\textsuperscript{112}

WHO also suffers from deficient processes and systems for accountability, which has severely undermined the Organization’s credibility. Proposed reforms outlined by the Advisory Group include establishing clear and strong lines of authority and accountability in incident management,\textsuperscript{113} leaving the Director-General ultimately accountable within the Organization.\textsuperscript{114} The Advisory Group also specified the need to establish “Incident Managers” at the national and regional levels who would be expected to develop “good working relationships with one another during the management of events and will be held accountable for doing so.”\textsuperscript{115} The Advisory Group also said that an independent and external oversight would be critical to fostering accountability and transparency. An external oversight group should comprise a range of experts and stakeholders, such as “Member States, donors, NGOs and civil society, private sector, and the UN system.”\textsuperscript{116} In short, the Advisory Group stressed a clear link between WHO’s lack of credibility and its system-wide failures of accountability.

The four global commissions that assessed WHO’s performance during the Ebola outbreak at the national and global levels – the WHO Ebola Interim Assessment Panel (WHO Interim Assessment), the Harvard University and the London School of Hygiene & Tropical Medicine’s Independent Panel on the Global Response to Ebola (Harvard/LSHTM), the Commission on a Global Health Risk Framework for the Future (CGHRF), and the United Nations High-Level Panel on the Global Response to Health Crises (UN Panel) – all arrived at the same conclusion. They called for the creation of a WHO Centre for Health Emergency Preparedness and Response (CHEPR) with adequate staffing and resources.\textsuperscript{117} The Centre would integrate and strengthen prepared-


\textsuperscript{115} WHO, Advisory Group on Reform of WHO’s Work in Outbreaks and Emergencies Second Report, supra note 99, at ¶ 36(f); Moon et al., supra note 98, at 11, Rec. 3.


\textsuperscript{117} Gostin, Mundaca-Shah & Kelley, supra note 80, at 1452; COMM’N ON A GLOBAL HEALTH RISK FRAMEWORK FOR THE FUTURE, supra note 15, at Rec. C.1; Moon et al., supra note 98, at Rec. 3; U.N. High-Level Panel on the Global Response to Health Crises, Protecting humanity from future health
ness, response, and humanitarian activities across its operations. However, it is unclear whether the recently launched Health Emergencies Programme would meet the standards set out by the commissions. The WHO Interim Assessment specified that an independent board would be needed to oversee the Centre and submit a report to the UN General Assembly on an annual basis—a recommendation that seeks to address the accountability issues present at WHO.

IV. UN SYSTEM

Epidemics pose a threat not only to health systems and the economy, but also peace and security. If not managed properly, epidemics can easily destabilize a country politically, cause civil unrest, and even affect neighboring countries and beyond. This was particularly apparent during the Ebola epidemic. For these reasons and because epidemics can escalate in intensity and become a threat to international peace and security, political action is pivotal in mobilizing resources and accelerating international action to combat international public health threats. The IHR itself explicitly grants this authority to the Director-General after declaring a PHEIC. However, in practice, WHO has struggled to coordinate with other UN agencies, regional networks, and non-state actors, leaving politically powerful countries to take the lead in ramping up and coordinating international efforts among public and private actors and across regions. For example, during the Ebola crisis, the United States allocated more than $1 billion to the global effort, while spearheading the historic Security Council Resolution 2177. Therefore, in times when an infectious disease outbreak intensifies and reaches the level of a humanitarian disaster, it is important to broaden the responsibility of WHO to include other parts of the United Nations, such as the Secretary-General, the Security Council, or the General Assembly, all of which have the political clout and authority to stiffen political will and coordinate diverse actors. After all, the overarching purpose of the U.N. is the preservation of international peace and security.

118. See Gostin et al., supra note 77, at 6-7.
122. See Gostin et al., supra note 77, at 9.
123. U.N. Charter art. 1.1.
Table 1. Recommendations from the Four Global Commissions Concerning Global Governance – WHO Emergency Operations and Response Reform*.

<table>
<thead>
<tr>
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<th>CGHRF</th>
<th>Harvard/LSHTM</th>
<th>UN Panel</th>
<th>WHO Interim Assessment</th>
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<tr>
<td><strong>Independent Centre for Preparedness &amp; Response</strong></td>
<td>WHO should create a Centre for Health Emergency Preparedness &amp; Response (CHEPR), governed by an independent Technical Governing Board, to coordinate global outbreak preparedness and response. (Rec. C.1)</td>
<td>WHO should create a unified Centre for Emergency Preparedness &amp; Response with clear responsibility, adequate capacity, and strong lines of accountability. (Rec. 3)</td>
<td>WHO’s Program for Outbreaks &amp; Emergency Management should be converted into a Centre for Emergency Preparedness &amp; Response (CEPR) with unified command and control authority. (Rec. 7)</td>
<td>WHO should establish a Centre for Emergency Preparedness &amp; Response that integrates its outbreak control and humanitarian functions. (Rec. 11) An independent board should oversee the Centre and provide an annual global health security report to the WHA and UN GA. (Rec. 12)</td>
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<td><strong>Create Contingency Fund for Rapid Response</strong></td>
<td>By the end of 2016, WHO should create a sustainable contingency fund of US$100 million to support rapid deployment of emergency response capabilities. (Rec. C.3)</td>
<td>No recommendation.</td>
<td>WHO should establish a contingency fund for emergency response, managed by the CEPR. Member States should provide at least US$300 million in financing. (Rec. 20)</td>
<td>Member States and partners should contribute to a contingency fund in support of outbreak response, with a minimum target capitalization of US$100 million. (Rec. 8)</td>
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<tr>
<td><strong>Communications &amp; Outbreak Monitoring</strong></td>
<td>WHO should generate a high-priority “watch list” of outbreaks, released daily to national focal points and weekly to the public. (Rec. C.7)</td>
<td>Responsibility for declaring a PHEIC should be delegated to a transparent and politically protected WHO standing committee. (Rec. 4)</td>
<td>WHO must re-establish itself as the authoritative body for health emergencies, capable of rapidly and accurately informing governments and the public about the severity and extent of an outbreak. (Rec. 14)</td>
<td>The IHR Review Committee should consider the creation of an intermediate level of emergency to alert the international community at an earlier stage of a health crisis before it becomes a global threat. (Rec. 5)</td>
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The four global commissions in one form or another proposed a more robust role for the United Nations in leading major global health and humanitarian emergencies. In particular, the commissions proposed that, upon WHO’s advice, the UN Emergency Relief Coordinator be charged with making the determination on moving the leadership role to other parts of the UN system. The UN criteria for the highest emergency level (Level 3 emergency) should be applied, including the scale of the epidemic, the degree of economic impact, and the threat for political destabilization.\textsuperscript{124} Considering the complexity of public health humanitarian crises, the UN Inter-Agency Standing Committee would be responsible for devising the procedures for UN inter-agency coordination of humanitarian assistance.\textsuperscript{125}

Charged with the “primary responsibility for the maintenance of international peace and security,”\textsuperscript{126} the UN Security Council (UNSC) may not only raise a health crisis to the top of the global agenda, but also adopt resolutions to drive political action. Under Article 25 of the UN Charter, UN Members are “to accept and carry out the decisions of the Security Council . . . ” As such, UNSC resolutions can be powerful tools for public health. For example, the UNSC’s two resolutions on HIV/AIDS raised the issue from a health concern to one that also threatened international security. The resolutions ultimately led to the creation of the Global Fund. The resolution issued on July 17, 2000, recognized “the importance of a coordinated international response to the HIV/AIDS pandemic, given its possible growing impact on social instability and emergency situations.”\textsuperscript{127} Likewise, in 2011, the UNSC issued Resolution 1983, which described HIV as “posing one of the most formidable challenges to the development, progress and stability of societies and requiring an exceptional and comprehensive global response, and noting with satisfaction the unprecedented global response of Member States.”\textsuperscript{128}

In September 2014, the UNSC issued a resolution for the first time declaring an infectious disease outbreak a “threat to international peace and security.”\textsuperscript{129} As WHO struggled to respond to the Ebola outbreak, the UNSC’s resolution called on Member States “to lift general travel and border restrictions, imposed as a result of the Ebola outbreak, and that contribute to the further isolation of the affected countries and undermine their efforts to respond to the Ebola outbreak.” Immediately following the resolution, the Secretary-General created the UN Mission for Ebola Emergency Response (UNMEER). Whereas peacekeeping missions are traditionally intended to address humanitarian crises stemming from conflict, UNMEER stands as the first-ever UN emergency

\begin{thebibliography}{99}
\bibitem{footnote124} See Gostin et al., \emph{supra} note 77, at 9.
\bibitem{footnote125} \textit{Id.}
\bibitem{footnote126} U.N. Charter art. 24, § 1.
\bibitem{footnote127} S.C. Res. 1308, ¶ 1 (July 27, 2000).
\bibitem{footnote128} S.C. Res. 1983, ¶ 1 (June 7, 2011).
\bibitem{footnote129} S.C. Res. 2177, ¶ 1 (Sept. 18, 2014).
\end{thebibliography}
mission aimed to answer to a public health crisis.\textsuperscript{130} Confined to the scope of its mandate, as with any other peacekeeping operation, UNMEER was conceived as a temporary organizational intervention to “harness the capabilities and competencies of all the relevant United Nations actors under a unified operational structure to reinforce unity of purpose, effective ground-level leadership and operational direction, in order to ensure a rapid, effective, efficient and coherent response to the crisis.”\textsuperscript{131} UNMEER, however, received considerable criticism for adding another bureaucratic layer, and hindering coordination. Still, if properly conceived and deployed, UN missions under the authority of the Secretary-General could play a role in future outbreaks. Overall, the United Nations system could drive governments to comply with WHO recommendations through a variety of means, including using resolutions, special representatives or envoys,\textsuperscript{132} and missions aimed at implementing UNSC directives.\textsuperscript{133}

The UN System also offers a “cluster approach,” which allows groups of UN and non-UN humanitarian organizations to join together to manage health and humanitarian responses. The cluster approach came about as part of humanitarian response reforms at the UN. Clusters works to “strengthen system-wide preparedness and technical capacity to respond to humanitarian emergencies, and provide clear leadership and accountability in the main areas of humanitarian response.”\textsuperscript{134} Similarly at the country level, this approach seeks to “strengthen partnerships, and the predictability and accountability of international humanitarian action, by improving prioritization and clearly defining the roles and responsibilities of humanitarian organizations.”\textsuperscript{135}

The Global Health Cluster (GHC) is led by WHO and consists of more than 40 international humanitarian health organizations. It aims “to build consensus on humanitarian health priorities and related best practices, and strengthen system-wide capacities to ensure an effective and predictable response.”\textsuperscript{136} To build global capacity in humanitarian response, the GHC: (1) provides guid-
ance, tools, standards, and policies; (2) establishes systems and procedures for facilitating the rapid deployment of experts and supplies, and (3) promotes global partnerships to further its mission for humanitarian health action.\(^{137}\) The GHC rests on a set of principles: equality, transparency, a result-oriented approach, responsibility, and complementarity – all of which can aid both the WHO and the UN on properly addressing public health crises.\(^{138}\)

Given the diverse tools at the UN System’s disposal, a UN-level response can bring not only leadership and coordination, but also legitimacy and, above all, the necessary political will that WHO has not been able to garner. As Richard Holbrooke, U.S. Ambassador to the United Nations, once stated, “if a country loses so many of its resources in fighting a disease which takes down a third of its population, it’s going to be destabilized, so it is a security issue.”\(^{139}\) Consequently, where a public health crisis constitutes a Level 3 emergency, WHO should look to the UN for reinforcement. To do otherwise could have catastrophic effects.

V. RESEARCH AND DEVELOPMENT: BIOLOGICAL COUNTERMEASURES AS A MAJOR TOOL OF PREPAREDNESS, PREVENTION, AND RESPONSE

Recent outbreaks such as Ebola and Zika unveiled major deficiencies in the availability of effective medical products. Preparedness and response to infectious disease outbreaks require rapid development and deployment of “effective and fit-for-purpose tools and technologies, such as vaccines, drugs, diagnostics, personal protective equipment (PPE), and medical devices.”\(^{140}\) The challenges underlying research and development (R&D) deficiencies are often directly attributable to the low priority placed on “episodic infections” by the private and public sectors, as well as the difficulties associated with carrying out human trials. The unpredictability of infectious disease outbreaks, however, calls for an effective and efficient R&D strategy, which would include “an international coordinating entity; sustainable investments; convergence of diverse regulatory pathways; and access to intellectual property, data, and biological samples – ensuring rigorous scientific standards.”\(^{141}\) Moreover, community participation is vital to the introduction of novel products.

Multiple stakeholders – governments, academics, industry, and civil society – should identify R&D priorities and lead a coordinating response. For example, WHO would benefit from establishing a “Pandemic Product Development Committee” (PPDC), an independent committee of high-level experts in discovery, development, regulatory approval, and medical product manufactur-

\(^{137}\) Id.

\(^{138}\) See IASC, \textit{supra} note 134, at 26-27.


\(^{141}\) Gostin, Mundaca-Shah & Kelley, \textit{supra} note 81, at 1452.
ing that works to streamline and more effectively expedite the process through which products must undergo before being introduced for human use.\textsuperscript{142} Reporting to the Technical Governing Board, this committee would drive the R&D strategy, helping to set priorities for R&D on pathogens that pose the most risk, mobilize resources, coordinate across actors (including private), prevent redundancy, and minimize cost. Such an effective R&D preparedness strategy would require significantly greater and new investment, specifically, $1 billion annually for at least 15 years.\textsuperscript{143} The PPDC would coordinate a meeting by the end of 2016 of stakeholders in the public and private sectors with an eye toward accelerating R&D and so promoting “regulatory convergence; the pre-approval of clinical trial designs; mechanisms to manage intellectual property, data sharing, and product liability; and efforts to expedite vaccine manufacture, stockpiling, and distribution.”\textsuperscript{144}

WHO should be well positioned to coordinate and lead R&D for neglected or episodic diseases.\textsuperscript{145} It can also work with developing countries in building R&D capacities for medical countermeasures, while fostering cooperation within the Global South.\textsuperscript{146}

Well-funded and coordinated R&D is vital to preventing major outbreaks and mitigating their impacts on human health. Given the complexity of promoting R&D for averting pandemics and promoting health equity, WHO has a critical role to play in “establishing the normative framework for R&D including priority setting, accelerating trial design and administration, regulatory pathways, and equitable access.”\textsuperscript{147}

\textbf{CONCLUSION: THE PEACE DIVIDEND}

Repeated threats to global health security have revealed major weaknesses in governments and international institutions to combat them. What is more, any failure at the national and global levels will have major impacts on the most marginalized and vulnerable. For this very reason, WHO needs to be empowered to live up to its constitutional mandate as the world’s health authority and make the necessary changes to ensure that the world is prepared. This can mean reaching out to politically more powerful entities (e.g., the UNSC, G7, and G20) to mobilize funding and political will. Equally important, national health systems, particularly the most fragile, require immediate attention. What this requires is a “peace dividend,” both financial and institutional, to remake the global health security system. Financially, a modest investment of $4.5 billion

\begin{footnotesize}
\begin{enumerate}
\item Gostin, Mundaca-Shah & Kelley, supra note 81, 1452.
\item Id. at Rec. 16.
\item WHO, Report of the Ebola Interim Assessment Panel, supra note 96, at Rec. 16; Gostin et al., supra note 77, at 10.
\end{enumerate}
\end{footnotesize}
(or 65 cents per person) could fill major funding gaps, while fundamental reform of WHO would help fulfill its mandate. If the international community fully recognizes the vast economic costs of epidemics, as well as the risks they pose of greater violence and instability, it will become clear that sustainable financing and strong governance is vital to enhance prevention, detection, and response. A peace dividend would yield enormous gains in human and economic security.