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GLOBAL LEADERSHIP AT A CROSSROADS: ARE WE PREPARED FOR THE NEXT PANDEMIC?

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GLOSSARY OF ABBREVIATIONS & ACRONYMS

AMR	Antimicrobial Resistance
BWC	Biological and Toxin Weapons Convention
CBEP	Cooperative Biological Engagement Programs
CDC	Centers for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovation
CRISPR	Clustered Regulatory Interspaced Palindromic Repeats
DARPA	Defense Advanced Research Agency
DDM	Data for Decision-Making Project
DHS	US Department of Homeland Security
DOD	US Department of Defense
DURC	Dual Use Research of Concern
EPT	Emerging Pandemic Threats
EU	European Union
FAO	Food and Agriculture Organization
GAVI	Global Alliance for Vaccines and Immunisation
GDD	Global Disease Detection
GDP	Gross Domestic Product
GHSA	Global Health Security Agenda
GVP	Global Virome Project
HHS	US Department of Health and Human Services
IHR	International Health Regulations
JEE	Joint External Evaluation
MDR-TB	Multi-drug resistant tuberculosis
NGO	Non-governmental Organization
OFDA	Office of Foreign Disaster Assistance
OIE	World Organisation of Animal Health
PCR	Polymerase Chain Reaction
R&D	Research and Development
SARS	Severe Acute Respiratory Syndrome
UK	United Kingdom
UN	United Nations
USAID	US Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

In this report, the Scowcroft Institute of International Affairs at The Bush School of Government & Public Service at Texas A&M University outlines eight priority areas and their accompanying recommended action items to address vulnerabilities in the current pandemic preparedness and response system. Collectively, they represent issues the international community should address in order to establish pandemic preparedness and response capabilities.

A: IMPROVING CAPACITY FOR EARLY DETECTION AND RESPONSE

1. Best Practices in Management of Animal Diseases

An estimated 75% of human emerging diseases are zoonotic and most pandemics begin in animals and spillover into humans. Due to the highly complex and interconnected nature of disease spread, a One Health approach that links humans and animal disease surveillance is critical for early detection, response, and containment of outbreaks. A typical response to any report of disease, is that the flocks and herds of diseased animals are ordered slaughtered or culled. Livestock producers and subsistence farmers not able to access compensation when their animals are killed, are motivated to conceal diseased animals rather than report them. Despite its common use, however, cull-

ing can be challenging, especially in the austere environments of the developing world. To minimize these challenges, we recommend that each country have written, practical compensation guidelines, and that governments can be held accountable by the international community. For countries not financially able, the World Organization of Animal Health (OIE), the Food and Agriculture Organization of the United Nations (FAO), and the World Health Organization (WHO) should establish a culling compensation fund, and the international community should explore disease prevention and containment options other than culling, such as vaccination and treatment.

2. Ensuring Community-Level Awareness & Action

In order to control outbreaks at the source, it is important that communities located within disease "hot spots"—or areas with ecological and demographic conditions likely to produce emerging diseases—have the training, education, and tools they need to identify a disease epidemic and take early response measures. We recommend that international non-governmental organizations (NGO) and local universities serve as the main components for local capacity building. In making this recommendation, we recognize that there are inherent risks to this approach, which include national government hostility toward NGOs and the often clientelist structure of local universities.

B: LIMITING HUMAN AND ECONOMIC IMPACT

3. Increasing Continuity in Supply Chains

Efficient and reliable transportation has changed the global economy and molded it into a system based heavily on the idea of comparative advantage. Now, countries around the world, including the United States, rely on "just-in-time" deliveries of goods, including vital medical supplies and equipment. This means that inventories are kept low and continual delivery of goods is required. A failure in the global supply chain during a pandemic could be deadly as it proved to be during the Ebola epidemic that occurred in West Africa. We recommend that the United States determine and document all the components of our most important supply chains (i.e.—medical equipment, pharmaceuticals, food) in the event of pandemic and considering different disease syndromes (e.g., respiratory vs. blood-borne). Developing this understanding is the first step towards adequately protecting our global supply chains.

4. Targeting Antimicrobial Resistance

Antimicrobial resistance is quickly emerging as

one of the greatest challenges in public health. The development of antibiotics has saved millions of lives and allowed for an explosion in livestock production and subsequent growth in the human population, but the massive overuse of these medications has also created new, resistant strains of bacteria that threaten both humans and livestock. To counter antimicrobial resistance, we recommend investing in research and the development of new antimicrobials, creating a stronger regulatory system and clear guidelines for veterinary and farm use of antibiotics, decreasing the misuse and/or overuse of antimicrobials in human health, and understanding that fighting antimicrobial resistance requires a One Health approach. As part of that approach, we need to consider the environmental, animal and human elements of disease emergence, transmission, prevention, and containment.

C: MAINTAINING INTERNATIONAL LEADERSHIP CAPACITY

5. Strengthening Leadership & Coordination

As we discussed in our 2017 White Paper, "The Growing Threat of Pandemics: Enhancing Domestic and International Biosecurity," leadership and coordination is critical to effective pandemic response. In this white paper, we encourage the development of a strategic direction for international leadership, the development of a communication strategy, and the United States maintaining its involvement in global health security and pandemic preparedness.

6. Maintaining United States Involvement in Pandemic Preparedness & Global Health Security

Building on the recommendations in section five of this document, we focus on the importance of the United States maintaining involvement in international health security and pandemic preparedness. We recommend that domestic experts frame the problem of pandemics to encourage a national defense perspective and for the United States to increase its international response capacity.

7. Ensuring that the Private Sector is Fully Involved

The financial cost of international health security and pandemic preparedness is significant and current needs are not being met. In order to strengthen international ability to respond to disease outbreaks, governments should encourage and incentivize the participation of the private sector. To help increase private sector involvement, we recommend greater economic investment and incentive policies from governments

for research, development, and production of vaccines, therapeutics, diagnostics, and non-pharmaceutical interventions. Lastly, we recommend that the private sector become formal participants in discussions and planning for pandemic preparedness and response.

D: PROVIDING ADEQUATE FINANCE

8. Continued Funding for Disease Detection & Prevention Programs

Our final topic area for this white paper is the importance of programs designed to detect and prevent disease outbreaks from becoming epidemics and pandemics. These types of programs include those funded by the United States Agency for International Development (USAID), Department of Defense (DOD), and the Centers for Disease Control and Prevention (CDC). Our recommendation in this area is simple: the United States should continue to support international disease detection and prevention and give priority to innovative and advanced research programs that employ a One Health approach in order to prevent animal-to-human spillover events. These are critical investments for international health security and pandemic preparedness.

INTRODUCTION

Pandemics remain a central international health security challenge. Emerging diseases, fluctuations in climate, global interconnectedness—both physically and economically—and greater interaction between animals and people, especially in the developing world, are just a few of the reasons that the international community should be more concerned about pandemics than ever. While we prioritize nuclear and military threats to our national security, we easily forget the power of plagues in history and it is important that we accept and prepare for pandemics for it is not a matter of *if*; it is a matter of *when*.

In October of 2017, the Scowcroft Institute of International Affairs at The Bush School of Government & Public Service at Texas A&M University held its Third Annual Global Pandemic Policy Summit in College Station, Texas to discuss some of the most daunting challenges facing pandemic prevention, detection, and response. This White Paper draws from and expands on conversations that took place during the two-day summit and proposes solutions for some of the biggest challenges. While there are numerous unresolved issues in pandemic preparedness and response, we chose to address eight that we think are most pressing. These include: 1) best practices in management of animal disease; 2) ensuring community-level awareness and action; 3) increasing continuity in sup-

ply chains; 4) targeting antimicrobial resistance; 5) strengthening leadership and coordination; 6) maintaining United States involvement in pandemic preparedness and international health security; 7) ensuring that the private sector is fully involved; and 8) continuing funding for disease detection and prevention programs.

The international community should address all of the eight areas listed above to strengthen the ability of individual countries and the international community to respond to outbreaks of infectious disease. Additionally, as we stress throughout this White Paper, the United States should remain involved in and committed to leadership and assistance in pandemic preparedness and response and international health security more broadly. As one of the largest contributors, in terms of economic, man-power, and technological contributions to global health security, American withdrawal from the world stage on this issue would be devastating to the ability to prevent disease outbreaks. Withdrawal would also threaten the well-being of the American people because disease does not respect national borders.

While some of the areas addressed in this White Paper overlap, each represents an important, independent area of prevention, detection, and response to pandemics. They are gaps in the system that the international community should remain committed to filling.

BEST PRACTICES IN MANAGEMENT OF ANIMAL DISEASE

Culling, or the practice of slaughtering animals to reduce population or control disease, has always been a central part of disease control strategy within livestock and wildlife populations. The goal of this practice is to destroy a population of potentially infected animals so that the disease cannot spread. While it can sometimes be effective, culling is an expensive disease control policy. The most recent avian influenza scare occurred in 2015 and lead to the destruction of roughly 49.5 million chickens and turkeys in the United States, which is estimated to have an economic cost of $1.57 billion (McKenna, 2015). That is just the direct cost of lost birds. If you examine the poultry industry as a whole—in losses in eggs, losses to food service firms, etc.—the total economic loss is closer to $3.3 billion (McKenna, 2015).

For areas in which subsistence farming dominates, the practicing of culling as a method of disease control becomes problematic. First, there is concern that if people kill their food source to prevent

the spread of disease, they will no longer have anything to eat. Secondly, there are often no guarantees that the farmers will receive compensation if they cull their animals. This was seen in the early-to-mid 2000s when farmers in Nigeria had trouble receiving compensation for preemptive culling, because the country was experiencing cash flow problems (Kanamori & Jimba, 2007).

Compensation

Culling livestock can create financial, psychological, and logistical issues. In order to minimize these potential problems, governments are strongly encouraged to compensate producers for the animals they cull. FAO lists seven reasons why all governments should implement compensation schemes. These reasons include: 1) it is the fair thing to do, 2) it is a powerful incentive for farmers to report sick animals and birds, 3) it helps safeguard public health, 4) it helps safeguard domestic trade, 5) it helps safeguard international trade, 6) it is good for a country's international reputation, and 7) it encourages industry cooperation.

As previously mentioned, without incentive to report sick animals, producers are highly unlikely to do so. In fact, it is more likely that they will sell off the sick animals or kill them and eat them themselves (FAO, 2017). Thus, establishing a compensation scheme is important to encouraging producers to report sick animals that they may have. In turn, if producers are encouraged to report sick animals in a timely manner, countries will be able to protect public health, domestic, and international trade. If countries learn about a problem early on, they are able to take steps to eliminate the problem and therefore, maintain confidence with trade partners (FAO, 2017). Some countries may not have the financial means to compensate producers for culled animals. In these instances, the international community—using an established culling fund at WHO, FAO, the World Bank, and OIE—should help compensate farmers.

Although there are many indirect costs that result from culling operations, only direct losses are compensated. The FAO suggests that compensation schemes should be developed to pay fair market price for each animal that was culled (FAO, 2017). This compensation can extend to eggs and occasionally feed that must be destroyed. In order to determine the fair market value of each animal, governments should establish a compensation rate that takes into account the animal's age, sex, size, and health as well as the region the animal is produced in and the season in which the animal was culled (FAO, 2017). All of these elements can help governments determine the appropriate compensation rate for culled animals.

In the United Kingdom, most compensation is only applied to healthy animals that were culled as part of the disease containment process. Animals that were sick with the disease the culling was targeted at are typically not compensated. The United Kingdom government puts animals into compensation categories based on a number of factors. For cattle, these factors include: age, sex, pedigree status, and type (beef or dairy) (Department for Environment, Food & Rural Affairs, 2014). Obviously, animals with higher pedigree status receive more compensation than animals with lower status. With regards to birds, determining compensation value means examining the bird's species, age, sex, what it was farmed for (meat or eggs), the cost of raising the birds, and any income that is derived from them (Department for Environment, Food & Rural Affairs, 2014). There is much greater variation in compensation rates for bird populations than there is for cattle populations.

The United Kingdom is just one example of a government compensation scheme. While it sets out guidelines to make sure that producers are compensated for culled animals, it does have flaws. First, producers are generally not compensated for sick animals. This may encourage a lack of transparency on the part of the producer because they will likely want to be compensated for all animals that are culled. Uniform culling compensation, meaning that producers are compensated for all animals that are killed as part of the government culling procedure, would serve to reduce some of this risk and increase transparency on the part of producers.

Problems with Compensation Inequality

Compensating producers for animals that are culled as part of a government program to prevent disease spread is important to ensuring open and honest communication, transparency, and the greatest effectiveness in disease containment. However, if compensation is promised to producers as part of their participation, the government should provide this compensation. As mentioned earlier, it will likely be more difficult to get subsistence farmers to participate in government culling programs because if they do not receive compensation or it does not come in a timely manner, they will have no animals to eat and no way to purchase food.

Recently, poultry producers in South Africa began to question whether they would truly be compensated for the large economic losses they suffered due to culling (Omarjee, 2017). More than three months after culling occurred, producers still had not been compensated. Failure to deliver on

promised compensation undermines the process and creates an environment in which producers are unlikely to trust government officials and will be less likely to participate (transparently, anyway) in government culling programs.

A 2006 standoff occurred between Israeli poultry farmers and the Agriculture Ministry over the issue of compensation. Producers went as far as to block inspectors and veterinarians from entering until they had guarantees from the government that they would be compensated for their losses (Cohen, 2006). The disagreement centered around compensation for indirect losses. The government does guarantee producers will be compensated for direct losses (i.e. dead birds), but they will not be compensated beyond that. Producers argue that there are numerous indirect losses that come from culling and should be compensated for those losses as well. Thus, problems with compensation do not just come from problems with governments not paying promised compensation, but also with a narrow focus on only compensating producers for direct costs.

Lastly, in cases where compensation is not forthcoming from the government, it can be easier for larger companies to get the compensation they are owed. Larger companies often have the financial capability to push the government to issue compensation that they are owed for culling animals under government order. Small farmers may not have these same means. Therefore, when compensation is not forthcoming, it is often the small farmers—who are likely suffering the most economically from the culling—who are unable to get the compensation that is owed to them. This further compounds the economic problems they are facing and in turn, makes it less likely that they will openly cooperate in the future.

Recommendations

1. Each country should have written compensation guidelines.

Although many countries have written procedures for culling compensation, it is not universal. In order to create a more transparent and fixed compensation system, every country that uses culling as a disease control strategy should have written guidelines for compensation. This serves as a contract with producers and provides a level of security for them as they move forward with culling their flocks and herds. While this does not solve issues of compensation payments not being made, it takes the first step in establishing a commitment to compensate producers for their economic losses.

2. Governments should be held accountable for not providing promised compensation.
As the above discussion demonstrates, occasionally a government promises to compensate producers and does not follow through on that promise. Governments that do not follow through with compensation payments should be held accountable. When governments do not provide compensation that is promised to producers, they are not only putting producers at economic risk but are also putting their country and the rest of the world at risk for zoonotic and other transboundary animal diseases, decreasing the likelihood that producers will cooperate in the future and may even hide outbreaks within their flocks or herds. OIE, FAO, and WHO should establish a mechanism that can be used to punish governments that do not provide promised compensation. This mechanism could come in the form of reduced funding or assistance, or it could be public reprimand, such as publishing the names of countries that fail in this regard.

3. The World Organisation for Animal Health (OIE), the Food and Agriculture Organization (FAO) of the United Nations, and the World Health Organization (WHO) should establish a culling compensation fund.
Some countries do not have programs to compensate producers when government culling occurs, and some countries may not even attempt culling as a disease control strategy due to a lack of resources. To help in these cases, the OIE, FAO, and WHO should come together to form a culling compensation fund. This fund would be supported by contributions from member states, multinational organizations, and the private sector and would help provide compensation to countries who do not have the financial resources to offer it.

4. Options other than culling should be explored.
While culling is currently the main method used for disease control in livestock, it does not have to be the only method. Not only are there problems with compensation and substantial industry-wide economic losses that accompany culling, but many question whether it is a humane practice. Should millions of animals be slaughtered when a handful are found to be infected? The United States and other countries should begin developing disease control strategies other than culling. The development of vaccines or treatment options once an animal is infected are both viable alternatives to the current system. To date, investments in animal vaccines, diagnostics, and other animal disease control strategies have been insignificant compared to similar investments for public health preparedness. Countries should adopt a One Health approach to this problem and begin investing in alternative animal disease control strategies.

ENSURING COMMUNITY-LEVEL AWARENESS & ACTION

Building Local Capacities

Often times, conversations of pandemic preparedness and response take place without the inclusion of the countries that are most likely to be affected by these outbreaks. Through the International Health Regulations (IHR), many WHO member states have taken steps to build local capabilities and resilience, but this has not gone far enough. "The lack of capacity in Guinea to detect the virus for several months was a key failure, allowing Ebola eventually to spread to bordering Liberia and Sierra Leone. This phase underscored the problem of inadequate investment in health infrastructure, despite national governments' formal commitments to do so under the International Health Regulations (2005) and awareness among donors that many lower income countries would need substantial external support" (Moon et al, 2015, p. 2206).

The challenges of building local capacities and resilience were starkly demonstrated during the

2014 Ebola outbreak in West Africa. As Sands et al. (2016) explains, "Identifying the outbreak in the community and raising alerts took too long. Local health systems were quickly overwhelmed. Response teams did not adequately engage communities and deepened distrust in health authorities" (p. 1281). If local communities are not prepared and do not have the capabilities to respond quickly and efficiently, outbreaks can become pandemics.

During any outbreak, the local community and the local public health capabilities of the affected country are the first line of defense. If disease outbreaks can be contained at the source before they are given an opportunity to cross national borders, regional epidemics or pandemics may be prevented from occurring in the first place. But this local source containment cannot be done without prioritizing community engagement, funding local and national capacities, and facilitating rapid response. Moon et al. (2015) argues that "all countries need a minimum level of core capability to detect, report, and respond rapidly to outbreaks" (p. 2204). In order to create this minimum capability, developed countries, in combination with WHO, need to create a strategy for helping countries develop health capacity.

In order to detect and quickly respond to disease outbreaks, developing countries, particularly those at the greatest risk for such outbreaks, need sustained investment in health infrastructure. While sustained investment is a challenge in many developed countries, it can seem almost impossible in developing countries, especially those experiencing conflict. Conflict often creates a lack of access to health services either because health facilities have been destroyed or because conflict prevents people from being able to travel for medical care (Kimrough et al., 2012). Sometimes, health infrastructure can be deliberately destroyed, and medical staff targeted, as is the case with Yemen in 2017 (Venters, 2017).

There have been ongoing attempts over the last several decades to strengthen local capacities. One notable project was the USAID-funded Data for Decision-Making Project (DDM). This project was implemented from 1991-1996 and focused on using data to inform decisions. The program operated in the countries of Bolivia, Cameroon, Mexico, and the Philippines (Pappaioanou et al., 2003). In these four countries, the program was able to help build health capacities through training programs in communication, management, epidemiology, and economics (Pappaioanou et al, 2003). It also helped develop and implement community health plans. In Cameroon in particular, the programs focused on strengthening epidemic preparedness (Pap-

paioanou et al, 2003). This is one example of a program designed to increase local capacities, but, like DDM, they are often not a sustained effort.

Encouraging Reporting

In addition to building capabilities of local communities to prepare for and respond to disease outbreaks, there is another problem area that receives little attention: reporting. If a country does have the ability to detect an outbreak of disease and it meets the requirements for a reportable disease under the IHR, they then must report it to the WHO. Unfortunately, there are often strong disincentives to report disease. Although it was pre-IHR, the impact of suppressing disease information was demonstrated by the 2003 Severe Acute Respiratory Syndrome (SARS) outbreak. If a country is fearful that reporting a disease will have economic repercussions, they are unlikely to feel compelled to report it in a timely manner.

Risks of a Community-Level Approach

While a community-level approach has the potential for significant positive outcomes, it is not without risks. Reliance on NGOs is likely to create some level of hostility among the host country government. Hostility toward NGOs from host country governments typically stems from a perceived challenge to the sovereignty of the state and is not a new problem. It could pose challenges, however, to the effective implementation of community-level interventions. Additionally, public universities in developing countries are not always independent, unbiased entities. Often times they serve as a part of the broader clientelist system, which may mute their role in establishing community-level resilience.

Recommendations

5. International NGOs and local universities should serve as a main component for local capacity building.

International nongovernmental organizations (NGOs) and local universities are often in a unique position in communities. Typically, they have established deep relationships with a village or town within which they work and are in a prime position to help with local capacity building, particularly with regards to knowledge development. International NGOs are also uniquely positioned because of their larger, streamlined structure. They are often able to develop broader, more efficient programs than smaller, regional or local NGOs.

NGOs and local universities should establish training and sustained educational programs for the local community. These programs should train physicians in what signs to look for when diagnosing infectious disease. They should train veterinarians, animal health paraprofessionals, and livestock producers in identifying and preventing spillover threats between animals and humans, and they should teach the lay public—families and individuals—about how to protect themselves from infection and when they should seek medical care. Creating more knowledge and understanding within all levels of the community could reduce the time it takes to detect, report, and respond to a disease outbreak.

6. There should be more international funding dedicated to building and maintaining health infrastructure in developing countries.

The international community and national governments should invest in building and maintaining health infrastructure in countries that are at the greatest risk for disease outbreaks. This means investing in the health infrastructure of a country at every step along the way. The international community should invest in helping countries build hospitals and health clinics; biosecure public health and university-based laboratory diagnostic capabilities, biosurveillance, and reporting systems; supply health facilities with the medical and reagent supplies they need; encourage and support health professionals so that they have less incentive to leave and work in another country; help facilitate health clinics' ability to reach populations in rural areas; and address any gaps identified by the Joint External Evaluation (JEE) of IHR and national planning process. Establishing stable, functioning health—laboratory and reporting—infrastructure will increase the chances that disease can be contained at the source. However, the structure of funding and accountability should move away from a rule-based ideology to better meet the needs of relationship-based societies. The international community and national governments need to develop programs that work within the clientelist structure of societies in developing countries. If these important structural differences continue to be ignored, it will be difficult to have a positive, long-term impact.

INCREASING CONTINUITY IN SUPPLY CHAINS

The Threat of Supply Chain Disruption

Today, it is possible to travel across the world in 24 hours. People and goods can be transported to the farthest corners of the globe at speeds that were unimaginable a century ago. Not only can goods and people move rapidly, but they can move reliably. That is to say that if you are boarding an airplane or a company is placing a container on a cargo ship, there is an exceedingly high probability that, in both situations, the person or cargo will make it to the intended destination within the intended time frame. Innovations of transportation have made it possible for people to explore the world and have changed the structure of the global economy simultaneously.

As speed and efficacy of trade movement increased, it was no longer economically advantageous for a country to produce all the goods and services that it needs. Rather, the idea of comparative advantage—meaning the ability of one country to carry out a particular economic activity more efficiently than another—took hold in the global economy and countries began to narrow and

streamline production. With comparative advantage, a country must weigh the opportunity costs of producing items they make less efficiently to determine if it is of economic benefit to keep producing them. Most times, the answer is no. These cost/benefit analyses have led to specialized economies and specialized production throughout the world. It's a phenomenon not only occurring with goods like food or cars but also pharmaceuticals and medical equipment. As Rodriguez, Luke, and Osterholm (2017) explain, "The global economy has been favored by the exploitation of comparative advantage and a tighter management of supply chains. Inventories are kept to a minimum. Virtually no production surge capacity exists. As a consequence, most markets depend on the timely delivery of many critical products (such as pharmaceuticals, medical supplies, food and equipment parts) and services (such as communications support)."

While this is economically beneficial, the new structure of our global economy increases the risk of catastrophe. It is important to note, however, that not all supply chains are created equal. A disruption in the automobile supply chain does not have the same impact as a disruption in the supply chain of insulin. Disruption in one means a shortage of cars on the market. A disruption in the other means a shortage or unavailability of vital insulin for diabetics. The supply chain disruptions we are focused on in this paper are ones like the latter. Ones that would create significant, life-threatening circumstances if they were disrupted by a pandemic. When the public—or government officials for that matter—think about pandemics, supply chains rarely come to mind. Instead, the focus of pandemic preparedness and response is centered on morbidity and mortality, as well as disease control measures. Possible supply chain disruptions rarely enter the conversation. But they should. Disruptions resulting from a pandemic could lead to increases in mortality, some of which would be preventable with the right supplies and equipment. To this point, in his 2017 book titled *The Deadliest Enemy: Our War on Killer Germs*, Osterholm explains that "virtually all of our generic lifesaving pharmaceuticals are manufactured overseas" (p. 63). In addition to overseas production of pharmaceuticals, the majority of N95 masks, which are respiratory masks designed to filter out airborne particles, are made in China.

The impact of Hurricane Maria on the supply of small bag IV saline provides a glimpse into the potentially devastating effects of disruptions in critical supply chains. The hurricane knocked out

electricity to the island, which effectively shut down the three Baxter International plants located there. The IV saline bag shortage that followed meant that nurses in some hospitals had to administer drugs slowly through syringes, which is a time consuming and much more dangerous process (Sheridan, 2017). Other hospitals even resorted to the use of Gatorade for patient rehydration (Fox, 2018). With the vast majority of our pharmaceuticals and medical supplies produced outside the United States, any disruption in the supply chain could have dramatic and deadly consequences during a pandemic.

How Does Disruption Occur?

The most obvious way that pandemics impact supply chains is through absenteeism. Absenteeism refers to the rate at which employees are missing work either because of their own illness or because of the illness of a family member. During a pandemic it is inevitable that the rate of absenteeism in the workforce will rise. The impact, however, will depend on the ability of the company or sector to cope with the reduced workforce.

A report from the National Infrastructure Advisory Council in 2007 found that 87% of health sector emergency service workers are deemed critical. This means that with an employee absentee rate of 13% or above, emergency services would begin to break down. In the transportation sector, the majority of supplies are transported via rail or truck. With an absenteeism rate of roughly 14%, the largest rail yards in the United States would begin to experience a backlog, resulting in noticeable delays (DHS, 2015). With regards to the trucking industry, its highly decentralized nature means that the majority of trucks are run by small companies. These companies are especially vulnerable to absenteeism and as few as five sick employees could halt the company's operations entirely (DHS, 2015).

At any given time, there are roughly 60,000 large cargo ships transporting freight across the world (Osterholm, 2017). Additionally, aircrafts transport 9.54 million tons of freight globally every year (Osterholm, 2017). Components of our critical medical infrastructure are almost always in transit. This danger is eloquently summed up by Osterholm (2017) as he explains, "Today, we live in a just-in-time-delivery economy where virtually nothing is warehoused for future sales, let alone stockpiled for a crisis situation. Not even the parts and components necessary to manufacture these critical supplies are warehoused and stockpiled. When a rolling

global pandemic takes its toll on the working population of a city in Asia, for example, the products and supplies that come from that city—and perhaps nowhere else—that we need to respond to a rapidly growing pandemic will not be available. No amount of money can buy something that doesn't exist" (p. 53).

Recommendations

7. Understand our critical supply chains

Supply chains are complex and often operate in the shadows. Few people think about the process that gets their food to the grocery store or, prior to Hurricane Maria, knew that almost half of America's supply of small bag IV saline was produced in Puerto Rico. The majority of the time, these supply chains involve multiple countries and transportation methods. In circumstances where products are made in one country or location, it is important that the United States looks into ways to diversify production to reduce the risk of supply chain disruption. This diversification cannot take place, however, until we fully understand where our critical supplies are made. Analysis should be conducted to first determine which of our supply chains are critical and then outline all of the components, choke points, and potential threats to those supply chains. Until there is identification of what our critical supply chains are and an understanding of how they operate, the United States will not be able to adequately prepare for potential disruptions.

TARGETING ANTIMICROBIAL RESISTANCE

The Scale of the Problem

Antimicrobials, or agents that kill microorganisms, changed the course of human disease history. The discovery and development of antibiotics is arguably one of the great achievements in human history. Prior to the discovery of penicillin in 1928, even a small scratch could be life-threatening. Following the discovery of penicillin and the development of numerous other antibiotics, infections that used to be deadly became treatable. For decades, people around the world have used antibiotics, and more recently antivirals, giving little thought to the genetic mutations occurring within the microscopic organisms. Today, antimicrobial resistance (AMR) has become endemic in almost every country and, if not addressed, society could be heading back into a world where the smallest of scratches could be deadly.

AMR is a result of the selective pressure placed on bacteria, viruses, fungi, and parasites due to their interaction with antimicrobials. As Ferri et al. (2017) describes, “AMR became an unavoidable

result of the fragile balance between bacteria and drugs with bacteria having infinitely more opportunities to gain resistance genes than humans have to create new antimicrobials…" (p. 2858). Ultimately, the rise of AMR was inevitable, due in large part to bacteria's ability to mutate more quickly than our ability to discover and develop new drugs to fight them.

It is estimated that in the United States, approximately 2 million people annually are infected with an antimicrobial resistant bacterium. Of these cases, roughly 23,000 people die as a direct result of that infection (CDC, 2017). On a global scale, the numbers become even more alarming. It is estimated that AMR is responsible for approximately 700,000 deaths worldwide every year (MacIntyre & Bui, 2017). Economically, in the European Union (EU) alone, costs associated with AMR are estimated at €1.5 billion annually (WHO, 2015). These numbers are expected to grow if nothing is done to reverse the trend.

One of the greatest worldwide AMR problems is multi-drug resistant (MDR) tuberculosis (TB). Each year, there are approximately 450,000 new cases of MDR-TB, with 150,000 of those cases resulting in death (Cole, 2012). Microbes are winning the battles in humans, animals, and the environment. A study of the New York City subways showed that 27% of environmental samples (swabs of subway surfaces) contained AMR bacteria (Afshinneko et al., 2015; Ferri et al., 2017). The scale of this problem is vast and the implications are serious.

What causes AMR?

There are a number of factors that have contributed to AMR, but the biggest and most important is the misuse and overuse of antibiotics. Over the years antibiotics have often been prescribed for viral infections or if a diagnosis is unknown. In many countries throughout the developing world, it is even possible to obtain antibiotics without a prescription (WHO, 2015). "Regulation of the use of antimicrobial agents is inadequate or poorly enforced in many areas, such as over-the-counter and Internet sales. Related weaknesses that contribute to development of antimicrobial resistance include poor patient and health care provider compliance, the prevalence of substandard medicines for both human and veterinary use, and inappropriate or unregulated use of antimicrobial agents in agriculture" (WHO, 2015). The area that experiences the largest misuse or overuse of antibiotics is neonatal care (Cole, 2012). In this sector of human health, antibiotics are often given before a diagnosis is confirmed, which results in 95% overuse (Cole, 2012). Reducing overuse in neonatal care could not only help slow

Deaths attributable to antimicrobial resistance every year by 2050

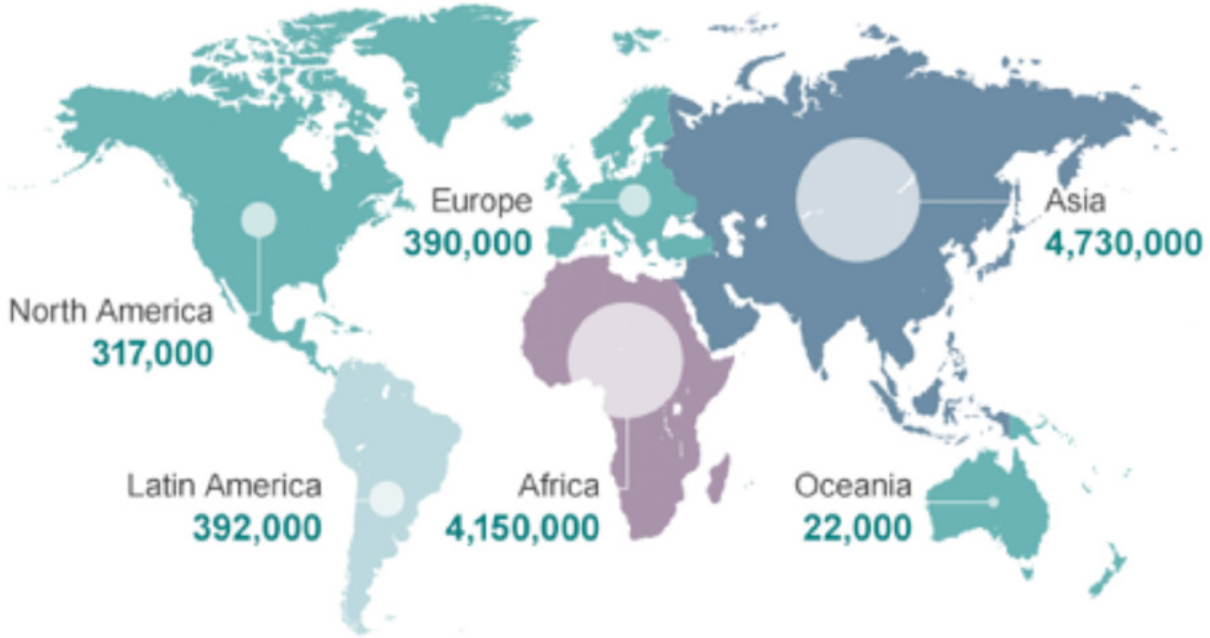


Figure 1. This figure shows the projected annual number of deaths from AMR by 2050.
(Source: Review on Antimicrobial Resistance 2014)

AMR, but it could also save millions of dollars per year (Cole, 2012).

The use of antimicrobials in agriculture is a particularly large problem. FAO (2016) estimates that in 2010 the livestock sector used 63,151 tons of antibiotics. In fact, 80% of antimicrobials in the United States are used in food animals and 70% of these are used for non-therapeutic, i.e. not medically necessary, purposes (Ferri et al., 2017). Additionally, countries like Brazil, China, and South Africa have seen a 99% increase in their consumption of antimicrobials (Ferri et al., 2017). Unregulated use of antibiotics in the livestock sector is a global problem, though the EU and United States have taken steps to reduce non-therapeutic use. Because of the scale of antimicrobial use in livestock, the United Nations (UN) argues that a One Health approach is vital to combating AMR.

Challenges Tracking AMR

While it has been determined that AMR is a problem in almost every country in the world, understanding the scope of the problem can be difficult. This is especially true in countries that lack adequate surveillance. A meta-analysis conducted by Tadesse et al. (2017) found that AMR data is not available for over 40% of countries in Africa, and even when data is available, the quality of the data may be lacking. From available data, however, it is clear that there is greater resistance to antimicrobials commonly used and less resistance to antimicrobials that are less commonly used. Thus, use of antibiotics is creating antibiotic resistant organisms.

As WHO (2015) points out, “Information on: the incidence, prevalence, range across pathogens and geographical patterns related to antimicrobial resistance needs to be made accessible in a timely

manner in order to guide the treatment of patients; to inform local, national, and regional actions; and to monitor the effectiveness of interventions." Even in local hospitals, near-real time AMR surveillance is needed to take timely corrective actions, so other patients and health care workers are not unnecessarily exposed.

This problem can become even more complicated when trying to track AMR in food production. It is well documented that large volumes of antibiotics used in livestock production leads to AMR agents in the environment (soil, etc.) and within the animals; what is less clear is if consumption of these animals leads to AMR in humans (Ferri et al, 2017). Proper cooking procedures should kill any bacteria, thus protecting humans from AMR transmission from food consumption, but bacterial persistence in the environment could lead to infection in humans. Additionally, in many parts of the developing world, it is extremely difficult to measure the extent of AMR in livestock populations.

AMR presents a significant global health challenge. As more bacteria become resistant, society inches closer to a world without antibiotics. In 2012 Margaret Chan, the former Director-General of WHO, stated, "...post-antibiotic era means, in effect, the end of modern medicine as we know it. Things as common as strep throat or a child's scratched knee could once again kill." Although some may be tempted to dismiss Chan's remarks as exaggerated, current statistics on AMR-related deaths demonstrate the growing extent of the problem. Without the development of new antimicrobials, a world without antibiotics will become a reality.

Recommendations

8. Increased investment in research, development, and production of new antimicrobials

Currently, microbes are developing resistance to antimicrobials faster than new drugs can be produced. This is partly because microbes have the advantage of short generation times, and partly because there is a lack of interest in developing new antimicrobials. Relative to other pharmaceuticals, the production of new antimicrobials is not as economically attractive to companies (Ferri et al., 2017). Additionally, for any pharmaceutical, development and production are the two most expensive parts of the process. If companies cannot anticipate sufficient profit margins, it is difficult to encourage them to spend the money to make the product. Although the WHO and the United States have begun to address AMR through the "Global Action Plan" on reducing AMR and "Combating

Antimicrobial Resistance National Strategy," respectively, more should be done to provide sound strategies and innovative financing models. The international community should enable effective public-private partnerships to develop new antimicrobials and, simultaneously, foster effective antimicrobial stewardship. Unfortunately, without the development of new antimicrobials, society will soon find itself in the post-antibiotic world described by Margaret Chan.

9. Create a stronger regulatory system for veterinary/farm use of antimicrobials

As discussed above, the use of antimicrobials in the livestock sector plays an important role in the rise of AMR. While countries like the United States and UK have taken steps to reduce non-therapeutic use in livestock, countries in the developing world are almost wholly unregulated. Complicating matters further, some high-income exporting countries like China are the largest users of antimicrobials in livestock, and regulations are not strictly enforced (Ying et al., 2017). The practice of "rent-seeking"—bribery, extortion, and discretionary redistribution of government funds for unethical purposes—in many developing countries also inhibits the ability to establish regulatory practices. While regulation in some countries is extremely difficult, governments and professional organizations should work with the veterinary and livestock production communities to help them understand the appropriate use of antibiotics and train them to instruct farmers on appropriate use also. Understanding how farmers are currently using antibiotics and educating them on appropriate use is central to reducing AMR in the livestock sector.

10. Decrease misuse and overuse of antimicrobials in human health

The livestock sector is not the only area experiencing overuse of antibiotics. Human medicine also has a problem with over-prescription or general misuse of antimicrobials. Both the medical community and the public should be educated on the appropriate use of antibiotics. With regards to neonatal care, standard of clinical care guidelines, institutional oversight protocols, and regulations should rapidly evolve, so that antibiotics are judiciously used until infection is confirmed by laboratory tests. While 90% of antibiotics used in the neonatal setting are unnecessary, early administration of treatment can be lifesaving in the other 10% of cases. Because of the importance and necessity of early treatment in these cases, there must be innovation in real-time surveillance and improvements in rapid diagnostics for newborns.

11. Understand that fighting AMR requires a One Health approach

AMR is a problem in humans, animals, and the environment. Addressing it in only one of these spheres is not sufficient to slow the development of resistance or mitigate the problem. The only way to have a real impact is to address all of the spheres at once through a One Health approach.

STRENGTHENING LEADERSHIP & COORDINATION

Our 2017 White Paper addressed the need to establish centralized leadership within the American preparedness and response enterprise. We extended our support for the idea put forth by the Blue-Ribbon Panel Study on Biodefense that authority should be centralized in the Vice President of the United States office, and that there should be clear lines of authority extending from there. While this remains a gap in America's ability to prepare for and respond to pandemics, whether that is vested within the Vice President or another high-level White House authority, we are now broadening the conversation to examine the need for strengthening international leadership and coordination. Most notably, there is a need for international organizations involved in pandemic response to develop a strategic direction, to understand the importance of communication during a crisis and develop steps and strategies to communicate effectively, and to create coordination between organizations and countries that are part of the preparedness and response effort.

First, in order to create effective pandemic response, the international community should develop a strategic direction and solidify response leadership. The development of a strategic direction requires all international organizations and national governments involved in response to develop a set of strategies, tactics, and values for pandemic response. Currently, the role of WHO in pandemic preparedness and response focuses on supporting member states in implementing their own national-level capabilities during an outbreak and strengthening these capabilities during the times between outbreaks. The UN operates in a similar manner to "help national authorities implement programmes with strong national ownership and adequate resources" (United Nations, 2017).

Institutions like the WHO and the UN are vital to creating a strategic direction for leadership in pandemic response. They should work in conjunction with FAO, OIE, and national governments to coordinate and mobilize response. Most importantly, it requires that well-respected institutions like these show national governments and the public what should be done when preparing for and responding to disease outbreaks and help to facilitate action when an outbreak occurs. A lack of strategic direction in leadership can lead to confused lines of authority and delayed response from international organizations and implementing NGOs. During the 2014 outbreak of Ebola, a lack of cultural understanding, insufficient medical equipment, supplies, and training, as well as confusion about which agency should lead the response, demonstrated the challenges of international response when there is a lack of direction and coordination.

Current international response would be even further complicated by the intentional release of infectious disease through an act of bioterrorism. With an act of bioterrorism, there is a clear malicious or criminal element, but the disease control and containment response would be similar. Thus, looking at an act of bioterrorism as a completely separate incident can undermine the ability to respond to naturally occurring outbreaks. Instead of treating preparation, prevention and response for bioterrorism as a separate and distinct challenge, it should be treated the same as a natural disease outbreak response with the additional element of a criminal or state party investigation with transparent reporting for attribution, requiring close coordination with host country law enforcement and security components during preparedness planning and response.

In addition to the connection between naturally occurring disease and bioterrorism, the United States and the rest of the world must recognize

the new era of synthetic biology and dual use research of concern. This is an era marked by all the positive and negative implications of a technology like Clustered Regulatory Interspaced Palindromic Repeats (CRISPR), which can be used to edit the base pairs of genes. A disease created with the use of CRISPR, if it were to be released intentionally or accidentally, could create a completely different scenario than a natural disease. These new pandemic and health security challenges should be accounted for when developing response plans.

In conjunction with a strategic direction, international organizations need to establish a communication strategy, using one individual as the crisis spokesperson, to help mitigate and contain fear during an outbreak. When facing a crisis, people develop their perception of the risk they are facing based on a number of factors. These factors include: past experience (Elder et al., 2007), feelings of control over the situation (Smith, 2006), and familiarity with the agent causing the crisis (Brug, Aro, Richardus, 2009). Thus, if people are faced with a disease they have no past experience with, feel powerless to protect themselves from, and have no knowledge or understanding of, it is a recipe for rampant and potentially destructive fear. Conversely, if it is a disease people have experience with and the last outbreak was mild or they feel that they have a limited chance of catching the disease, it will be difficult to motivate people to take action to protect themselves. In both of these scenarios, a communication strategy and an effective spokesperson are vital to leading and coordinating response.

As Peter Sandman (1993), one of the leading scholars in risk and crisis communication argues, there are two important parts to risk communication: scaring people and calming them down. Which one of these strategies international organizations will need to use during a pandemic will depend on the disease and risks, but most likely, they will be working to calm people down. It is the role of the spokesperson to build trust between themselves, the organization they represent, and the public. Information about the outbreak and how people can protect themselves should be communicated in a clear and timely manner. Having information about how the outbreak is progressing, setting realistic expectations that information will evolve until the outbreak is contained, and actions that can be taken to protect themselves will help to alleviate some of the fear surrounding the outbreak.

A realistic challenge to creating good leadership, however, is governmental corruption and lack

of public trust in many developing countries. Because of widespread governmental corruption, many citizens of developing countries do not trust government officials and will not be receptive to communication coming from these individuals. For this reason, it is important to include religious leaders, tribal leaders, and traditional healthcare practitioners in message dissemination. If these groups of individuals can be encouraged to spread the message, it is more likely that the public will listen and respond accordingly.

Defining Good Leadership

The following characteristics should be present in order for leadership to be qualified as good: 1) clear lines of authority and responsibility; 2) responsibility and authority to compel on-the-ground action; 3) an absence of responsibility without authority; 4) ability to bring multiple groups together in collaborative effort; 5) clear and consistent communication with the public; and 6) clear and consistent two-way communication between organizations, agencies, and governments participating in response.

The first three characteristics of good leadership, all refer to establishing responsibility and authority. Clear lines of responsibility and authority are vital to any effective response. If agencies, organizations, and governments do not understand their roles and who they report to, it will be difficult for them to mount the kind of response needed to control an outbreak of infectious disease. Each member of the response team should know their responsibility for the response effort and have the authority to carry it out; thus, they should have the ability to compel action on the ground.

Lastly, and arguably most important, individuals cannot be given responsibility for response without also being given the authority and resources to carry out those responsibilities.

Good leadership also requires clear and consistent communication with the public. During a crisis, it is important to keep the public appraised of the situation. If the public hears different messages from different groups—or even from two people within the same organization—it is going to erode trust in leadership. Clear and consistent two-way communication between all the organizations involved in response is extremely important to good leadership but particularly important for good coordination. All agencies, organizations, and governments involved in response should be able to maintain open lines of communication throughout the response. This is important to problem solving any challenges that arise, keeping supply chains open and running efficiently, and coordinating the general logistics of a large response. Without all the characteristics discussed above, it is not possible to have a proper and effective response.

Recommendations

12. Create a Strategic Direction for Leadership

Our first recommendation is for the international community to establish a tiered set of response framework and plans, outlining the strategic direction for leadership during pandemics. Plans should outline the following: 1) the lead agency and their responsibilities; 2) supporting agencies and organizations, responsibilities, and triggers for supporting agencies to surge quickly when response needs go beyond public health; 3) roles of the national and local governments and all implementing NGOs; and 4) where resources will come from to support the response.

Tiered response plans should encompass not only member state governments but also multinational organizations. The plans should identify collaboration and integration points tiered from multinational and regional organizations to national and local governments. WHO, FAO, and OIE should continue to update preparedness plans and provide public health, animal health, and regulatory guidance, but they should also establish trigger points for supporting agency activation. Trigger points are important for an effective, whole-of-society response.

Similar to a previous recommendation from the Scowcroft Institute of International Affairs, we call for the United States to establish an international response framework analogous to the national response framework for domestic disaster response. This international response framework should clearly identify USAID's Office of Foreign Disaster Assistance (OFDA) as the lead for the international response to epidemics and pandemics requiring United States government interagency involvement and coordination.

Additionally, the response framework should specifically address bioterrorism, biowarfare, and accidental release of biological agents. A section detailing the threats posed by dual use research of concern and diseases produced from synthetic biology should also be included. Areas of the response plan addressing intentional use of biological agents should support United Nations Resolution 1540 and the Biological and Toxin Weapons Convention (BWC). Although the public health response may be similar, the framing of intentional use is different and will require close coordina-

tion with law enforcement and security authorities during preparedness planning and response. The United States should lead diplomatic efforts with strategic international partners and member states of the United Nations Security Council. It is important to remind member states of their obligations under BWC and require the timely and transparent initiation of outbreak investigations and reporting. WHO, FAO, OIE, and UN member states should serve as supporting agencies in response efforts.

13. Develop Communication Strategy

Proper communication plays an important role in mitigating irrational fear, instructing people on what actions to take to protect themselves and their families, and maintaining continuity of operations. Each organization that is involved in pandemic response should develop a plan for their internal communication. Additionally, WHO should develop an effective strategy for communication between agencies, organizations, regions, and governments and with the public. Having this overarching strategy will help to decrease confusion and minimize any unnecessary panic.

14. Maintain United States Involvement

Our final recommendation for strengthening leadership and coordination is that the United States should remain involved. The United States has a great deal of infrastructure, expertise, and capabilities that are important to creating effective response. If the United States does not remain engaged with the international community, it will be more difficult to mount an effective and timely response. Diseases do not respect borders. If the next pandemic is caused by influenza, or something similar, it will be impossible for the United States to keep the disease out. The more the United States does to prevent, detect, and respond to outbreaks with pandemic potential internationally, the more time the response enterprise will have to implement domestic preparedness plans for the inevitable spread to the United States.

MAINTAINING UNITED STATES INVOLVEMENT IN PANDEMIC PREPAREDNESS & GLOBAL HEALTH SECURITY

Pandemics are a Global Problem

Pandemics, as the name implies, are a global problem. Disease is a microscopic enemy that can travel around the world inside human bodies before there are any outward signs of trouble. Diseases can travel by car, rail, ship, airplane, or foot. It can travel with passengers or it can travel with cargo.

Even when complete border shutdown does not occur, pandemics can have a large global economic impact. During the Ebola outbreak, the impact on Guinea's GDP was estimated to be a 1% decrease (Hamilton, 2014). This is due in part to disruption in the tourism industry, but also because the border closures in West Africa had a negative impact on trade. Additionally, it is estimated that Toronto

lost $1 billion as a result of the SARS outbreak, and this is without a large disruption in goods trade (CBC News, 2003). The important takeaway from these examples is that disease has a significant economic impact and this impact will only be exacerbated by closing borders.

Preparing the International System for Response

The international community should ensure that the international system is willing and able to respond to disease outbreaks throughout the world. Pandemic preparation and response cannot fall by the wayside during the time between pandemics. Each country should be aware of its response capabilities, who will serve in response leadership roles, and which entities from the national government will work with international organizations like WHO and the UN. Understanding these elements requires consistent and meaningful discussion, financial commitment, and training. All players in the international system have an obligation to know where they fit into response and to be prepared.

Strengthening the Global Health Security Agenda

The Global Health Security Agenda (GHSA) was launched by the United States in 2014 as a five-year initiative to increase global preparedness and response capabilities for infectious disease outbreaks. The GHSA has the goal of making the world safe and secure from infectious diseases of any cause (natural, accidental, and intentional). The GHSA is implemented through 11 action packages to improve capabilities to prevent, detect, and respond to outbreaks. Importantly, the GHSA goes beyond traditional public health to include animal health and biosecurity, antimicrobial resistance, mitigating zoonotic disease spillover from animals to humans, creating emergency operations centers, laboratory biosafety/biosecurity, and a requirement to work with law enforcement.

To date, the United States has been the largest contributor to the initiative, but other countries are also making significant contributions. However, with only one year left before coming to the end of the five-year milestone, there is no sign that the Trump Administration plans to renew the initiative. The former Secretary of Health and Human Services (HHS), Tom Price, announced to the World Health Assembly in May 2017 that the United States remains committed to GHSA, but many are concerned GHSA will not survive without significant United States involvement and support (Nuzzo, Ciero, & Inglesby, 2017). Some argue that GHSA can only work in stable, middle-income

countries because failed states or countries going through massive shocks, such as famine will not have the motivation or ability to conduct the Joint External Evaluation assessments (JEE). While this is true, GHSA has increased the ability to identify specific gaps in the diseases preparedness system with a goal to target available resources and demonstrate accountability to donors. This is the next step in the right direction....

Recommendations

15. Change the way infectious disease problems are framed

Understanding the potential impact of a pandemic can be difficult and the impact can vary based on the assessment measurement used (morbidity, mortality, economic impact, adjusted disability life years, etc). Despite recent outbreaks, it continues to be difficult to convince people and governments to invest in preparing for the next pandemic. The international community needs to reframe the conversation from something that might happen to something that will happen with catastrophic economic impacts that could erode regional stability and international security. Additionally, combining the conversation of bioterrorism and potential negative impacts of synthetic biology with the conversation about pandemic preparedness and response could help to encourage investment.

16. Increase international response capacity

In line with changing the way problems are framed is increasing international response capacity. As the 2014 Ebola, 2016 Zika, and the ongoing plague outbreak in Madagascar demonstrate, large infectious disease outbreaks requiring international support are becoming more common. WHO has made progress in addressing Ebola after-action findings, to improve their ability to support member states, and to scale up their own capabilities to react more quickly to disease outbreaks. However, continual evaluation of response effectiveness, quality, and ability to effectively work with regional WHO organizations is important to make sure that these abilities are fully established, resourced, and sustained.

All countries, including but not limited to the United States, should continue to make financial contributions to international health security that increase the capacity of vital organizations to respond to international disease emergencies. Member states should establish a reserve public health corps that can provide personnel surge capacity. Emergency funds should be readily available for all response needs. Delays in response because WHO, responding member states, and the United States response teams do not have access to funds coupled to a functioning international response framework could be the difference between containing an outbreak at its source and a pandemic.

ENSURING THAT THE PRIVATE SECTOR IS FULLY INVOLVED

The challenge of preparing for and responding to pandemics remains a significant international health challenge. Despite the obvious need, the world is at a crossroads with some large country contributors—notably the United States—seeking to decrease investment in global health. There is also a problem of discrepancies between the amount of investment pledged by a country and the amount that is actually given. As government contributions decrease, it is important that private industry helps fill the gap. Currently, around $160 billion is spent on health research and development (R&D) annually (Schneider, Villasenor, & West, 2017). The majority of this R&D is focused on the developing world, though neglected diseases receive the least amount of funding from private investors (Schneider, Villasensor, & West, 2017). Additionally, pharmaceutical companies serve as the major investors, with non-Western companies, notably those from China and India, providing substantial increases in investments.

While $160 billion may seem like a large number, it is not nearly sufficient enough to prepare for the threat of a pandemic. Approximately 50% of that funding goes to research on HIV/AIDS, tuberculosis, and malaria (Schneider, Villasensor, & West, 2017) and there is virtually no interest in funding R&D in emerging or potentially pandemic diseases. This lack of investment is particularly troubling at a time when the United States is significantly decreasing their commitment to global health. In the FY2017-2018 Appropriations request, there was an 18% decrease in the amount requested for HIV, 100% decrease in funding for Family Planning/Rural Health, 17% decrease for the Global Health Fund, and a 12% decrease in funding for Global Health Security (Kaiser Foundation, 2017). Importantly, the FY2017-2018 request shows a cut in every sector of global health ranging from 14% to 100% (Kaiser Foundation, 2017).

The large-scale cuts seen in the FY2017-2018 request reflect a significant challenge for pandemic preparedness and response. If funding is not available to prepare for and respond to outbreaks, it will be impossible to protect the world from a major disease outbreak. This is why private industry involvement is increasingly important. Funding needs for pandemic preparedness and response are not currently being met and the gaps and challenges will become worse as governments decrease funding.

Most companies take on substantial financial risk to contribute to pandemic preparedness, which is why they do not tend to make these investments. Take vaccine development as an example: Vaccines are expensive and time consuming to produce. This is particularly true when talking about new vaccines. As a concept paper from Global Alliance for Vaccines and Immunization (GAVI) explains, “High fixed costs and steep learning curve make new vaccines relatively more expensive, as the investments in R&D and production facilities need to be paid off and optimum production techniques need to be perfected to bring down variable production costs.” The average total cost to develop a vaccine is estimated to be between $200 million and $500 million (Serdobova & Kieny, 2006).

Further complicating the problem is that there is no market for the products (e.g., vaccines, antivirals, etc.) if there is no pandemic. This means spending large sums of money to create a pharmaceutical intervention that will likely never offer a chance for economic profit. Because of this, the incentive structure needs to change if private companies are to invest their resources in global health.

In addition to pharmaceutical and biotechnology companies that have an obvious role in pandemic preparedness, almost all companies should have plans for their own continuity of operations and to protect their employees and support their communities in the event of an epidemic or pandemic. Some multinational corporations, particularly those in energy exploration and extraction have operations in geographic infectious disease hot spots and are leading by example through good corporate citizenship. Their continuity of operation plans are not only in place to protect their own employees, but they also support health security institutional capacity building in host countries. Resilient communities in disease hot spots are essential to international health security.

Recommendations

17. Greater economic investment from governments—not just the United States—in research, development, and production of vaccines, antivirals, therapeutics, and other pharmaceutical interventions

The cost of developing new vaccines and treatments are extremely high. Direct cost, opportunity costs, regulatory hurdles, technical challenges, and legal risks are barriers to companies developing vaccines and treatments for diseases with pandemic potential, because they may never earn a profit—or even break-even—from their product investments. In order to offset some of the direct and opportunity costs, governments should contribute economically and establish effective policies to incentivize private sector investment. United States government acquisition and contracting mechanisms should account for pharmaceutical and biotechnology business best practices and optimize use of transaction authorities from Congress. Congress and the Executive Branch should also provide multi-year appropriations and clear execution plans, similar to the original Project Bioshield Act of 2004. While not covering the majority of costs, it would help to offset some financial risk companies take on during development, production, and licensure, and it would also signal to the private sector that the United States and international community are truly interested in and committed to the development of pandemic countermeasure products.

18. Private industry should have a seat at the table.

The challenge faced by the international community with regards to pandemic preparedness, detection, and response is larger than any one country can handle, and the United States can no longer afford to be the only country with significant appropriations for biodefense and pandemic medical countermeasures development and procurement. The United States is not the Strategic National Medical Stockpile for the international community. Vaccines and pharmaceuticals are high cost and high-risk investments. As government contributions decrease, the gap needs to be filled by the private sector and philanthropic donors. However, if the private sector is going to commit its resources to pandemic preparedness and response, they should be given a seat at the table and incentivized to participate in requirement setting, financing, regulatory, and contracting policies. Providing the private sector with a role throughout the process will help grow confidence and alleviate concerns about risks associated with public/private partnerships. The Coalition for Epidemic Preparedness Innovation (CEPI) is a step in the right direction and should be supported by donor governments and philanthropic investors.

CONTINUING FUNDING FOR DISEASE DETECTION & PREVENTION PROGRAMS

What is the importance of disease detection and prevention programs?

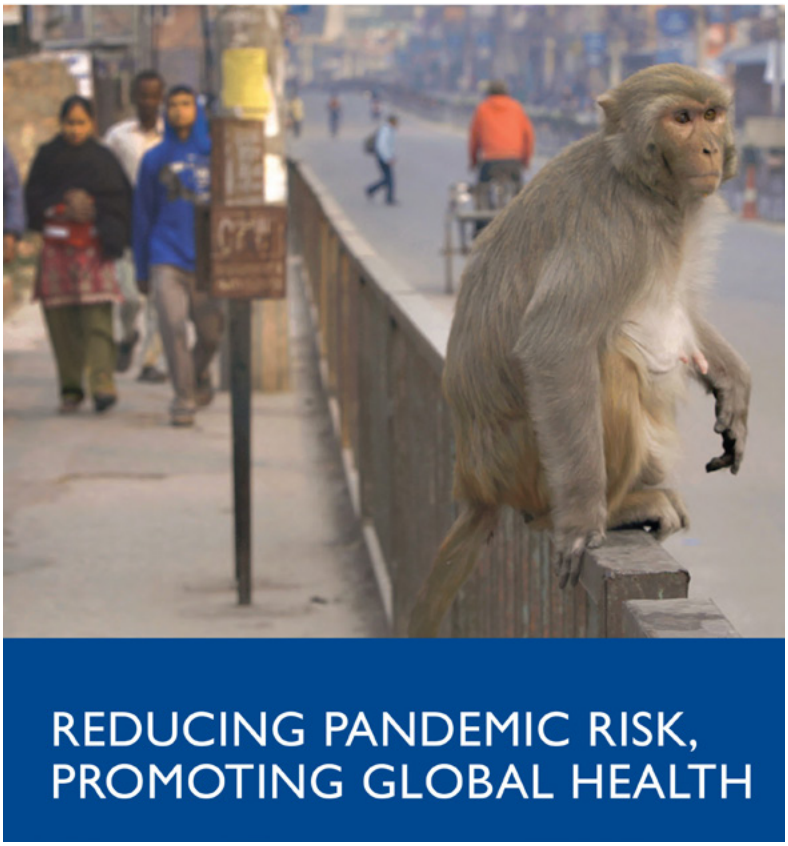
There are a handful of major United States funded disease detection and prevention programs currently operating internationally. They include the CDC Global Disease Detection (GDD) Program, USAID Emerging Pandemic Threats (EPT) Program, Department of State Biological Engagement Program, and the DOD Global Emerging Infections Surveillance and Cooperative Biological Engagement (CBEP) Programs. Along with the CDC GDD that maintains international laboratories for early warning, DOD also operates long-standing Army and Navy overseas research laboratories that provide unique laboratory and biosurveillance capabilities in host countries and surrounding regions, facilitating international collaboration and protection of deployed United States service members and allies.

PREDICT is just one program within the Emerging Pandemic Threats (EPT) program at USAID. Overall, the EPT program focuses on various ways to strengthen disease prevention, detection, and response capabilities in developing countries, through their PREDICT, PREVENT, IDENTIFY, and RESPOND programs.

Out of the four EPT programs, however, only PREDICT is focused on identifying deadly diseases before they spillover into the human population. DOD's Defense Advanced Research Agency (DARPA) announced a new initiative to prevent spillover of emerging pathogenic threats — PREEMPT — using innovative systems biology approaches to enable near-real time surveillance and interventions in high risk countries, and CBEP is placing more emphasis on establishing laboratory institutional capacities in priority, high-risk countries.

PREDICT currently works in 30 countries, using the One Health approach and minimizing pandemic risk through a number of areas. These areas are: surveillance, laboratory platform, behavioral risk, capacity strengthening, modeling and analytics, and information management (UC Davis, 2017).

As a follow on to PREDICT, the Global Virome Project (GVP) has been proposed by USAID and other NGOs. The proposed project is a 10-year public/private consortium with the goal to identify unknown viruses from around the world. By attempting to identify and categorize viruses from around the world, the GVP is working to determine what viral threats the world is facing before they cause a major pandemic. The goal of the program is not only to identify unknown viruses, but also host ranges and behaviors that lead to spillover.



The GVP anticipates six key benefits from the program. The first is that the project will characterize the geographic scope and host range of viruses. Through the work of the project scientists will have a better understanding of reservoirs and transmission dynamics. The second key benefit is that GVP can identify behaviors that cause spillover and implement mitigation strategies. Third, the project can monitor the movement of viruses across regions. Fourth, the project will allow countries and international organizations to establish global surveillance networks and strengthen local disease surveillance capacity. Lastly, the GVP is expected to identify "transmission

and pathogenicity markers" for viruses considered high risk and help establish legal and regulatory framework for sharing this data.

While USAID and DOD are supporting the most innovative disease detection and prevention programs as envisioned by the National Strategy for Biosurveillance, there is a need for additional innovation, high-risk host country institutional capacity building, and resources focused on identifying potentially deadly diseases before they spillover into the human population. The vast majority of emerging diseases are of zoonotic origin and often experience contact with humans on several occasions before they are able to make the jump to human-to-human transmission, requiring a One Health approach. Identifying these viruses and mitigating the risk they pose to the human population is vitally important to pandemic preparedness and global health security into the future.

Recommendations

19. Continue funding for innovative biosurveillance, detection, and prevention programs.
Our recommendation is simple: continue funding innovative infectious disease detection and prevention programs along with risk-based investments in host country institutional capacities to realize near-time biosurveillance and situational awareness as envisioned in the National Strategy for Biosurveillance. This is vital to enable rapid response and focused preparedness investments. These programs are countries' first line of defense against the next pandemic. If scientists can identify diseases before they reach the human population, millions of lives may be saved. But these programs cannot operate without funding commitments from the United States government. The United States should make these programs a priority.

CONCLUSION

When scientists, policy-makers, and the lay public alike ask the question: “Are we ready for the next pandemic?” the answer is always a qualified “No.” No, the world is not ready for the next pandemic, as demonstrated by large-scale disease outbreaks over the last decade, but countries are getting closer. But, countries’ is getting closer. The work of scientists and policy-makers concerned with infectious disease outbreaks have helped develop new ways to monitor, detect, and respond to disease. The international community has worked hard to learn from the mistakes of past responses and correct them.

Despite these improvements, there is still a long way to go before the international community is able to say, “Yes, we are prepared.” This White Paper examines several areas that we believe are vital to strengthening pandemic preparedness and response. Most importantly, however, the United States and the international community should remain committed to pandemic preparedness.

It is likely that the next international crisis will be a pandemic, and by following the recommendations laid out in this paper, the United States and the international community will move one step closer to swift and effective pandemic preparedness and response.

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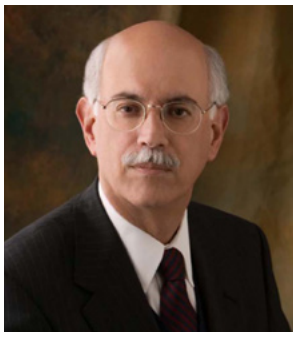

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