

Taiwan's Public Health Emergency Preparedness Programs 10 Years after SARS

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REPORT ON TAIWAN'S PUBLIC HEALTH EMERGENCY PREPAREDNESS PROGRAMS 10 YEARS AFTER SARS

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EXECUTIVE SUMMARY

The Center for Biosecurity of UPMC is pleased to provide this review of public health preparedness in Taiwan, which was conducted initially at the request of Minister Wen-Ta Chiu, Taiwan Department of Health, when he visited the Center in August 2011 and later under an open-bidding contract. The purpose of this assessment is to document the noteworthy progress that has been made since the SARS outbreak in 2003, identify the strengths of Taiwan's public health preparedness systems, and recommend possible new or complementary approaches to improving preparedness and continuing to strengthen existing systems in advance of a future epidemic.

This assessment was derived from background research on the origins, history, and current structure of Taiwan's public health and healthcare systems conducted by reviewing pertinent literature, government reports, and discussions with Taiwanese colleagues and by a week-long research visit to Taiwan that included extensive bilateral briefings with senior government, public health, and medical officials.

Over the past 15 years, Taiwan has experienced several major outbreaks of infectious diseases, including Enterovirus 71, SARS, and 2009 H1N1 influenza. These 3 outbreaks illustrate the national urgency of and rationale for building strong preparedness systems and plans to control highly contagious disease outbreaks. Each outbreak spurred investments to improve response to epidemics and yielded systems that have proven useful in subsequent outbreaks.

FINDINGS AND RECOMMENDATIONS

Taiwan has made many impressive gains in boosting its national preparedness for public health emergencies. Over the past 10 years, the Department of Health (DOH) and the Taiwan Centers for Disease Control (CDC) have built a number of important and robust programs aimed at providing earlier detection and controlling the spread of infectious diseases. Indeed, many aspects of these programs should be emulated by other countries committed to improving public health preparedness.

Comparing Taiwan's current state of readiness with its readiness levels 10 years ago, it is clear that the country has made concerted and focused efforts to advance the health of its citizens and its critical public health preparedness programs. For example, Taiwan has achieved success in:

- improving collection of disease surveillance data;
- running a state-of-the-art Epidemic Intelligence Center that can integrate, analyze, and report on surveillance data from a variety of diverse sources;
- creating a functional network of laboratories that can perform diagnostic tests and rapidly report results;

- establishing a medical network that includes 6 respected Regional Commanders who can provide expert advice and recommendations to DOH and CDC on medical response and disease control issues in the event of an outbreak;
- exercising systems to practice response activities and to regularly test readiness levels;
- raising general awareness of the public and international travelers of the risks of infectious diseases and good practices for controlling transmission; and
- investing in a domestic vaccine manufacturing capability to help ensure that Taiwanese people have access to influenza vaccines, even during times of worldwide surges in demand for vaccine.

In addition to the many essential preparedness programs established over the past 10 years, Taiwan is fortunate to have dedicated leaders and experts in government who are committed to improving national readiness for disease outbreaks. Taiwan's government servants who are responsible for these issues have a strong sense of purpose, and key personnel at all levels recognize that the systems will be challenged by new infectious disease outbreaks in the future.

The World Health Organization (WHO) and infectious disease experts and researchers around the world understand the serious challenge posed by emerging zoonotic infectious diseases, which include both new pathogens and mutated versions of existing pathogens. Therefore, it is critical in Taiwan and elsewhere to give priority to the continuing improvement of existing public health preparedness systems and programs.

This report proposes a range of suggestions for consideration and review by the DOH as it seeks independent views on possible improvements to existing systems. Taking into consideration its own priorities and resources, the DOH may wish to consider the following activities:

- Exploration of the use of benchmarks to measure progress in building national preparedness;
- Maintenance of modern technical capabilities in its surveillance and laboratory diagnostic systems;
- Analyses to assess current personnel levels and future personnel needs;
- Continuing assessment of the contents and adequacy of the national stockpile;
- Review of how the current system of designated isolation hospitals would be tested if challenged by a highly contagious and fast-spreading infectious disease outbreak, and ways of bolstering critical care capabilities for infected patients;
- Continued planning for scarce resource scenarios;
- Consideration of the benefits of the current airport quarantine strategy;

- Preservation of domestic capacity to manufacture vaccines for yearly use as well as in a crisis by further strengthening the current public-private relationship between government and the local vaccine producer;
- Assessment of Taiwan's legal framework for response to communicable disease outbreaks to permit flexible decision making to minimize the spread of disease while effectively caring for infected patients;
- Expansion of tabletop exercises and scenarios to include political leaders so as to increase political support and public awareness of the importance of public health emergency preparedness programs; and
- Further publication of the many successes and lessons learned in Taiwan following the 2003 SARS outbreak so as to engage with the international community on these important topics.

CONCLUSION

The above suggestions reflect the fact that preparedness for public health emergencies is not an end state, but rather an ongoing commitment to support the people, information systems, technologies, and other assets that contribute to overall public health resilience in the face of infectious disease threats. We encourage Taiwan to maintain the state-of-the-art capabilities that will protect the people of Taiwan from future public health emergencies.

REPORT ON TAIWAN'S PUBLIC HEALTH EMERGENCY PREPAREDNESS PROGRAMS 10 YEARS AFTER SARS

THE IMPORTANCE OF ASSESSING TAIWAN'S PUBLIC HEALTH EMERGENCY PREPAREDNESS PROGRAMS

The SARS epidemic was transformative. It alerted governments to the acute and prolonged health, economic, and social impacts that infectious diseases can have. The global outbreak prompted many governments, including the government of Taiwan, to examine whether they had the plans, policies, resources, and expertise to protect their people in the face of emerging infectious disease threats and to invest in improving these areas. Taiwan, like the rest of the world, was challenged again in 2009 during the H1N1 pandemic. Other infectious disease threats can be expected to emerge and reemerge, but often in unpredictable ways. The purpose of this assessment is to take account of the progress that has been made since the SARS outbreak, to identify the strengths of Taiwan's public health preparedness systems, and to recommend ways to further improve such systems in advance of a future epidemic.

Over the past 15 years, Taiwan has experienced several major outbreaks of infectious disease. In April 1998, an outbreak of hand, foot, and mouth disease, caused by Enterovirus 71, began. The total reported cases reached 129,106, which were estimated to be only 10% of the actual number of cases. By the end of the summer, 78 young children had died as a result of the disease.¹ Patients flooded emergency rooms and outpatient facilities, and many children were admitted for observation. A portion of admitted patients were moved to intensive care units after developing complications including pulmonary hemorrhage and pulmonary edema. The health system was additionally challenged by the lack of any antiviral treatment for Enterovirus 71. The outbreak caused worry and confusion among the population, particularly because some atypical deaths were caused by a disease that had not previously been known to be lethal.² Many changes were implemented following the outbreak. The government of Taiwan invested in developing a vaccine and increased laboratory capacity and testing for all enteroviruses.

In 2003, Taiwan experienced the third largest SARS epidemic, after mainland China and Hong Kong, with 346 confirmed cases and 73 deaths.³ At the epidemic's peak, there were 20 confirmed cases per day, but many more suspected cases were being reported: up to 90 per day. The first case was imported from Guangdong province in late February before the World Health Organization (WHO) issued its first alert. Approximately 2 dozen cases were imported from mainland China and Hong Kong over the course of the epidemic, but the vast majority of cases were attributable to local spread within hospitals in Taiwan. The largest hospital outbreak occurred at Hoping Hospital, where 43 healthcare workers were infected. On ward B8, 15 of 24 staff (62%) became infected. Hoping Hospital was closed to new patients, and hospital personnel were placed on home quarantine. But prior to these measures, the outbreak had spread from Hoping Hospital to several other hospitals. In total, during the epidemic, 131,132 people

(50,319 close contacts and 80,813 travelers from affected areas) were placed in quarantine.³ The economic loss attributed to SARS in Taiwan was estimated at 0.49% of Taiwan's GDP in 2003, or approximately \$1.5 billion.⁴

The SARS epidemic highlighted a number of challenges, especially related to hospital infection control and timely reporting of cases. After 2003, Taiwan invested in many efforts to strengthen their infectious disease response capabilities. These included changes in laboratory biosafety standards and practices,⁵ a nationwide emergency department-based syndromic surveillance network,⁶ strengthened infection control practices, changed hospital accreditation, and education of the public to change behavior.

At the onset of the 2009 H1N1 pandemic, when WHO raised the influenza pandemic alert to phase 4, the Taiwan CDC convened the Central Epidemic Command Center (CECC), according to its Pandemic Response Plan. The CDC made H1N1 2009 an immediately notifiable disease and directed that all suspect patients should be hospitalized in isolation. Many of the surveillance and alert systems that had been introduced after SARS were applied during the H1N1 pandemic of 2009. On-board quarantine inspections were conducted on direct flights from North America in which passengers were encouraged to report flulike symptoms to quarantine officers. On-board screening was suspended after the first imported case was confirmed. Subsequent contact tracing revealed multiple imported cases from a variety of countries. Six weeks after the first confirmed case, virologic surveillance confirmed community transmission in Taiwan.⁷

Initially, during the spring wave of the 2009 pandemic, schools were closed when a single student case was identified. In the fall, the policy was changed such that only classrooms in which 2 or more students came down with suspected influenza in a 3-day period would have classes suspended for 5 days (the "325" rule).⁸ The number of class suspensions peaked in late November, when more than 2,000 classrooms were under suspension. By this time half of the students in elementary or middle school had been vaccinated, and the rule for class suspension shifted from "325" to "814," meaning that if more than 80% of the students in a class had been vaccinated for more than 2 weeks, class suspension was no longer indicated.⁹

The CECC began the process of acquiring H1N1 2009 vaccine at the beginning of June. Eventually, 15 million doses of vaccine, enough for 60% of the population, were purchased from Adimmune and Novartis. A vaccine priority list was developed during the late summer, in advance of a mass vaccination campaign that began in November. Healthcare workers were vaccinated first, followed by certain high-risk groups and school-aged children.¹⁰ On December 12, 2009, vaccination was made available to everyone, and a "National Immunization Day" campaign was conducted. Vaccination stations were set up in hospitals, clinics, department stores, and community centers.¹¹ Over 2% of the population was vaccinated on that one day. By the end of January, approximately 24% of the total population of Taiwan had been immunized. Special telephone lines were set up by local health departments to enable the

public to make appointments for vaccination. Vaccination stations were set up in airports and rail stations in February to vaccinate travelers during the Chinese New Year travel season.

To communicate with the public, Taiwan CDC provided daily and weekly updates of H1N1 statistics through its website. CDC and other government officials conducted press conferences and issued press releases when there was important news. Celebrities were recruited to make public health videos.¹² The CDC operated a 24/7 hotline for the public that received up to 3,000 calls per week. The CECC used an online publication to disseminate clinical information to healthcare providers.

These 3 outbreaks—Enterovirus 71, SARS, and 2009 H1N1—have spurred investments in improving response to epidemics and yielded systems that have proven useful in subsequent outbreaks. For example, systems built after SARS were employed during the 2009 influenza pandemic to monitor disease in the population.

The government of Taiwan is to be commended on the remarkable improvements that have occurred in its systems, policies, and practices for responding to emerging infectious diseases and public health emergencies. Yet, Taiwan, like all countries, continues to face a difficult task in protecting its population from emerging diseases. This assessment is intended to help identify the many public health preparedness gains that need to be preserved while advising additional ways to improve these systems to prepare for future epidemics.

CENTER FOR BIOSECURITY OF UPMC

Over the past decade, the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) has undertaken in-depth and independent evaluations of US public health emergency preparedness efforts and programs. As the leading US nongovernmental organization focused on these issues, the Center has insights into the relative merit of various government initiatives aimed at increasing preparedness, response, and community resilience to public health emergencies. The Center offers a unique interdisciplinary approach, providing expert advice in public health, medicine, infectious diseases, law, basic science, drug and vaccine development, and social sciences. Center staff members have extensive experience in government, public health practice, medicine, and other related fields.

The Center was founded by Dr. D. A. Henderson, a world-renowned expert in public health, infectious disease, and global health issues. Dr. Henderson has served as a leader of the WHO smallpox eradication program and subsequently held high academic posts at the University of Pittsburgh and Johns Hopkins University and taken leadership in the federal government on public health issues in the White House and the US Department of Health and Human Services. Dr. Henderson has also previously advised the government of Taiwan on infectious disease preparedness and response, particularly concerning pandemic influenza.

Research Team (see appendix for complete biographical information):

- Tom Inglesby, MD, Director and CEO*
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- Eric Toner, MD, Senior Associate
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- Ryan Morhard, JD, Associate

* Participated in the research visit to Taiwan

Methodology

The Center for Biosecurity conducted background research on the origins, history, and current structure of Taiwan's public health and healthcare systems, including how these entities have been governed and funded. This research was conducted by reviewing pertinent literature and government reports and engaging in discussions with Taiwanese colleagues.

A 4-member team (Inglesby, Cicero, Nuzzo, and Adalja) from the Center conducted a week-long research visit to Taiwan. The agenda of this visit included meetings with the Minister of Health, the Deputy Minister of Health, the Director General of Taiwan CDC, former leaders in the Department of Health and the CDC, and many government, public health, and medical officials in meetings arranged by the liaison of the Taiwan DOH. Logistics and coordination were provided by the Taiwan CDC. See Appendix B for the detailed agenda. During the visit the Center research team provided briefings to the Taiwan CDC on:

- US Preparedness Efforts for Public Health Disasters
- US Response to the 2009 H1N1 Influenza Pandemic
- Biosurveillance in the US: Current Approaches and Lessons Learned
- US Approach to Developing and Acquiring Medical Countermeasures for the Civilian Population

In addition, the Center team provided a briefing on Healthcare System Preparedness for Mass Casualty Events at a meeting with the Director General of Taiwan CDC and the 6 Regional Commanders. See Appendix C for the presentations used in these briefings. The Center team received a number of informative briefings throughout the week, including presentations from Taiwan CDC officials on, among other topics, the 2009 H1N1 response in Taiwan, the country's infectious disease surveillance systems and laboratory diagnostic capabilities, and Taiwan's Epidemic Intelligence Center. The report authors also toured the Adimmune facility, a number of hospitals, and the Health Bureau of New Taipei City.

This report and the findings and recommendation herein are derived solely from this background research and these meetings.

FINDINGS AND RECOMMENDATIONS

Taiwan has made impressive strides in boosting its national preparedness for public health emergencies. Over the past 10 years, the DOH and CDC have built a number of important and robust programs aimed at providing earlier detection and controlling the spread of infectious disease threats. Indeed, many aspects of these programs should be emulated by other countries committed to improving public health preparedness.

Comparing Taiwan's current state of readiness with its readiness levels 10 years ago, it is clear that the country has made concerted and focused efforts to advance the health of its citizens and its critical public health preparedness programs. For example, Taiwan has achieved success in:

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- raising general awareness of the public and international travelers of the risks of infectious diseases and good practices for controlling transmission; and
- investing in a domestic vaccine manufacturing capability to help ensure that Taiwanese people have access to influenza vaccines, even during times of worldwide surges in demand for vaccine.

In addition to the many essential preparedness programs established over the past 10 years, Taiwan is fortunate to have dedicated leaders and experts in government who are committed to improving national readiness for disease outbreaks. As we learned, Taiwan's government servants who are responsible for these issues have a strong sense of purpose, and key personnel at all levels recognize that the systems will be challenged by new infectious disease outbreaks in the future.

WHO and infectious disease experts and researchers around the world understand the serious challenge posed by emerging zoonotic infectious diseases, which include both new pathogens and mutated versions of existing pathogens. Therefore, it is critical in Taiwan and elsewhere to give priority to continuing to improve existing public health preparedness systems and programs.

A range of suggestions are discussed below for consideration and review by the DOH, as it seeks independent views on possible improvements to existing systems. Taking into consideration its own priorities and resources, the DOH may wish to consider the following activities.

- **Further Development of Operational Exercises and Benchmarks to Measure Progress**

Measuring public health preparedness at the national and local level is recognized by many countries as both important and challenging. Taiwan DOH and CDC have a clear interest in further developing their own approaches to measuring public health preparedness. Taiwan is continuing to improve and refine drills and functional exercises. We were encouraged to hear that Taiwan CDC has retained an outside consultant to help it evaluate the exercises being used by the Communicable Disease Management Network. Some countries have developed systems for measuring the quality of an exercise and for measuring improvements in capabilities made over time. For example, the United States has created a national benchmark for assessing performance during exercises. The Homeland Security Exercise and Evaluation Program (HSEEP) provides a methodology and terminology for exercise design, development, conduct, evaluation, and improvement planning.¹³ Toolkits like those available on the HSEEP website may be a helpful resource for Taiwan DOH and CDC to consider.

Another important means of gauging progress that Taiwan DOH and CDC might consider would be the establishment of an annual index or report that quantifies various key public health measures. In the United States there are a few notable examples of such efforts that might be worth examining in Taiwan. The Trust for America's Health (TFAH) "Ready or Not?" report,¹⁴ written by a respected public health advocacy organization in the US, gauges 10 categories of preparedness in each of the 50 US states each year. It is a widely cited and influential independent assessment of US state public health preparedness.

Another effort in development in the US now is the National Health Security Preparedness Index, which is being developed by a coalition of federal agencies, state and local health agencies, laboratories, professional associations, and academic organizations. Its purpose is for participants to come to broad

agreement on a series of state metrics that will be measured and benchmarked each year and used to assess progress and inform future investments.

If Taiwan were to undertake such measurements, it could focus on elements of preparedness such as per capita numbers of medical personnel in different areas of the country, numbers of isolation beds and intensive care unit beds, numbers of mechanical ventilators per capita, numbers of epidemiologists in a given region, capacity to do mass distribution of medicine and vaccines, and specific lab capacity measures. These numbers could be examined against available benchmarks from other countries and could help identify potential preparedness disparities between population centers in different geographic locations (eg, New Taipei City vs Taipei) to help shape future areas of investment and work.

- **Maintenance of Technical Capabilities in the Surveillance and Laboratory Diagnostic System**

Ensuring the availability of surveillance information is critical for rapid detection and response to public health infectious disease threats and to keep political leadership informed so that they can advise and reassure their constituents during a crisis. Recent reports have found that having a robust national surveillance capability is an essential component of national and global security from health threats.¹⁵⁻¹⁷ Although there are many important components of an effective national surveillance program, 2 key elements stand out: (1) maintaining a functional network of laboratories that can perform tests and rapidly report results; and (2) maintaining an ability to integrate data from multiple surveillance programs.¹⁸

Over the past 10 years, Taiwan has developed outstanding surveillance programs, and it should endeavor over the next 10 years to sustain these gains and to keep these systems current with new technologies. The national laboratory network and the Epidemic Intelligence Center are 2 aspects of Taiwan's surveillance system that are highly valued by practitioners involved in Taiwan's preparedness programs. Together, these 2 assets help create a well-rounded, modern capability for conducting surveillance for known priority disease threats, as well as to provide an early indication of newly emerging disease situations.

Taiwan CDC's Epidemic Intelligence Center serves to integrate ongoing traditional, indicator-based, and syndromic surveillance, with information obtained through event-based surveillance. These functions are important components of a modern surveillance program for infectious disease outbreaks and other public health emergencies. WHO has identified event-based surveillance as one of the "essential components of a single national surveillance system" and has recommended that countries develop such systems to complement traditional (indicator-based) public health surveillance approaches.¹⁹

Taiwan's national laboratory program is also a critical element of its surveillance capabilities. Greatly expanded during the SARS epidemic, Taiwan's national reference laboratories and network of participating clinical laboratories seem well-positioned to diagnose routine public health threats

and, during a crisis, to expand capabilities for conducting surveillance for previously unrecognized pathogens, such as the recent cases of novel coronavirus that were detected among people from the Middle East. Taiwan should continue to support its laboratory capacity and may want to give priority in the future to enhancing existing efforts to improve electronic reporting of laboratory data. Electronic laboratory reporting can provide a standardized and near real-time snapshot of a disease of interest, thus enhancing situational awareness. Although there are ongoing efforts to implement electronic reporting from laboratories, more work is needed to ensure full participation of clinical labs. In addition, work will be needed to ensure that the laboratory reports received from clinical labs can be integrated with existing surveillance systems.

Both Taiwan's laboratory assets and the Epidemic Intelligence Center will require continual upgrades to ensure they stay up to date, relevant, and effective. As technology evolves, both of these assets require investments in hardware (new diagnostic equipment, computers, servers, etc.) and continual training of personnel. Planning for sustained investments in these areas is critical but does not appear to be a part of routine budgetary consideration. It may be wise to set aside reserve funds on an annual or semiannual basis to provide training and hardware improvements to ensure that these surveillance assets can continue to function to effectively track disease and keep leadership informed during crises.

- **Evaluation of the Adequacy of Current and Anticipated Personnel Needs**

The strength of public health preparedness programs is in the caliber of the experts that staff them. The field of public health preparedness is growing more complex, with an ever-increasing need for highly skilled technical personnel. Taiwan DOH and CDC are already considering the adequacy of current staffing levels, and they have concerns regarding their capacity to recruit the highly qualified, expert people who will be needed to run critical programs in the future. Many governments, including that of the US, have had a difficult time recruiting and retaining well-trained personnel, such as epidemiologists, laboratorians, and bioinformaticists, to staff critical preparedness programs. In the United States, traineeship funding and scholarships have been used to support the pipeline of individuals trained and qualified to work in critical fields, including public health.²⁰ Taiwan might benefit from establishing similar kinds of programs to recruit, train, and retain needed personnel before there are significant gaps in staffing.

- **Assessment of the National Stockpile Contents**

The Taiwan national stockpile is comprised of influenza antivirals, influenza vaccine, and personal protective equipment. Moving forward, Taiwan might consider comparing its stockpile approach with that of other nations, while recognizing that these comparisons would need to be informed and guided by Taiwan's own national risk assessments and epidemic response strategy. The US Strategic National Stockpile (SNS) contains a wide range of items that reflect a threat analysis that includes many hazards, such as bioterrorism, natural disasters, and other mass casualty events in addition to infectious disease

epidemics. The SNS was first established in response to terrorism. It was not until the threat of an influenza pandemic was fully appreciated, coinciding with the reemergence of H5N1, that the stockpile expanded to contain items essential for the response to pandemic influenza. The US response strategy assumes that the full spectrum of care, including critical care services, will be provided to all patients to the degree possible. Accordingly, the US stockpile includes medical countermeasures against all category A bioagent diseases (anthrax, smallpox, plague, tularemia, and botulism), mechanical ventilators, and medical supplies such as thoracostomy tubes as well as personal protective equipment, influenza antivirals, and influenza vaccines.^{21,22} Canada and Australia take a similar approach, reflecting an “all-hazards” preparedness strategy.^{23,24}

With the information gleaned from cross-national comparisons, Taiwan will be in a position to review its stockpile in the context of its own strategy. Taiwan may choose to continue its current approach, or it may alter or augment the types of materials stored. For example, stockpiling mechanical ventilators might be considered if the overall isolation hospital strategy includes plans to provide critical care on a large scale during an event.

Additionally, a strategic view as to how the stockpile should be managed might best reflect the fact that funding flows differently during a crisis situation than in a prepandemic or preoutbreak period. When public health and political interests are aligned in responding to a present threat, procuring government funds for such purposes may not face much difficulty. However, as time passes after an acute event such as the SARS epidemic, the impetus for sustained investments in preparedness activities wanes, as has occurred in the US. One means to maintain momentum on these issues is to use the numerous smaller-scale infectious disease outbreaks and disasters that occur regularly as reminders to both the public and political leaders of the need for preparedness.

An exploration of the noninfectious public health emergencies for which Taiwan prepares, through the DOH’s Bureau of Medical Affairs, may reveal areas of potential integration, synergism, and economies of scale that may defray costs and harness additional expertise. In the US, an “all-hazards” approach to preparedness is embraced in which preparedness for infectious disease emergencies are integrated with preparedness activities for natural disasters, radiological emergencies, and other incidents that have an impact on the health of the nation’s residents. Using such an approach minimizes duplicative efforts while fostering expertise in responding to these incidents in a manner that engages multiple facets of the government.

- **Assessment of the Benefits of Alternative Planning Scenarios for Major Outbreaks of Communicable Diseases**

Taiwan's current strategy for the management of a category I or category V communicable disease outbreak within its borders includes the mandatory hospitalization of patients in 22 designated isolation hospitals located throughout the country. Category I diseases include such conditions as smallpox, SARS, H5N1 influenza, and anthrax, while category V diseases refer to novel emerging infectious diseases. These hospitals are described as being medium sized, affiliated with larger hospitals, and fitted with a varying number of low acuity nursing wards that maintain negative pressure isolation standards. These designated contingency hospitals serve the purpose of sequestering potentially infectious patients from the remainder of the population and healthcare system in an attempt to prevent nationwide spread.

This system was created in the aftermath of the SARS pandemic and is the foundation of Taiwan's infectious disease healthcare response. Essential to the operation of this system are the 6 regional medical commanders of the Communicable Disease Network. These commanders, who are all distinguished physicians with extensive expertise, have the responsibility for the critical medical decision making in the 6 regions of Taiwan. Depending on the need, they could provide medical personnel and equipment to assist designated hospitals during a public health emergency. Through the medical commanders' guidance to DOH and CDC, direction of exercises, and coordination of crucial medical assets, Taiwan is poised to respond in a highly coordinated and well-informed fashion to infectious disease emergencies on a nationwide scale—a significant advance from the pre-SARS era.

As DOH continues its ongoing efforts to evaluate, test, and refine national response plans for infectious disease emergencies, it will be useful to consider the medical challenges that a highly contagious SARS-like disease could present to the designated contingency hospitals. While the hospital plan provides great detail and strategy regarding the containment of contagious disease outbreaks, there are 2 particular challenges to the existing plan that are likely to arise in the event of a large infectious disease emergency: the need for mechanical ventilation and the need for surge care.

Most of the contingency hospitals where patients would be isolated and hospitalized in Taiwan in a major infectious disease emergency are not major medical centers. This is by design, to support the goal of preserving the capacity of major medical centers so they can continue to provide health care for the rest of the community without losing overall organizational capacity and being quarantined. This is what occurred at Hoping Hospital in 2003.

The reason that mechanical ventilation and intensive care is likely to be a challenge is that infectious disease emergencies historically often lead to a large number of critically ill patients. During the SARS epidemic, 20% to 38% of patients required ICU admission, and 59% to 100% of those patients required mechanical ventilation.^{25,26} Given that infectious disease epidemics of the future (unless they are quite small) will also likely lead to high numbers of patients needing mechanical ventilation, Taiwan DOH and

CDC may want to consider planning that would expand their capacity to provide critical care and mechanical ventilation in such a crisis. Such capacity would depend on the provision of mechanical ventilators in intensive care units along with the necessary trained personnel (eg, critical care physicians, respiratory therapists, critical care nurses). Adding critical care capabilities at the designated isolation hospitals would require additional funding, which may or may not be available. It may be more cost-effective to augment existing infection control measures at the major hospitals where critical care is routine. In considering the attributes and potential challenges of this type of alternative approach, planners could take note of the fact that once careful attention to infection control was implemented during the SARS outbreak, nosocomial spread of the SARS virus ceased.²⁷ Patients were successfully and safely treated in intensive care units with adequate infection control measures in place.

The other related challenge in future infectious disease epidemics will be the need to effectively respond to a sudden surge in patient load. The designated isolation hospitals are committed to this mission, and they conduct regular training. But despite those efforts, these hospitals could be overwhelmed by a large number of patients during an outbreak. Planning should allow for some scalability and flexibility in responding to events of differing magnitudes. Such “surge” planning could take into account limitations of facility infrastructure in addition to personnel, equipment, and supplies. Facility limitations include the number of potential beds but also include fixed infrastructure, such as the adequacy and reserve capacity of oxygen delivery in hospitals. Unpublished data from the US indicate that some US hospitals may not be able to deliver adequate oxygen flow rates to power large numbers of additional ventilators because of inadequate oxygen piping, and they must reevaluate their oxygen delivery systems.

An approach that Taiwan may wish to evaluate is to match the acuity of the patient with the capabilities of the hospital. For example, during the 2009 H1N1 influenza pandemic, many patients in the US were transferred to large academic medical centers where they could receive “rescue” therapies such as extracorporeal membrane oxygenation.²⁸ The United States has also followed a similar approach with those infected with the hemorrhagic fever virus, Sin Nombre hantavirus.²⁹ Canada, a nation that experienced 251 cases of SARS and 43 deaths,³⁰ also follows an approach that relies on the provision of care for the critically ill and contagious patients at major medical centers.³¹ In the UK, a similar approach is followed, in which the ability to “increase capacity of these [critical care] services are an important aspect of planning.”³² This stance on the provision of critical care to patients in the UK is illustrated by the recent ICU admission of a novel coronavirus patient.³³

To date, there has been relatively little financial support to hospitals for preparedness. An investment in augmenting infection control measures may pay significant dividends for both routine patient care and infectious disease emergencies.

As Taiwan refines components of its epidemic preparedness strategy, the ability to optimally care for the critically ill could be a consideration in selecting the facilities tasked with response. Providing additional flexibility for regional commanders to delineate sites and levels of care during an outbreak could also be considered.

- **Continued Planning for Scarce Resource Scenarios**

In its pandemic influenza plan, Taiwan has appropriately developed a policy of identifying priority groups for potentially scarce resources such as vaccines and antivirals during an event. These priority groups were implemented for mass vaccination of the population during the 2009 H1N1 pandemic. Priority groups may also need to be identified in order to allocate resources other than medical countermeasures. Therefore, extending this approach to encompass a broader “allocation of scarce resources” approach, with continuous dialogue with relevant stakeholders, may further augment preparedness. A plan that also incorporates a method for how ventilators, hospital beds, intensive care unit beds, and other medical procedures can be employed in the most effective manner would complement the work already undertaken with respect to vaccines. Such planning for allocation of scarce resource is one aspect of a broader “crisis standards of care” dialogue that is currently underway in the US. Taiwan may want to review the results of the US Institute of Medicine’s (IOM) recent Crisis Standards of Care project.³⁴

The IOM approach reflects the fact that, during certain emergencies, “substantial change in the usual health care operations and the level of care it is possible to deliver” will occur and be “justified by specific circumstances and . . . formally declared by a state government in recognition that crisis operations will be in effect for a sustained period.”³⁴ As a disaster unfolds, with the ensuing surge of patients, the standard of patient care will move along a continuum. The IOM refers to normal patient care as conventional care, in which all the hospitals’ resources are employed as needed. When the capacity for conventional care is exceeded, “contingency” care occurs, in which a normal standard of care is maintained by modifications such as converting a recovery room to an intensive care unit. Once capability for contingency care is exceeded and there are insufficient resources to care for patients in the usual manner, “crisis” care standards will be used.³⁵

The framework of the IOM’s work includes a system-wide approach to planning for catastrophic disaster that reflects the need for the entire community of healthcare and other stakeholders (not just hospitals) to plan for such a modification of the standards of care. The IOM calls for such plans to be integrated into existing hospital, hospital coalition, and national disaster plans. By planning for such a drastic change in standards of care, it is believed that overall morbidity and mortality can be minimized. Moreover, by engaging all relevant stakeholders in a preevent discussion of how resource allocation decisions will be undertaken, public and political resistance may be dampened.

- **Evaluation of Airport Quarantine Strategy**

Taiwan uses an airport quarantine strategy to identify febrile travelers. In addition to its screening function, this post-SARS effort, by its mere presence, serves to enhance awareness among travelers of global infectious disease threats. Furthermore, it serves a public education function by dispensing general advice regarding hygiene as well as information on warning symptoms of particular diseases. The system involves thermal scanning coupled with a mandatory evaluation of febrile patients. These patients may be released to home or hospitalized, depending on the situation. Under this system, a number of imported dengue fever cases and other medical cases have been identified.

Some elements of this program differ from the airport quarantine strategies used by other nations such as Canada and the US. The following information about Canada's approach is provided in response to DOH's request for international benchmarking data in this area.

Canada's experience with quarantine measures during the SARS outbreak may be instructive. Canada's border screening for SARS involved 3 components costing Can\$7.55 million. The first was an information phase in which health alert notices were distributed to passengers arriving from Southeast Asia that advised them of the signs and symptoms of SARS and advised them to consult a physician if symptoms developed. Similarly, alerts were distributed to departing passengers asking them to *self-defer* travel to avoid the risk of exporting SARS. The second, or screening, phase (prompted by the ongoing spread of SARS) involved the requirement that all passengers respond to a questionnaire regarding potential SARS symptoms and risk factors. If considered at risk for SARS, the passenger was referred to a nurse for more detailed evaluation that would result in referral or release. In conjunction with these measures, a pilot project of thermal scanning was also deployed. The final phase involved special measures such as passenger contact tracing.

The Public Health Agency of Canada, in a review of these measures, deemed them to be of limited benefit for identifying SARS for several reasons, including the nonspecific nature of the screening and the low prevalence of the emerging disease. In fact, of the 5 SARS patients who entered Canada during March through May of 2003, none had symptoms at the airport. These findings prompted Canadian officials to conclude that "the positive predictive value of a positive screening result is essentially zero." Canadian officials also warn of the false sense of reassurance such measures may engender among the populace and political leadership.³⁰ A similar lack of cost-effectiveness has been identified in the tracing of the spread of measles from an airport³⁶ and with thermal scanning in Japan.³⁷ There are, of course, other considerations in addition to cost-effectiveness that Taiwan and other countries take into account when setting their airport quarantine policies.

- **Preservation of Domestic National Capacity to Manufacture Vaccines in a Crisis**

Taiwan deserves praise for becoming the 15th nation to develop the domestic capability to manufacture influenza vaccines. Countries without such capacity are vulnerable to vaccine shortages during pandemics and periods of a surge in worldwide demand. Maintaining a viable domestic manufacturing base therefore helps to ensure that Taiwan can care for its own citizens during a pandemic.

In the future, preserving and adequately supporting this domestic capacity will be an important component of the self-reliance and resilience that characterizes preparedness. Taiwan CDC currently has a public-private partnership with Adimmune, whereby CDC has a modest ownership interest in the company and purchases a certain amount of domestically produced seasonal influenza vaccine yearly. This type of public-private partnership will be crucial, but not necessarily easy, to sustain. A number of market realities make it difficult, if not impossible, for a domestic company such as Adimmune to stand at the ready to fulfill government needs if it lacks other sources of revenue or support during periods of decreased government demand. In the United States, the government and private companies that are engaged in the development of medical countermeasures for bioterror agents also struggle with the dilemma that government funds are limited but companies are unable to sustain development and manufacturing capabilities without significant government support, since there is not a robust commercial market for these countermeasures.

Adimmune appears to be responsibly undertaking a number of strategies to address the reality of the natural fluctuations in government demand. Such strategies include developing novel vaccines for pandemic use, attempting to expand its presence in international markets, offering contract manufacturing services, and providing fill and finishing capabilities for other companies. In addition to these strategies, it would also be worthwhile for DOH to consider the use of advanced purchase agreements with multiyear commitments. These types of arrangements may strengthen the public-private partnership and allow the company to have a more secure and predictable financial footing as it expands operations and pursues innovative vaccine approaches (eg, potentially pursuing cell-based influenza vaccines).

In the United States, seasonal influenza vaccine is primarily a private purchase made by individual healthcare facilities and providers. However, a large proportion of this vaccine is not produced domestically. In light of the threat of avian influenza and the necessity for a large domestic manufacturing base, the US government has in recent years decided to provide funding to bring on line new domestic manufacturing capacity for influenza vaccines. For example, with US government support, Novartis recently opened the first American cell-based influenza manufacturing plant—the culmination of a \$1 billion private-public partnership.³⁸

- **Integration of Public Concerns with Public Health Law**

In addition to pharmaceutical interventions, nonpharmaceutical interventions, such as isolation of contagious sick people and social distancing, may help to limit the spread of communicable diseases. The effectiveness of quarantine—that is, the preemptive sequestration of individuals who are not yet sick but may have been exposed to a contagious disease—is less clear. Some experts have cautioned that quarantine may have unintended consequences, such as enhanced spread of the disease in the quarantined population, violence among those quarantined, the need to employ force to maintain the quarantine, stigmatization of the affected population, and economic disruption.³⁹⁻⁴¹

Nonpharmaceutical measures available to public health authorities vary worldwide, as does the legal authority for public health officials to enforce these measures.⁴²In fact, law itself may appropriately be considered a form of nonpharmaceutical intervention, and, thus, legal preparedness is an essential part of public health preparedness.*

Quarantine and isolation authority in Taiwan is defined by the Communicable Disease Control Act, which has undergone significant revision since SARS, including as recently as January 2009. The Act requires relatively expansive disease control measures for managing the occurrence, infection, and spread of communicable diseases through isolation and quarantine, as well as penal provisions for not complying with instructions from public health authorities or otherwise interfering with infection control. Indeed, relative to other countries, there is widespread support among the people of Taiwan for aggressively attempting to control infectious disease spread through using expansive compulsory quarantine.⁴³ Still, citizens of Taiwan have significant worries about their own health and well-being, should they be quarantined.⁴³ Thus, it is worth considering potential benefits to addressing concerns about social stigma, economic loss, and medical treatment for those who are quarantined.

Large-scale quarantine is likely to be most effective when it is willingly participated in, rather than enforced with criminal penalties.³⁹ Laws aimed at controlling the spread of disease should incentivize compliance and reduce the likelihood that potentially infected individuals make efforts to avoid control measures, such as occurred in China during SARS.⁴⁴ Therefore, legal authority for nonpharmaceutical interventions such as quarantine and isolation could address concerns the public may have about being quarantined. This in turn could improve the likelihood of the public's acceptance of and active participation in infection control measures. Toward this end, laws that enable health authorities to flexibly scale implementation of treatment and control measures according to patient needs and population concerns may be more effective than a one-size-fits-all approach.

* Legal preparedness contains at least 4 core elements: laws (statutes, ordinances, regulations, and implementing measures); the competencies of those who make, implement, and interpret the laws; information critical to those multidisciplinary practitioners; and coordination across sectors and jurisdictions.

In the US, most states have wholly or partially adopted the Model State Emergency Health Powers Act (MSEHPA), which aims to ensure effective response while also respecting individual rights.^{45,†} MSEHPA contains a comprehensive framework for quarantine and isolation, both with notice and without notice, and defines conditions and principles for the public health authority to adhere to when isolating or quarantining individuals or groups of individuals. The model legislation prescribes that failure to obey rules and orders concerning quarantine and isolation shall constitute a misdemeanor.[‡] Among conditions and principles outlined are requirements that:

- Measures taken are the least restrictive means necessary to prevent the spread of the disease;
- Quarantined or isolated individuals are regularly monitored;
- Needs of people isolated and quarantined shall be addressed in a systematic and competent fashion, including, but not limited to, providing adequate food, clothing, shelter, means of communication with those in isolation or quarantine and outside these settings, medication, and competent medical care;
- Premises used for isolation and quarantine are to be maintained in a safe and hygienic condition and be designed to minimize the likelihood of further transmission of infection or other harms to people isolated and quarantined; and
- Individuals are immediately released when they no longer pose a substantial risk of transmitting the disease to others.

Beyond the scientific, disease-specific analysis required for developing an effective disease containment strategy, public health law plays an important role in limiting the spread of disease. Given support in the population of Taiwan for quarantine and isolation, there is an opportunity to improve compliance by using law to accommodate the concerns of those potentially subject to quarantine.

[†] In the United States, state and local governments have the primary authority to control the spread of dangerous diseases within their jurisdictions and states conduct quarantine and isolation activities in accordance with their particular state laws and policies.

[‡] In the United States, misdemeanors are considered lesser offenses relative to felonies and are generally punishable by monetary fines, probation, community service, and/or short-term jail terms.

- **Consideration of the Strategic Use of Tabletop Exercises and Scenarios**

Taiwan DOH may wish to consider the development of public health preparedness exercises and scenarios aimed at political leadership with the explicit purposes of raising awareness of the national challenges posed by epidemics and providing the rationale for strong public health preparedness programs. After the SARS epidemic, public confidence in the Taiwan government was threatened by dissatisfaction with the government response, highlighting the political importance of these issues. Devising tabletop exercises that emphasize these dimensions of response will allow political leaders to become acutely aware of the vital role infectious disease preparedness plays in national security.

Tabletop exercises are frequently used to inform leaders about the issues raised and decisions that must quickly be made during times of national crises. These types of exercises are as important as operational drills and exercises, but they are designed differently and for a different audience.

Since 2001, there has been an increasing use of exercises for public health emergency scenarios. Two high-profile exercises convened by the Center for Biosecurity of UPMC, Dark Winter (2001)⁴⁶ and Atlantic Storm,^{47,48} have been instrumental in raising the profile of infectious disease outbreaks among political leaders in the US and Europe. Both of these exercises prompted significant media attention and Congressional testimonies and hearings and ultimately helped leaders reexamine existing policies for responding to infectious disease outbreaks. In 2006, WHO along with participants from several member nations of the Global Health Security Initiative (GHSI), a collaboration among Canada, the US, Mexico, France, Italy, Germany, Japan, the UK, and the European community, participated in the Global Mercury exercise, which highlighted the importance of international collaboration, communication, and resource sharing during a bioterrorism event.⁴⁹ Reviewing the lessons and outcomes of exercises like these may be helpful to Taiwan DOH as it considers how to sustain national support for its preparedness initiatives.

- **Consideration of Broader Publication of Lessons Learned**

Compared to many other nations, Taiwan has made great strides in strengthening its preparedness for infectious disease outbreaks. Taiwan DOH and CDC should consider how best to share these accomplishments with the international community.

In many countries, it continues to be a struggle to analyze, document, and incorporate into future plans the lessons learned from exercises and real public health emergencies. The US has made some effort to improve this process by setting up a secure website for practitioners, called Lessons Learned Information Sharing (or LLIS.gov), to post and share lessons with their peers. Although the existence of this website has improved the sharing of lessons in the practitioner community, applying these lessons to existing plans continues to be a challenge for the US preparedness community. Preliminary evaluations of the recent response to Hurricane Sandy, which struck the US east coast in October 2012, suggest the need for better incorporation of lessons learned into plans for handling public health emergencies.⁵⁰

It may be beneficial for the staff of the Taiwan DOH and CDC to document advances made and publish peer-reviewed articles that describe program changes and lessons learned since SARS. Enhanced recognition of Taiwan's preparedness program will help to sustain national commitment to these programs and will facilitate ongoing and additional collaborations with international organizations with an interest in public health preparedness.

CONCLUSION

The report recommendations reflect the fact that preparedness for public health emergencies is not an end state, but rather an ongoing commitment to support the people, information systems, technologies, and other assets that contribute to overall public health resilience in the face of infectious disease threats. We encourage Taiwan to maintain the state-of-the-art capabilities that will protect the people of Taiwan from future public health emergencies.

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APPENDIX A: RESEARCH TEAM BIOGRAPHICAL SKETCHES

THOMAS INGLESBY, MD

Dr. Inglesby was appointed Chief Executive Officer and Director of the Center for Biosecurity of UPMC in November 2009. He served as Chief Operating Officer and Deputy Director from 2004 to 2009, and was one of the Center's founding members in 1998.

Dr. Inglesby is an internationally recognized biosecurity expert whose work over the past decade has helped shape the development of the field. He played a leading role in all of the Center's high-impact initiatives, including the *Atlantic Storm* and *Dark Winter* exercises and a series of seminal *JAMA* articles on medical and public health response to the most dangerous biological agents. Dr. Inglesby has played a central role in development of the Center's strategic priorities and programs over the years. He has expanded and deepened the Center's expertise in biosecurity while at the same time establishing new initiatives to improve response to emerging infectious diseases and natural disasters and preparedness for nuclear terrorism and radiation disasters.

Dr. Inglesby was recently named Chair of the Board of Scientific Counselors to CDC's Office of Public Health Preparedness and Response. He has been chair or a member of a number of National Academy of Sciences committees, and he has served in an advisory capacity to the Defense Science Board, the US Departments of Health and Human Services and Homeland Security, the National Institutes of Health, and the Office of the Director of National Intelligence. Most recently, in 2009-2011, Dr. Inglesby was a member of the National Academy of Sciences expert committee that reviewed the scientific approaches used during the investigation of the 2001 anthrax letters.

Dr. Inglesby has been invited to brief White House officials from the past 3 presidential administrations on national biosecurity challenges and priorities, and he has delivered Congressional testimony on biological threats and preparedness.

Since 1999, Dr. Inglesby has authored or co-authored more than 75 peer-reviewed articles, reports, and commentaries on a wide range of public health and national security issues. In 2010, he co-authored "Necessary Progress in Biosecurity" with Senator Tom Daschle for the *Harvard Law and Policy Review*. He is Coeditor-in-Chief of the journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, which he helped establish in 2003 as the only peer-reviewed journal in the field. In addition, Dr. Inglesby was principal editor of the 2002 *JAMA* book *Bioterrorism: Guidelines for Medical and Public Health Management*. He is regularly consulted by major news outlets for his expertise and insight on issues pertaining to biosecurity, biodefense, and response to public health disasters.

Dr. Inglesby is an Associate Professor of Medicine and Public Health at the University of Pittsburgh Schools of Medicine and Public Health. He completed his internal medicine and infectious diseases

training at Johns Hopkins University School of Medicine, where he also served as Assistant Chief of Service in 1996-97. Dr. Inglesby received his MD from Columbia University College of Physicians and Surgeons and his BA from Georgetown University.

ANITA CICERO, JD

Ms. Cicero joined the Center in early 2010 as Chief Operating Officer and Deputy Director. Working with Dr. Inglesby, she directs operations, strategic and budget planning, and program development. Since her arrival at the Center, she has helped to expand its initiatives in the realms of nuclear preparedness and detection and response to international disease epidemics. In collaboration with Nuclear Threat Initiative, she recently provided strategic and governance advice for the creation of CORDS, a new international organization dedicated to improving global infectious disease detection and response through linkage of regional disease surveillance networks.

Ms. Cicero has nearly 2 decades of experience as a practicing attorney in both the US federal government and the private sector. Before joining the Center, Ms. Cicero served as Managing Partner in charge of the Washington, DC, office of Drinker, Biddle & Reath, LLP, where she was responsible for more than 300 lawyers and staff.

At Drinker, Biddle, and Reath, she formed and managed a range of biopharmaceutical consortia focused on scientific, regulatory, and policy issues, through which she acquired considerable skills in structuring consensus approaches to complex regulatory and scientific challenges. Her work in that realm required collaboration with members of the US Congress, the World Health Organization, the European Commission, the US Food and Drug Administration, and the Environmental Protection Agency, as well as the US Departments of State, Defense, and Health and Human Services. On behalf of her clients, Ms. Cicero led a number of major initiatives related to compliance with international environmental treaty mandates, international data protection and security laws, and human subject research protections for clinical trials.

In the realm of biosecurity, Ms. Cicero managed a consortium of companies that focused on advancing public policy to foster research and development of medical countermeasures. Among its accomplishments, the consortium provided invited analysis to the US government on strategy and organizational capacity and developed recommendations for advancing the science of efficacy studies for countermeasures in the absence of human subject data.

Before entering private practice, Ms. Cicero focused on environmental litigation and counseling. As a trial attorney in the Honors Program at the US Department of Justice, Environmental Enforcement Section, Ms. Cicero represented the EPA in civil litigation under the Clean Air Act, the Clean Water Act, and the Comprehensive Environmental Response, Compensation and Liability Act.

Ms. Cicero is a graduate of the Yale Law School and Oberlin College.

JENNIFER NUZZO, SM

Ms. Nuzzo is a Senior Associate at the Center for Biosecurity of UPMC. An epidemiologist by training, her work focuses on international and domestic biosurveillance, situational awareness, and disease mitigation strategies. She also has worked on problems related to water security, public/private partnerships for public health preparedness, mass critical care, and hospital preparedness.

Ms. Nuzzo is an Associate Editor of the peer-reviewed journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, and she was Co-managing Editor of the *Biosecurity Briefing*, a weekly internet-based news, science, and policy update. Ms. Nuzzo has published in the scientific literature on waterborne pathogens and has co-authored several manuals on environmental policy and planning.

In addition to her work at the Center for Biosecurity, Ms. Nuzzo has advised national governments and nonprofit organizations. She served as a consultant to the National Biosurveillance Advisory Subcommittee, as a member of the US Environmental Protection Agency's National Drinking Water Advisory Council (NDWAC), and as a member of the NDWAC's Water Security Working Group. She has also served as a project advisor for the American Water Works Association Research Foundation (now called the Water Research Foundation), a primary funding organization for drinking water research in the United States. Ms. Nuzzo has also been consulted on pandemic influenza planning efforts in the Republic of Indonesia.

Ms. Nuzzo joined the Center for Biosecurity at its founding in 2003. Before that, she served as a Research Analyst with the Center for Civilian Biodefense Strategies at the Johns Hopkins Bloomberg School of Public Health.

In 2002 and 2003, Ms. Nuzzo worked as a public health epidemiologist for the City of New York, where she was involved with disease and syndromic surveillance efforts related to the city's Waterborne Disease Risk Assessment Program. Central to her duties in New York was management of the city's drug sale monitoring program for surveillance of diarrheal illness. She also worked on a local climate change initiative for the City of Cambridge, MA.

AMESH ADALJA, MD, FACP

Dr. Adalja is a Senior Associate at the Center for Biosecurity, Assistant Clinical Professor in the Department of Critical Care Medicine, Assistant Clinical Professor in the Department of Emergency Medicine, and Adjunct Instructor in the Department of Medicine's Division of Infectious Diseases at the University of Pittsburgh School of Medicine and UPMC. He is board certified in internal medicine, emergency medicine, infectious diseases, and critical care medicine.

Dr. Adalja is a member of the Allegheny County (PA) Metropolitan Medical Response Team, the American College of Emergency Physicians Pennsylvania Chapter's EMS & Terrorism and Disaster

Preparedness Committee, the Allegheny County Medical Reserve Corps, and the US Department of Health and Human Services' National Disaster Medical System Disaster Medical Assistance Team (PA-1), with which he was deployed to Haiti after the earthquake in 2010. He previously was a member of Allegheny County's Metropolitan Medical Response System

Dr. Adalja is an Associate Editor of the quarterly journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*. He is a contributing author for the *Handbook of Bioterrorism and Disaster Medicine*, and he has published in such journals as *Journal of Infectious Diseases* and *Emerging Infectious Diseases*. He also serves as a book reviewer for *JAMA*.

Dr. Adalja is a fellow of the American College of Physicians, and a member of various medical societies, including the American Medical Association, the Infectious Diseases Society of America, the HIV Medical Association, the American College of Emergency Physicians, and the Society of Critical Care Medicine.

Prior to joining the Center, Dr. Adalja completed 2 fellowships at the University of Pittsburgh—one in infectious diseases, for which he served as Chief Fellow, and one in critical care medicine. He completed a combined residency in internal medicine and emergency medicine at Allegheny General Hospital in Pittsburgh, where he served as Chief Resident and as a member of the infection control committee.

He is a graduate of the American University of the Caribbean School of Medicine, and he obtained a Bachelor of Science degree in industrial management from Carnegie Mellon University.

ERIC TONER, MD

Dr. Toner, who is an internist and emergency medicine physician, is a Senior Associate with the Center for Biosecurity of UPMC. His primary areas of interest are healthcare preparedness for catastrophic events, pandemic influenza response, and medical response to bioterrorism. He is a Managing Editor of *Clinicians' Biosecurity News*, which provides clinical biosecurity reports to thousands of clinicians across the country and around the world. He is an Associate Editor of the journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, the leading peer-reviewed journal in this field.

Dr. Toner has authored numerous scholarly papers, commentaries, and editorials on hospital and pandemic preparedness, and he has organized several meetings of national leaders on the topics of hospital preparedness, pandemic influenza, mass casualty disasters, biosecurity, biosurveillance and nuclear preparedness. He has spoken at many national and international conferences on a range of biosecurity topics and appeared on several high-profile national television and news features on pandemic flu and bioterrorism preparedness. He was the principal investigator of a multi-year project to evaluate the achievements of the HHS Hospital Preparedness Program and to propose a vision and strategy for healthcare preparedness for the future. He also led a project for HHS to improve healthcare

situational awareness. Dr. Toner is a member of the Institute of Medicine's Forum on Medical and Public Health Preparedness for Catastrophic Events.

Dr. Toner has been involved in hospital disaster planning since the mid-1980s. Prior to joining the Center, Dr. Toner was the Medical Director of Disaster Preparedness at St. Joseph Medical Center in Towson, Maryland, where he practiced emergency medicine for 23 years. During this time, he also headed a large emergency medicine group practice, founded and directed one of the first Chest Pain Centers in Maryland, and co-founded and managed a large primary care group practice and an independent urgent care center. In 2003, he spearheaded the creation of a coalition of disaster preparedness personnel from the 5 Baltimore County hospitals, the Health Department, and the Office of Emergency Management.

Dr. Toner received his BA and MD degrees from the University of Virginia. He trained in internal medicine at the Medical College of Virginia.

KUNAL RAMBHIA, MS

Mr. Rambhia is the Managing Senior Analyst at the Center for Biosecurity of UPMC. He conducts research in support of Center programs, with a focus on hospital and healthcare preparedness, pandemic influenza, biotechnology, infectious disease agents, and international biosecurity issues. Mr. Rambhia is Co-managing Editor of *Biosecurity News Today*, a daily biosecurity news update. He also serves as an Associate Editor of the peer-reviewed journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*.

Prior to joining the Center, Mr. Rambhia worked as an intern for 454 Life Sciences, where he was involved in DNA sequencing projects. In 2005 he traveled to Ghana as part of the Unite for Sight program, providing basic eye care, access to surgery, and eye health education in rural areas of the country. He also served as a member of AmeriCorps in 2004.

Mr. Rambhia obtained a Master of Science degree in biotechnology at the Johns Hopkins University Zanvyl Krieger School of Arts and Sciences in 2011. Mr. Rambhia earned a BS degree in molecular, cellular, and developmental biology and a BA in political science from Yale University in 2007. His thesis was a study of light-dependent plant development with a focus on ubiquitin-directed proteolysis in *Arabidopsis thaliana*.

RYAN MORHARD, JD

Mr. Morhard is an Associate at the Center for Biosecurity of UPMC whose research focuses on biosecurity and nuclear preparedness policy, and related legal, governmental, legislative, and technical issues and developments.

Mr. Morhard co-authored the *Rad Resilient City Preparedness Checklist* (www.radresilientcity.org) and has briefed the checklist to numerous federal, state, and local officials, as well as to medical, public health, and public safety professionals.

Mr. Morhard is an Associate Editor of *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* and Editor of the journal's *Legal Perspectives* column. Mr. Morhard is also Editor of *Preparedness Pulsepoints*, the Center's weekly update on US government action on readiness and response.

Mr. Morhard graduated in spring 2011 from Washington University in St. Louis School of Law, where his studies focused primarily on legal aspects of national security, international relations, and foreign policy. He received his BS in neuroscience and in the history and philosophy of science from the University of Pittsburgh. As an undergraduate, he researched, published, and presented on methods to improve neurological condition following emergency preservation and resuscitation procedures as well as attention deficits following traumatic brain injury.

APPENDIX B: ANNOTATED AGENDA OF UPMC EXPERTS VISIT IN TAIWAN, DECEMBER 1–7, 2012

DECEMBER 1:

- Meeting with Professor Chien-Jen Chen, Vice President of Academia Sinica. Discussion topics included the history and organization of the SARS response in Taiwan in 2003, public health programs developed since SARS, and the role of Academia Sinica in supporting the research and development enterprise in Taiwan.

DECEMBER 3:

- Meeting with Minister of Health, Professor Wen-Ta Chiu. Minister Chiu and Dr. Thomas Inglesby, CEO and Director of the Center for Biosecurity of UPMC, discussed the Minister's commitment to pursue an independent assessment of Taiwan's public health preparedness programs and reviewed the agenda of meetings organized during the week to facilitate the Center for Biosecurity's assessment.

DECEMBER 4:

- Meeting led by Director-General of Taiwan CDC, Professor Feng-Yee Chang. This meeting included several presentations by CDC officials. Dr. Chin-Hui Yang presented on the 2009 H1N1 response. Dr. Wan-Ting Huang presented on the infectious diseases surveillance system. Dr. Ho-Sheng Wu presented on the laboratory diagnostic capabilities. CDC director Dr. Feng-Yee Chang moderated the session and presented an overview of the CDC. Experts from the Center for Biosecurity also made a series of presentations. Dr. Inglesby presented on US preparedness efforts for public health disasters. Dr. Adalja presented on US response to the 2009 H1N1 influenza pandemic. Ms. Jennifer Nuzzo presented on current approaches to biosurveillance in the US and lessons learned. Deputy Director Anita Cicero presented on the US Approach to developing and acquiring medical countermeasures for the civilian population.
- Center for Biosecurity experts were given a tour of the EIC by Medical Officer, Dr. Yu-Lun Liu.
- Dr. Feng-Yee Chang moderated a meeting of the 4 Center for Biosecurity experts and the 6 Regional Commanders of the Communicable Disease Control Network. Drs. Shan-Chwen Chang, Hsieh-Shong Leu, Jen-Hsien Wang, Yin-Ching Chuang, Yao-Shen Chen, and Jen-Jyh Lee each provided information and observations about their role in the Network. The focus was on understanding the system constructed to respond to infectious disease outbreaks and the role of the commanders in directing regional response. During the meeting, Dr. Amesh Adalja presented on US healthcare system preparedness for mass casualty events.

- The Center for Biosecurity experts were taken on a tour of the National Taiwan University Hospital, guided by Dr. Yi-Chun Lo, Director of FETP. The tour included a focus on both inpatient and outpatient infectious disease care areas.

DECEMBER 5:

- The Center for Biosecurity experts visited the Taoyuan General Hospital and Hsinwu Hospital. These meetings included discussions with the leaders of each hospital, including Dr. Yuan-Nian Hsu, Superintendent of Taoyuan General Hospital, and Dr. Fan Chiang Yu Lung of Hsinwu Hospital. Participants discussed Hsinwu's role as a designated isolation hospital, preparedness activities that have been undertaken, and challenges.
- Center for Biosecurity experts visited Adimmune Corporation for a meeting and tour. President, Dr. Hung-Cheng Liu, and other senior leadership provided a detailed briefing on the history and current activities of Adimmune. Following a tour of the vaccine facilities led by Jack Hsu, the group reconvened to discuss challenges related to maintaining a national vaccine manufacturing capability and discussed various approaches used in Taiwan and in the United States.

DECEMBER 6:

- Dr. Ming-liang Lee, Distinguished Investigator, Institute of Population Health Sciences, met with Center for Biosecurity experts to discuss the ways in which Taiwan responded to SARS, the role of the SARS Task Force, relevant history related to development of domestic vaccine manufacturing capability in Taiwan, and ongoing opportunities and challenges.
- Center for Biosecurity experts met with Taiwan CDC leadership, including Dr. Feng-Yee Chang, to provide preliminary observations and findings of the Center's assessment.
- Center for Biosecurity experts met with representatives of the Health Bureau of New Taipei City. Lee Chia-Chi, Chief of the Health Bureau provided an overview of local health department activities, influenza preparedness, and their coordination with the Taiwan CDC.
- A radiological emergency official from the Jin-Shan Branch Hospital gave a presentation that highlighted the hospital's response plans for a nuclear power plant emergency.
- Center for Biosecurity experts were given a tour of Taiwan Power Company nuclear power plant visitor's center, led by Daniel K.M. Juo, Subsection Head, North Visitors Center.

The UPMC team also engaged in substantive conversations during informal meetings with the following people: Deputy Minister of Health Tzou-Yien Lin; Department of Health Director of Medical Informatics Center Min-Huei Hsu; Taipei Medical University Professor Nai-Wen Kuo; YFY Biotech Management Company Chairman and CEO Hong-Jen Chang; Food and Drug Administration Director-General Jaw-Jou Kang; and Taipei City Department of Health Commissioner Chi-Hung Lin.

APPENDIX C: PRESENTATIONS BY CENTER FOR BIOSECURITY OF UPMC TO TAIWAN CDC

US Preparedness for Public Health Disasters

Tom Inglesby, MD, Chief Executive Officer, Center for Biosecurity of UPMC

US PREPAREDNESS FOR PUBLIC HEALTH DISASTERS

The ongoing efforts at federal, state, and local levels to prepare to protect the health of the public following epidemics, natural disasters, technological accidents, and terrorism

- **Federal roles:** Provide scientific guidance, funding, technical assistance during health emergencies
 - Two major funding streams: CDC for public health agencies; HHS Assistant Secretary for Preparedness and Response (ASPR) for hospitals.
- **State and local roles:** On the ground preparations and response: epidemiology, surveillance, risk assessment, public communication, emergency vaccination programs, hospital care, etc.

HOW FEDERAL RESPONSIBILITIES ARE DIVIDED IN PUBLIC HEALTH PREPAREDNESS

- White House National Security Staff: Policy setting, strategy, coordination.
- HHS—ASPR: Hospital preparedness programs; BARDA (medical countermeasures development); National Disaster Medical System; volunteer registration programs.
- HHS—Public Health Service: Public health professionals on call to respond to crises
- CDC—Office of Public Health Preparedness: Support for state and local public health programs, national pharmaceutical stockpile, select agent program, and emergency operations.
- DHS: Environmental surveillance.
- FDA: Approval of new medicines, vaccines, diagnostics, and devices.
- Department of State: International biosurveillance and capacity building programs.
- Department of Defense: International biosurveillance programs and medical countermeasure development.

PUBLIC HEALTH EMERGENCY PREPAREDNESS PROGRAM (PHEP)

- Run by the CDC; provides funding and technical assistance to 50 states, 4 major cities, and 8 territorial public health departments.
- Established in 2002 after 9/11 and anthrax letter attacks; provides yearly guidance and reporting requirements.
- In 2011, implemented systematic process to define set of public health preparedness capabilities to measure progress.
- Funding:
 - FY 2010 (actual): \$761 million
 - FY 2011 (actual): \$664 million
 - FY 2012 (estimated): \$657 million
 - FY 2013 (budgeted): \$642 million

PHEP PROGRAM GOAL: BUILDING KEY CAPABILITIES

Biosurveillance

- Public health laboratory testing
- Public health surveillance and epidemiologic investigation

Community resilience

- Community preparedness
- Community recovery

Countermeasures and mitigation

- Medical countermeasure dispensing
- Medical material management and distribution
- Nonpharmaceutical interventions
- Responder safety and health

Incident management

- Emergency operations coordination

Information management

- Emergency public information and warning
- Information sharing

Surge management

- Mass care
- Medical surge
- Fatality management
- Volunteer management

US NATIONAL HOSPITAL PREPAREDNESS PROGRAM

- Run by HHS Assistant Secretary for Preparedness and Response (ASPR).
- Assists states, cities, hospitals, healthcare coalitions to identify gaps in preparedness, determine priorities, develop plans for building healthcare capacity.
- Established in 2002 at same time as PHEP grants, with same 62 grantees.
- Began to align with PHEP grants in 2011 and identified 8 capabilities, in conjunction with 15 PHEP capabilities.

Funding:

- FY 2010 (actual): \$417 million
- FY 2011 (actual): \$375 million
- FY 2012 (estimated): \$375 million
- FY 2013 (budgeted): \$255 million

HPP PROGRAM GOAL: BUILDING KEY CAPABILITIES

- Healthcare system preparedness
- Healthcare system recovery
- Emergency operations coordination
- Information sharing
- Medical surge
- Responder safety and health
- Fatality management
- Volunteer management

HPP PERFORMANCE MEASURES

- **Healthcare Coalition (HCC):** A collaborative network of healthcare organizations and their respective public and private sector response partners in a region that help coordinate preparedness, response, recovery, and mitigation efforts related to healthcare organization disaster operations.
 - Percentage of HCCs that have demonstrated their ability to function and execute the capabilities for healthcare preparedness, response, and recovery as defined by ASPR.
 - Percentage of HCCs that have developed processes for short-term recovery of healthcare service delivery and continuity of business operations.

LESSONS LEARNED IN MEASURING PREPAREDNESS

- There needs to be measurement. Program started out without a measurement plan. Major weakness.
- Then there was too much measurement. Public health flooded with reporting requirements. Overwhelming.
- Need to measure the right things. Just because it's measurable does not mean it is meaningful.

- Progression from assets (capacities) to capabilities. Capabilities harder to measure, but more important.
- Fed/state/local collaboration needed to identify performance indicators. Cannot sort these out from national position without local knowledge and input.
- Tension between accountability and continuous quality improvement.
 - Accountability—people afraid to show weaknesses.
 - Quality Improvement—the point is to identify weaknesses.

OUTSIDE SCIENTIFIC ASSESSMENTS

US Government makes use of outside scientific assessment to get expertise not available in government, to gather independent views, to answer complex questions.

- Scientific advisory boards, eg:
 - Institute of Medicine Preparedness Forum (National Academy of Sciences)
 - ASPR National Biodefense Science Board
 - CDC OPHPR Board of Scientific Counselors
 - CDC National Biosurveillance Advisory Subcommittee

PREPAREDNESS AND EMERGENCY RESPONSE RESEARCH CENTERS (PERRCs)

- Research to evaluate the structure, capabilities, and performance of public health systems for preparedness and emergency response.
- Requirement to help translate the research to public health practice.
- Priorities include: Best approaches to public health training, programs for at-risk populations, legal issues related to preparedness.
- Multi-year funding for 9 universities: Harvard, Pittsburgh, Emory, Johns Hopkins, UC Berkeley, UCLA, University of Minnesota, University of Washington, University of North Carolina.

CONGRESSIONAL OVERSIGHT

- Many committees of US Congress (Senate and House of Representatives) oversee these programs.
- Annual budget hearings.
- Oversight hearing driven by external events, audits, interests of Congressional leadership, and need for new legislation.
- Many hearings and Congressional inquiries during H1N1, SARS, H5N1 events.
- Government Accounting Office (GAO) & Congressional Research Service (CRS).

HOSPITALS RISING TO THE CHALLENGE: THE FIRST FIVE YEARS OF THE US HOSPITAL PREPAREDNESS PROGRAM AND PRIORITIES GOING FORWARD, MARCH 2009

- **Methodology:** >150 hours of interviews and 14 site visits with >120 hospital and PH officials from all states.
- **Findings:** Hospitals are individually better prepared:
 - Emergency Managers designated
 - More realistic planning
 - Improved training, better exercises
 - Upgraded communications
 - Stockpiled supplies and equipment

- **Most importantly:** Coalitions of hospitals, PH agencies and emergency management agencies have been created in every location.
 - Improvement is mostly due to federal government funding and guidance.
 - BUT no hospitals prepared for catastrophic disasters.

TRUST FOR AMERICA'S HEALTH: *READY OR NOT?*

- NGO focused on community health, making disease prevention a national priority.
- Provides independent analysis of public health preparedness.
- Examines series of 10 indicators of preparedness across each state.
- States receive score based on those indicators, one point for achieving an indicator.
- Each state receives overall score from 0-10.

NATIONAL HEALTH SECURITY PREPAREDNESS INDEX

- **Objectives**
 - Identify current state public health and health system capabilities, assess gaps.
 - Assess investments made to date, inform future funding decisions.
 - Provide consistency in measures over time.
- **Approach**
 - Design index collaboratively—feds, states, professional societies, academics.
 - Gather indicators from each state that reflect the extent to which states have developed major public health and hospital preparedness capabilities.
 - Weigh them appropriately through expert judgment and models.
 - Combine them into index score, measure annually.
- **Timeline**
 - Prototype index to be released in March.

US EXPERIENCES THAT HAVE SHOWN THE VALUE OF PUBLIC HEALTH PREPAREDNESS

- Annual report from CDC describing the public health successes of the PHEP program—from responses to disease epidemics, wildfires, floods, tornadoes.
- Hospital evacuations in NY during hurricane—1,000 patients moved from NYU Langone and Bellevue under austere conditions with one immediate untoward effect).

JOPLIN, MISSOURI, TORNADO: 2011

- EF-5 tornado hit the heart of the city destroying or damaging 8,000 homes, killing 161, and injuring 1,371.
- Made a direct hit on St. John's Hospital, killing 6, injuring hundreds; 183 patients were evacuated in 90 minutes.
- Coalition had planned for evacuation of one hospital to another and had just exercised it.

PUBLIC HEALTH PREPAREDNESS: CHALLENGES AHEAD

- Public health preparedness is a common good.
 - People value it, but it's not always clear how to pay for it.
- Sustaining resources for this work is a challenge.
 - Swings from crisis to crisis.

- Need to tell the story, make the case strongly, persuade national leaders of the benefits and of the consequences of not funding.
- We should learn from each other's mistakes & successes.
 - We all have something to teach, something to learn.
- Epidemics spread; we are all at risk together.
 - We all are safer and better prepared when we work together.

US Response to the 2009 H1N1 Influenza Pandemic

Amesh Adalja, MD, FACP, Senior Associate, Center for Biosecurity of UPMC

PILLARS OF PREPAREDNESS BEFORE 2009

- Several surveillance systems
- 4 antivirals
- Public health and hospital preparedness for bioterrorism and H5N1

CDC INFLUENZA SURVEILLANCE SYSTEMS

- | | |
|---|----------------------------------|
| ● Multi-component US surveillance system: | ● Geographic spread of influenza |
| ● Outpatient illnesses | ● Virologic data |
| ● Influenza hospitalizations | ● BioSense |
| ● Influenza/pneumonia deaths | |

SYSTEM COMPONENTS

- **Virologic**—National Respiratory and Enteric Virus Surveillance System: 140 labs submit data on number of samples tested and number positive (type, subtype, age of patient).
- **Outpatient**—Influenza-Like Illness Surveillance Network: 3,300 healthcare providers submit number of patients seen and number with influenza-like illness (collaborations with state/local health departments).

SYSTEM COMPONENTS

- **Hospitalizations:** Emerging Infections Program
 - Collaboration among CDC, state health departments, and academic centers in 10 states; covers 7% of US population.
- **Deaths:** 122 Cities Mortality Reporting System
 - 122 US-wide cities submit weekly reports on total number of death certificates received and number of certs listing pneumonia or influenza.
 - Influenza-associated Pediatric Mortality Surveillance System—reports of nationally notifiable conditions.
- **Geographic spread:** Reported by state epidemiologists.

BIOSENSE

- CDC program launched in 2003 to establish an integrated national public health surveillance system.
- Syndromic surveillance using chief complaint data from emergency departments in collaboration with state and local health departments.

- Pools information from Department of Veterans Affairs, DoD, and civilian hospitals around US, tracking emergency department visits and hospitalizations.
- Example: During the 2009 H1N1 pandemic, BioSense gathered info from EDs, labs, and pharmacies, and shared data with state/local public health departments and CDC.

LIMITATIONS OF FLU SURVEILLANCE

- Reporting time lag: ~1 week in best scenarios.
- Not a comprehensive nationwide system.
- Severity indicators not robust.
- No risk factor delineation.

DRUGS & DIAGNOSTICS

- **Drugs:** Amantadine, Rimantidine, Oseltamivir, and Zanamivir.
 - No IV formulations; all are oral + inhaled formulations.
- **Diagnostics:** Chiefly rapid antigen detection tests.
 - Some academic centers had PCR, fluorescent antibody, viral culture.
 - Commercial PCR tests not available.
 - Luminex

H5N1 PREPARATIONS USEFUL FOR H1N1

- Develop new diagnostic tests and improved diagnostic capabilities
- Improve surge capacity
- Develop policy and regulatory preparedness
- Improve access to viruses and reagents
- Provide guidance for clinicians
- Improve virologic surveillance
- Conduct antiviral resistance testing

US DETECTION OF 2009 H1N1 VIRUS

- March 2009: 2 cases of febrile respiratory illness in children (un-related, no pig contact); residents of adjacent counties in southern California ill in late March.
- April 15, 2009: CDC began pandemic influenza A (H1N1) virus testing.
- April 22, 2009: CDC activated EOC.
- April 26, 2009: US declares national public health emergency.
- June 11, 2009: WHO declares global pandemic of novel influenza A (H1N1) virus.

DETECTION OF 2009 H1N1 VIRUS

- **1st Case**—CDC and US Navy program using Meso scale diagnostic device: Untypable → Marshfield Clinic, WI State DOH.
- **2nd Case**—Border Infectious Disease Surveillance Project in collaboration with US Navy: Untypable → CDC

IMPLICATIONS OF 2009 H1N1 DETECTION

- When influenza surveillance is being conducted, untypeable isolates must be followed up—high yield.
- Programs in place to systematically analyze untypeable strains will foster this approach as standard of care.
- Discovery of next pandemic strain may be late due to limitations in diagnostics (rapid antigen testing vs. PCR).

NATIONAL PUBLIC HEALTH EMERGENCY

- HHS Secretary made public health emergency and public readiness and emergency preparedness (PREP) act declarations.
- US president declared national emergency.
- June 2009: \$5.8 billion funding.

CDC RESPONSE

- **Strategic National Stockpile (SNS):** Began release of 25% of specific supplies.
 - 11 million drug regimens
 - Personal protective equipment (39 million)
 - Purchased more oseltamivir
- **Diagnostic support:** Test kits based on CDC PCR.
 - May 1: shipped to public health labs
- **Heightened surveillance:** New system that addressed problems of other systems:
 - Aggregate Hospitalizations and Deaths Reporting Activity—web-based system used to track state reports of laboratory-confirmed and syndromic flu-related hospitalizations and deaths
 - Clinical guidance; antivirals, infection control, etc.

FDA RESPONSE: EMERGENCY USE AUTHORIZATION (EUA)

- Project Bioshield Act (2004) included EUA.
- Allows distribution of unlicensed products.
- Multiple EUAs issued for respirators, diagnostic tests, and peramivir.

VACCINE ISSUES

- Pandemic occurred during production of regular trivalent seasonal vaccine.
- CDC created vaccine seed stock in April 2009; distributed to manufacturers.
- Difficulty growing; delays in delivery.
- FDA approval September 15, 2009.
- Priority groups.
- September 30, 2009: States able to place first orders for 2009 H1N1 vaccine.
- First doses administered on October 5, 2009.

NONPHARMACEUTICAL INTERVENTION: SCHOOL CLOSINGS

- Several states closed schools (e.g., NYC).
- Issues arose, i.e., caretakers, congregation outside of school, etc.
- Efficacy in future pandemics questionable.

HOSPITAL ISSUES

- Use of ECMO at tertiary care centers.

- Heightened use of antivirals emphasized, especially for high-risk groups (pregnant women, obese people).
- Mandatory vaccination for healthcare workers.
- Use of N-95 vs. surgical masks.

N-95 VS. SURGICAL MASKS

- Component of airborne transmission of influenza.
- National Academies of Sciences (IOM) and CDC endorsed N-95 use based on CDC (NIOSH) study.
- American Hospital Association and CDC's Healthcare Infection Control Practices Committee did not concur.
- Economic and supply issues: ~35% of hospitals did not agree that N-95s were readily available in Society for Healthcare Epidemiology study. Another study reported 26% of hospitals ran out of N-95s.
- UPMC and many hospitals used N-95s only for aerosol generating procedures.

CONCLUSIONS

- US government pandemic response involved augmenting prior influenza activities and instituting new approaches based on H5N1 preparedness and bioterrorism policy.
- Several hurdles remain:
 - Vaccine technology (adjuvants, cell-based, whole virion)
 - Infection control

Biosurveillance in the US: Current Approaches and Lessons Learned

Jennifer Nuzzo, SM, Senior Associate, Center for Biosecurity of UPMC

INSUFFICIENT INFORMATION DURING 2001 ANTHRAX ATTACKS

- Insufficient surveillance → difficulties in determining scope of attack.
 - No rapid test to rule in/out anthrax among those at hospitals.
 - Hospital-based surveillance systems were quickly overloaded with reports due to nonspecific nature of anthrax symptoms.
- Not enough information to guide clinical care of anthrax patients.
 - Clinical community largely unfamiliar with anthrax disease.
 - CDC did not publish information aimed at clinicians.
- Leadership did not have enough information to address the public.
- Regarding first anthrax patient, HHS Secretary Thompson said: "We do know that he drank water out of a stream when he was traveling to North Carolina last week."

"BIOSURVEILLANCE"

- No single definition.
- Many potential sources of information:
 - Traditional public health surveillance systems, data from environmental monitoring systems, school/worker absenteeism reports, purchases of over-the-counter medicines/products, hospital admissions and chief complaint data, unstructured open-source information such as social media, etc.
- Most data come from nonfederal sources.
 - State and local health departments are critical.

AIMS OF BIOSURVEILLANCE

Have sufficient information to answer at least the following:

- What is happening now?
 - How many people are already sick?
 - How is the disease spreading?
 - How severe are the cases?
- Who is most at risk?
 - How is this event likely to unfold?
 - How will the epidemic unfold?
 - What interventions are useful?
- Do we have what we need to respond?
 - What treatments are beneficial?
 - What is the supply of countermeasures?
 - What medical resources are available?

BIOSURVEILLANCE BEFORE 2001

- States/locals had very limited capacity:
 - Fewer than half of state and local public health departments had continuous access to high-speed internet or the ability to send broadcast faxes to alert clinicians about important outbreaks.
 - Few health departments had 24 hour/7 days a week monitoring capabilities.
 - Public health laboratories were not connected and were not equipped to detect many biological agents.
- Few dedicated sources of funding or policies aimed at improving capabilities.

MANY IMPROVEMENTS AFTER 2001

- National Center for Emerging Zoonotic and Infectious Diseases, Division of Preparedness and Emerging Infections, Laboratory Response Network Branch.
- Improved Biosurveillance became a goal, eg:
 - The 9/11 Commission Report
 - HHS: National Health Security Strategy
 - NSC: National Strategy for Countering Biological Threats
 - National Strategy for Biosurveillance

IMPROVED SURVEILLANCE NOW AN INTERNATIONAL OBLIGATION

- **International Health Regulations (2005):** US has legal obligation to improve its capacity to detect and respond to disease outbreaks and to help other countries improve theirs as well.
 - Improving biosurveillance capabilities across the globe now a key program of several US agencies, including Department of Defense.

CURRENT US APPROACH TO BIOSURVEILLANCE

- States and locals receive federal funding for biosurveillance and other preparedness efforts.
- Many US agencies are involved:
 - Health, Defense, State, Homeland Security, Intelligence Community, Agriculture, Commerce, Transportation, Energy, Environmental Protection, Postal Service, etc.

- Many disparate systems already in place (too numerous to count).
- US spends >\$300 M/year on international biosurveillance.
- The Center for Biosecurity and other outside groups have called for a unified biosurveillance strategy and better coordination at federal level.

BioWATCH

- Managed by Department of Homeland Security since 2003.
- Deployed in 30 cities (outdoors and indoors).
- Current technology uses filters that collect air samples, filters that must be collected manually and tested at state/local public health laboratories.
 - Results obtained 12-36 hours.
- Program has been highly controversial.
 - Pushback from users.
 - Questions about how to respond following positive results.
 - Efforts to modernize technology experiencing setbacks.

BioSENSE

- Operated by US CDC since 2003.
- Aggregates syndromic data from states and hospitals.
- Initially launched to be a national early warning system for bioterrorism and other emergencies.
- Concept of operations has changed since inception; redesigned several times.

PULSENET

- Coordinated by the US CDC since 1996.
- Operates in all US states and in many countries.
- National network of public health and food regulatory agency laboratories that perform standardized molecular subtyping of foodborne disease-causing bacteria.
 - Has led to meaningful improvements in food safety by identifying unrecognized pathogens and sources of contamination.
- Frequently cited as most valued national surveillance program due to specificity of information provided.

LESSONS LEARNED SO FAR: DESIGN OF BIOSURVEILLANCE MUST INVOLVE USERS

- Users must value data in order to participate support program.
 - Public health agencies still don't trust BioWatch results and won't act on them without conducting separate investigations.
 - Redesign of BioSense started with asking users what they wanted out of program.
- Compulsory reporting may not better than voluntary.
 - Redesigned BioSense leaves data sharing decisions to states.
 - CDC expects they will get greater participation and more complete/timely data than earlier iterations of program.

LESSON: FASTER IS NOT ALWAYS BETTER

- Initial US approach to biosurveillance sought “more data, faster.”
- Resulted in development of systems that overwhelmed users with data and alerts.

- Did not provide actionable information.

LESSON: BIOSURVEILLANCE SHOULD SUPPORT DECISION-MAKING

- US did not give sufficient attention to information needs for responding to event once it is detected.
- During 2009 H1N1 flu pandemic, decision makers could not implement existing pandemic response plan due to lack of adequate information.
- Focus of new US Strategy for Biosurveillance is information to support decision-making.

LESSON: BIOSURVEILLANCE MUST IMPROVE EXCHANGE BETWEEN PUBLIC HEALTH AND HEALTH CARE

- Improved information flow from the clinical sector is essential for biosurveillance.
 - Problems with compliance and timeliness of disease reports.
 - Few systems capture in-patient data.
 - Need better information about health system demand and available resources.
 - Need faster, more complete information on deaths.
- Electronic health records (EHRs) are seen by many as an important step in improving information exchange between public health and healthcare sector.
 - Current efforts to develop/adopt EHRs doesn't adequately address public health's needs.

BIOSURVEILLANCE REQUIRES INFORMATION FROM MULTIPLE SECTORS

LESSON: BIOSURVEILLANCE REQUIRES LONG-TERM INVESTMENTS

- Biosurveillance requires skilled analysts more so than technology.
- Requires sustained funding, rather than onetime purchase.
 - Loss in federal funding, combined with state budget cuts has made it difficult for health departments to maintain newly developed surveillance systems and analytical staff.
 - Local health departments have lost 15% of their workforce since 2008.
 - In US, 40% of public health departments have reduced programs and services, including emergency preparedness efforts.

US Approach to Developing and Acquiring Medical Countermeasures for the Civilian Population

Anita Cicero, JD, Chief Operating Officer, Center for Biosecurity of UPMC

BRIEF HISTORY OF US MCM STRATEGY

- **Prior to 2001**
 - MCM programs for military use
 - No structured MCM program and no market for civilian population
- **After 2001**
 - Congress set up a fund to procure MCMs for civilian use
 - Congress established new authority at HHS to fund and oversee advanced development of MCMs
- **Currently**
 - FDA has new initiative focused on speeding up regulatory process for MCMs

- Ongoing efforts to secure adequate funding and to acquire needed MCMs

CREATION OF FUND TO PURCHASE MCMs

- **Need for legislation:**
 - Following the 9/11 attacks, the US committed to developing new diagnostic tests, drugs, vaccines, and other treatments to respond to an attack of chemical, biological, radiological, or nuclear (CBRN) agents.
 - The pharma industry was not invested in CBRN MCMs because of lack of a significant commercial market.
- **Purpose of “Project BioShield” Act of 2004**
 - Set up \$5.6 billion fund from FY2004-FY2013 for procurement of MCMs for the national stockpile
 - Guaranteed a federal government market for new CBRN medical countermeasures
 - Permitted “emergency use” of medical countermeasures not yet approved by the FDA

“VALLEY OF DEATH” FOR MCMs

- NIH funds basic research
- Prior to 2006, no funding for advanced development of MCMs [“Valley of Death”]
- BioShield funds procurement of countermeasures

FUNDING ADVANCED DEVELOPMENT OF MCMs

- In 2006 Congress created the Biomedical Advanced Research and Development Authority (“BARDA”) in the Department of Health & Human Services
- Mission is to fund advanced development of MCMs for chemical, biological, radiological, and nuclear incidents; pandemic influenza; and emerging infectious diseases
- BARDA funding bridges the “valley of death” during the late stages of product development

CENTERS FOR INNOVATION IN ADVANCED DEVELOPMENT AND MANUFACTURING

Goals:

- Develop public/private partnerships for MCM development and manufacture
- Assist smaller companies that don’t have resources or expertise to do advanced development/manufacturing
- Build plants to incorporate flexible manufacturing platforms that can be used to produce more than one product. The facilities will use modern cell- and recombinant-based vaccine technologies that have the potential to produce vaccines for pandemic influenza and other threats.

AGENCY RESPONSIBILITIES RELATED TO MCMs

- **NIH/NIAID**
 - The National Institute of Allergy and Infectious Diseases (NIAID) supports the basic research and discovery work needed to develop countermeasures against emerging infectious diseases and agents of bioterrorism.
 - NIAID funds internal and extramural research, with an operating budget in FY2013 of \$1.3 billion
- **Department of Homeland Security**
 - DHS assesses the risk for bioterrorism in analyses called “Material Threat Assessments” and “Material Threat Determinations”
 - DHS gathers scientific information, intelligence, and expert/stakeholder input to develop an MTA
 - MTDs are issued following consideration of all threats for which there is an MTA
 - HHS/BARDA is responsible for setting priorities in MCM development based on these MTDs

- **Department of Health and Human Services**
 - The Assistant Secretary for Preparedness & Response in HHS has leadership of medical countermeasure development
 - Within ASPR, BARDA has responsibility for developing and acquiring medical countermeasures
 - BARDA works with DHS to determine priorities, with FDA to address regulatory challenges, and with industry to guide the development of products
- **Food and Drug Administration**
 - The FDA is responsible for approving safe and effective products in two main centers
 - Center for Drug Evaluation and Research
 - Center for Biologics Evaluation and Research
 - Diagnostics are evaluated by the Center for Devices and Radiological Health
 - In addition to its regular role in biopharmaceutical regulation, FDA has dedicated resources to biosecurity
 - Medical Countermeasures Initiative (MCMi) \$23.6 million
 - FDA Bioterrorism MCM development \$121.3 million
- **Centers for Disease Control and Prevention**
 - CDC manages the Strategic National Stockpile, which maintains stockpiles of MCMs purchased by BARDA
 - \$486 million in FY2013
 - CDC is also responsible for coordinating the distribution of MCMs during a public health emergency
 - CDC also advises the USG and the states on how to deploy vaccines, via the Advisory Committee on Immunization Practices
- **Department of Defense**
 - Department of Defense has different needs than civilian biodefense agencies, but often collaborates with HHS, DHS, and FDA to develop MCMs
 - The primary goal for DoD is to develop MCMs to protect US troops and personnel against biological weapons, endemic diseases, and emerging infectious diseases
 - DoD has its own dedicated R&D funding arm and a separate acquisition structure

MCMs PROCURED UNDER PROJECT BIOSHIELD

- HHS has entered into ~9 contracts for development and acquisition of CBRN MCMs valued at over \$2 billion and has stockpiled 17 MCMs against CBRN threats
- Examples of MCMs in the stockpile:
 - Monoclonal antibodies to treat anthrax
 - Anthrax immune globulin to treat anthrax
 - Anthrax vaccine
 - Botulinum antitoxin
 - New smallpox vaccine
 - Potassium iodide for pediatric use
 - Treatments for internal radioactive particle contamination
 - 50 million doses of H5N1 vaccine

INFLUENZA EFFORTS

- US goal is to make vaccine available for all Americans within 6 months of the emergence of a virus with pandemic potential
- The USG provides support for influenza vaccine manufacturing, as part of pandemic preparedness efforts.

- The government has purchased potential pandemic vaccines for stockpiling.
- BARDA has invested approximately \$2 billion since 2005 on domestic and international manufacturing capacity using current HA-head, egg-based, or cell-culture-based vaccines.

BARDA GOALS FOR INFLUENZA VACCINE

- Develop more modern platforms for manufacturing influenza vaccines in order to increase flexibility, surge capacity, and reliability of production
 - Develop improved vaccine seed strains, sterility tests, and potency reagents and testing
 - Support development of faster, more scalable next-generation recombinant influenza vaccines
 - Complete development and evaluation of adjuvanted pandemic influenza vaccines
 - Expand number of FDA-licensed influenza vaccines, to include cell-based products

CELL BASED INFLUENZA VACCINES

- US investment in cell-based technology
 - Domestic plant opened in December 2011 capable of producing 25% of US vaccine needs
 - Approximately \$1B total government investment in facility and vaccine
 - Novartis and US partnered to develop vaccine and facility
- First cell-based vaccine approved by FDA in November 2012
 - Previous experience with cell-based vaccines for polio, rubella, and Hep A
- Advantages:
 - Ability to maintain an adequate supply of readily available, previously tested and characterized cells for use in vaccine production—not reliant on egg supply
 - Increased speed and faster start-up of the vaccine manufacturing process in the event of a pandemic
 - Cell-based technology is more flexible and adaptable for making other vaccines—eg, for an emerging infectious disease

LESSONS LEARNED

- Secure government funding for developing and purchasing MCMs for dangerous pathogens was needed to incentivize industry
- Government should not wait until the end of the process to consider:
 - The concept of use for MCMs
 - A plan and resource allocation for warm base manufacturing
 - Life cycle management issues for MCMs in stockpile
- Lack of government clarity and consistency on specific needs and product requirements discourages biotech companies and venture capitalists from investing in MCMs
- The uncertain regulatory approval process for MCMs is a major barrier to development

REMAINING CHALLENGES

- Difficulty of developing broad spectrum countermeasures
- Unclear return on investment for industry
- Challenge of obtaining sufficient and sustained funding for advanced development and procurement of MCMs
 - Over a decade since anthrax attacks, so policymakers not as focused on MCMs for civilian population
 - Hard for Congress to understand high product failure rate in advanced development and to accept inevitability of funding unusable products

- Setting priorities in MCM development during austere funding environments
- Unclear regulatory pathway for MCMs for diseases with no patient population
- Developing plans on how to use MCMs strategically in the event of an epidemic or attack

Healthcare System Preparedness for Mass Casualty Events

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DEFINITIONS

- **Mass casualty event:** Any event, of any type, that requires the coordinated response of at least several hospitals within a community to provide adequate medical care for those affected.
 - Could be as small as a bus accident or as large as a pandemic
- **Catastrophic health event:** Any natural or manmade incident, including terrorism, that results in a number of ill or injured persons sufficient to overwhelm the capabilities of immediate local and regional emergency response and healthcare systems.

ELEMENTS OF US HOSPITAL PREPAREDNESS

- Varies among hospitals; based on size, location, specialty status, etc.
- Major improvements occurred after 9/11 and in response to pandemic concerns
- Several federal efforts to augment preparedness have been implemented (e.g., Hospital Preparedness Program)

HEALTHCARE PREPAREDNESS: SIGNIFICANT EVENTS 1989-2007

- | | |
|--|--|
| • 1989: Loma Prieta earthquake | • 1999: National pharmaceutical stockpile established |
| • 1991: Gulf war—discovery of Iraq’s biological weapons program | • 2001: 9/11; anthrax letters; JC updates emergency management standards |
| • 1992: Disclosure of Soviet bioweapons program | • 2002: P.L. No. 107-188; CDC PHEP funding established; NBHPP created |
| • 1993: World Trade Center bombing | • 2003: SARS; NPS became SNS |
| • 1994: Northridge earthquake | • 2004: Indian Ocean tsunami; CRI established |
| • 1995: Aum Shinrikyo Sarin gas attack (Japan) | • 2005: Hurricane Katrina |
| • 1995: Oklahoma City bombing | • 2006: PAHPA |
| • 1996: MMRS created | • 2007: ASPR created; HPP moved to ASPR |
| • 1997: CDC “Emergency – Ready” public health department funding | |

INDIVIDUAL INSTITUTIONS: IMPORTANT POINTS

- The appropriate extent of planning and preparedness efforts will vary among healthcare institutions.
 - No one template or set of capabilities will fit all institutions
 - Not all institutions will fulfill the capabilities in the same way
- Healthcare institutions could be overwhelmed and unable to provide patient care in the usual way.
 - Limited resources must be allocated optimally
- Disaster victims will need care, as will the healthcare institution’s usual patients and patients who cannot access their normal site of care

HOSPITALS RISING TO THE CHALLENGE

- **Purpose:** Assessment of the progress in healthcare preparedness for mass casualty disasters achieved as a result of the first 5 years (2002-2007) of the HPP
- **Methodology:** Comprehensive literature review and extensive interviews
 - 91 interviews with 133 individuals involved in public health and hospital preparedness (in all states and major cities)
- **Findings:**
 - The state of preparedness of individual hospitals improved significantly from 2002-2008
 - Planning for catastrophic health events, including crisis/disaster standards of care, is in its early stages
 - Hospitals are much more prepared than they were in 2001, in large part due to the HPP
 - Grants: Funding for staff, disaster coordinators, exercises and drills; process stimulated development of a forum for collaborative work on preparedness
 - Healthcare coalitions and partnerships have developed and are the most effective instruments for advancing preparedness and utilizing grant resources effectively
 - Engagement of hospital leadership varies; this is most significant in communities that have faced disasters and threats in the past, i.e., “their local threat”
 - Large hospital systems have internal disaster response plans for hospitals in multiple states or regions
 - Drills, exercises, approach to incident command and NIMS needs to be standardized and reviewed for relevance to healthcare setting
 - Situational awareness and communication: There has been progress in bed tracking; less progress in tracking of personnel, supplies, pharmaceuticals
 - Catastrophic health event emergency planning—considered “too hard, paralyzing” in most cases; most plan are for smaller-scale, more frequent occurring disasters. The most common areas for catastrophic emergency planning are pandemic flu and evacuation
 - Allocation of scarce resources in a disaster: Shift from individual to population based priorities is under discussion
 - Alternative care sites: Planning has started in many states, but no clear definition of scope of care and concept of operations

“HEALTHCARE COALITION”

- Formal collaboration among hospitals that includes public health.
- May include other healthcare entities.
- Close relationship with emergency medical services and emergency management Agency.
- Should have role in both preparedness and response.

HEALTHCARE COALITIONS: IMPORTANT CHARACTERISTICS

- Include and formally link at least all hospitals, public health and emergency management agencies, and emergency medical services
- Conduct joint threat assessment, planning, purchasing, training, and drills
- Serve as an information clearinghouse with systems for tracking patient load and assets
- Have a formal role in local/state incident command system
- Coordinate volunteers in healthcare settings
- Provide forum for decisions regarding allocation of resources
- Coordinate alternate care facilities

PRELIMINARY EVIDENCE OF COALITION VALUE

Events in which coalitions improved response (examples from HPP interviews and HFPP reviews)

- Virginia Tech shooting (2007): Southwest Virginia Healthcare Coalition
- Minnesota bridge collapse (2007): Regional Hospital Resource Center
- Tulsa tornados & ice storm: Medical Emergency Response Center
- Seattle snow storm (2008): Seattle-King County Healthcare Coalition
- Hurricanes Gustav and Ike (2008): Galveston, Texas
- Alaska RSV outbreak (2008): All Alaska Pediatric Partnership
- Southern California wildfires (2005): Disaster Resource Centers
- Florida hurricanes, wild fires, and race horse poisoning: Palm Beach, FL, Healthcare Emergency Response Coalition

H1N1 (2009)

- Seattle, Northern Virginia, NYC, Los Angeles, and Connecticut activated medical coordination centers
 - Collected healthcare situational awareness data
 - Coordinated plans to distribute/use stockpiled antivirals
 - Translated, coordinated, and distributed clinical guidance
 - Coordinated messages to media
- UC Davis Emergency Care Coalition
 - Initiated rural telemedicine connection to coalition hospitals to support care of critically ill H1N1 patients

THE NEXT CHALLENGE IN HEALTHCARE PREPAREDNESS: CATASTROPHIC HEALTH EVENTS

Description of capabilities of a prepared healthcare system

- Analysis of current response strategy and structure
- Recommendations to build on current successes and existing structures to make all-hazards healthcare preparedness and response scalable to include catastrophic health events
- Provisional assessment criteria for ongoing assessment of progress toward these national preparedness and response capability goals

A HEALTHCARE SYSTEM PREPARED FOR CATASTROPHIC EVENTS IS ABLE TO...

- Provide care for disaster victims, protect the well, and maintain essential healthcare services for the general population
- Respond quickly and agilely to mass casualty events of all sizes and causes, including those that cross jurisdictional boundaries
- Function under a variety of adverse circumstances:
 - Prolonged surge of patients
 - Patients needing prolonged care
 - Contaminated or contagious environment
 - Loss of infrastructure
 - Imperfect situational awareness and disruption of incident management
- Harness all useful national resources, public and private
- Recover quickly after a disaster, still providing essential healthcare to the population

PROBLEMS DERIVED FROM CHE SCENARIOS

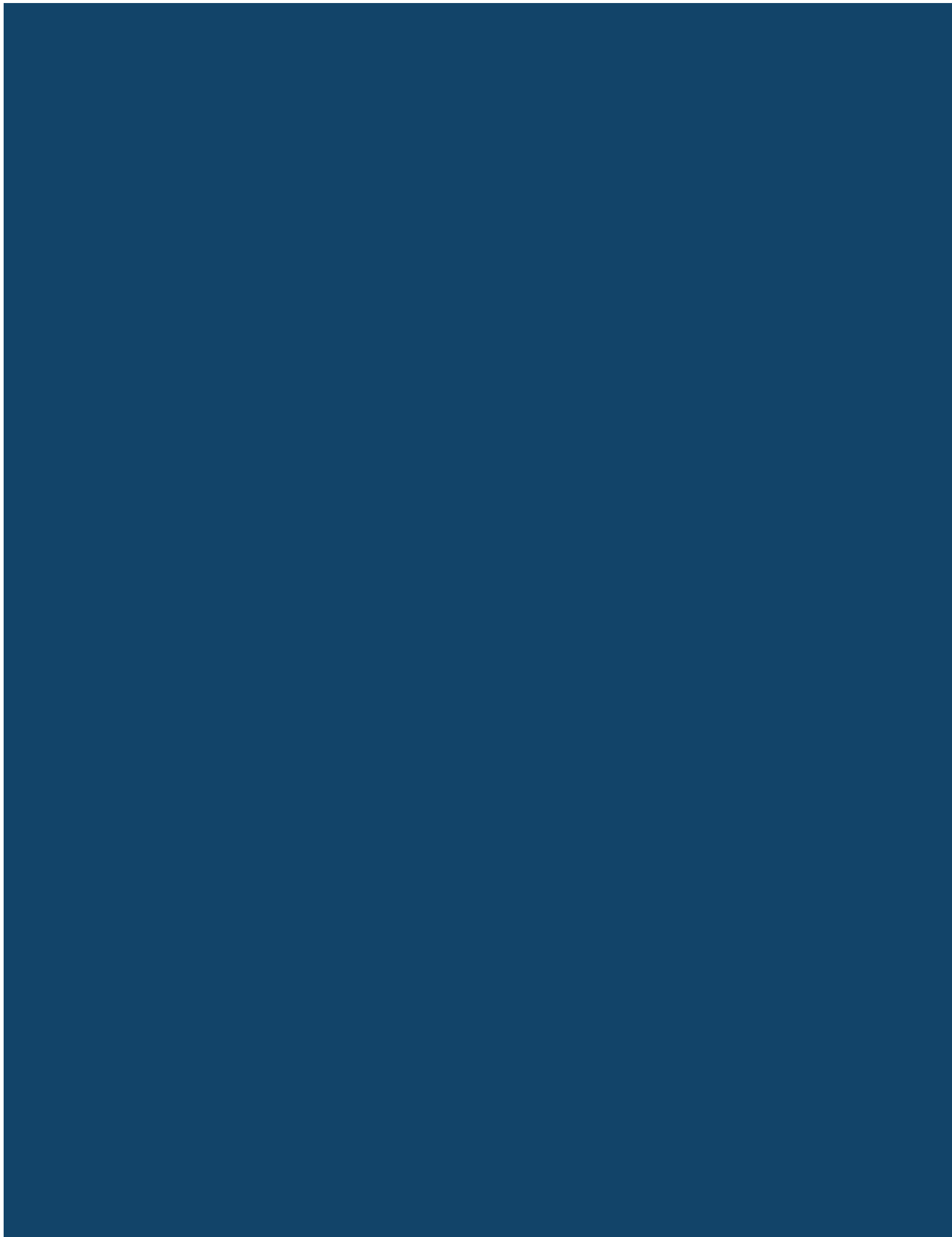
- Local hospitals are at risk of becoming dysfunctional quickly and may not be able to care for the sick and injured
- The need for critical care services will far exceed the local and geographically contiguous regional capacity
- Triage/first aid centers will be needed immediately and in large numbers
- Screening will be needed for patients who might have had significant exposures (radiation, combined injury, incubating anthrax), but no rapid diagnostics exist
- Deployable medical resources are too few and too slow
- Local, state and federal governments do not have sufficient situational awareness capabilities or transportation capacity to move patients to where they can get care and track them
 - ~13,000 in both scenarios will need to be moved within 100 miles
 - In the nuclear scenario, an additional 100,000 patients with ARS will need to be transported to hospitals beyond 100 miles before they become critically ill

2009 H1N1 EXPERIENCE REVEALS VULNERABILITIES

- Cannot predict where or when next pandemic will arise or how severe it will be
- Challenges in this mild pandemic reveal persistent vulnerability for truly catastrophic health events
 - Time required to produce, deploy novel vaccine or medical countermeasure
 - Screening and situational awareness limited by absence of good rapid diagnostic testing
 - Limitations of disease containment strategies
 - Inadequacy of medical surge capacity

HEALTHCARE RESPONSE TO CHE: STRATEGIC CHALLENGES AND RECOMMENDATIONS

- **Strategic Challenges**
 - No mechanism exists to achieve situational awareness needed to coordinate all public and private healthcare resources and manage and track distribution of patients.
 - Current transport plans and resources are grossly inadequate to move the expected number of patients in time to save lives and maintain essential services.
 - Incident management structures may be inefficient early on in CHE due to inadequate situational awareness, long chains of authority, overwhelmed decision makers, and “analysis paralysis.”
 - Large parts of the healthcare sector (e.g., urgent care and surgical centers, long term care facilities) are not well integrated into disaster preparedness systems; they may provide additional surge capacity and maintain essential medical services.
- **Recommendations**
 - Promote fully functional healthcare coalitions in every community.
 - Ensure close operational relationships between neighboring healthcare coalitions (even across state lines) for mutual aid to supplement state and federal incident command systems.
 - Incentivize all healthcare entities to participate in healthcare coalitions for disaster response.
 - Create a patient transportation system that harnesses private sector resources.
 - Create a National (not federal) concept of operations plan for healthcare response to a CHE down to the local level.



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