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Introduction

Chairman McSally and Ranking Member Payne, my name is Dr. Charles Cairns and it is an honor to be providing this testimony. I currently serve as the Interim Dean of the College of Medicine, Professor of Emergency Medicine, and Vice President of Clinical Research of the University of Arizona.

Prior to Arizona, I served as the Chair of the Department of Emergency Medicine at the University of North Carolina and as Director of Emergency Research at the Duke Clinical Research Institute of Duke University.

I have served as the Principal Investigator of the National Collaborative for Bio-preparedness and as the Director of the United States Critical Illness and Injury Trials Group.

In both of these programs, the government has invested in improving its surveillance and detection capability in support of, and enabling of more efficient response to and recovery from biological events. The overall goal is to intervene early enough during a bio-event to save lives.

National Need: Timely Intervention

As an emergency physician, I know that timely diagnosis and clinical intervention can save lives – both for individual patients and across populations and geographies. I have been involved in the development and implementation of a statewide system of heart attack care that has resulted in having a rapidly diagnosis and treatment plan for every emergency medical services agency in every county of North Carolina every day. The system integrates the statewide 9-1-1 system with pre-hospital technology to

diagnose heart attacks with destination plans to deliver heart attack patients directly to the right healthcare resource or hospital (Mears, et al, *Curr Opin Crit Care* 2009). The result of this system has been to have a plan to rapidly diagnose every heart attack in the state and rapidly deliver life-saving care. This system has been shown to save lives (Glickman, et al, *Ann Emerg Med* 2012) and has been replicated across the country.

Thus, we have proven that we can effectively develop and implement systems that can provide timely, life-saving interventions for anyone, anywhere, anytime (Cairns, et al, *Ann Emerg Med* 2012) and to extend these systems to biological threats.

National Collaborative for Bio-Preparedness

The National Collaborative for Bio-Preparedness (NCBP) is a system designed to provide rapid recognition of clinically significant biological events, whether they are due to disease outbreaks, contaminations or poisonings due to either natural causes or terrorism. (Arasaratnam M, et al. *Online J Public Health Inform*, 2013). NCBP utilizes a web-based system (https://ncbp.bioprep.us/) of near real-time data collection, automated assessment and analysis to detect relevant disease conditions and symptoms. The system is designed to meet the bio-surveillance needs of key local and regional stakeholders while providing awareness and transparency of events to state and national decision makers. In addition, the NCBP system is providing information on critical healthcare infrastructure and relevant interventional needs and care resources. Thus, rapid recognition of events can be matched to the necessary resources on a timely and geographically relevant basis, providing a context of when local or state resources are insufficient to match the needs of the affected population.

The NCBP is a project sponsored by the US Department of Homeland Security (DHS) through a cooperative agreement with the University of North Carolina at Chapel Hill (UNC). Begun in 2010, the NCBP mission is to:

> "Enable its users to recognize events occurring in the biosphere that have significance to the health and security of people and infrastructure in users' jurisdictions, leading to more effective decision making in health and emergency response at the Federal, State and Local level."

On September 15, 2014, NCBP released an operational data visualization and analytics system capable of real-time analysis of streaming health data to detect meaningful changes in the data and visualizing the information in a geographic format. The system also enables users to search records by clinical symptoms, user-defined syndromes, and free text within the health records. The system has been developed using human health data from Emergency Medical Services (EMS), 911, Emergency Department (ED) and Poison Control Centers, with incorporation of statewide hospital bed and resource availability, live weather data, critical infrastructure (schools, roads, hospitals, federal facilities) and internet search feeds (Google searches). NCBP

architecture can now support the integration of virtually any data source for simultaneous analysis and layered visualization to provide greater insight and fidelity for the nation's preparedness resources and decision makers.

NCBP is unique in offering near real-time clinical data and custom analytics that generate signals and communicate them to users as the analysis occurs, with the goal of providing warnings of significant anomalies, in time to inform decision makers and support a response. The system is available to users 24/7/365.

The system was originally developed for analysts within DHS' National Biosurveillance Integration Center (NBIC), the project's sponsor, as a tool to detect incidences of bioterrorism. However, DHS appreciates that the system offers the opportunity to collaborate with state and local officials in the sectors of public health preparedness, human health, infrastructure protection, and agriculture. This collaboration provides more sensitive and specific insights, and thus a higher level of security for the nation, than DHS attempting to monitor the nation singlehandedly. NCBP is therefore offering the system to state and local officials and infrastructure owners who can contribute to the system's development and design.

For example, DHS has operated the nation's environmental detection system for bioterror events, known as BioWatch. To date, local BioWatch jurisdictions have a difficult time correlating these environmental measurements to clinical data. In other words, local officials are not in the position to take action with public health countermeasures needed in the event of biological attack without a keen understanding of whether people and animals are becoming ill or are likely to become ill. The NCBP system and the US Critical Illness and Injury Trials (USCIIT) Group are designed to provide this important perspective and to support the decisions necessary deploy public health countermeasures. Local jurisdictions have long recognized this need for clinical context to the BioWatch signals and I suggest Congress support the efforts of the DHS NBIC program to provide NCBP information to them. Local officials are the ones making the decision to deploy public health countermeasures and thus, federal agencies should be providing local officials the information needed for effective decision support.

Among various sources of human health data, data from Emergency Medical Services (EMS) has turned out to be the most timely and consistent. These near real-time data are entered by trained providers utilizing standardized forms and our group has pioneered the development of these systems, especially for EMS (Mears, et al, *Prehosp Emerg Care* 2010). EMS data is population based and is gathered by local EMS professionals who record emergency health data in free text, and they transmit it daily to the NCBP data center partner. NCBP currently incorporates every EMS call in NC, SC, and (soon) WV, MS, IN and AZ into its analysis, most within 24 hours. EMS data are acquired in a nationally standardized format National EMS Information System (NEMSIS), containing patient complaints, provider assessment, time stamps and the geocoding that enables geospatial analysis. As a result of this standardization, EMS data will be the most expedient source for NCBP to expand rapidly to other states.

In 2015, NCBP is entering the phase of development for expansion of the system toward a nationwide network of biosurveillance users, in order to provide ultimate value to the Federal government, and enables a wide network of state and local users to contribute to the nation's biopreparedness. With adequate funding, NCBP will incorporate additional states, implement additional analytic and visualization tools, add other data types (such as animal health and agricultural data) and engage new users from those disciplines. The goal for NCBP is to transition the system into a self-sustaining, not-for-profit entity to provide service to the Federal government.

National Need: A Rapid, Effective Clinical Response System

The appropriate treatment of critically ill or injured patients can vary minute-to-minute. Thus, timely access to reliable data is one of the foundations of contemporary intensive care. It follows then that optimal responses during public health emergencies, for both clinicians and decision makers, would benefit from comprehensive, real-time event reporting. This should include physiological patient data that are needed to provide immediate insight into the impact of the event on critical health care resources and to identify groups with high risk for morbidity and mortality.

Importantly, this reporting should include the highly granular patient data that is needed to 1) characterize clinical features, 2) provide immediate insight into the impact of the event on critical health care resources (e.g., mechanical ventilation, dialysis, medication availability), 3) assess healthcare staffing availability and training/educational needs, 4) identify groups of patients with high risk for morbidity and mortality, and 5) determine the efficacy and safety of treatment and medical countermeasures. Recent experiences globally, however, indicate that real-time clinical data aggregation, analysis, and reporting remain a strategic vulnerability during public health emergencies. (Lurie, et al. *N Engl J Med* 2013).

The United States Critical Illness and Injury Trials Group (http://www.usciitg.org) through its **Program for Emergency Preparedness (USCIITG-PREP)** aims to significantly enhance the national capability to rapidly glean crucial information regarding the clinical course of acute illness and injury and guide clinical resource requirements during emergent events:

- Real-time collection of clinical data by a coordinating center during a regional or national public health emergency
- Rapid analysis of clinical data to address key analytic outcomes, answering both clinical and operational questions:
- What was the nature of the clinical insult and the resulting phenotype?
- As a clinical responder, what, if anything, did you have to do differently?
- Did clinical diagnostics, countermeasures, and therapies work as expected?
- What was the operational impact on the patient and care setting?
- Was there anything essential needed that you did not get?
- What is the best/worst case that could happen next time?
- Timely dissemination of event-related information to inform front-line treatment

of disease and resource allocation, assuring patient confidentiality, data security, and strict version control.

Working with the Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR), leading professional organizations, and the Homeland Security Information Network (HSIN), **USCIITG-PREP has been developing mechanisms for rapid clinical data collection, analysis, and dissemination of findings during public health emergencies.** Pre-event work on protocols, data collection processes, rapid analysis techniques, and means to quickly disseminate findings to stakeholders are all crucial to making clinical science networks effective at enhancing the response. The USCIIT Group will leverage existing infrastructure to both strengthen pre-event operational science capabilities and provide timely data and situational awareness across the emergency care continuum during public health emergencies. Critical illness and injury professional organizations will use this rapid dissemination plan to inform their membership, in aggregate representing over 150,000 front-line clinicians, thereby saving lives and minimizing suffering based on the timely accurate guidance gleaned from operational science.

Furthermore, optimal outcomes in response to public health emergencies require rapid feedback on how well medical countermeasures (MCM) work to protect and treat affected individuals and their families. This information is used by clinicians in the field to guide therapy and by public health agencies responsible for mobilizing the necessary resources at both the regional and national levels. The overarching goal of USCIITG-PREP is to facilitate development of MCM's to protect against threats, specifically, select public health emergencies. **USCIITG-PREP is working to develop and implement strategies to assess, evaluate, and monitor medical countermeasure safety, performance, and patient compliance in response to a public health emergency.** The communication systems, infrastructure, data analysis and reporting algorithms, and sample collection and processing protocols that USCIITG-PREP develops for seasonal influenza could be applied directly to protect against other threat agents, including pandemic influenza (such as 2009 pH1N1), emerging respiratory viruses (such as H7N9, MERS-CoV, Ebola), and other biothreats agents such as inhalational anthrax . This work is also important because USCIITG-PREP uniquely catalyzes communication and builds infrastructure across the care continuum (prehospital, emergency department, intensive care units, rehab, adult and pediatric), linking HHS agencies, academic medical centers, community medical centers, critical illness and injury professional organizations, and industry. The USCIITG-PREP Steering Committee includes representatives from FDA, NIH, CDC, ASPR, and BARDA.

United States Critical Illness and Injury Trials Group

The United States Critical Illness and Injury Trials (USCIIT) Group serves as a "network of networks", with the dual missions to *foster investigator-initiated hypothesis testing* and to *develop recommendations for strategic plans at a national level*. (Cobb JP, et al. *J Trauma* 2009; Blum, et al. *Chest* 2013). To these ends, the USCIIT Group provides a venue for investigator communications, supports a multi-society task force for

research strategic planning, catalyzes HHS inter-agency dialog for endorsement of transforming initiatives (*e.g.*, NIH-ASPR-FDA-CDC-BARDA), and fosters innovative, multidisciplinary, multicenter studies the results of which will improve clinical care and preparedness (Cobb*, Crit Care Med* 2009; Deutschman CS, *Crit Care Med* 2012). The USCIIT Group is endorsed by all major U.S. critical illness and injury professional organizations spanning the specialties of anesthesiology, emergency medicine, internal medicine, nursing, pediatrics, pharmacy and nutrition, surgery and trauma, and respiratory and physical therapy. The USCIIT Group has grown to include over 200 investigators across more than 30 academic and community hospitals. *Collectively, USCIIT Group investigators have enrolled over 10,000 patients in studies during the last four years.* For more details, please visit the USCIIT Group web page at www.usciitg.org.

The USCIIT Group organizes some of its investigator-initiated projects (now numbering more than 50) into several, large-scale, collaborative Programs, consistent with the recent consensus strategic plan for critical illness and injury research in the U.S.

- **Program for Prevention of Organ Failures (USCIITG-PROOF):** Efforts to prevent organ failure are hampered by three barriers: i) compartmentalization of care (emergency department, operating room, ICU, *etc.*), ii) the difficulty of identifying early those at risk, and iii) lack of proven, effective preventative interventions. Building on the success of the Lung Injury Prevention Study (USCIITG-LIPS),(5) the unique, multidisciplinary, USCIIT Group network, and CTSA-funded infrastructure, USCIITG-PROOF addresses all three barriers simultaneously through rapid cycle, multicenter clinical trials that span clinical domains to test a variety of interventions that prevent organ failure in those at risk.

- **Program for Critical Illness Outcomes (USCIITG-CIOS):** Care delivered in intensive care units is high-intensity, high-cost, and has tremendous geographic and organ-specific variation. Little is known about which ICU organizational and structural factors are associated with high quality care and optimized outcomes. To determine which of these factors are most strongly associated with high quality critical care, USCIITG-CIOS enrolled ~6,400 patients across 69 ICU's in the US.(6) CIOS-2 planning is underway with grant submissions planned for this calendar year. There are numerous new collaborative opportunities for ancillary studies for those interested (we're especially interested in supporting new investigators).

- **Program for Early ICU Rehabilitation (USCIITG-PEIR) and USCIITG-Burn:** Physical therapists, respiratory therapists, speech language pathologists, and occupational therapists are essential for coordinating rehabilitation of critically ill or injured patients. Early rehabilitation can help to ameliorate and even avoid severe deconditioning associated with post-ICU syndrome (PICS), which presents as long-term physical, cognitive, and mental health problems after severe critical illness or injury. USCIITG-PEIR seeks to identify areas of heterogeneity of care and to improve early rehabilitation for critically ill or injured patients. Funded by the DOD, USCIITG-PEIR collaborates with USCIITG-Burn to actively enroll patients in a

multicenter, randomized controlled clinical trial to measure the effect of early rehabilitation on hospital stay, muscle loss, and functional outcomes in burn patients with acute respiratory failure.

- **Program for Emergency Preparedness (USCIITG-PREP):** There are insufficient capabilities internal to HHS to rapidly collect clinical data to inform decision makers and key end-users in public health emergencies, especially on illness severity and physiology. The USCIITG-PREP Group was funded by the Office of the Assistant Secretary for Preparedness and Response (ASPR/HHS) to create an electronic Core Data Set for public health emergencies (7). Version 1 of the data set was tested and validated across 12 clinical sites (HHS contract, Rapid Assessment of Acute Illness and Injury to Enhance the U.S. Response to Public Health Emergencies) with data analysis and dissemination within 24 hours of data collection. USCIITG-PREP is seeking support to operationalize data set capabilities at the national level, including IRB innovations to insure patient safety and protect privacy during emergent events as well as data analysis and rapid dissemination plans.

- **USCIITG-PREP PULSE Project:** USCIITG-PREP has been supported by ASPR to convene internet forums to address preparedness and response for threats to public health. The goal is to get near real-time feedback from USCIITG critical care volunteers distributed across the U.S. For example, some parts of the country are experiencing a shortage of normal saline and others a resurgence of severe respiratory failure from H1N1; other regions are not. This new tool is designed for USCIITG-PREP to document this variance in experience and assess health system stress. For USCIITG-PREP and ASPR to keeps its fingers on the "pulse" of a potential threat, feedback from our investigators in the form of answers to a few questions, say weekly, would be extremely helpful. Thus, we've called this internet-based tool "USCIITG-PREP Pulse", or simply Pulse, for short. After a successful pilot project on saline shortages, we are compiling a list of additional investigators/members who are interested in participating in Pulse. The project is sensitive to investigator time with the expected response burden for each forum will be minimal (less than 10 questions). We also expect that use of the tool will quickly evolve, making the response network more efficient and robust, and the Pulse tool easier and easier to use.

- **USCIITG-PREP Medical Countermeasures Project:** Optimal outcomes in response to public health emergencies require rapid feedback on how well MCM's work to protect and/or treat affected individuals and their families. This information is used by clinicians in the field to guide therapy and by public health agencies responsible for mobilizing the necessary resources at both the regional and national levels. The overarching goal of USCIITG-PREP is to facilitate development of MCM's to protect against threats, specifically, select public health emergencies. The overarching goal of this FDA proposal is to develop and implement strategies to assess, evaluate, and monitor medical countermeasure safety, performance, and patient compliance in response to a public health emergency. Influenza was chosen as the prototypic test case for this FDA proposal as it is one of the most predictable

and serious public health threats. Moreover, the communication systems, infrastructure, data analysis and reporting algorithms, and sample collection and processing protocols that USCIITG-PREP develops for seasonal influenza could be applied directly to protect against other threat agents, including pandemic influenza (such as 2009 pH1N1), emerging respiratory viruses (such as H7N9 or MERS-CoV, ebola), and other biothreats agents such as inhalational anthrax . This work is also important because USCIITG-PREP uniquely catalyzes communication and builds infrastructure across the care continuum (prehospital to rehab, adult and pediatric), linking HHS agencies, academic medical centers, community medical centers, critical illness and injury professional organizations, and industry. The **USCIITG-PREP Steering Committee** includes representatives from FDA, NIH, CDC, ASPR, and BARDA.

National Need: Cooperation and Collaboration

None of these initiatives will be successful ultimately, without the full cooperation and collaboration across Federal agencies, the states, and local governments. However, the current climate is not necessarily one of collaboration and cooperation. The reasons for this are multi-factorial and probably rooted in interagency claims of primacy and in segregated budget lines and congressional oversight. The nation's biodefense effort requires high-level direction and coordination from The White House. In past years, the various initiatives and programs of the nation's biodefense apparatus were overseen and coordinated directly by The White House, through a Special Assistant to the President for Biodefense. This position was vacated in 2009 and has not been filled. I would urge the Congress to unify its oversight of these biodefense programs so that money is spent more wisely and the agencies are working on behalf of each other rather than in competition.

This lack of programmatic unity is most felt at the state and local level, which is the tip of the spear for the nation's biodefense. It will be the hospital systems and EMS agencies that will first detect abnormalities in illness patterns. These same healthcare institutions will be expected to deliver lifesaving care in real time, currently without the perspective of what resources will need to be available and consumed during such an event. Local emergency managers will need to execute their contingency plans well before any federal disaster is declared or FEMA shows up.

Conclusion

The programs I have described above are important examples of programs that capitalize on local health and safety officials and practitioners' information and awareness to inform the Federal agencies. I encourage Congress to ensure that any biodefense program take into account the capabilities and the responsibilities of local and state institutions, which must be weaved into the fabric of national preparedness.

Thank you for the opportunity to testify before the subcommittee today.

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