



Healthcare Preparedness for Children in Disasters:

**A Report of the NACCD
Healthcare Preparedness Working Group**

November 13, 2015

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Executive Summary

The National Advisory Committee on Children and Disasters (NACCD) was established in 2014 under the [Pandemic and All-Hazards Preparedness Reauthorization Act of 2013](#) to provide expert advice and consultation to the Secretary of the US Department of Health and Human Services (HHS) and the Assistant Secretary for Preparedness and Response (ASPR) on the medical and public health needs of children before, during, and after a disaster or public health emergency. The NACCD is comprised of 15 voting members who are experts in the pediatric healthcare sector; state and local government representatives with expertise in disaster preparedness and response with a child focus; and federal agency representatives from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Department of Homeland Security (DHS), the Department of Education (DOE), and the Office of the ASPR.

On November 12, 2014, the ASPR signed a task letter for the NACCD to examine healthcare preparedness for public health threats, medical disasters, and mass-trauma/casualty emergencies as it concerns the pediatric population. Specifically, the ASPR asked that the NACCD assess the following as the basis of the formation of its report:

- *The current state of healthcare (both pediatric and non-pediatric) facility preparedness to care for children in mass disasters. Examples of variables may include site management, surge, transport, medical countermeasure capabilities, workforce development, innovative programming, communications streams, and partnership/coalition-building.*
- *A review of best practices, recommendations of potential long-term strategies, and a summary of practical tools to improve the ability of healthcare coalitions to effectively care for children after disasters.*
- *A summary of potential mitigation strategies for identified gaps.*
- *An assessment of current granting structures for pediatric healthcare capacity building.*

In response to this task from the ASPR, the NACCD narrowed the focus of this report to three key areas directly tied to our Nation's readiness to care for children affected by disasters: coalition building, workforce development, and medical countermeasure readiness. The NACCD realizes many other areas of importance need to be addressed (e.g., human services readiness, the power of children as resources during times of crisis, evacuation and reunification of unaccompanied minors, funding streams). We are looking forward to tackling these other important aspects of pediatric readiness in the near future.

In these three areas, the NACCD assessed the current state, assessed gaps, and developed potential mitigation strategies that are presented as recommendations to the HHS Secretary and the ASPR. We are confident these recommendations will serve as fuel for the ongoing national efforts between federal and nonfederal groups to work collaboratively in order to increase our nation's readiness to care for children in times of disaster. However, the NACCD realizes these recommendations are simply a snapshot in time and that only through ongoing dialogue, planning, and reassessment can our nation continue on a journey of improvements in pediatric readiness and children's health and wellness outcomes post-disaster.

Summary of Recommendations (Please see text for full analysis and recommendations):

- 1) **Coalitions:** The NACCD examined the structure, function, and constituents that make up the “ideal” pediatric coalition. These coalitions, both large and small, are aimed at assuring that the needs of children are addressed during disasters across agencies and across disciplines. While coalitions have matured in their structure and membership, the NACCD believes the federal government can play a key role in the enhancement and improvement of children’s disaster coalitions.

A brief summary of our recommendations:

- A) HHS/ASPR should support the utilization of a Pediatric Disaster Coalition model to develop and coordinate a comprehensive, integrated, multi-disciplinary, regionalized, team approach to plan for and manage disasters involving children by matching needs to resources for the pediatric population (i.e., a special needs group that comprises approximately 25% of the US population) and thereby, obtain optimal outcomes before, during, and after the events.
- B) HHS/ASPR should support the development of guidance for managing pediatric surge and evacuation that includes requiring an addendum to the hospitals’ annual Hazard Vulnerability Analysis/Exercises and the CDC’s Cities Readiness Initiative Exercises.
- C) HHS/ASPR should expand the definition of first responder for disaster preparedness to include all individuals who are qualified and poised to give care, including school nurses and child care providers. This expansion could occur initially within federally funded entities; however, the public sector could also encourage its partners in private jurisdictions to consider any worker who has child contact responsibilities as a response asset.
- D) HHS/ASPR should support the removal of a silo approach to pediatric disaster management by facilitating the incorporation of all entities that care for children in disasters into coalitions. This includes, but is not limited to, first responders, local, state and federal governmental agencies, pediatric national organizations, and both for-profit and nonprofit community-based organizations, including those not in the health-care sector.
- E) HHS/ASPR should work to establish within the National Disaster Medical System (NDMS) a cadre of pediatric professionals who would have the requisite training and expertise to serve on Department of Defense (DOD) aircraft to treat and stabilize pediatric patients with high acuity (e.g., evacuation of NICUs, children’s hospitals).
- F) HHS/ASPR should support the education and engagement of alternate caregivers in advocating for children in a disaster.
- G) HHS/ASPR should support the development of a process to operationalize pediatric disaster management by creating a guideline and template best practice plan for regional pediatric disaster coalitions that can be customized and utilized by all coalitions to provide a standardized approach and best outcomes for children in disasters.
- H) HHS/ASPR should allocate, whenever possible, and provide appropriate funding support for comprehensive pediatric disaster planning and management that includes support of

pediatric disaster coalitions. Furthermore, the Secretary /ASPR should promote — and when possible, facilitate — acquisition of other funding resources from the public and private sectors that include grants and financial support from corporations, foundations, non-governmental organizations, and others.

- 2) Work Force Development:** In addition to the key importance of strong coalitions, the front line personnel who are charged with caring for children affected by disasters need to be trained, organized, and resilient. This important group includes paramedics, emergency medical technicians (EMTs), nurses, physicians and other important caregivers. The NACCD examined the current state of workforce development (e.g., training, drills) and offered both high-level and operational recommendations for the Secretary and the ASPR aimed at improving the readiness of this vital workforce.

A brief summary of our recommendations:

- A) HHS/ASPR should work with appropriate organizations to develop pediatric disaster training standards for:
 - 1. Physicians
 - 2. Nurses
 - 3. School Nurses
 - 4. Federal Response Teams
- B) HHS/ASPR should explore tasking the NACCD (with guidance from subject matter experts at the CDC, AAP, and other interested parties) to develop recommendations that will guide curriculum development for a pediatric disaster preparedness training program.
- C) HHS/ASPR should include all appropriate types of first responders in education and training for pediatric disaster preparedness, including school nurses and child care providers.
- D) HHS/ASPR should develop and deliver a bystander disaster training curriculum to address personnel shortages in a large-scale disaster.
- E) HHS/ASPR should assess the need for a dedicated organization to house a center for healthcare disaster modeling.
- F) HHS/ASPR should continue to disseminate best practices in facility and site management for pediatric care in disasters.
- G) HHS/ASPR should develop a national strategy, together with both public and private partners, to improve pediatric emergency transport and patient care capabilities for disasters, including to or from alternate healthcare facilities such as school sites.
- H) HHS/ASPR should assess the state of existing technology to aid in tracking and reunification, including identification of significant gaps. HHS should develop and fund competition-style programs (e.g., similar to the XPRIZE), “hackathons”, and other programs of the type currently being used by the technology sector to promote innovation in order to encourage remediation of these gaps.

- I) HHS/ASPR should incorporate pediatric-specific standards into the Healthcare Preparedness Capabilities guidance document and should assess pediatric preparedness in Hospital Preparedness Program (HPP) applicants and funding recipients.
 - J) HHS/ASPR should promote Incident Command System training and exercises/drills for healthcare professionals and other facilities that provide care to children to improve crisis coordination and communication.
 - K) HHS/ASPR should recommend the development, testing, and regular use of communications strategies and capabilities as a vital component of coalitions. CDC's public health communication training and related resources are examples of best practices that HHS/ASPR should promote and disseminate.
 - L) HHS/ASPR should work with the Federal Emergency Management Agency (FEMA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to improve the Crisis Counseling program. Specifically, the program should have the flexibility to address preexisting mental health conditions that might be exacerbated by disaster.
- 3) Medical Countermeasures:** The final section of this report includes an important look at medical countermeasures for children. Thanks to the hard work of federal and non-federal agencies, the nation's ability to dispense medical countermeasures to children has significantly improved over the past decade. Gaps do remain, however, and our report supplements excellent work done by other advisory committees aimed at addressing how best to prepare for the needs of children affected by natural or man-made calamities requiring medical countermeasures.

A brief summary of our recommendations:

- A) HHS/ASPR should collaborate with federal partners to provide anthropometric tapes and the necessary training to use them correctly.
- B) HHS/ASPR should collaborate with other federal partners to promote the development of weight bands for dosing¹ to more readily estimate emergency drug doses. By this method, a range of child weights could be designated a single drug dose, depending on the specific drug. This method could reduce safety concerns regarding larger doses. Extensive training on this equipment will be critical as well.
- C) HHS/ASPR should promote the development of alternative drug delivery methods that are facile for any responder to use with minimal potential difficulties, e.g., an alternative to utilizing pumps to maintain flows or drips.
- D) HHS/ASPR should collaborate with other federal partners to prioritize grant funding for studies to define how adult auto-injectors might be adapted for use in the pediatric population.

¹ Larson, C. P., Sauv , L., Senkungu, J. K., Arifeen, S. E., & Brant, R. (2015). Development and Validation of Weight, Height and Age Bands to Guide the Prescription of Fixed-Dose Dispersible Tablet Formulations. *The Journal of Pediatric Pharmacology and Therapeutics*, 20(1), 24–32.

- E) HHS/ASPR should prioritize and allocate funding for the immediate development and production of solid oral dosage forms which are palatable, orally dissolvable or dissolvable in small amounts of liquid, in pediatric strengths and sizes.
- F) HHS/ASPR should raise awareness of EUA/EUI/IND practices, clearly delineating distinctions between these mechanisms wherever possible. First responder personnel especially need to be aware that medications can be used off-label in an emergency with appropriate authorization, and have access to existing instructions on the appropriate uses of EUA/EUI in pediatrics.
- G) HHS/ASPR should thoroughly review the legal and ethical issues surrounding distribution of investigational agents prior to an event, and promote the availability of this information (along with overall guidance on the process) to those who will be administering these MCMs under a special authorization. Information on EUA's and EUI's — both general and legal/ethical — should be known and readily understood by clinicians, pharmacists, nurses, and emergency responders.
- H) HHS/ASPR should develop and pursue collaborations among the Biomedical Advanced Research and Development Authority (BARDA), FDA, and NIH, or among BARDA, Defense Advanced Research Projects Agency (DARPA), FDA, NIH, and the pharmaceutical industry to develop improved pediatric drug formulations in the CHEMPACK or Strategic National Stockpile (SNS), using the NIH-FDA Formulations Platform² as a model.
- I) HHS/ASPR should facilitate a collaboration among key stakeholders (e.g., American Academy of Pediatrics [AAP], CDC, FDA, American Pharmacists Association) to develop a standard list of medications and devices (e.g., face masks, needles, and syringes for children) which should be stocked in pharmacies for chemical and biologic emergencies.
- J) HHS/ASPR should facilitate the collaboration of key partners (e.g., AAP, CDC, and FDA) and public health law experts to consider, review, and develop innovative emergency consenting methods that focus on rapid delivery of care.

In total, the NACCD believes this report addresses much of the request from the ASPR. We have examined the important role of coalitions, discussed appropriate workforce training and development, and updated the Secretary of the current state of medical countermeasure readiness. However, as stated above, much work remains to be done. The NACCD stands ready to assist in the important and continuous journey to better prepare our nation to care for children affected by disasters.

² U.S. Department of Health and Human Services. National Institute of Health. 2009. Pediatric Formulations Platform. Retrieved from: <http://bpca.nichd.nih.gov/collaborativeefforts/initiatives/Pages/index.aspx>

Introduction

A. About the National Advisory Committee on Children and Disasters

The National Advisory Committee on Children and Disasters (NACCD) was established in 2014 by the [Pandemic and All-Hazards Preparedness Reauthorization Act of 2013](#) (PAHPRA) to provide expert advice and consultation to the Secretary of the US Department of Health and Human Services (HHS) and the Assistant Secretary for Preparedness and Response (ASPR) on the medical and public health needs of children related to all-hazards emergencies, and to provide input on preparedness activities ranging from disaster drills and exercises, to grants and cooperative agreements.

The 15-member NACCD (see Appendix C) comprises public health and medical experts from federal, state, and local health agencies and child experts experienced in disaster preparedness and response. NACCD members understand that children have unique needs and should not be treated like little adults when it comes to public health emergencies and disasters. The NACCD seeks to build upon the foundational work already accomplished by many organizations and individuals to ensure the health needs of children are met nationwide during public health emergencies and disasters.

B. Healthcare Preparedness Task

In November 2014, the ASPR sent a task letter (see Appendix A) to the NACCD requesting an assessment of the current state of healthcare readiness nationally to care for pediatric patients after disasters. With multiple national disaster scenarios that could harm children in communities across the nation, it is imperative that healthcare capabilities such as transport systems, medical countermeasures, the workforce, and coalitions account for and accommodate pediatric patients. Without strong pediatric preparedness, the wellbeing of children is at risk. The ASPR requested the NACCD to provide their expert insight, identify gaps, and form strategies to improve pediatric healthcare preparedness. This report summarizes the gap analysis and identifies mitigation strategies. The NACCD assessed current preparedness in children's and non-children's hospitals from several angles to provide a comprehensive set of recommendations relevant to federal policymaking decisions.

C. Methods

The NACCD formed the Healthcare Preparedness Working Group (HCPWG) (see Appendix B) under its auspices to gather the experts of pediatric preparedness within the NACCD to respond to the task letter. The HCPWG also enlisted additional experts from outside the NACCD to be members. It is with this variety of experts with experiences and knowledge of the current state of healthcare preparedness to care for children in disasters that this report with recommendations was developed. HCPWG discussions were also forward-thinking in an effort to identify trends for the ASPR's awareness.

Subject matter experts (see Appendix D) with background, training, expertise, and real-world experiences in disaster preparedness and response in healthcare systems were invited to share their insights and augment the HCPWG's knowledge base. The HCPWG also reviewed published and unpublished literature with the help of the National Library of Medicine (NLM) and the newly developed ASPR Technical Resources Assistance Center and Information Exchange (TRACIE) to gather additional

information on gaps and lessons learned from previous notable emergencies and disasters. Finally, the HCPWG invited ASPR staff from across the agency to deliberate on several areas of hospital preparedness, children, and disasters. Members considered the essential question: ***What areas of healthcare might the ASPR and the HHS Secretary influence to improve preparedness to care for injured or ill children in disasters?***

D. Gaps and Recommendations

Experts identified many gaps that exist within the healthcare industry when it comes to caring for children in disasters. Their concerns included issues at the local, regional, and state levels or within private institutions, all of which fall outside federal authority, influence, or responsibility. The HCPWG believes that although those issues are relevant and pertinent to pediatric preparedness, they were not the focus of this report. The report specifically aims to provide the ASPR and the HHS Secretary with a snap shot of those issues as they may lend themselves to future considerations, but primarily seeks to provide recommendations which the ASPR will implement at the federal level.

I. Partnerships and Coalition Building

Background

Over the past several years, it has become apparent that children are better cared for in disasters (whether a local incident or national catastrophic event), when local, regional, and federal resources and agencies have planned, drilled, and/or worked together *before* the event. Pre-event resiliency-building and the provision of medical, behavioral health, family, and social services³, up-to-date risk communication to providers and the lay population, as well as food, power, shelter, and security are paramount and essential elements of pediatric disaster plans. Pediatric disaster coalitions, incorporated into overall disaster planning and management, are now recognized as a most effective mechanism to match resources to needs during catastrophic events and thereby provide the best outcomes for pediatric victims and their families.

Pediatric disaster coalitions have grown from grass roots efforts of two to three healthcare providers and agencies planning together, to more formal, structured entities that include the full gamut of pediatric disaster response units. While the potential effectiveness of utilizing pediatric disaster coalitions is clear, several questions remain. What is the ideal make up, governance, subject matter expert operational capability, capacity, and funding resource for pediatric disaster coalitions? How do they fit into the overall disaster response? How can best practices and standards of care become part of this new paradigm of disaster response? This section covers the current state of affairs, gaps, mitigation strategies, and best practices delineated in the focus areas below and makes recommendations to HHS/ASPR that are intended to provide optimal outcomes for children affected by disasters. Likewise, where applicable, the NACCD has identified those areas that may require further research or investigation.

A. Pediatric Hospital Coalitions: Local, Regional State, Interstate, and Federal

1. Current State and Gaps:

Significant variation exists in the development and strength of healthcare coalitions. The trend appears to be that coalitions in major metropolitan areas, with already robust pediatric resources, have established stronger and broader regional networks than rural or interstate coalitions. These latter coalitions tend to have pediatric-specific resource needs spread over large geographic areas with more limited access to immediate and ongoing pediatric critical, trauma, and mental health care. There is currently a realization that non-pediatric facilities, previously omitted in pediatric disaster response planning, must develop pediatric-specific annex operational plans that are routinely incorporated into training and exercise processes.

The majority of children in the United States are cared for at “general” emergency departments and hospitals that will be required to surge to care for pediatric disaster victims during catastrophic events. Much of the current information known about the state of pediatric readiness for emergency departments nationwide comes from the Health Resources and Services Administration’s (HRSA) Emergency Medical Services for Children (EMSC) National Pediatric Readiness Project. This project conducted a voluntary survey among emergency departments and received an 83% response rate. The National Pediatric Readiness Assessment

³ The terms “social services” and “human services” are interchangeable.

revealed a significant gap in non-pediatric hospital preparedness. Only 47% of hospitals actually have disaster plans that include pediatric-specific needs. All hospitals currently conduct an annual Hazard Vulnerability Analysis; however, they often do not address the pediatric population. Adult-centered hospitals may have significant gaps in the level of pediatric-specific equipment, medications, and training that they have available for children. To address this situation, a pediatric toolkit has been created by EMSC that provides essential domains for pediatric preparedness for hospitals to adopt and integrate into their existing plans. These toolkits can be utilized by a pediatric disaster coalition to enhance its planning and create significant pediatric surge capacity and capability.

Additional cited barriers to preparing and responding to pediatric disasters include lack of resources or expertise in partnership building to establish an effective pediatric coalition that works effectively within an overall response. Silos related to resource management, segmentation of health and mental health care, family and social services, and incident command structure, often inhibit the best practice provision of a pediatric disaster response.

Within many disasters, the limitations of a pediatric response may currently rest on a single choke-point represented by a lack of sufficient qualified responders, adequate communications, transport capability, or sufficient community and hospital resources. Some pediatric coalitions have already or will be addressing these problems in the future.

Gaps remain in planning and management for pediatric patient-specific groups requiring a surge or evacuation during disasters. These groups include Pediatric Intensive Care Unit (PICU) patients, Neonatal Intensive Care Unit (NICU) patients, and pediatric nursing home patients, women in labor and newborns, as well as special needs patients. Some pediatric disaster coalitions have already developed pediatric-specific guidelines and template surge and evacuation plans to address these needs; however, they have not been disseminated or adopted nationally by consensus. Doing so would greatly facilitate best outcomes for these populations.

Significant funding shortages currently exist that may prevent the development of best practice, comprehensive pediatric disaster coalitions nationwide from a local, regional, interstate, and federal standpoint nationwide. There remains a need to develop funding resources from all sectors to support this need. (The NACCD is currently examining the state of funding streams tied to pediatric disaster readiness.)

2. **Best Practices and Mitigation Strategies:**

Some longstanding pediatric disaster coalitions have developed integrated and coordinated entities that provide planning, management, training, and exercises for the care of children in disasters. In some areas, they have been able to create best practice responses to pediatric disasters that include initial incident scene first response, primary and secondary transportation, hospital and facility surge, and evacuation during events, as well as, resiliency building, mitigation, and post-event recovery strategies. Thus the “Mutual Aid” approach is ideal, utilizing these coalitions’ structure and activities as models to support the development of others. Although no two coalitions are the same due to disparities in geography, resources, training, and funding, it is important that we develop best practices and mitigation strategies that build on existing knowledge and resources while incorporating lessons learned from exercises and real world events.

Pediatric disaster coalitions require a significant number of members and partners (see list in NACCD recommendations) to effectively accomplish their goals of providing an optimal response to pediatric disasters. This comprehensive membership includes local, state, regional, and federal resources, providers, and agencies. A coordinated, integrated, team approach that breaks down silos and allows for professional collaboration between the varied entities is paramount.

Every Medical Coordinating Center should have a pediatric liaison that can provide field support to Emergency Medical Services (EMS) and assist with placement, mental health needs, reunification plans, and medication dosing instructions. In addition, every hospital should have a pediatric liaison represented within regional coalitions.

In preparing for small- or large-scale incidents, especially those involving children, pediatric mental health experts and providers should be an integral part of the coalition team approach to disaster planning and mitigation. It is essential that pediatric disaster-related mental and behavioral health issues are addressed to provide immediate (i.e., pediatric psychological first aid), ongoing, and post-event care. Many of the excellent resources from the National Child Trauma Stress Network (NCTSN) and SAMHSA can be utilized as training and educational resources.

Pediatric ethicists should be included in coalitions, and pediatric ethical decision-making guidance should be added to the pediatric medical surge and evacuation plans of pediatric and general hospitals.

In recognition that there is great diversity across the country in coalition missions, makeups, functions, and formalities, pairing the healthcare community with the academic or scientific community builds competency for integrating scientific investigation and complex modeling into preparedness plans and post-disaster research. This pairing also lays the groundwork for developing best practices.

Pairing with private corporate partners can provide access to otherwise untapped resources that heighten innovation and efficiency. The utilization of corporate philanthropy and corporate responsibility has opened the door for more collaboration with healthcare providers.

It can also be extremely helpful for coalitions to have lay community members, such as parents, as part of the collaborative process to serve as advocates for children in determinations of resource allocation.

Coalition-led pediatric disaster and emergency preparedness planning and subsequent exercises to operationalize plans should be based on vulnerability analyses that apply an all-hazards approach. This could include requiring the addition of pediatric surge/evacuation response to hospitals' annual Hazard Vulnerability Analysis/Exercises and the CDC's Cities Readiness Initiative Exercises. Pediatric-specific plans should be incorporated by all regional medical coordinating centers that oversee public health operations, such as phone banks, home visit dispatch, provision of medical advice, security, Medical Reserve Corps and Community Emergency Response Teams (CERT) operations, antiviral dispensing, and EMS coordination. The pediatric plans should be an integral part of the overall incident command system applied across all pertinent silos of disaster management. Pediatric planning should include guidelines and template plans that comprehensively cover the pediatric population, including pregnant women, sick neonates, well newborns, children, adolescents, and special needs patients,

including those in nursing homes. This process includes pediatric-specific pre-hospital, hospital, and community disaster planning and management from initial scene to primary and secondary transport and arrival at the hospital or other point of care.

To address the previously mentioned gaps in non-pediatric hospital preparedness, these hospitals should utilize the EMSC hospital pediatric toolkit and domains to ensure that they have a pediatric annex in their disaster plan that provides for pediatric-specific space and equipment, as well as training and expertise in providing pediatric care during a disaster-related event. Pediatric coalitions should include these hospitals in their disaster planning and management strategies with special emphasis on rural areas and those that lack adequate pediatric first responder or hospital resources.

When establishing or strengthening a coalition, creating a network map and conducting a survey of participating public and private agencies can provide a comprehensive map of resources and expectations of participants.

Many effective coalitions have developed operational definitions to accurately inventory pediatric resources across facilities. This includes tiering of hospitals based on capacity and capability to care for critically injured children with trauma and medical/surgical problems to pediatric and non-pediatric facilities that can care for mild to moderate casualties based on planning and resources. Standardized definitions of capabilities (e.g., Pediatric Intensive Care Unit, subspecialty services, and pediatric-capable emergency departments) could be used by pediatric disaster coalitions nationwide.

Medical Coordinating Centers and the facilities in their coalition should use the same resource tracking software to ensure efficient appropriation of supplies in chaotic times. This software can be tested as pediatric- and adult-centered hospitals hold joint exercises. Non-pediatric hospitals should be required to test pediatric response capabilities in large-scale disasters. A state-wide dispatching system can divide the state into regions and designate regional coordinators or dispatchers. This type of system maximizes the utility of all available resources against demands, and can fluidly change routings as situations at facilities change.

Effective strategies when resources are limited include grassroots relationship building between planners, responders, and providers, as well as utilizing existing community, hospital, social service, and mental health resources that may supplement funding for coalition building.

3. **NACCD Recommendations:**

- a. HHS/ASPR should support the utilization of a Pediatric Disaster Coalition model to develop and coordinate a comprehensive, integrated, multi-disciplinary, regionalized, team approach to plan for and manage disasters involving children by matching needs to resources for the pediatric population (i.e., a special needs group that comprises approximately 25% of the U.S. population) and thereby, obtain optimal outcomes before, during, and after the events.
- b. HHS/ASPR should support formal operational definitions of essential pediatric components needed to respond to a disaster to aid in coalition development and support. These definitions include units of care, such as a Pediatric Intensive Care Units, policies, and equipment minimums.

- c. HHS/ASPR should support the development of guidance for managing pediatric surge and evacuation that includes requiring an addendum to the hospitals' annual Hazard Vulnerability Analysis/Exercises and the CDC's Cities Readiness Initiative Exercises.
- d. HHS /ASPR should support the inclusion of pediatric-specific training that includes medical and mental health elements (e.g., pediatric psychological first aid) in the immediate response and post-recovery phases for all healthcare providers and emergency responders.
- e. HHS/ASPR should support the following structure and activities of pediatric disaster coalitions:
 - 1) Coalition experts from varied local groups (e.g., community participants, governmental agencies, children's hospitals, and pediatric academic centers of excellence) should develop and continually update disaster plans based on evidenced based medicine, shared best practices, lessons learned from exercises and real world disasters, as well as literature reviews utilizing the resources of the NLM and TRACIE. Whenever possible, pediatric disaster-related information should be readily accessible and updated through web-based and other communication portals (e.g., list serves).
 - 2) Where possible, coalitions should have additional representation from the following entities:
 - a) First responders including Fire, EMS, Offices of Emergency Management
 - b) Security-related groups, including local and state law enforcement, National Guard and other federal agencies, including Department of Homeland Security (DHS) and Department of Defense (DOD)
 - c) Local Trauma Centers, Emergency Departments, Pediatric and Non-pediatric Hospitals, community healthcare providers, including independent practitioners, clinics, and urgent care centers
 - d) Social media experts, poison control centers, pediatric pharmacy and medical countermeasures experts, representatives from national organizations (e.g., American Academy of Pediatrics [AAP], Trauma Nursing, Nursing, Red Cross), mental health practitioners, experts in bioethics, schools and departments of education, social and behavioral services related to children and families, and representatives of the lay population.
- f. HHS/ASPR should support the utilization of resources (e.g., HPP, BARDA, TRACIE) to continue to enhance an ongoing working relationship and communication with other partners including EMSC/HRSA, CDC, NIH, DOD, and FEMA/DHS, to foster the development of comprehensive integrated disaster management plans that include the special needs of the pediatric population. (For example, EMSC and HPP could work together to further develop pediatric domains, guidelines, and template installation plans for all non-pediatric hospitals, thereby greatly increasing the resources available for children during disasters.)
- g. HHS/ASPR should review and disseminate best practices, recommended long-term strategies and practical tools of emerging local, state, and regional pediatric (including newborns, neonates, children and adolescents and special needs patients) disaster coalitions to improve the ability of other healthcare coalitions to effectively care for children after disasters.

- h. HHS/ASPR should allocate, whenever possible, and provide appropriate funding support for comprehensive pediatric disaster planning and management that includes support of pediatric disaster coalitions. Furthermore the Secretary /ASPR should promote — and when possible, facilitate — acquisition of other funding resources from the public and private sectors that include grants and financial support from corporations, foundations, non-governmental organizations, and others.

B. First Responders

1. Current State and Gaps:

The amount of pediatric-trained first responders will be small in most large-scale disasters. In a disaster situation, the definition of first responders needs to be expanded beyond the traditional EMS provider to adequately handle the needs of children. Police, child care providers, and school nurses are examples of individuals poised to respond.

The outcome of care depends on the adequacy of the initial assessment and implementation of appropriate interventions. An organized systematic approach to trauma management in centers with qualified caregivers is crucial for optimizing patient outcome. These centers need to be prepared to provide consultation to other satellite facilities where the healthcare response is delivered when patient transport is limited or not feasible.

2. Best Practices and Mitigation Strategies:

Pediatric prehospital disaster triage protocols exist and have been successfully implemented in disaster situations. These triage systems need to be integrated into the overall first responder framework that includes all populations.

Successful integration occurs when first responding agencies test pediatric response capabilities in large-scale disasters. Models exist that demonstrate strategies to training, testing, and implementing pediatric responses in large-scale disasters that include participation by first responders and bystanders.

School nurses are most certainly first responders in the school setting during emergencies and disasters. Their comprehensive and broad education places them in a pivotal position to lead first aid teams. The school nurse is often the leader at the school district level to initiate communication with local emergency response partners to assist with planning efforts. Child care providers play a similar role for children outside the school system. They are responsible for the health and well-being for children under their care. School nurses and child care providers therefore need to be formally defined as “first responders” when consideration is being given to staffing of healthcare personnel in acute care facilities and in emergency medical services roles for disaster preparedness. They should also be included by the medical community to provide support for any type of disaster or tragedy that occurs in the school setting or community.

3. NACCD Recommendations:

- a. HHS/ASPR should expand the definition of first responder for disaster preparedness to include all individuals who are qualified and poised to give care, including school nurses and child care providers. This expansion could occur initially within federally funded entities;

however, the public sector could also encourage its partners in private jurisdictions to consider any worker who has child contact responsibilities a response asset.

- b. HHS/ASPR should include all appropriate types of first responders in staffing for pediatric disaster preparedness.

C. National Pediatric Organizations

1. Current State and Gaps:

Our nation is fortunate to have many national organizations devoted, at least in part, to improving the health and well-being of children affected by disasters. These include not only pediatric-focused bodies, but also professional associations representing those directly involved in the care of children in the field. These organizations contribute to the care of children by publishing guidelines, producing policy statements, designing continuing education courses, and by providing real time guidance and advice to coalitions both before and during disasters. Likewise, programs such as Emergency Medical Services for Children (EMS-C) provide grants to support local and regional efforts at improving the care of children in disasters, small as well as catastrophic.

2. Best Practices and Mitigation Strategies:

In order to continue paving and navigating the nation's road to improving the care of children affected by disasters, powerful and dedicated national leaders must be consistently engaged in not only building capacity locally and regionally, but in strengthening the national capacity to care for children.

3. NACCD Recommendations:

- a. HHS/ASPR should look to national pediatric organizations as an important consultative and operational group to:
 - Work in collaboration with Federal Advisory Committees and ASPR staff in developing best practices for pediatric coalitions
 - Review current state of pediatric readiness
 - Act as content experts as pediatric guidelines and training are developed
 - Disseminate protocols and best practices developed by the ASPR and its Federal Advisory Committees
 - As needed, serve as a real time resource for support of federal response to disasters
- b. HHS/ASPR should encourage more national groups of great importance to pediatric readiness and response (e.g., Children's Hospital Association), to stand up groups that are dedicated to improving care for children regionally affected by disasters.

D. Other Federal Partners in Pediatric Readiness (e.g., DOD, National Guard, NDMS)

1. Current State and Gaps:

The Department of Defense (DOD) plays a major role in preparing for and responding to national disasters, and coordinating and cooperating with defense partners is an integral part of all-

hazards readiness. Likewise, in large-scale disasters, the DOD is charged with the evacuation of civilian patients to Federal Coordinating Centers (FCC).

2. **Best Practices and Mitigation Strategies:**

While these key defense partners are of great value in not only preparing for but responding to disasters affecting children, their pediatric knowledge and experience is quite variable. Thus DOD representation in pediatric disaster coalitions is critical.

Under the ASPR, the National Disaster Medical System has been working to increase not only its baseline pediatric training but has worked to increase its ranks with pediatric specialists such as pediatric surgeons, pediatric EM physicians, and ICU specialists. These special government employees could serve as important caregivers in large-scale national disasters; therefore, they should also serve as pediatric disaster coalition members.

3. **NACCD Recommendations:**

- a. HHS/ASPR should work in collaboration with the Department of Defense in establishing best practices for the care of children requiring evacuation to FCCs by DOD.
- b. HHS/ASPR should work to establish within NDMS a cadre of pediatric professionals who would have the requisite training and expertise to serve on DOD aircraft to treat and stabilize pediatric patients with high acuity (e.g., evacuation of NICUs, children's hospitals).

E. Engagement of Non-Healthcare Sectors

1. **Current State and Gaps:**

The clinical healthcare system is only one support system that helps children in times of disaster. Other systems include behavioral, family, public health, schools, early childhood programs, child care, Head Start, child welfare, foster care, employee assistance programs, neighborhood and community institutions, and recreational centers. These systems are capable of assisting children by providing structure and routine that prevents health problems during a disaster as well as during recovery.

Children can spend a significant amount of time outside the home in these education, child care, and community sectors. Children in poverty have fewer resources to respond to a disaster and rely on these sectors for essential support. These sectors provide resources that can include shelter, food, healthcare services (including behavioral health), and financial support.

There is currently a strong bond between public health and emergency management, but these two systems are unfamiliar with the actual workings of essential social services. Providers do not know the social services to call, which is a responsibility often placed on healthcare facility social workers.

The HHS Administration for Children and Families established the Children and Youth Task Force in Disasters, which has published a model for how to coordinate the different health and human services agencies and professionals in a disaster response. They have published a set of guidelines on how to develop the model on local and regional scales, which provides examples from the 2011 Joplin tornado and 2012 hurricanes Sandy and Isaac.

Returning to normalcy after a disaster is one of the top priorities for human service agencies. This includes returning to a safe home environment and school or regular child care.

2. Best Practices and Mitigation Strategies:

Achieving health security requires breaking down the silos and obstacles to integration of health and human services. Strengthening key alliances will help everyone involved to carry forward the same plan in unity. Healthcare coalitions can serve as a locus of coordination for healthcare and non-healthcare sectors. They can model effective approaches for care of the child after a disaster and provide practical strategies and tools.

An effective response to a large-scale event will leverage multiple social systems. Alternative caregivers and care sites must be considered. Teachers, schools, daycares, and similar should be included in healthcare coalitions, disaster planning, and exercises. Thinking beyond the basic necessities of food and water to planning for power, special needs, special equipment, foster care, supervision, reunification, security at mass shelters, and privacy will lead to a comprehensive response and improved health outcomes in children.

3. NACCD Recommendations:

- a. HHS/ASPR should identify non-healthcare sectors, such as human services, as critical resources and elements in Federal disaster preparedness strategies.
- b. HHS/ASPR should review best practices of healthcare coalitions for the integration of non-healthcare sectors in the overall disaster response and recovery strategy.
- c. HHS/ASPR should consider a report on best practices for the integration of non-healthcare sectors for widespread circulation to state and regional partners.
- d. HHS/ASPR should support the education and engagement of alternate caregivers in advocating for children in a disaster.

II. Workforce Development

Background

The current culture of preparedness in healthcare is reactive instead of proactive. For instance, the 2014-2015 Ebola outbreaks in West Africa caused panic waves around the world, demonstrating our enhanced connectedness and resulting vulnerability. The outbreak also forced us to respond to a threat in ways that we had not predicted, causing healthcare facility capital expenditures that were based on loose estimates. Furthermore, the training requirements needed to prepare staff for safety and appropriate care were underestimated and, thankfully, not tested under a real surge of infected or potentially infected patients. Children were a part of the Ebola planning conversations, but the realities of caring for an infant or toddler during an incubation period were incomplete and matching theory to practice presented challenges.

Part of the challenge in healthcare preparedness and response in the United States lies in the designation of different federal, state, and local powers and responsibilities. The state and federal governments have the benefit of the broadest vision and access to expertise, but the actual engagement and response takes place on a local level, using the resources and knowledge of unique conditions therein. Communities are tasked with limited funding, variable capabilities, but also the challenge of coordinating everyday operations while simultaneously preparing for disaster. This section assesses the status of ground-level, front-line capabilities and operations of our nation's communities to treat children in a disaster, which many subject matter experts have commonly called "space, staff, and stuff." This section also proposes how HHS/ASPR can use its resources and influence to enhance these efforts.

A. Physician/Nurse/First Responder Training

1. Current State and Gaps:

Pediatric preparedness information and training are available, but there are deficits. There is no complete central repository for pediatric preparedness resources, such as validated training content, training platforms, or just-in-time materials. Over recent years, a number of preparedness training courses were developed and many of these programs lacked sufficient pediatric subject matter. There is little work done that shows the efficacy of these approaches, and in most cases, the material is only designed for physicians and nurses rather than the full spectrum of healthcare workers that comprise a response and treatment team. Several organizations have begun work to address these gaps in core material and delivery. For example, the American Academy of Pediatrics stood up a disaster committee that meets semi-annually to address ongoing pediatric preparedness issues and policies. This committee has identified education as a key factor in mitigating the ill effects of catastrophic disaster.

The following section covers pediatric-specific workforce issues and concerns by job category, including first responders; emergency physicians and nurses at hospitals; physicians-in-training (residents); pharmacists, physicians, and nurses in ambulatory care/the community; and nurses in schools. We will indicate areas for growth and better understanding of the appropriate workforce development needs in caring for children following disasters.

First responders would greatly benefit from further pediatric training. Disaster preparedness training institutes offer modules on pediatric care during a disaster; the depth and frequency of trainings is lacking, however. Where institutional trainings fall short, some municipalities are

holding less formal trainings and lectures among the EMS, medical facilities, and academic communities. These “Pediatric Boot-Camp” trainings create an intensive program that focuses on the special needs of children.

The top three requested nursing trainings through the Emergency Nurses Association are for trauma, pediatrics, and disaster education. Nurses in all healthcare settings will be better prepared to care for children in disasters by receiving education, training, and experience in acute care nursing.

Preparing primary care providers to provide basic disaster/triage care for infants and small children is not presently on the radar. Non-pediatric residencies often lack pediatric emergency response training. The return on investment for training primary care providers on disaster/triage care is yet unknown. Both non-pediatric residents and primary care providers will have to care for patients in a disaster, however, and opportunities for training are therefore necessary.

Pharmacist training is also needed; aside from serving as a critical resource for a response, pharmacists should be involved in developing communications regarding medication supply and resource shifting. Pharmacists will also be integral to distribution of MCMs during disasters, including during special programs such as emergency use authorizations.

While ambulatory care clinicians may not be best suited for mass casualty triage, they will be necessary for vaccination, treating infections and acute radiation syndrome, providing post-incident follow-up, and a host of other critical roles that warrant thorough pediatric preparedness training.

The level of emergency preparedness among school districts and schools (i.e., public, independent, parochial, and charter) differs greatly across states and the nation. Unfortunately, the ability to care for children in mass disasters is dependent upon educational leadership’s understanding or lack thereof, of federal disaster preparedness directives, state laws, and tenets of the emergency management cycle (i.e., prevention, preparedness, response, recovery, and mitigation) and unlikely implementation of a realistic emergency operations plan reflective of an all-hazards assessment for the school community. The ability for school leadership and school health personnel to respond to the needs of children in disasters is also dependent upon their typically limited knowledge of the National Incident Management System and the Incident Command System *as they apply to schools*. School leadership must consider a changing school climate and the factors that contribute to school safety in today’s schools. This requires a paradigm shift in thinking about how we prioritize school safety in an academically-focused environment.

There is not an organized, systematic training process across the country that includes “schools”. Typically, school districts initiate training and assistance with emergency/disaster planning and response, and are rarely included in local and state planning on a routine basis. Funding for schools to seek training, or purchase equipment and supplies, is also very limited. Many times, not until the disaster has occurred are schools included in planning efforts.

School nurses are often overlooked as an asset in public disasters. The school nurse is a leader in first aid, care for students with special healthcare needs, staff education, surveillance for infectious diseases, as well as planning for a single emergency event or multiple casualties as a

result of a disaster. School nurses are also positioned to educate and train other school personnel to assist them with first aid and emergency response efforts.

2. Best Practices and Mitigation Strategies:

A gold standard of pediatric disaster preparation and response training is lacking. In 2011, the National Center for Disaster Medicine and Public Health convened a Pediatric Disaster Preparedness Conference. Much of the initial groundwork for development of a pediatric disaster preparedness curriculum, including the identification and prioritization of target audiences, requisite role-specific CBRNE curriculum content, and delineation of expected skills and competency levels, was the product of this conference. HHS would achieve great impact on reducing pediatric morbidity and mortality after an incident by applying this groundwork to the designing and implementation of pediatric disaster training for healthcare responders. Such design and implementation would realize significant cost savings due to the following factors:

- Many of the identified roles have significant curriculum content overlap, thus making the development of a modular-based program feasible;
- Much of the content of a pediatric disaster preparedness education and training program could also be used to treat adults; and
- Current availability of high-quality, previously vetted literature and Web-based resources enable the easy development of “user-friendly” platforms for educational purposes.

Emergency planning stakeholders can also apply lessons learned from cities that host major events, such as the Boston Marathon. These sites practice their preparedness and response plans through the experiences as a “planned disaster”, especially when they know that attendees will be faced with adverse environmental conditions such as excessive heat or cold.

Pediatric physicians should receive pediatric disaster medicine response training during their residencies; internal medicine and family medicine physicians should receive emergency pediatric training during residencies as well. The development of a training and education program specific to nurses that addresses pediatrics, emergency preparedness, and trauma would also greatly advance healthcare workforce readiness.

There should be more or specific effort nationally on assuring that school nurses can provide basic triage care in a disaster. Federal agencies should improve the preparedness of schools and school districts by providing additional support to states, including the Department of Education, which should target programs and training to enhance the ability of school personnel to support children during the response and recovery phases of a disaster. Additional potential partners include American Academy of Pediatrics, American Heart Association, Emergency Nurses Association, American College of Surgeons, National Association of School Nurses, Emergency Medical Services for Children, FEMA, EMI, Trauma Nurses Association, state school board associations, EMS (Prehospital Trauma); state centers for safe schools; mental health; and local, state, and national emergency management. This training should include engagement in local and state-wide drills, functional exercises, and full-scale exercises. School nurses also need to be formally defined as “first responders” when consideration is being given to education and training of healthcare personnel in acute care facilities and in emergency medical services roles for disaster preparedness. School nurses could also receive training to participate in the mobilization of Points of Dispensing (PODs) in public health disasters.

An integral component of pediatric training should be pain assessment. Appropriately addressing pain can also influence the selection of medications and time of medication delivery, in addition to stabilizing emotional states.

Providing family-centered care to children during disasters that involve infectious disease outbreaks can be a difficult task. Emotional upheaval, separation and social isolation due to infection control precautions, communication barriers, and changes in parental and professional roles (i.e., caregivers serving as “pseudo parents”) present challenges.⁴ Pediatric healthcare training should consider effective clinical approaches for navigating these obstacles.

Training in pediatric-specific decontamination protocols, which incorporates knowledge of the range of children’s sizes, surface area, skin permeability and susceptibility to hypothermia, metabolism, comprehension levels, and communication approaches is particularly critical. Facilities also need training on standard operating procedures on how to handle situations where parent and child are different genders in a decontamination setting.

In a truly mass casualty event, EMS system will be overwhelmed. Expanded sources of trained personnel are essential. In conjunction with Federal agencies (e.g., FEMA, EMS for Children) and state partners, HHS could consider development and delivery of a disaster level first responder course for training bystanders as lay providers (e.g., high school students, community members, teachers). An optimal curriculum would be kept current and simple to ensure retention by lay providers.

3. NACCD Recommendations:

- a. HHS/ASPR should partner with one or more organizations (e.g., National Center for Disaster Medicine and Public Health, Accreditation Council for Graduate Medical Education, American Academy of Pediatrics, American Academy of Family Physicians) to develop pediatric triage and disaster care training for appropriate physicians.
- b. HHS/ASPR should work with the Joint Commission and other regulatory bodies to design and enforce mandatory pediatric disaster management training and exercises for healthcare institutions.
- c. HHS/ASPR should mandate minimum levels of pediatric training for Medical Reserve Corps units and other federal agencies that would potentially be responsible for care for children. HHS partnerships with entities such as DOD, DHS/FEMA, SAMHSA, and NDMS to deliver such programs, or serve as bridges or referrals to these opportunities, would significantly advance this effort. HHS should also assess barriers to such linkages (i.e., working in silos) and ensure an integrated, cohesive effort.
- d. HHS/ASPR should partner with the aforementioned organizations to develop and provide pediatric and CBRNE training as a next step for prioritized EMS, ED/hospital, and ambulatory care providers.

⁴ Koller, D. F., Nicholas, D. B., Goldie, R. S., Gearing, R., & Selkirk, E. K. (2006). When Family-Centered Care is Challenged by Infectious Disease: Pediatric Health Care Delivery During the SARS Outbreaks. *Qualitative Health Research Journal*, 16(1), 47-60.

- e. HHS/ASPR should explore tasking the NACCD (with guidance from subject matter experts at the CDC, AAP, and other interested parties) to develop recommendations that will guide curriculum development for a pediatric disaster preparedness training program.
- f. HHS/ASPR, along with government partners, should issue a federal recommendation or guidelines for all hospitals to conduct exercises and drills that include children with special needs. This would particularly encourage the essential buy-in and compliance among non-pediatric hospitals.
- g. HHS/ASPR should encourage institutions and grantees conducting exercises and training to solicit participation and involvement of community and primary care pediatricians.
- h. HHS/ASPR should also require physicians, through public service announcements, social media, and collaboration with the AAP, the AMA, and state and local medical societies, to enroll in Medical Reserve Corps units and Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) registries, and to sign up for Health Alert Network alerts.
- i. HHS/ASPR should develop and/or provide pharmacist training in developing communications regarding medication supply and resource shifting. This training would include distribution of MCMs during disasters, including during special programs such as emergency use authorizations.
- j. HHS/ASPR should improve the preparedness of schools and school districts by providing additional support to states, including the Department of Education, which would target programs and training to enhance the ability of school personnel to support children during the response and recovery phases of a disaster.
- k. HHS/ASPR should include all appropriate types of first responders in education and training for pediatric disaster preparedness, including school nurses and child care providers.
- l. HHS/ASPR should develop and deliver a bystander disaster training curriculum to address personnel shortages in a large-scale disaster.

B. Disaster Preparedness Modeling

1. Current State and Gaps:

Academia and private industries have expertise in complex systems modeling, and their partnerships serve as a source of innovation in the field. Disaster models use computers to create various scenarios, such as an infectious outbreak in a community, and then assess outcomes under different conditions. While some disaster-related models can be relatively straightforward – such as predicting the radioactive plume from a nuclear detonation – others are terribly complicated, involving nonlinear feedback, human behavior, economic effects, outside influences, and other unpredictable factors. Models enable a facility or community to test scenario responses and outcomes in a cost-effective way, as well as assessing situations that could be ethically or practically very difficult to simulate otherwise. Models can be limited by unknown variables and variables that have no known probability curves; therefore, models remain incomplete. Data collection during an actual event would help refine and validate models, but such collection is difficult due to the rarity and unpredictability of disasters.

2. Best Practices and Mitigation Strategies:

Modeling can help predict outcomes in a way that complements tabletop exercises. During tabletop exercises, key personnel assigned to emergency management roles and responsibilities are gathered to discuss and role-play various simulated emergency situations. Members review the actions they would take in a particular scenario, testing their emergency plan in an informal, low-stress environment. For the purposes of a tabletop exercise, actions can be described instead of fully simulated, which sacrifices fidelity but has advantages in terms of cost, resources, and time. Tabletop exercises are used to assess plans, policies, and procedures and identify additional mitigation and preparedness needs. Models can also serve to guide healthcare facilities and communities in resource allocations and improving operations by assessing the probability of different outcomes and the impact of certain variables or actions. Models have been already shown to be useful in assessing availability of hospital-based resources, planning for dispersal of CBRN agents, and assessing the effectiveness of community mitigation strategies against such agents. Ideally, models will help to develop better tabletop exercises, which then can be studied to further refine the models. Modeling can also help create more realistic and/or targeted full exercises, which can then be tested and analyzed to improve the models and predictions of outcomes.

More observational and focused studies of real events would help to understand what actually happens in a disaster response—for instance, how local resources are used and shared, how large numbers of patients engage with and impact the healthcare system, how first responders react, and how training translates to practice. This type of research will better identify gaps and possible solutions to improve responses, as well as inform modeling systems. Research and modeling would also help in optimizing the content, format(s), frequency, and other characteristics of training. Training should include discussion of lessons learned and gap analyses from prior events to ensure the best outcomes in future events and prevention of repeating past mistakes. Consideration also should be given to the development and use of targeted "just in time" training programs that are readily available immediately before and during disasters based on information learned from exercises, models, and real-time events.

A dedicated center for healthcare disaster modeling could serve as a pioneer and a resource for modeling, including enlistment, provision, and coordination of interdisciplinary expertise from around the country, development of best practices for testing and refining models, and determination of scenarios that would best benefit from modeling to improve preparedness. A healthcare disaster modeling center could help predict pediatric healthcare needs, including how pediatric resources could be best coordinated, and how resources in non-pediatric facilities might be utilized or transformed for pediatric use. As an additional benefit, such a center would help create standardized operational definitions for pediatric beds, units, facilities, and other resources.

Incorporation of general drug/therapy capacity factors (e.g., inventory, authorized staff for compounding) would significantly augment models. Models should not only explore hospitals but drugstores, post offices, and other key players in the regional response.

Such a center should pair the modeling with evidence-based medicine based on literature searches and subject matter expert input on the optimal plan design. This validation ultimately develops a gold standard guideline on space, staff, and stuff that would be adaptable to all sites.

Ideally, the center’s models would live “primetime” via a Web-facing portal. Hospitals and other disaster response sites would enter crude data, yield a plan, test it, and report real feedback to inform refinement of the formulas and algorithms for re-testing. This framework would require considerable resources, back-end program operations, and security protections.

Recognizing that overwhelming situational awareness variations in real-time could render a plan useless, adaptability and just in time adjustments to plans are essential. Thus, it would be ideal for the center to gather data from a number of healthcare facilities, formulating a Master Scenario Events List. This product would allow for implementation of a tabletop exercise with diverse situational awareness. Healthcare responders could also evaluate the usefulness of this modeling tool in yielding positive planning outcomes. The list may reveal overlooked data inputs or potential scenarios as well as systems that are not as developed (e.g., ambulance availability, transfer plans).

3. NACCD Recommendations:

- a. HHS/ASPR should assess the need for a dedicated organization to house a center for healthcare disaster modeling.
- b. HHS/ASPR should raise awareness of existing modeling resources among its disaster response networks and encourage their testing and evaluation.

C. Site Management

1. Current State and Gaps:

Site management is the prediction, planning, acquisition, and administration of space and assets utilized in emergency response. In support of suggestions offered in this report’s Coalition section, proper site management reflects a clear understanding of the operational responsibilities of all responders, including the provision of medical, behavioral health, family and social services, as well as up-to-date communication to providers and the lay population. It is essential that the site management component of pediatric disaster plans cover the full gamut of the pediatric population, including pregnant women, sick neonates, well newborns, children, adolescents, and special needs patients including those in nursing homes. Plans should exist for pre-hospital, hospital, and community sites; account for movement from initial scene to primary and secondary transport; and address special cases such as surge and evacuation. A comprehensive site plan moves beyond the basic necessities of food and water to power failure, special needs, special equipment, foster care, supervision, security at mass shelters, and privacy. The development of site management plans can be challenging when faced with a slow-moving biological event, or if a disaster coincides with a mass infection, such as influenza.

Currently there is no national monitoring database for healthcare assets, including pediatric resources. The National Disaster Management System (NDMS) tracks beds in disasters. Participating NDMS hospitals report the current number of available beds (within 12 hours) and the maximum number of beds within the six NDMS bed categories that could be made available within 24 and 48 hours. When NDMS is activated, these data are requested by NDMS federal coordinating centers (FCCs) as frequently as once per week. The Department of Health and Human Services’ Agency for Healthcare Research and Quality has established a classification and

tracking system titled HAvBED. The HAvBED system created eight different classifications of beds.

It is important to note that there are sometimes inconsistencies among hospitals on definitions of disaster resources. Although NDMS and HAvBED have provided bed category definitions, discrepancies in practice still exist. For instance, those two systems list any bed for people under 17 years old as a pediatric bed, with no distinction between neonatal or adolescent beds.

There is limited ability to procure or produce additional medical supplies in the event of a severe shortage, particularly for office-based practitioners. Pharmaceuticals, particularly for children, also leave community pharmacies quickly, hampering the ability to provide outpatient care for children. Experiences with vaccines for both seasonal and pandemic (i.e., H1N1) influenza demonstrate that adequate supply and timely distribution are still variable and problematic. Community pharmacies in the United States experienced shortages of potassium iodide (KI) after the 2011 Fukushima reactor meltdown. However, KI is available from the Nuclear Regulatory Commission, which provides it to states that have nuclear reactors and allows those states to disburse it as they see fit. The SNS functions as an additional repository with its stock of KI.

Community shelters are designated to have certain amenities for children, including age-appropriate food. Children's hospitals have food, clothing, diapers, and similar supplies for children as part of their daily operations. Adult-oriented community hospitals may have limited supplies of these items, which could be problematic should these facilities need to be a "shelter-in-place" for families or to provide extended care for children. Facilities need to prepare for security needs in advance of a disaster, particularly with regards to ensuring the safety of children (see also "Pediatric Identification and Reunification" later in this section).

If a community is significantly damaged by a physical disaster, infrastructure and availability of usable space may be problematic. Mitigation and hardening of existing resources may help in advance, but state and national level coordination may be required after an event. The destruction or incapacitation of a hospital may require cooperation from nearby facilities or establishment of temporary facilities, such as mobile hospital units under the National Guard, NDMS' Disaster Medical Assistance Teams, or other organizations. It goes without saying that such arrangements need to be able to provide medical care for children. Outpatient physician offices may also be destroyed; while private non-profits may be eligible for assistance, private practices – which deliver the majority of care – are generally not able to procure federal assets for temporary office space, and are left to their own devices and ingenuity.

2. Best Practices and Mitigation Strategies:

The CHEMPACK program from the SNS attempts prepositioning (i.e., positioning of supplies to meet a perceived or anticipated need) for potential fast-moving attacks. The SNS is not to be relied on as a first response, but rather for resupplying hospitals when their stock is exhausted. It is recognized that state health departments lack resources to stockpile MCM, but they are expected to stockpile information and a repository list of available personnel.

Site plans should also consider and address challenges in maintaining family connections while caring for children during infectious disease outbreaks. Possible solutions include communications assets such as cell phones and laptops. If parents' presence onsite is allowed,

the facility will have to account for the need for personal protective equipment (PPE) and training.

If a hospital or other healthcare facility cannot afford pediatric healthcare supplies now, they need to conduct a needs assessment for future planning and develop a plan to correct this. Ideally, facilities should have multiple vendors they can call upon for supplies, and sharing arrangements with nearby community facilities and institutions. Likewise, if there is a chance there will be personnel shortages in a surge, facilities need to address this in their surge plans, such as using force multiplication with task shifting and cross training.

School districts are often resource-rich in terms of communications, transportation vehicles, school nurses, health aides, food services, security or police, facilities, maintenance personnel, emergency managers, mental health counselors, and psychological resource personnel. Mutual Aid Agreements could be in effect allowing utilization of schools as alternative collection sites for treatment of victims who are triaged with minor injuries (i.e., “walking wounded” and “worried well”).

Essential Pediatric Domains and Considerations for Hospital Disaster Preparedness is an excellent checklist reference for site management. The American Academy of Pediatrics also has a number of resources to help pediatric outpatient practices prepare for disaster.

3. NACCD Recommendations:

- a. HHS/ASPR should issue the AAP’s pediatric MCM info sheet for nationwide dissemination to response sites. This document outlines MCMs likely to be used for pediatric care in an emergency and provides a framework for how and when to administer each drug.
- b. HHS/ASPR should work with the Joint Commission and other regulatory bodies to design and enforce mandatory disaster site management plans for healthcare institutions. The plans must include operations that account for pediatric needs.
- c. HHS/ASPR should identify and track pediatric resources and assets to help assist in regional, state, and local coordination.
- d. HHS/ASPR should clarify HAVBED and NDMS bed definitions to better identify and track specific pediatric capabilities.
- e. HHS/ASPR should continue to disseminate best practices in facility and site management for pediatric care in disasters.

D. Transportation and Evacuation

1. Current State and Gaps:

The current pediatric transportation system is a patchwork of EMS providers, hospital-based teams, private transport, and potentially the Department of Defense. While some transportation has been coordinated regionally, regions may overlap, creating confusion and false expectations of availability. Payment for interstate transport is inconsistent, particularly among state Medicaid programs, and can limit transport options.

Healthcare facilities and coalitions also need to recognize that transportation is not only focused on getting patients from a disaster site to the hospital, but for how and when to move patients away from a hospital to either other healthcare facilities or other alternative facilities (e.g., school gymnasium) for patients that are stable and requiring less hospital resources.

2. Best Practices and Mitigation Strategies:

Improving the capability of emergency medical services to transport pediatric patients and provide comprehensive pre-hospital pediatric care during daily operations and disasters is a critical need. Regionalized networks, such as those developed for trauma, NICU, and PICU care, appear to work well to coordinate resources such as transportation. Some local units have prepared “Pediatric Packages” with pediatric-specific equipment, medication in dosing units more pediatric-appropriate, and importantly, instructions on pediatric medication calculations or delivery and rapid dosing guides such as Broselow tapes.

EMSC National Resource Center has performance measures that address the inter-facility transport of children. It aims to ensure that every hospital has an established inter-facility transfer agreement and guideline. Current data can be found on the NEDARC website.⁵

3. NACCD Recommendations:

- a. HHS/ASPR should develop a national strategy, together with both public and private partners, to improve pediatric emergency transport and patient care capabilities for disasters, including to or from alternate healthcare facilities such as school sites.
- b. HHS/ASPR should continue to collaborate with EMSC to improve the pediatric capability and training of EMS units.
- c. HHS/ASPR should maintain an inventory of national deployable pediatric transport assets and be ready to help coordinate mobilization and usage of such when requested. Additional consideration should be given to categorizing transport resources by pediatric capabilities: for instance, dedicated pediatric assets, adult or mixed-use assets with pediatric capability, and adult assets that would need modification and preparation for pediatric use.

E. Pediatric Identification/ Reunification

1. Current State and Gaps:

Reunification remains a top area for needed improvement. Most hospitals do not have policies or plans for reunification, a family information or support center, or a plan for the identification of children in foster care.

In the event of a mass injury or mass casualty event, hospitals will experience an influx of distressed family members looking for their children, as well as unaccompanied minors, and this surge may be overwhelming for many hospitals. In addition, security threats during a disaster

⁵ U.S. Department of Health and Human Services. Health Resources and Services Administration. Emergency Medical Services for Children. National EMSC Data Analysis Resource Center. 2010-2011. National Data on Hospitals with Inter-Facility Agreements. Retrieved from: <http://www.nedarc.org/performanceMeasures/nationalData/201011GrantYear.html#agreements>

can undermine reunification plans. While keeping parents with children is a goal for EMS, security issues have prevented this in the past.

2. Best Practices and Mitigation Strategies:

Keeping a parent with his or her child is the ideal; however, if this becomes impractical, tagging the pair with a barcode or serial wristband is the best backup system.

Anecdotally, local responders (e.g., hospitals, police, EMS, fire) may be unclear on what information they can share with other people or organizations in a disaster while still complying with the Health Insurance Portability and Accountability Act of 1996 (or the Family Educational Rights and Privacy Act if the children are needing medical care while in school). The Red Cross and the National Center for Missing and Exploited Children have developed programs and databases to help facilitate identification and reunification. The Unaccompanied Minors Registry (UMR) is another resource that is available 24 hours, seven days a week. UMR was built with the ability to speak with other tracking/reunification systems and has a field specific for someone reporting from a medical institution.

3. NACCD Recommendations:

- a. HHS/ASPR should assess the state of existing technology to aid in tracking and reunification, including identification of significant gaps. HHS should develop and fund competition-style programs (e.g., similar to the XPRIZE), “hackathons”, and other programs of the type currently being used by the technology sector to promote innovation in order to encourage remediation of these gaps.
- b. HHS/ASPR should promote the inclusion of pediatric tracking, identification, and reunification in planning, exercises, and drills. Schools, child care facilities, hospitals, national organizations such as the Red Cross, and law enforcement should be encouraged to collaborate on these issues.
- c. HHS/ASPR should clarify the legal framework for sharing of information for purposes of identification in a disaster.

F. General Hospital Capabilities

1. Current State and Gaps:

Much of the current information known about the state of pediatric readiness for emergency departments nationwide comes from the HRSA’s EMSC National Pediatric Readiness Project. This project conducted a voluntary survey among emergency departments and received an 83% response rate. The National Pediatric Readiness Assessment revealed that only 47% of hospitals actually have disaster plans that include pediatric-specific needs. Current resources are based on existing infrastructure, and that existing infrastructure is oriented toward the provision of adult healthcare.

Hospitals are familiar with almost all treatment protocols in a disaster, except for nerve agent exposure. Low familiarity with nerve agents comes from lack of experience dealing with accidental exposures to high doses of pesticides. Hospitals should strive to be ever more proficient and expert in these scenarios; this ensures that they are prepared for containment

and decontamination in the case of even a single patient exposed to a transmissible chemical or biological agent and can prevent further exposure of staff or other patients.

2. Best Practices and Mitigation Strategies:

Adult-centered hospitals need to be prepared to receive and care for pediatric patients in case of disaster. Hospitals need to be ready to use disaster triage systems that address the physiologic differences between children and adults. Existing standards of care may need to be stretched to allow expanded use of existing assets, such as pediatric use of adult materials, supplies, or medications. Allocation of resources in the face of limited assets may need to give prioritization to children over adults. Some coalitions have begun to identify existing and potential (surge) resources and capabilities for treating children. First-tier institutions, with the highest-level pediatric capabilities, are designated first-line recipients for children; these usually represent children's hospitals. Second-tier institutions, with more limited capabilities, commit to maintaining adequate pediatric capacity in the event of a surge that overwhelms the first tier. Many community hospitals can fulfill this role, even if they are not normally pediatric-focused institutions.

3. NACCD Recommendations:

Pediatric facilities should take the lead in helping adult-oriented counterparts become more knowledgeable and proficient in the care of children.

- a. HHS/ASPR should work with national accrediting organizations, such as the Joint Commission and NCQA, and CMS to evaluate the inclusion of pediatric disaster preparedness capabilities as part of the accreditation and certification process.
- b. HHS/ASPR should incorporate pediatric-specific standards into the Healthcare Preparedness Capabilities guidance document and should assess pediatric preparedness in Hospital Preparedness Program (HPP) applicants and funding recipients.

G. Healthcare Disaster Communications

1. Current State and Gaps:

Experience with large-scale, multijurisdictional events has revealed the potential for numerous problems in coordination and communication during disaster response. Fire, police, EMS, public health, and healthcare facilities may have different, incompatible communications systems on different frequencies. Each discipline has its own jargon and acronyms; common words or phrases may have drastically different meanings, depending on their use or user. For instance, a "4 by 4" could mean a piece of wood, an all-terrain vehicle, or gauze square.

The National Incident Management System and Incident Command System create common terminology and structure for response to incidents. While most first responders and emergency management personnel are trained in ICS, members of the healthcare system may not be familiar with this system. This can hamper their ability to interact with other responders and participate in an organized response.

On-scene first responders may not know what information is important to communicate to healthcare facilities that are receiving or due to receive patients being transported from the

scene of disaster. Chemical, biological, or radiological exposure may require specialized decontamination, isolation, and/or treatment procedures. Specialty services for children in particular may be available only at tertiary or even more specialized institutions; examples include pediatric burn units or pediatric neurosurgery. Established metropolitan trauma systems utilizing triaged, coordinated care have proven usefulness in directing patients to the best receiving facilities and coordinating communications. Regional pediatric networks for pediatric intensive care and neonatal intensive care can mobilize a broader response and utilization of more distant resources and expertise. In addition, enhanced and accurate communication from first responders to receiving institutions can help those healthcare facilities mobilize additional staff, specialists, emergency department teams, intensive care beds, and operating rooms (as demonstrated in the Boston Marathon bombing).

Situational awareness among responding entities can be helped or hindered by informal and social media communications. Social media can provide some of the first real-time information from the scene, initial responders, and engaged institutions. On the other hand, without verification of accuracy, social media may also propagate misinformation and rumors, which then become disseminated by responders, security personnel, and healthcare personnel, necessitating catch-up and damage control.

2. Best Practices and Mitigation Strategies:

With a clear communication strategy, responders and incident commanders are able to exercise better situational awareness and coordinate the transportation of patients to the most appropriate healthcare facilities without creating an overwhelming surge on any particular location. Pediatric resources need to be identified and real-time utilization and capabilities shared among responder networks. General community hospitals need to be included so they can mobilize and ramp-up their pediatric capabilities also. Pediatric trauma, intensive care, and neonatal intensive care networks and Emergency Medical Services for Children should be strengthened during everyday operations in order to be ready for larger scale surge events. Relationships need to be created well before an event, where familiarity of personnel, resources, procedures and responsibilities are renewed on a regular basis. Sharing of equipment and supplies during everyday patient transfers (e.g., between transport teams and transferring and receiving institutions) lays further groundwork for enlisting regional coordination and cooperation during mass casualty events. Equipment and systems need to be tested in advance of a disaster to ensure compatibility. A dedicated mutual aid radio channel can serve as the communication stream that bridges various municipalities, zones, and zone commanders. Fusion Centers, coordinating disparate first responder agencies, have the potential to increase informational transfer and common messaging. These Centers have generally focused on crime and anti-terrorism activities, but should be engaged for health-related events as well.

Multi-jurisdictional events, such as marathons and other large sporting events, provide an opportunity to exercise NIMS, ICS, and disaster communications by way of central command. Community healthcare responders should be brought into these exercises and other drills whenever possible. In order to facilitate participation, training in ICS (such as through FEMA's free online courses) should be promoted and encouraged to as broad an audience as possible, including pediatricians, nurses, and administrators from all manner of practice settings. Other

facilities that provide daily care to children, such as schools, Head Start, child care centers, after-school programs, and camps should also be included.

Following recommendations from the 9/11 Commission Report and lessons learned from Hurricanes Katrina and Rita, Congress identified the need for stronger coordination and national leadership to identify needs and address gaps in emergency responders' abilities to communicate across jurisdictions and functions. To address these issues, Congress authorized the establishment of the Emergency Communications Preparedness Center (ECPC). The ECPC was established to serve as the focal point for federal interagency efforts to support and promote the ability of emergency response providers and relevant government officials to continue to communicate in the event of natural disasters, acts of terrorism, and other man-made disasters; and to support interoperable emergency communications. Consideration should be given to establishing a pediatric desk or a team of interagency pediatric experts within the ECPC.

3. NACCD Recommendations:

- a. HHS/ASPR should promote Incident Command System training and exercises/drills for healthcare professionals and other facilities that provide care to children to improve crisis coordination and communication.
- b. HHS/ASPR should conduct a gap analysis of current systems, equipment and resources that support the communications strategies of response networks and explore funding options that will further mobilize broader, triaged, coordinated healthcare management.
- c. HHS/ASPR should coordinate with ECPC participating federal partners and emergency responder providers to ensure that communications during disasters includes addressing pediatric needs.

H. Community Communications

1. Current State and Gaps:

The general public may receive health-related crisis communication from a number of sources: state and local Emergency Management, Departments of Health, local and regional hospitals, media organizations, social media, and primary care physicians, to name a few. Studies have shown that families place high degrees of trust in communications from their primary care physicians and prefer to receive information from them over other sources. Current health crisis communications tend to be “top-down,” and are often hospital-focused. Communications that involve primary care pediatricians can potentially reach thousands of families at a time, and enable pediatricians to receive valuable information back from them. Pediatricians also maintain communication with the state and national AAP — and the reach and resources of those organizations — and can provide feedback to public health authorities regarding the effectiveness of messages.

2. Best Practices and Mitigation Strategies:

Communications need to be bidirectional and in a variety of formats. Messages should be consistent across sources. Public health communications should be honest, informative, and either actionable or reassuring. The CDC and others offer training in effective public health

communication. Facilities that treat children should have communication strategies, including social media, considered in advance of a crisis.

Parents and caregivers serve as the main advocates for a child during a disaster and are therefore a critical communications audience; however, they may be ill-equipped to navigate the potential resources available. Parents may not prioritize preparedness before a disaster and need to be educated on their essential role in an effort to mitigate potential negative outcomes. Messages that underscore the importance of a disaster management plan, as well as offer guidance on applying for support and assistance, are critical. It is also essential to reinforce the need for printed materials and records of key information, such as prescriptions and medical contacts. In the stressful time leading up to or during a disaster, it may be hard for caregivers to remember to collect important documents; therefore a checklist may help mitigate forgetting necessary items.

At the national level, the presence of the CDC Children’s Desk during recent health crises (such as H1N1) has proven to be a tremendous resource for fielding questions from community pediatric practitioners and disseminating pediatric-specific information. The standing-up of a dedicated pediatric desk also creates a powerful message of recognition and support of children’s needs, enhancing communications as well as confidence among the pediatric community.

3. NACCD Recommendations:

- a. HHS/ASPR should encourage primary care pediatricians and public health officials to reach out to each other and establish regular communications. Such communications can be informal (e.g., relationship-building) or formal (e.g., periodic status updates, breaking alerts).
- b. HHS/ASPR should recommend the development, testing, and regular use of communications strategies and capabilities as a vital component of coalitions. CDC’s public health communication training and related resources are examples of best practices that HHS/ASPR should promote and disseminate.

I. Psychological First Aid

1. Current State and Gaps:

Healthcare providers recognize that children’s mental health needs should not be neglected in a disaster. The American Red Cross and other organizations offer training in Psychological First Aid. Pediatricians address mental health needs for children and families on an everyday basis, but often lack any disaster-specific training.

2. Best Practices and Mitigation Strategies:

Adults should take care of their own needs first before attempting to help children, similar to being on an airplane when the oxygen masks are lowered. Psychological support should not be limited to the hours and days after a disaster, as the following months can be a vulnerable time for children as well.

Primary care pediatricians can be an important source of emotional support and referral to community resources in a disaster. Community resources are often insufficient, however, even in everyday situations, particularly for children with Medicaid or with limited English proficiency.

Schools and child care facilities can also help children and families by screening for mental health needs, providing brief psychological first aid, and connecting children to resources.

3. NACCD Recommendations:

- a. HHS/ASPR should work with FEMA and SAMHSA to improve the Crisis Counseling program. Specifically, the program should have the flexibility to address preexisting mental health conditions that might be exacerbated by disaster.
- b. HHS/ASPR should work with organizations such as the AAP to encourage pediatricians to be educated in how to help children and families cope with disaster. For example, this collaboration could entail the dissemination of existing psychological aid materials and development of best practices for AAP members.

III. Medical Countermeasure Readiness and Capabilities

Background

A recent U.S. Government Accountability Office (GAO) 2013 review noted that, “About 60% of chemical, biological, radiation, and nuclear (CBRN) medical countermeasures (MCM) in the Strategic National Stockpile (SNS) has been approved for children, but in many instances approval is limited to specific age groups. Specifically, Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) officials stated that about 38% of the CBRN MCM in the SNS has been approved for children of all ages for treatment of certain CBRN threats.”⁶ A recent 2014 review on the labeling and potential availability of MCMs in the SNS for pediatrics was presented to PHEMCE. In brief, the FDA concluded that much progress has been made and “for most CBRN diseases for which there are MCMs in the SNS, there is parity between adult and pediatric preparedness.” Some pediatric MCMs in the SNS still lack approval for the intended pediatric indications, and their availability and use during an emergency will be dependent on emergency regulatory mechanisms for access. In addition to lack of regulatory approvals, some products that will be used in a CBRN situation lack scientific data on dosing, safety, and efficacy. Some of these products are commonly used off-label while others may be completely unfamiliar to medical personnel. Development of products intended to treat nerve agent exposure are of particular need. There is urgent need for an approved pediatric auto-injector for delivery of pralidoxime and atropine (i.e., a pediatric form of the adult DuoDote® delivery system) for rapid delivery of these organophosphorus nerve agent antidotes. Alternatives to the auto-injector, such as drawing up medication from a vial into an intramuscular (IM) syringe, while wearing PPE, will result in a lack of timely therapy for the pediatric population and a higher rate of morbidity and mortality.

A. Pediatric Requirements for Dosing, Preparation, and Delivery Systems

1. Current State and Gaps:

Many who have experience providing medical care in disasters and other similar events have stated that medical and nursing personnel not accustomed to caring for the pediatric population have difficulty calculating doses, mixing preparations, and delivering the correct amount and volume to pediatric patients. Even when providing routine care on a regular day, determining appropriate doses for children can be rife with challenges, which are further exacerbated in the setting of a disaster. Accurately determining and delivering appropriate doses for children would be ideal but highly problematic in times of stress such as a mass casualty event. Complex mathematical formulas as well as simple calculations may be written on whatever may be available at the moment, including scraps of paper, scrubs, and bed sheets, for lack of more efficient and permanently documentable means.

While the national gold standard of weight-based (e.g., mg/kg) dosing is considered the most accurate for pediatric therapies, this method has its challenges. The GAO report noted that

⁶ United States Government Accountability Office. Report to the Committee on Energy and Commerce. (2013). National Preparedness: Efforts to Address the Medical Needs of Children in a Chemical, Biological, Radiological, or Nuclear Incident. Retrieved from: <http://www.gao.gov/assets/660/654264.pdf>

dispensing treatment facilities should have an accurate means to estimate weights to determine drug doses which are weight-based. This could be by scales or balances, or use of a measuring tape device such as the Broselow tape. However consideration of weight alone may not be the best approach. Responders must consider other factors in dosing calculations, such as age-based metabolic and elimination differences as well as medical condition. Some circumstances prevent administering therapies based on weight in an emergency (e.g., lack of universal acceptance by all emergency responders and desire to balance feasibility or speed with accuracy). The urgency to treat children, given their greater vulnerability to CBRN agents related to factors such as metabolic immaturity and increased surface area, offers responders some latitude in dosing accuracy but having a simple, easily stored, and practical instrument like a Broselow[®] tape (see Best Practices below for more details) should help alleviate much anxiety and improve accuracy and feasibility.

For potentially lethal diseases of considerable public health impact such as inhalational anthrax, currently a large driver of MCM development, establishing an intravenous (IV) line is generally the gold standard for delivering appropriate medical therapy. For children, starting and maintaining an IV line can be challenging and requires skill and practice not every medical or nursing provider has. When intravenous access cannot be obtained, interosseous (IO) pumps, especially in very young children, are indicated to deliver doses in high demand, surge-type situations. However, the pressure in the marrow will often build and trigger pump alarms, leading providers to believe the pump is malfunctioning and exchange it or to even try another IO site.

In a nerve agent event, immediate administration of the appropriate antidote is crucial. The use of auto-injectors is prevalent in adults and allows for attaining effective drug concentrations rapidly. There is no approved pediatric auto-injector for the combination atropine-pralidoxime therapy, the primary antidote for nerve agent or insecticide exposures. The adult auto-injector is not formulated for use in children, in particular infants < 10 kg, which is the average weight for a one year-old child. A linear model of weight-based dosing may not be optimal, since pediatric metabolism, especially those of infants and neonates may not be linear with age—i.e., the dose needed in a 3.5 kg child may not be 1/20 of the dose to treat a 70 kg adult and may be higher or lower.

In the absence of pediatric auto-injectors, there is currently no consensus regarding emergency responders' using adult auto-injectors on children versus drawing up individual doses while wearing PPE. PPE can hinder drawing doses into syringes; although that delay could be reduced with practice.⁷ However, any delay could adversely impact survival. Accepting the lack of a rapid dose delivery preparation and relying on an alternative approach, for which responders may or may not have experience and may or may not be familiar with pediatric dosing requirements, does not provide parity for children with what is available for adults and is unacceptable.

⁷ Castle, N., Bowen, J., & Spencer, N. (2010). Does Wearing CBRN-PPE Adversely Affect the Ability for Clinicians to Accurately, Safely, and Speedily Draw Up Drugs? *Clinical Toxicology*, 48(6) 522-27.

2. Best Practices and Mitigation Strategies:

For medication dosing requiring any calculation, such as antibiotic dosing by weight (i.e., mg/kg dosing), a quick weight based assessment for dosing should be available for those not familiar with pediatric dosing. Measuring tapes currently exist to provide the appropriate dosing for various weights based on an infant's length or child's height. The Broselow[®] Pediatric Emergency Tape measures a child's length and relates it to a weight, which can then be associated with the appropriate medication dosing as well as the emergency equipment size. The Broselow[®] tape is an inexpensive, simple tool and can help address the issue of quickly identifying size appropriate doses. The Emergency Nurses Association published a position paper⁸, endorsed by the American College of Emergency Physicians and American Academy of Pediatrics, that states pediatric weights should only be taken in kilograms and that Broselow[®] or similar color coded tape should be used for zone dosing when calculations are too difficult. High stress environments are prime examples of such a situation in which the brain's ability to make mathematical calculations may be impeded and where a color-coded system might greatly improve speed and accuracy. Of course, even these simple tools as well as pediatric dosing charts and other similar resources require at least some minimal training and experience so that critical time is not wasted during an event trying to determine how to correctly use these tools. Given the prevalence of smartphones, a simple application or app that computes dosing based on children's characteristics could serve as an efficient and readily available tool during an event. However, severe emergencies, such as Superstorm Sandy, can produce power outages for days to weeks and thereby limit, if not completely curtail cellular phone usage. Therefore, while a smartphone app might be a powerful tool, best practice would dictate maintaining either electronic or digital and hardcopy formats to assure redundancy should one option fail.

Not having to make any calculations and immediately administer a therapy would be ideal, especially when mass casualties demand attention. For some scenarios, a tool such as the auto-injector is available and can be a major advantage. However, until a pediatric version is developed and/or a method to adapt the current adult dose is developed (e.g., determining the allowable minimum pediatric age or weight limit to receive the dose contained in an auto injector), this tool remains inaccessible for the care of children.

Medical countermeasures training and drills should also simulate power outages, which will force caretakers to calculate dosing and find alternative methods of administration that are not electricity- driven. Nurses are currently accustomed to using electronic pumps for infusions; therefore, training on back-up systems using drip rates is necessary. If these are not available, another non-electronic system must be developed.

3. NACCD Recommendations:

- a. HHS/ASPR should collaborate with federal partners to provide anthropometric tapes and the necessary training to use them correctly.

⁸ American Academy of Pediatrics, American College of Emergency Physicians, & Emergency Nurses Association. (2009). Joint Policy Statement: Guidelines for Care of Children in the Emergency Department. Retrieved from: <http://www.acep.org/Clinical--Practice-Management/Guidelines-for-Care-of-Children-in-the-Emergency-Department/>

- b. HHS/ASPR should collaborate with other federal partners to promote the development of weight bands for dosing¹ to more readily estimate emergency drug doses. By this method, a range of child weights could be designated a single drug dose, depending on the specific drug. This method could reduce safety concerns regarding larger doses. Extensive training on this equipment will be critical as well.
- c. HHS/ASPR should encourage healthcare facilities to maintain and use hardcopy/paper guides for pediatric dosing, dispensing, and monitoring. Training sessions should include situations without electricity to deter dependence on cellular phones, pumps, and other electronic devices to determine and administer pediatric doses.
- d. HHS/ASPR should promote the development of alternative drug delivery methods that are facile for any responder to use with minimal potential difficulties, e.g., an alternative to utilizing pumps to maintain flow or drips.
- e. HHS/ASPR should collaborate with other federal partners to prioritize grant funding for studies to define how adult auto-injectors might be adapted for use in the pediatric population (e.g., if half volumes could be used in pediatric patients). This will require potentially a review of modeling studies using known pharmacokinetics in both adults and children⁹ using half the usual adult dose, pediatric-relevant animal model studies on adverse effects of exposure at the higher doses¹⁰, and assessments of needle length issues for smaller mass legs and arms.
- f. HHS/ASPR should ensure that the pediatric auto-injector similar to DuoDote[®], which currently exists outside the United States, is made available as soon as possible in the domestic market.

B. Pediatric Formulations

1. Current State and Gaps:

In general, there exists a lack of reasonable formulation options specific to the pediatric population when considering their particular developmental issues. While some medications may be produced as tablets, capsules, and liquids, with very few orally dissolvable tablets and one mini-tablet formulation approved in the United States, this array of formula options are not available for every medication or many key medical countermeasures. Tablet crushing or cutting is commonly used for children to provide an easier-to-swallow dose or a more weight-appropriate reduced dose. This practice continues, despite the fact that unless a tablet is scored, the amount of active ingredient is not necessarily evenly dispersed within the tablet, so half of a

⁹ Schexnayder, S., James, L. P., Kearns, G. L., & Farrar, H. C. (1998). The Pharmacokinetics of Continuous Infusion Pralidoxime in Children with Organophosphate Poisoning. *Journal of Toxicology and Clinical Toxicology*, 36(6), 549-55.

¹⁰ Pereira, E. F., Aracava, Y., DeTolla, L. J. Jr., Beecham, E. J., Basinger, G. W., Wakayama, E. J., & Aluquerque, E. X. (2014) Animal Models That Best Reproduce the Clinical Manifestations of Human Intoxication with Organophosphorous Compounds. *Journal of Pharmacology and Experimental Therapies*, 350(2), 313-21.

tablet may not provide one-half of the doses of the original tablet¹¹. Tablet crushing leads to a loss of the drug in the process and an inaccurate dose. The lack of palatability of crushed or scored tablets (e.g., ciprofloxacin) can inhibit ingestion of these medications by young children. Subsequently, the more palatable food or liquid agent with which a crushed tablet is mixed (e.g., juice, apple sauce, chocolate syrup) can also impact the active ingredient's availability.¹² Ciprofloxacin and tetracycline such as doxycycline, for example, should not be added to dairy products or calcium-fortified juices. The FDA has posted on its Website instructions for appropriate crushing and utilization of a number of MCM products which do not have pediatric preparations.¹³

Liquids are often easier for children to ingest; however, unlike tablets and capsules, they offer challenges to overall emergency planning and response. For example, they tend to have a shorter shelf life, require larger storage space, are generally more expensive, and are a burden (i.e., increased volume and weight) to transport.

2. Best Practices and Mitigation Strategies:

The ongoing problem with lack of oral pediatric formulations prompted development in 2009 of an Inter-Agency Agreement between the NIH and the FDA.² This agreement, entitled the Pediatric Formulations Platform¹⁴, utilized NIH funding through the Best Pharmaceuticals for Children Act to support FDA chemists in assessing pediatric product formulations and subsequently producing publicly available approaches to manufacture oral pediatric formulations. This collaboration demonstrated that taste-masked and easy-to-swallow oral dosage forms could be developed. As there are currently multiple online locations for MCM product guidance, the development of a single, comprehensive source for clear directions on these as well as other pediatric formulations would be of great benefit to pediatric disaster coalitions.

3. NACCD Recommendations:

- a. HHS/ASPR should prioritize and allocate funding for the immediate development and production of solid oral dosage forms which are palatable, orally dissolvable or dissolvable in small amounts of liquid, in pediatric strengths and sizes. Using this formulation method, a single "mini tablet" or dissolvable thin film that would provide a fraction of the adult potency/dose could be given for an infant and multiple tablets/films would be appropriate for an adult.

¹¹ U.S. Department of Health and Human Services. Food and Drug Administration. (2009). Tablet Splitting: A Risky Practice. Retrieved from: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm171492.htm>

¹² National Consumers League & U.S. Food and Drug Administration. Avoid Food-Drug Interactions: A Guide from the National Consumers League and the U.S. Food and Drug Administration. Retrieved from: <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/GeneralUseofMedicine/UCM229033.pdf>

¹³ U.S. Department of Health and Human Services. U.S. Food and Drug Administration. (2014). Pediatric Counter-Terrorism Measures. Retrieved from: <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm063814.htm>

¹⁴ U.S. Department of Health and Human Services. (2009). Inter-Agency Agreement between the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the U.S. Food and Drug Administration Final Report. Retrieved from: http://bpca.nichd.nih.gov/collaborativeefforts/initiatives/Documents/Formulations_Platform_Report2.pdf

- b. HHS/ASPR should initiate a partnership between the National Library of Medicine (NLM) and ASPR TRACIE to build and design a streamlined repository of instructions for extemporaneous compounding of pediatric products. This undertaking would entail collating materials from FDA and other partners and centralizing them on a Web-facing platform with easy accessibility and intuitive navigation.

C. Uses of Emergency Use Authorizations/Emergency Use Instructions/ Investigational New Drug Application /Off-Label (EUA/EUI/IND/Off-Label)

1. Current State and Gaps:

For most CBRN diseases for which there are MCMs (medical products [e.g., vaccines, other biologics, drugs and medical devices] used to diagnose, treat, or prevent a serious or life-threatening CBRN disease or condition) in the SNS, there is an identified mechanism for product use in pediatric populations. In some situations where there are a number of products approved for use against certain agents, some of the products lack approval for certain age categories. Lack of approval is unacceptable to first responders when faced with patients in need. During an event, one does not want those affected—especially the vulnerable pediatric population—to go without treatment or to be treated with other than the optimal therapy because a product is not approved for this group.

Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship an investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. An expanded access IND or IDE, the means through which the sponsor technically obtains this exemption from the FDA, is a potential mechanism to provide access to investigational MCMs. When a drug's sponsor screens the new diagnostic or therapeutic candidate for pharmacological activity and acute toxicity potential in animals and identifies it as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. At that point, the candidate changes in legal status under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and becomes an IND subject to specific requirements of the drug regulatory system.¹⁵ Clinicians may be more familiar with the procedures for obtaining access to an investigational product for individual patients. However, expanded access IND's and IDE's provide potential for wider access, allowing for more streamlined informed consent and minimal data collection, reporting and recordkeeping than a clinical trial.

The IND for emergency use for a product for an indication that is not approved has a process that any physician can utilize, while the EUA allows large groups of people to utilize such a product in a nationally declared health emergency. Issuing a EUA authorization legally enables response stakeholders to use, or prepare to use, an MCM without violating the FD&C Act. The EUA mechanism allows use of unapproved MCMs (e.g., still in development) or unapproved use

¹⁵U.S Food and Drug Administration. Investigational New Drug (IND) Application. Retrieved from: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>

of an approved MCM (e.g., not approved for the CBRN disease) when certain statutory criteria are met, including scientific evidence to support such a use, and no adequate, approved and available alternatives. The DOD, DHA, and HHS Secretaries must make a determination that there exists the type of emergency or threat for which an EUA could be authorized, and the HHS Secretary then must make a declaration that issuance of an EUA by the FDA Commissioner is justified. FDA must consult with ASPR, CDC and NIH, to the extent reasonable to believe that the MCM may be effective for the intended use and that the known and potential benefits outweigh the known and potential risks, taking into consideration the threat or emergency.¹⁶ An MCM may be prepositioned and a EUA issued before an emergency. However, because a EUA allows use without traditional human subject protections (e.g. informed consent, IRB review), a request to issue a EUA is made on a case-by-case basis and is a mechanism of last resort.

PAHPRA specifies that the HHS Secretary may, acting through an appropriate HHS official, create and issue EUIs about an MCM to inform health care professionals and patients/recipients about the MCMs approved, licensed, or cleared conditions of use before or during an emergency. This authority enables CDC to make available—before an emergency occurs—information about the emergency use of an approved product. This will enable stakeholders to be better prepared for and more familiar with the emergency use of the MCM if an emergency were to occur, rather than waiting for an EUA and its accompanying authorized fact sheets to be issued at the time of an event.¹⁷

Experience from previous responses to national emergency events has demonstrated that not enough responders and physicians may be fully aware, especially at the time of a disaster, of what MCMs might be used under a EUA/EUI or under an expanded access mechanism. Related to this, clinicians, nurses, and responders may harbor confusion and legal concerns regarding who can administer an MCM under which mechanism and under what circumstances. Adding to the potential confusion is the use of different “temporary” authorizations for normal, routine product investigational activities such as IND’s for drugs and Investigational Device Exemptions (IDEs) for devices, which may also be used for individual therapeutic emergency situations. Institutions and individuals who are not aware of the ability to utilize an otherwise unapproved therapy (particularly a therapy that is unfamiliar to them) under these mechanisms, or are not aware of conditions, processes and legal/ethical issues associated with their use, may choose not to provide the therapy and utilize a possibly less appropriate therapy.

2. Best Practices and Mitigation Strategies:

The FDA provides guidance regarding its policies for emergency use authorization of medical products¹⁸ as well as maintains a current list of EUAs to help inform stakeholders. Additionally, some professional public health organizations have developed information as well to help advise

¹⁶ U.S. Food and Drug Administration. (2007). Emergency Use Authorization of Medical Products Guidance. Retrieved from: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>

¹⁷ U.S. Food and Drug Administration. (2014). Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 Medical Countermeasure Authorities: FDA Questions and Answers for Public Health Preparedness and Response Stakeholders. Retrieved from:

<http://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/UCM380269.pdf>

¹⁸ U.S. Food and Drug Administration. (2015). Emergency Use Authorization. Retrieved from: <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm>

stakeholders regarding the difference between EUAs and INDs/IDEs.¹⁹ Where there exist no FDA-approved labeling in pediatrics for specific products, EUI sheets with modified dosing along with dispensing and screening procedures would be made available. Training may be useful for stakeholders to better understand these mechanisms for access.

3. NACCD Recommendations:

- a. HHS/ASPR should raise awareness of EUA/EUI/IND practices, clearly delineating distinctions between these mechanisms wherever possible. First responder personnel especially need to be aware that medications can be used off-label in an emergency with appropriate authorization, and have access to existing instructions on the appropriate uses of EUA/EUI in pediatrics.
- b. HHS/ASPR should thoroughly review the legal and ethical issues surrounding distribution of investigational agents prior to an event, and promote the availability of this information (along with overall guidance on the process) to those who will be administering these MCMs under a special authorization. Information on EUA's and EUI's — both general and legal/ethical — should be known and readily understood by clinicians, pharmacists, nurses, and emergency responders.
- c. HHS/ASPR should develop healthcare training modules to educate responders on EUA/EUI mechanisms, particularly as their use relates to pediatric emergency care through investigational drugs, biologics, and devices.

D. Incentivizing Industry for Pediatric MCM Development

1. Current State and Gaps:

Industry, academia, and the U.S. government have collaborated to ensure products with FDA approval or EUAs to cover all the pediatric populations are being developed for SNS placement. For example, PHEMCE Integrated Program Teams (IPTs) provide an end-to-end vision of MCMs against a particular threat type (e.g., anthrax, smallpox) or capability (e.g., diagnostics) that ranges from requirements-setting (i.e., establishing targets and product characteristics) through stockpiling, delivery and dispensing, and monitoring and evaluating MCM effectiveness. To help mitigate gaps for critical MCM for children, the PHEMCE Pediatric and Obstetrics IPT identify and make recommendations to the Enterprise Executive Committee regarding key pediatric MCMs in the SNS. Additionally, industry, CDC and the PHEMCE may come together to consider an IND, which may be the only way data could be collected from a pediatric population during an event, to inform determinations on issuing an EUA in future circumstances.

Although mechanisms exist to use most currently available MCMs to cover the majority of the pediatric population, full FDA approval for some pediatric indications is still lacking, and pediatric formulations remain problematic. The supporting data for safe and effective pediatric use of some SNS MCMs is simply deficient. The FDA cannot compel the MCM industry to

¹⁹ Association of State and Territorial Health Officials. (2011). Comparing Emergency Use Authorization to Investigational New Drug & Investigational Device Exemption Protocols Factsheet. Retrieved from: <http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Use-Authorization-Toolkit/Comparing-Emergency-Use-Authorization-to-Investigational-New-Drug---Investigational-Device-Exemption-Protocols-Fact-Sheet/>

conduct those studies; they can only request industry to direct studies, but participation is voluntary. As noted previously, education and training of frontline personnel—especially, clinicians and responders—is critical. Without such, efficient and timely utilization of products from local stocks and the SNS will be impeded.

2. Best Practices and Mitigation Strategies:

The NIH, the FDA, and the Defense Advanced Research Projects Agency (DARPA) are collaborating in a research initiative called the Tissue Chip program,²⁰ with the objective to develop human organ tissue systems which can reliably test drug candidates efficiently and accurately. Other cross-agency collaborations, such as the previously mentioned Inter-Agency Agreement between NIH and FDA for a Pediatric Formulations Platform¹⁴, can be applied toward MCM development.

Incentives to manufacturers to develop pediatric products have been successful. The Best Pharmaceuticals for Children Act has effectively promoted the development of products that sponsors were either not originally interested in marketing or would have not done so in a timely manner. More than 200 products have been studied in the pediatric population utilizing this incentive program, which grants sponsors six additional months of marketing exclusivity (protecting them from any competitor coming onto the market during this period for any product composed of the molecular entity studied in the pediatric population, even if only one of many approved uses of the product were studied in pediatrics). Orphan exclusivity for products for rare diseases has also been a successful incentive program.

3. NACCD Recommendations:

- a. HHS/ASPR should continue to invest in development of novel and rapid vaccine production technologies, establishing partnerships with industry as appropriate.
- b. HHS/ASPR should develop and pursue collaborations among the Biomedical Advanced Research and Development Authority (BARDA), FDA, and NIH, or among BARDA, Defense Advanced Research Projects Agency (DARPA), FDA, NIH, and the pharmaceutical industry to develop improved pediatric drug formulations in the CHEMPACK or Strategic National Stockpile (SNS), using the NIH-FDA Formulations Platform¹⁴ as a model.
- c. HHS/ASPR should review and consider incentives that have been used to stimulate activity in pediatric labeling. Additional incentives should be implemented to provide new pediatric formulations that are non-liquid, temperature stable, and palatable.
- d. HHS/ASPR should evaluate various means to incentivize device manufacturers to seek FDA approval of pediatric auto injectors which are available in non-US countries. Incentives could include patent protection and extension of the priority voucher program.

²⁰ U.S Department of Health and Human Services. National Institutes of Health. (2015). About Tissue Chip. Retrieved from: <http://www.ncats.nih.gov/tissuechip/about>

E. Prepositioning

1. Current State and Gaps

Although public health preparedness agencies in states and territories have established plans and conducted drills and exercises in collaboration with their respective key healthcare and responder partners, the extent of plans for regional communication among hospitals, pharmacies, and emergency responders regarding the location of critical supplies in facilities and the redirection of patients or supplies to the needed area may vary among jurisdictions. As previously noted, limited pediatric-specific MCMs and other supplies exist in these stockpiles.

2. Best Practices and Mitigation Strategies:

Two federal programs currently exist to support state and local response to emergencies or disasters. The CHEMPACK program¹⁴ strategically prepositions MCMs against nerve agents within jurisdictions to enhance state and local capability to respond immediately in the event of a nerve agent attack or disaster. This program allows for local control to assure that clinicians and first responders on the ground can administer timely critical life-saving agents. The SNS program²¹ is also strategically positioned throughout the United States to provide states and territories with large quantities of medications and other medical resources within 12 hours of a jurisdiction's request to respond to an emergency or disaster. These assets may be prepositioned within a jurisdiction before an event to allow for more timely availability.

3. NACCD Recommendations

- a. HHS/ASPR should issue the AAP's pediatric MCM info sheet for nationwide dissemination to state and local response networks. This document outlines MCMs likely to be used for pediatric care in an emergency and provides a framework for how and when to administer each drug.
- b. HHS/ASPR should continue to encourage MCM distribution planning to involve nontraditional responder partners (e.g., local pharmacies, schools, and day care centers).
- c. HHS/ASPR should facilitate a collaboration among key stakeholders (e.g., AAP, CDC, FDA, American Pharmacists Association) to develop a standard list of medications and devices (e.g., face masks, needles, and syringes for children) which should be stocked in pharmacies for chemical and biologic emergencies.
- d. HHS/ASPR should assure that prepositioned packages and federal stockpiles include pediatric dosing tables, dosing tapes, and pediatric-specific equipment with instructions for use.
- e. HHS/ASPR should encourage testing and drilling, especially utilizing scenarios in which medication shortages may occur in certain areas while sufficient stock exists elsewhere. Depending on the scenario, either the population or the resources could be shifted. The types of data needed for those decisions can subsequently inform the development of algorithms or models.

²¹ U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (2015). Strategic National Stockpile. Retrieved from: <http://www.cdc.gov/phpr/stockpile/stockpile.htm>

F. Ethical Issues

1. Current State and Gaps

Children cannot provide consent for medications or procedures and must rely on their parents or legal guardians to consent for them. There is a need to streamline the consenting or permission process for emergencies. Long and seemingly, especially for the lay person, complicated consent forms should be made concise and readable for the average U.S. adult.

Another critical consideration is that an IND-driven study involving children during an event is very likely, where the needed treatment product has not been studied in pediatrics and previously could not be studied ethically.

2. Best Practices and Mitigation Strategies

In an effort to make the emergency care consenting process more efficient, mass consenting or obtaining of permission (e.g., by many people in one room at a time) is a possible solution.

There have been ongoing and periodic discussions and collaborations among various stakeholders (e.g., AAP, CDC, FDA) regarding pediatric ethical considerations and MCMs, most notably related to the potential event of anthrax or smallpox exposure.²² Consideration has been given to the challenges of addressing pediatric issues in an emergency (e.g., the National Biodefense Science Board, now National Preparedness and Response Science Board, in 2011 with a report²³ of the challenges in the use of anthrax vaccine in the pediatric population). Experts, although few, in the bioethics of children in disasters have been identified and are utilized by federal and academic groups as specific resources in ongoing discussions and research.²⁴ NIH has developed a number of resources to address the specific issues of why children should or should not participate in clinical trials.²⁵ Therefore, there is some movement to better answer the various ethical challenges in addressing children's needs.

3. NACCD Recommendations

- a. HHS/ASPR should facilitate the collaboration of key partners (e.g., AAP, CDC, FDA) and public health law experts to consider, review, and develop innovative emergency consenting methods that focus on rapid delivery of care.

²² U.S. Food and Drug Administration. (2013). 2013 Meeting Materials of the Pediatric Advisory Committee to the Food and Drug Administration. Retrieved from:

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm341096.htm>

²³ National Biodefense Science Board. (2011). Challenges in the Use of Anthrax Vaccine Absorbed (AVA) in the Pediatric Population as a Component of Post Exposure Prophylaxis (PEP). Retrieved from:

<http://www.phe.gov/Preparedness/legal/boards/nprsb/recommendations/Documents/avwgrpt1103.pdf>

²⁴ Presidential Commission for the Study of Bioethical Issues. (2013). Safeguarding Children: Pediatric Medical Countermeasure Research. Retrieved from: http://bioethics.gov/sites/default/files/PCSBI_Pediatric-MCM508.pdf

²⁵ U.S. Department of Health and Human Services. National Institutes of Health. (2012). The Importance of Children in Clinical Studies. Retrieved from: <http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>

- b. HHS/ASPR should continue to encourage increased public health research by federal and other partners (e.g., DOD pediatric studies, juvenile and pregnant animal studies) to decrease the number of products utilized for pediatrics that require EUAs or INDs during an event.
- c. HHS/ASPR should encourage national and jurisdictional exercises that include children and the use of the specific resources (e.g., weight issues, delivery systems) required for them to assure and increase familiarity with pediatric needs, formulations, calculations, delivery systems, use of EUA's for pediatrics and other equipment.
- d. HHS/ASPR should work with partners (e.g. HRSA, the Children's Hospital Association, state and local public health) to encourage active relationships among pediatric facilities and local fire, police, and ambulance services.

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Appendix A: Task Letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for
Preparedness & Response
Washington, D.C. 20201

Michael R. Anderson, MD, MBA, FAAP
Chair, National Advisory Committee on Children and Disasters
11100 Euclid Avenue
Cleveland, OH 44106

Dear Dr. Anderson and Members of the NACCD:

The Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) is a leader in preparing the Nation and its communities to prepare for, respond to, and recover from public health and medical disasters, and emergencies. Section 2811 of the Public Health Service (PHS) Act, added by the 2006 Pandemic and All-Hazards Preparedness Act (PAHPA), and amended by the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), established the ASPR as the principal adviser to the HHS Secretary, responsible for providing integrated policy coordination and strategic direction with respect to all matters related to public health, medical preparedness, and deployment of the federal response for public health emergencies and incidents. As you are also aware, in 2014 the National Advisory Committee on Children and Disasters (NACCD) was established pursuant to section 2811A of the PHS Act. The NACCD was formed specifically to inform the Secretary and the ASPR on matters related to the health and well-being of children affected by disasters.

The hospital sector has undergone dramatic reforms with a focus on performance values, and increased emphasis on quality of care. As integrated healthcare delivery systems enhance their program growth, coordination, and efficiency, the development of disaster preparedness, response, and resilience strategic plans that meet the long-term needs of children will be vital. I would like the NACCD to address the topic of pediatric healthcare delivery systems in the event of a mass casualty/large-scale disaster. I also encourage the NACCD to identify opportunities for hospitals to link preparedness to hospital quality control programs. In developing the report, I would like the committee to examine the following:

1. The current state of healthcare (both pediatric and non-pediatric) facility preparedness to care for children in mass disasters. Examples of variables may include site management, surge, transport, medical countermeasure capabilities, workforce development, innovative programming, communications streams, and partnership/coalition-building.

2. A review of best practices, recommendations of potential long-term strategies, and a summary of practical tools to improve the ability of healthcare coalitions to effectively care for children after disasters.
3. A summary of potential mitigation strategies for identified gaps.
4. An assessment of current granting structures for pediatric healthcare capacity building.

I believe, given the NACCD's expertise, that this report will generate key guidance to improve the care of children after disasters. I look forward to receiving the NACCD's recommendations by August 28, 2015.

Thank you for your continued support in the work of ensuring the public health preparedness of our nation's children.

Sincerely,

Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response

Appendix B: Healthcare Preparedness Working Group (HCPWG)

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