



Medical Countermeasures for Children in Public Health Emergencies, Disasters, or Terrorism

DISASTER PREPAREDNESS ADVISORY COUNCIL

Significant strides have been made over the past 10 to 15 years to develop medical countermeasures (MCMs) to address potential disaster hazards, including chemical, biological, radiologic, and nuclear threats. Significant and effective collaboration between the pediatric health community, including the American Academy of Pediatrics, and federal partners, such as the Office of the Assistant Secretary for Preparedness and Response, Centers for Disease Control and Prevention, Federal Emergency Management Agency, National Institutes of Health, Food and Drug Administration, and other federal agencies, over the past 5 years has resulted in substantial gains in addressing the needs of children related to disaster preparedness in general and MCMs in particular. Yet, major gaps still remain related to MCMs for children, a population highly vulnerable to the effects of exposure to such threats, because many vaccines and pharmaceuticals approved for use by adults as MCMs do not yet have pediatric formulations, dosing information, or safety information. As a result, the nation's stockpiles and other caches (designated supply of MCMs) where pharmacotherapeutic and other MCMs are stored are less prepared to address the needs of children compared with those of adults in the event of a disaster. This policy statement provides recommendations to close the remaining gaps for the development and use of MCMs in children during public health emergencies or disasters. The progress made by federal agencies to date to address the needs of children and the shared commitment of collaboration that characterizes the current relationship between the pediatric health community and the federal agencies responsible for MCMs should encourage all child advocates to invest the necessary energy and resources now to complete the process of remedying the remaining significant gaps in preparedness.

abstract

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Events over the past 2 decades are a stark reminder that disasters, human-caused or natural, can affect children directly. Despite our best efforts to protect children, this population may be the chance target of natural disasters or the intended target for acts of violence or terrorism. Children represent a particularly vulnerable population during a pandemic, natural disaster, or act of terrorism. Medical countermeasures (MCMs), defined as medications, antitoxins, vaccines, immunoglobulins, medical devices, and pediatric age-appropriate life-saving medical equipment and supplies required to protect or treat children for possible chemical, biological, radiologic, or nuclear (CBRN) threats, are of paramount importance to the health security of children and the nation as a whole.¹⁻³

Children have unique needs that must be taken into consideration for communities to be truly prepared to respond to disasters and public health emergencies and to remain resilient in their aftermath.⁴ It has been well documented that children differ from adults by virtue of their unique anatomic, physiologic, and developmental/behavioral characteristics.⁵ The National Commission on Children and Disasters examined the current state of pediatric disaster readiness in the United States and made recommendations in the *2010 Report to the President and Congress*.⁵ In particular, this report included a recommendation that the US Department of Health and Human Services (DHHS) and the US Department of Homeland Security (DHS)/Federal Emergency Management Agency should ensure the availability of and access to pediatric MCMs at the federal, state, and local levels for CBRN threats.² Formed in 2014, the DHHS National Advisory Committee on Children and Disasters provides advice and consultation to the DHHS Secretary

on issues related to the medical and public health needs of children as they relate to disasters.⁶

MCM RESEARCH, DEVELOPMENT, ACQUISITION, AND SUPPORT

The DHHS Office of the Assistant Secretary for Preparedness and Response (ASPR) leads the nation's preparedness efforts for response and recovery from the adverse health effects of emergencies and disasters. Within the ASPR, the Biomedical Advanced Research and Development Authority (BARDA) oversees the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies through advanced research, development, and acquisition contracts and grant awards.

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is a federal interagency body responsible for providing recommendations to the DHHS Secretary on MCM priorities and the development, acquisition, and distribution of MCMs within the Strategic National Stockpile (SNS). The SNS is a federally maintained cache of MCMs for rapid deployment and use in response to a public health emergency or disaster. The PHEMCE coordinates federal efforts to enhance preparedness for CBRN and emerging infectious disease threats with respect to MCMs and conducts an annual review of the SNS contents. The PHEMCE is led by the ASPR and includes 3 primary DHHS internal agency partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health as well as several interagency partners, including the US Department of Defense (DoD), the Department of Veterans Affairs, the US Department of Agriculture, and the DHS (see

www.phe.gov/Preparedness/mcm/phemce/Pages/mission.aspx).

The ongoing analysis of health security threats and the nation's MCM portfolio is informed by the efforts of 10 integrated program teams (IPTs). The IPTs provide an end-to-end vision of MCMs against a particular threat type (eg, chemical, radiologic, nuclear), capability (eg, diagnostics), or cross-cutting issues, such as at-risk populations. The Pediatric and Obstetric (PedsOB) IPT supports all threat-based PHEMCE IPTs with strategies for identifying, developing, acquiring, deploying, and utilizing high-priority MCMs for children and pregnant women. The PedsOB IPT serves as a subject matter expert (SME) community of practice for the interagency vetting and input on issues relevant to MCMs and pediatric readiness (see www.phe.gov/about/OPP/mcsr/Pages/threat-analysis.aspx).

The CDC provides clinical guidance to health care providers and facilities and coordinates the development of guidance to state, territorial, and local public health departments in support of efforts to detect and respond to public health emergencies. The CDC also oversees the distribution of MCMs from the SNS to individual states. The FDA ensures the safety and effectiveness of MCMs while regulating the approval, licensure, development, and certain postmarket surveillance of medical products. The FDA may authorize the emergency use of an unapproved or unlicensed medical product or an unapproved or unlicensed use (such as for a pediatric subpopulation) of an already approved product if certain public health emergency criteria are met or declarations are made.⁷ The National Institutes of Health collaborates with other agencies to conduct research and provide funding necessary for the development of new or enhanced MCMs. The DHHS and PHEMCE MCM acquisition strategy is based

on a multistep process that includes assessing the threat and potential public health consequences of CBRN agents, determining the type and quantity of needed MCMs, evaluating the public health response capability, and developing and acquiring countermeasures for the SNS. The Project BioShield Act (Pub L No. 108-276 [2004]) requires the DHHS to assess the public health consequences of exposure to CBRN agents that the DHS determines are material threats to the nation and to determine for which of these agents MCMs are necessary to protect the public's health.

EMERGENCY ACCESS TO UNAPPROVED MCMs

The FDA has several mechanisms to allow emergency access to unapproved medical products (see www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351261.pdf). One mechanism is the Emergency Use Authorization (EUA).⁸ Under section 564 of the Food, Drug, and Cosmetic Act (Pub L No. 110-85 [2007]), the FDA may authorize the emergency use of medical products (drugs, biologics, devices) including diagnostics that were not previously FDA approved, as well as the unapproved use of an approved product. These authorizations require a declaration that circumstances exist to justify the issuance of an EUA, on the basis of a determination made by the Secretary of DoD, DHS, or DHHS. This approach was used during the H1N1 influenza pandemic in 2009 to allow the emergency use of certain antiviral drugs in children and personal respiratory-protection devices. A modified EUA mechanism, emergency use instructions, was established under the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA; Pub L No. 113-5), which allows the CDC, at the direction of the DHHS Secretary, to authorize

pediatric indications of MCMs for emergency use before an emergency is known or imminent. This process has become a useful tool in creating a more timely solution to emerging or perceived threats, especially for children, until sufficient research on pediatric use has been collected on an MCM already approved for adults and/or until research on new MCMs for children has been completed. Information on the EUA process and other resources may be found on the FDA Web site (see www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatorandPolicyFramework/ucm182568.htm). The general authorities within the PAHPRA are also useful in situations involving children. The link to the page with the listing of current EUAs is as follows: www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatorandPolicyFramework/ucm182568.htm#current.

SNS AND MCM DISTRIBUTION PLAN

To protect the health security of children and families during a public health emergency, the contents of the SNS ultimately need to reach the end user. The SNS, depending on the threat, is intended to supplement state and local supplies used for immediate care during the initial response, within 12 hours of notification/incident. Local and state funding challenges have resulted in decreases in state and local caches, underscoring further the need to ensure a well-stocked and rapidly deployed SNS. Because of the nature of certain threats, such as nerve agents, some MCMs are stored in local advance-deployed caches to allow for immediate access and administration to victims. Although the federal government maintains the

SNS and makes the ultimate decision to release SNS assets, the distribution of MCMs to the affected population is the responsibility of state and local government and public health and emergency management agencies. Each state and many local agencies have specific MCM distribution plans. It is critical that pediatricians (including primary care pediatricians and pediatric medical and surgical subspecialists) collaborate in advance with public health colleagues at the state and local levels to ensure that MCM distribution plans incorporate the needs of all children, including various subgroups such as infants, those with disabilities, and others with access and functional needs.

A broad array of potential MCM distribution strategies exist, ranging from utilizing the US Postal Service for home delivery in cities⁹ to using large facilities as distribution centers or points of dispensing (PODs), thereby leveraging public and private sector partnerships. Each state has plans on file to receive and distribute MCMs to local communities as quickly as possible. The CDC Cities Readiness Initiative (see www.bt.cdc.gov/cric/) supports planning to respond to a large-scale bioterrorist event by dispensing antibiotics to a specific population within 48 hours. The POD system concept has been widely discussed and tested.¹⁰⁻¹³ Many POD locations will likely be open-public sites, such as schools and community centers, visited by the population at risk who have been advised to report to that site for MCMs. Other PODs may be closed, dispensing MCMs to a select at-risk population (eg, employees of a large company, university students/faculty/staff) and not to the general public.

Furthermore, all health care providers need to be knowledgeable of MCMs and their appropriate use so that they can effectively perform their role within their community

and medical home and serve as reliable sources of information in the event of a public health emergency.^{14,15} Pediatricians, pediatric health care providers, and others who will be providing medical care for children in the event of a disaster will need specialized education and training that includes knowledge on when and how MCMs should be used as well as possible adverse reactions (see www.aap.org/disasters/educationandtraining). At present, few, if any, pediatric office practices or medical homes¹⁵ have made arrangements to be used as a POD for MCM distribution, although the medical home may be considered as a means of distribution for certain MCMs (eg, vaccines) or for some populations, such as children and youth with special health care needs. In any event, the medical home should be viewed as an entity that can be a vital component of any community's response to or recovery from a public health emergency.^{16,17} Pediatricians can also advocate for the inclusion of considerations for children and families within the existing POD plan in their community.

THE SNS AND PEDIATRIC MCM CHALLENGES

When considering the stockpiling and rapid distribution of MCMs in response to a CBRN event, the unique requirements of the pediatric population pose several challenges. Liquid and other pediatric formulations of most MCMs are limited within stockpiles; liquid formulations are bulky, may be more expensive per dose, and cost more to store. Pediatric formulations also typically have a shorter shelf-life and are therefore more expensive to maintain. Certain critical MCMs are prepackaged in dose aliquots or in auto-injector devices to facilitate rapid delivery for victims in the field. For these same MCMs to be delivered safely and as efficiently

to children, pediatric-sized vials or auto-injectors must be available, although stockpiling both adult- and pediatric-sized delivery devices may also increase cost.

Moreover, until recently, there has been a relative lack of pediatric MCM development and procurement; many MCMs were initially developed for use by the military and have been evaluated and tested only in adults. Furthermore, the primary market for many MCMs has been the military. Outside of the DoD, the BARDA and the PHEMCE have federal responsibility to stimulate and drive the market for advanced research and for the development and procurement of MCMs, especially those for which there is not a commercial market. Reliance on traditional market mechanisms for public health preparedness and response to disasters is risky. In the specific circumstance of MCM development for children, traditional market mechanisms for preparedness and response would create a gap that can be life-threatening for children.

Developmental aspects of children also account for some of the challenges with pediatric MCMs. Children may have trouble swallowing pills and may refuse to consume formulations that are not palatable. Limited drug pharmacokinetic data and adverse reactions/sensitivities to medications (eg, antibiotics that stain teeth or disrupt growth plates) pose additional challenges.

PRACTICAL CONCERNS RELATED TO RESEARCH ON MCMs IN CHILDREN

There are reasonable concerns about conducting certain types of MCM research in the context of the special protections afforded to children as human subjects,¹⁸⁻²⁰ related in part to their relative vulnerability and general inability to provide their own informed consent.

These practical considerations and necessary additional protections often result in further financial costs and the perception of increased risk when conducting research with children instead of adults. Any additional cost that may result from including children in a meaningful way in clinical drug trials is not an appropriate rationale to limit or exclude them from such research. Likewise, the investigational or unlicensed use of an MCM in the pediatric population during a disaster imposes consent requirements that could impede timely distribution. An excellent example of this dilemma may be found in recommendations for the pre-event study of anthrax vaccine in children made by the DHHS National Biodefense Science Board (now known as the National Preparedness and Response Science Board) and the Presidential Commission for the Study of Bioethical Issues.^{19,20}

PRIORITIZING PEDIATRIC PREPAREDNESS: WHAT DOES THE AMERICAN PUBLIC EXPECT?

As an organization devoted to advancing the needs of children and families, the mission of the American Academy of Pediatrics (AAP) includes public policy advocacy on a broad scope of concerns relevant to the health and well-being of children. In an effort to stimulate discussion on the use of resources related to disaster planning and response specific to children's issues, the AAP and Children's Health Fund collaborated on a 2010 telephone survey, conducted by the Marist College Institute for Public Opinion. The majority of people surveyed supported giving higher priority to children and their needs over adults. Opinions remained consistent across various demographics, including region, household income, education, age, race, gender, and political party.²¹

RECOMMENDATIONS FOR MCMS FOR CHILDREN EXPOSED TO PUBLIC HEALTH EMERGENCIES, DISASTERS, OR ACTS OF TERRORISM

Recommendations and key considerations regarding MCMs for children include the following:

In the interest of preparing to meet the needs of children exposed to public health emergencies, disasters, or acts of terrorism, federal, state, and local governments should acquire and maintain adequate amounts of MCMs appropriate for children of all ages in caches such as the SNS.

The SNS and other federal, state, and local caches should contain MCMs appropriate for children in quantities at least in proportion to the number of children in the intended population for protection by the cache. To meet the needs of children of all ages, stockpiles should include MCMs with appropriate formulations (eg, liquids), delivery devices (eg, pediatric auto-injectors), and age- or size-based dosing instructions. Concern for incremental cost, storage space, or inconvenience for MCMs intended for pediatric use must not be used as a rationale for lesser protection for children. As mentioned, ensuring protection for children is viewed as a priority by the US public.²² To ensure the presence of appropriate MCMs, pediatric SMEs should be part of decision-making bodies, such as the PHEMCE and BARDA, on an ongoing basis. Such experts should be represented in sufficient numbers and in positions of authority so that their involvement can substantially determine the outcome of decision-making processes as appropriate.

Federal agencies, collaborating with industry, academia, and other BARDA partners, should research, develop, and procure pediatric MCMs for all public health emergency, disaster, and terrorism scenarios and report on progress made.

The federal government should make it a priority to develop MCMs appropriate for use in children (in terms of agent, dose, formulation, and necessary equipment and delivery devices) that ensures successful treatment while minimizing long-term medical and developmental consequences. The FDA should begin by taking full advantage of all pathways currently available to ensure that products can be tested in pediatric populations. Initial efforts might focus on MCMs presently available for use in adults that do not yet have approved pediatric formulations, dose ranges, or indications that cover the full spectrum of pediatric subpopulations, and target the highest priority gaps (ie, gaps for which a serious threat exists and alternative agents are unavailable). The federal government should create a strategic plan to eliminate all gaps in pediatric MCMs and provide an annual report to appropriate authorities on progress made.

All future MCMs developed or procured with the use of governmental funds should include provisions for use in pediatrics and/or sufficient study of pediatric indications that will facilitate emergency use before FDA approval unless there are compelling reasons, other than cost, for not doing so.

Biomedical research funded by the federal government that involves MCMs should include

reasonable steps to accommodate the special protections afforded to children as human subjects, but such protections should not justify the failure to identify pediatric indications for MCMs.

Standards of therapeutic evidence in children should be congruent with adult standards. Whenever feasible, guidance for the use and dosing of MCMs in the pediatric population should be based on evidence garnered from research. The MCM research should take reasonable steps to accommodate the special protections afforded to children as human subjects related to their relative vulnerability, but such protections and associated practical considerations should not be permitted as a rationale for the failure to identify pediatric indications for MCMs that may ultimately be life-saving, because this may only render children more vulnerable.¹⁷ Likewise, the additional costs that may be inherent in clinical trials involving children as research subjects do not constitute an appropriate rationale to limit or exclude them from study, nor should those same factors preclude the stockpiling of pediatric formulations.

Research to develop pediatric dosing guidelines and formulations of MCMs already approved for adult use should be deemed a high priority. These endeavors may facilitate MCM administration in other at-risk populations, including the elderly and medically complex adults, especially those who have difficulty taking pills because of preexisting developmental or medical problems.

Federal, state, and local government, along with private sector and community stakeholders, should address the needs of children and families

in MCM implementation, distribution, and administration planning.

Mechanisms for the forward deployment and distribution of MCMs should consider the needs of children as a priority. Locations where children congregate (eg, schools and before- and after-school programs, Head Start and other early education and child care programs, camps, and other community programs) should be explored as opportunities for advance cache storage and rapid distribution to families with children. These sites may be well suited to handle the unique characteristics of pediatric dosing, such as weight-based dosing, and the possible need for suspension or other reformulating requirements or may better support the need to obtain informed consent from parents for the distribution of unlicensed or investigational MCMs to children. The distribution of MCMs to adults might also be accomplished at such sites. Such a plan could align with the CDC/state-local government public-private partnership closed PODs and potentially with increasing school-located vaccine efforts.¹⁰⁻¹² To facilitate their development, the costs of creating caches in such locations should be borne by public health and emergency preparedness budgets and not as an unfunded mandate imposed on schools, child care facilities, or community organizations.

Easy-to-follow instructions (eg, the use of pictograms, videos, and other visual aids) regarding proper preparation, dosing, and administration of MCMs for use by children should be developed before any incident in formats that can be readily understood by caregivers, who will undoubtedly be under great stress during an emergency and who may have limited health literacy themselves and/or an incomplete preexisting understanding of medication preparation, dosing, and administration.⁸ These instructional materials should also be available translated in the languages of the

population to be protected and modified to ensure access to children and adults with disabilities. The CDC has already engaged caregivers and pediatric SMEs in the development and pilot testing of such dosing aids; further efforts should be supported and expanded.

Consideration for the liberalization of FDA-approved dosing guidelines during a public health emergency for medications (such as dosing guidelines that would otherwise result in the administration of a portion of an adult pill, tablet, or capsule or liquid reformulation of pills/tablets/capsules that require complicated instructions to determine the appropriate volume for children on the basis of weight) will facilitate the ease and success of dosing in the context of a crisis. These adjustments should be considered when the risk of such dosing modifications is small when compared with the risk of contracting the illness if the medication is not administered because of the complexity of the instructions. The compounding of pills or capsules into liquids and dosing by families to a high level of specificity may be unrealistic in the midst of a public health emergency and certainly in the context of a crisis in which there are large-scale distribution challenges with limited medical supervision and support. If the instructions are overwhelming, they are likely to be ignored or misunderstood, resulting in improper dosing or poor compliance.

The federal government should proactively identify anticipated uses of MCMs in children during a public health emergency and, where pediatric FDA-approved indications do not exist, establish a plan to collect sufficient data to support the issuance of a pre-event EUA that includes

information such as safety and dosing information.

The AAP supports the continuing efforts of the DHHS, ASPR, CDC, FDA, and others to address this gap in pediatric dosing guidelines through the creation of a process that allows for the advance approval of off-label use of MCMs in children before the declaration of an imminent threat (ie, before an EUA can be issued). Specifically, the PAHPRA has stated that at the direction of the DHHS Secretary, authorization of pediatric indications of MCMs may occur for emergency use before an emergency is known or imminent. The government should continue actively engaging pediatric SMEs in the development of such recommendations. The AAP will continue its efforts to educate pediatric health care providers and others about its recommendations with regard to the off-label use of drugs in children.²²

The federal government should use existing entities with pediatric SMEs, such as the PHEMCE, PedsOB IPT, and the DHHS National Advisory Committee on Children and Disasters, and continue to collaborate with private sector partners offering pediatric expertise to provide advice and consultation on pediatric MCMs and MCM distribution planning.

The DHHS National Advisory Committee on Children and Disasters was established by Congress under the PAHPRA as an expert body composed of nonfederal and federal SMEs to provide advice and consultation on all ASPR activities related to children, including MCMs, as well as state emergency preparedness and response activities pursuant to the recommendation of

the National Commission on Children and Disasters.² Other entities, such as the PHEMCE PedsOB IPT,²³ exist to support and advance pediatric MCMs and MCM distribution planning within the federal government. To make meaningful and sustained progress to address gaps in pediatric MCMs, these expert entities should be maximized by the federal government, and others should be created as needed to ensure that sufficient sustained attention to the unique needs of children related to MCMs are addressed consistently. In addition to leveraging the pediatric expertise within government, the federal government should continue its collaboration with private sector partners as a means to access a broad array of subject matter expertise and as a mechanism to engage the support of those partners.

Pediatric health care professionals should be provided with access to current information on the appropriate use of MCMs and local distribution plans so that they can provide effective health care to children and advise families during a public health emergency.

Pediatricians and others who will be taking care of children in the event of a disaster will need requisite knowledge of when and how MCMs should be used. To best support the needs of children and families, health care providers must be familiar with appropriate dosing, drug/food interactions, and possible adverse reactions. Because MCM distribution plans may vary by location, it is important for pediatricians and other pediatric health care providers to collaborate with public health and emergency management officials so that these plans incorporate the needs of children of all ages, including preterm infants and children/youth with special health care needs. In

any event, the physician's office, the community health center, and the medical home should all be viewed as vital components of any community's response to a public health emergency and as a core asset toward resiliency.

CONCLUSIONS

Children represent nearly a quarter of the US population, but they are affected disproportionately by most disasters and public health emergencies. Children are highly vulnerable to the effects of CBRN agents and have unique anatomic, physiologic, and developmental characteristics that need to be addressed. The protection of children has also been identified by the US public as the highest priority. Although important progress has been made over the past decade in strengthening the nation's emergency and disaster preparedness for children, including considerations for the use of MCMs in children, meaningful gaps still exist. The recommendations outlined in this statement should be used to guide pediatricians; federal, state, and local government agencies; and others in addressing this need.

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ABBREVIATIONS

- AAP: American Academy of Pediatrics
- ASPR: Assistant Secretary for Preparedness and Response
- BARDA: Biomedical Advanced Research and Development Authority
- CBRN: chemical, biological, radiologic, and nuclear
- CDC: Centers for Disease Control and Prevention
- DHHS: US Department of Health and Human Services
- DHS: US Department of Homeland Security
- DoD: US Department of Defense
- EUA: Emergency Use Authorization
- FDA: Food and Drug Administration
- IPT: integrated program team
- MCM: medical countermeasure
- PAHPRA: Pandemic and All-Hazards Preparedness Reauthorization Act of 2013
- PedsOB: Pediatric and Obstetric
- PHEMCE: Public Health Emergency Medical Countermeasures Enterprise
- POD: point of dispensing
- SME: subject matter expert
- SNS: Strategic National Stockpile

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