

DISASTERS AND PUBLIC HEALTH

Scenario: A bioweapon has been used in your community. As part of your public health response, you request assistance from the Strategic National Stockpile (SNS), which will include an unapproved medical product for the treatment of victims. What should happen next?



Project BioShield Act of 2004 (Public Law 108-276).² Section 564 permits the FDA Commissioner to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces, or a significant potential to affect national security. The U.S. Department of Defense, the U.S. Department of Homeland Security, or the U.S. Department of Health and Human Services must determine an emergency. The U.S. Secretary of Health and Human Services then issues a declaration of emergency allowing for an Emergency Use Authorization (EUA). The Secretary will consult with the EUA Working Group; other technical experts from FDA, NIH, and CDC; and other agencies and private entities, where appropriate, to identify products that may be eligible for an EUA in light of the circumstances of the emergency and to facilitate timely submission of the EUA request by an appropriate entity

After the U.S. Secretary of Health and Human Services issues a declaration of an emergency allowing for an EUA, the FDA Commissioner has the authority to issue an EUA authorization to use an unapproved medical product or an approved medical product for an unapproved use. Products and uses that are eligible for authorization are those that "may be effective" to prevent, diagnose, or treat in humans serious or life-threatening diseases or conditions that can be caused by the specified biological, chemical, radiological, or nuclear agent(s) that led to or caused the declared emergency. Examples include the following:

- Use of an antibiotic for treatment of a disease that is not included in the FDA-approved labeling (i.e., package insert).
- Use of additional materials or instructions that are not consistent with the FDA-approved labeling.
- Distribution of a prescription drug by a non-licensed provider.
- Administration of a vaccine to a person younger than the age covered by the approval.

An EUA can only be issued if the FDA Commissioner concludes that

- The agent specified in the declaration of emergency can cause a serious or life-threatening disease or condition. ...
- Based on the scientific information available, it is reasonable to believe that the medical product might be effective in diagnosing, treating or preventing the disease or condition specified in the declaration of emergency or caused by *Next page...*

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Special points of interest:

- * FEMA courses for teachers
- * Get Ready Day

another medical product.

- The known and potential benefits outweigh the known and potential risks of the product when it is used to diagnose, prevent, or treat the disease or condition that is the subject of the declaration.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

Scenario: Plague has been used as a bioterrorism agent in your community. The CDC submitted a request for and has been issued an EUA to allow the use of an antibiotic that has not yet been approved for the treatment of plague, but is approved to treat other infectious diseases. You've received a shipment of the antibiotic from the Strategic National Stockpile.. What should you do next? The FDA Commissioner may elect, given the circumstances of the emergency, to place conditions on the use of the medical product under an EUA, to ensure it is used safely and effectively by healthcare providers/authorized dispensers and its recipients. It is the

Types of EUA Conditions
Information for Healthcare Providers and Authorized Dispensers*
Information for Recipients*
Adverse Event Monitoring and Reporting*
Recordkeeping and Access*
Restricted Distribution*
Restricted Administration*
Data Collection and Analysis*
Compliance with Good Manufacturing Practices (GMP)
Advertising

*Of particular interest for public health emergency planner responsibility of the healthcare community to review these restrictions before using the medical product. Although informed consent is not required for administration of an EUA product and the information dissemination requirements of section 564 are mandatory only to the extent conditions establishing such requirements are practicable, FDA recommends that recipients be given as much appropriate information as possible given the nature of the emergency and the conditions of the authorization. Ordinarily, FDA expects that some form of written information will be given to recipients, similar to the Fact Sheet for health care providers or authorized dispensers. To assure that individuals of all educational levels comprehend the

information provided, FDA recommends that it be written in the simplest language possible and using other techniques to improve health literacy. Additionally, records should be kept that include patient, dose, date, admin site, and adverse events reported to MEDWATCH or VAERS.

The declaration of emergency upon which an EUA is based will be in effect for one year or the length of the declared emergency, whichever is shorter. A declaration of emergency can also be renewed. The FDA Commissioner can revoke the EUA

- if the criteria of issuance are no longer met, or
- if it is no longer necessary to protect public health or safety under the EUA.

Scenario: Following a bioterrorism attack, the FDA Commissioner issues an EUA for a smallpox vaccine that has not yet been licensed by the FDA. The vaccine will be used in your vaccination clinics. How can the EUA reduce the delay in vaccine administration that might be encountered with use of the product under an IND?

Some public health officials are more familiar with the utilization of an IND (Investigational New Drug) application for the use of unapproved drugs or biologics or an IDE (Investigational Device Exemption) for the use of unapproved medical devices (or diagnostics). During a declared emergency, an unapproved medical product can be utilized either under an EUA or an IND/IDE, but it is important to realize that EUA and IND/IDE are different mechanisms with their own distinct statutory and regulatory requirements.

The conditions of authorization will usually require that patients be provided certain information about the medical product, and health departments should plan to maintain dispensing records, but the patient no longer has to provide written and witnessed informed consent. An EUA allows for patient information to be provided in the form of a fact sheet (subject to the terms of a particular EUA), and consent to receive the medical product may be granted verbally.

Resources:

- EMERGENCY USE AUTHORIZATION
An online course developed by the FDA and CDC
<http://www.bt.cdc.gov/training/eua/index.html>
- Emergency Use Authorization of Medical Products Guidance - Emergency Use Authorization of Medical Products July 2007
U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of Counterterrorism Policy and Planning

From the American Public Health Association:



Make plans now for your Get Ready Day event! Set up a booth on your school or campus, or pass out materials at your health department or workplace. Work with a local grocery store to promote preparedness and stockpiling to shoppers through displays or fliers. Or just put a link on your website!

Need more ideas? Visit our event planning page for tips and to request hard copies of materials for use in your activities.

<http://www.getreadyforflu.org/getreadyday/index.htm>

From the American Medical Association:

CitizenReady

CitizenReady® is a standardized, national disaster health education program that provides critical medical and mental health information to help individuals protect themselves and others in a disaster or other serious emergency.

The CitizenReady program will: (1) provide competency-based education to help citizens protect themselves, assist others, and enhance national efforts to prepare for, respond to and recover from incidents of terrorism and other catastrophic events; (2) incorporate ways to make the training widely available; and (3) encourage public participation in local preparedness and response efforts. The courses are intended to be delivered at no charge or at cost.

For detailed information, please view the [CitizenReady guide: How you can prepare for disasters and public health emergencies](#).

<http://www.ama-assn.org/ama/pub/physician-resources/public-health/center-public-health-preparedness-disaster-response.page>

Announcements

Looking for volunteers for the following ongoing activities: We have been going to various Senior groups and presenting short 10-15 minute talk about putting together a go-kit. We have done this in an informal way talking with groups at Senior centers and at AARP meetings. We have given out more than 300 starter backpacks and have more requests. Please call 978-928-3834

Looking for someone to put together a program on Cultural Diversity in Disasters. Have some materials to start. Hoping to have a program on Animal Care in a Disaster in the Fall. Want to help? Call 978-928-3834

There are also preliminary plans for a program on Special Needs and for a fun disaster exercise. Interested in working on working on training? Call 978-928-3834

Looking for someone to do Blood Pressure Clinic every 3rd Monday at the Legion Hall in Templeton at 12:30pm. Call 978-928-3834

Also looking for volunteer to help set up a smoking cessation program at an elderly housing project. Give us a call if you can help us put this program together. Call 978-928-3834

We are presently revamping the MRC to be more formal in its structure. We have grown and matured as an organization and to move forward to sustainability and increasing partnerships, we must review and revise as needed. A draft business plan was presented at the April 26th meeting and includes some new positions. We will continue to refine this plan, and review our Bylaw and Standard Operation Plan for revisions. If you have a suggestion, idea, something you saw work well in another organization, a concern, or discussion point, please email at wachusettmrs@juno.com or leave a message 978-928-3834.

Watch your emails for opportunities to participate in various trainings or conferences. If you haven't sent us your email address or your email address has changed, please do so. Also don't forget to check the website for updates.

Our email: wachusettmrc@juno.com

Our website: wachusettmrc.org

Cool Links/Ideas

bReddi Facebook App helps you manage your preparedness needs and to create a safety net inside and outside of your community. Your family and friends need to know what they can do in case of an emergency. With bReddi, you can establish how you will help your Lifelines before a disaster happens. You can set meeting places and Lifeline roles so there's no question of what to do, where to go or who to contact when disaster comes your way. bReddi features a summary page will keep you up to date on the latest threats to you, your friends and your family. bReddi can also alert you when the threat level changes for you or anyone you are a Lifeline for via text message, Facebook or Twitter.

www.phe.gov/lifeline/Pages/default.aspx

Project: Lifeline Facebook App draws on your existing social networks to help keep you communicate with your Lifelines during a disaster. Before a disaster strikes, Project: Lifeline will help formalize your communications networks and establish whose aid you will count on if you need it. Lifelines will be able to update your status in an emergency status list and keep your friends informed of your well being. The app also helps you find resources that will teach you about disaster risks and how to keep yourself safe. www.phe.gov/lifeline/Pages/default.aspx



The official **American Red Cross First Aid** app puts expert advice for everyday emergencies in your hand. Available for iPhone and Android devices, the official American Red Cross

First Aid app gives you instant access to the information you need to know to handle the most common first aid emergencies. With videos, interactive quizzes and simple step-by-step advice it's never been easier to know first aid. www.redcross.org/FirstAidApp

The FEMA App contains preparedness information for different types of disasters, an interactive checklist for emergency kits, a section to plan emergency meeting locations, information on how to stay safe and recover after a disaster, a map with FEMA Disaster Recovery Center locations (one-stop centers where disaster survivors can access key relief services) and Shelters, general ways the public can get involved before and after a disaster, and the FEMA blog. Terms of Use for the FEMA App: <http://www.fema.gov/app>.

IS-36: Multihazard Planning for Childcare

Course Description

This course covers the steps to help childcare providers prepare for incidents to ensure the safety of the children at their site. Childcare providers must have plans and procedures to keep children safe from everyday hazards and to respond and recover when an emergency happens.

The goal of this course is to provide childcare providers, of all sizes and with responsibility for children of all ages, with the knowledge and tools to analyze the hazards and threats at the site, to develop a plan to address these hazards and threats, and to implement processes to update and practice the emergency plan.

The topics addressed in this course include:

Knowing your hazards.

Developing a plan.

Testing and updating your plan.

Primary Audience

This course is designed for childcare providers of all sizes and for all age children, including, but not limited to, home childcare sites, childcare facilities, nursery schools, camps, scouts, sports programs, faith-based programs, and after-school programs. However, anyone with a personal or professional interest in childcare site preparedness is welcome to participate. Teachers, camp counselors, parents, volunteers, scout leaders, and coaches alike will find useful information in this course.

<http://training.fema.gov/EMIWeb/IS/is36.asp>

IS-362.a Multi-Hazard Emergency Planning for Schools

Course Overview

This course covers basic information about developing, implementing, and maintaining a school emergency operations plan (EOP). The goal of this course is to provide students with an understanding of the importance of schools having an EOP and basic information on how an EOP is developed, exercised, and maintained. The topics addressed in this course include:

Understanding incident management.

Forming the planning team.

Understanding the situation.

Developing a school emergency operations plan.

Incorporating the Incident Command System principles and roles in the school emergency operations plan.

Training, exercising, and maintaining the school emergency operations plan.

Primary Audience

This course is designed for teachers, substitute teachers, counselors, parent volunteers, coaches, bus drivers, and students. However, anyone with a personal or professional interest in school preparedness is welcome to participate. School administrators, principals, and first responders alike will find useful information in this course.

<http://training.fema.gov/EMIWeb/IS/is362a.asp>

The 2012 Integrated Medical, Public Health, Preparedness and Response Training Summit

<http://www.integratedtrainingsummit.org>

The 2012 Integrated Medical, Public Health, Preparedness and Response Training Summit is sponsored by the U.S. Department of Health and Human Services (HHS). This training summit brings together HHS partners including the National Disaster Medical System (NDMS), the Medical Reserve Corps (MRC), the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), and the United States Public Health Service (USPHS). It was held in Nashville, Tennessee at the Gaylord Resort May 22-25.



MRC Luncheon and Awards Ceremony



Opening Ceremony



Poster Presentations



A few of New England's MRC leaders with the Deputy Surgeon General and others from the Regional Offices.

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Lightning is one of the most underrated severe weather hazards, yet ranks as one of the top weather killers in the United States. According to NOAA, lightning strikes in America kill about 58 people and injure hundreds of others each year. Unlike other weather hazards that often involve sophisticated watches and warnings from NOAA's National Weather Service, lightning can occur anywhere there is a thunderstorm.

And if you've ever heard someone say lightning never strikes the same place twice... **WRONG!** Lightning often strikes the same place several times during one storm.

Did you know...

...there are an estimated 25 million lightning

flashes each year?!

...at any given moment, nearly 2,000 thunderstorms can be in progress over the face of the earth?!

...lightning can travel 60 miles or more, often extending up to 10 miles away from the cloud that formed it?! Generally, however, a bolt travels 10 miles or less. ...the temperatures of a bolt may reach 50,000F ... 5 times hotter than the surface of the sun?!

...it is estimated that there may be as many as 100 lightning strikes around the globe each second creating a continuous power of about 4,000,000,000 kilowatts of energy?!

...Venezuelan residents on the Catatumbo River get a spectacular show of 40,000 lightning strikes a night almost 300 nights a year?!

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