Keynote Address—The Role of Clinical Pharmacy in Emergency Preparedness and Response
Activity No. 0217-0000-11-064-L04-P (Knowledge-Based Activity)

Sunday, October 16
8:00 a.m.–8:50 a.m.
Convention Center: Spirit of Pittsburgh Ballroom A

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Faculty Conflict of Interest Disclosures
Debra A. Yeskey: no conflicts to disclose.

Learning Objectives

1. Describe the roles of clinical pharmacists in planning for, and provision of pharmacy services in the event of a natural disaster/epidemic/terrorist attack.
2. Review the logistical approach to starting medical care in disaster situations.
3. Describe opportunities for professional organizations to support pharmacist involvement in emergency preparedness.

Self-Assessment Questions

Self-assessment questions are available online at www.accp.com/am
The Federal Government Emergency Preparedness Plan and the Role of the Pharmacist

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OVERVIEW

• Federal Preparedness Landscape
• Federal Public Health and Medical Support
• Your role...

Pre 9/11 Preparedness

• Federal Response Plan (ESF8)
  — National Disaster Medical System (NDMS)
• National Institutes of Health
  — Early studies to support future pipeline of products
• Centers for Disease Control and Prevention
  — National Pharmaceutical Stockpile (NPS)
    • Antimicrobials for anthrax, plague, tularemia
    • Fluids, bandages, tubing etc...
  — Bioterrorism Preparedness and Response Program
    • Identify the 6 Category A threat agents
    • Grants to build infrastructure at state/Local departments of public health
    • Laboratory Response Network (LRN)

Early Post 9/11 & Anthrax Attacks

• Creation of:
  — Department of Homeland Security
  — Within HHS:
    • Office of Public Health and Emergency Preparedness (OPHEP)
    • Office of Research and Development Coordination (ORDC)
• Increase in funding
• Increased attention

Pandemic and All Hazards Preparedness Act (PAHPA)

• The purpose is “to improve the Nation’s public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural.”
• Established a new Assistant Secretary for Preparedness and Response (ASPR) within HHS
• Biomedical Advanced Research and Development Authority (BARDA)
  — Procure medical countermeasures
  — Fund advanced research and development
  — Pandemic influenza and emerging infectious diseases
• National Health Security Strategy
• ASPR Strategic Plan:
  - Promote resilient communities, fostering a nation able to withstand and recover from public health emergencies
  - Strengthen Federal public health and medical preparedness, response, and recovery leadership and capabilities
  - Promote an effective medical countermeasures enterprise
  - Strengthen ASPR’s leadership role in coordinating and developing public health and medical emergency preparedness, response, and recovery policy for the Department
  - Improve the preparedness and integration of health care delivery systems
  - Improve management of the ASPR organization and investment in its people

Preparedness Policies

• Homeland Security Presidential Directives (HSPD)
• Presidential Policy Directives (PPD)
• Executive Orders (EO)
• National Health Security Strategy (NHSS)
• National Strategy for Pandemic Influenza
• The National Strategy for Pandemic Influenza Implementation Plan
  - HHS Strategic Plan
  - Public Health Guidance for State and Local Partners
  - HHS Implementation Plan

PPD-8: National Preparedness

• PPD-8 is aimed at strengthening the security and resilience of the United States through systematic preparation for the threats that pose the greatest risk to the security of the Nation, including acts of terrorism, cyber attacks, pandemics, and catastrophic natural disasters.
• Public-private partnerships
• Capabilities based
• Sets a strategic vision for national preparedness using a comprehensive approach to preparedness. These include:
  - National Preparedness Goal
  - National Preparedness System
  - Campaign to Build and Sustain Preparedness
  - National Preparedness Report

National Health Security Strategy

• NHSS is the first comprehensive strategy focusing specifically on protecting people’s health in the case of a large-scale incident that puts health and well-being at risk.

CDC’s Cities Readiness Initiative (CRI)

• A federally funded program designed to enhance preparedness in the nation’s largest cities and metropolitan statistical areas where more than 50% of the U.S. population resides. Through CRI, state and large metropolitan public health departments have developed plans to respond to a large-scale bioterrorist event by dispensing antibiotics to the entire population of an identified MSA with 48 hours.
Postal Model for Medical Countermeasures Delivery and Distribution

- President Obama issued Executive Order 13527 on December 30, 2009, directing the HHS, DHS and the USPS to establish a National USPS Medical Countermeasure dispensing model.
- National Postal Model:
  - **Scenario**: Outdoor aerosolized release of anthrax is the baseline for planning related to bio-attacks requiring the deployment of post exposure prophylaxis.
  - **Goal**: Provide preventive antibiotics to 100 percent of the potentially exposed population as quickly as possible, ideally within 48 hours of the decision to deploy such assets.
  - **HHS Support**:
    - Provide Home Antibiotic Kits for the USPS volunteers and members of their households under EUA;
    - Medical screening for the antibiotics; and
    - Applicable personal protective equipment including the fit testing for N-95s.

Public Health Emergency Medical Countermeasure Enterprise

- Coordinated interagency effort responsible for:
  - Define and prioritizing requirements for medical countermeasures
  - Focusing on research, development and procurement activities
  - Establishing deployment and use strategies
- Led by the ASPR and includes 3 primary HHS Operational Divisions: FDA, CDC, and NIH
- Takes a comprehensive, end-to-end approach to planning that considers multiple aspects of the medical countermeasure mission.

HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

Office of Preparedness and Emergency Operations (OPEO)

- Responsible for developing operational plans, analytical products, and training exercises to ensure the preparedness of the Office, the Department, the Federal Government and the public to respond to and recover from domestic and international public health and medical threats and emergencies.
- OPEO is the lead for interagency planning and response activities required to fulfill HHS responsibilities under ESF #8.
- Other responsibilities include:
  - Management of the Secretary’s Operations Center (SOC)
  - Management of the Incident Response Coordination teams (IRCT)
  - Planning and evaluation of Departmental and interagency response exercises
  - Coordination of the HHS Continuity of Operations (COOP)

Office of Preparedness and Emergency Operations (OPEO)

- OPEO maintains a regional planning and response coordination capability, and has operational responsibility for HHS functions related to the National Disaster Medical Systems (NDMS).
- OPEO acts as the primary operational liaison to emergency response entities within HHS (e.g., FDA, HRSA, SAMHSA, CDC), within the interagency community (e.g., HDS, VA, DoD), and the public.
- National Disaster Recovery Framework (NDRF) — Recovery Support Function (RSF) for medical and social services.
- Hospital Preparedness Program (HPP)

Department of Health and Human Services

- HHS is the lead agency for Emergency Support Function (ESF) #8 in the National Response Framework (NRF)
  - HHS Secretary delegates to ASPR the leadership role for all health and medical services support function in a health emergency or public health event.
- Federally coordinated system that augments the Nation’s medical response capability.
- Temporarily supplements Tribal, State and Local capabilities by funding, organizing, training, equipping, deploying and sustaining a specialized and focused range of public health and medical capabilities.
- Components of the National Disaster Medical System
  - Medical response to a disaster area in the form of personnel, teams and individuals, supplies, and equipment.
  - Patient movement from a disaster site to unaffected areas of the nation.
  - Definitive medical care at participating hospitals in unaffected areas.

NDMS Teams

- Disaster Mortuary Operational Assistance Team (DMORT)
- International Medical Surgical Response Team (IMSURT)
  - Medical specialists who provide surgical and critical care during a disaster or public health emergency
- National Veterinary Response Team (NVRT)
- National Medical Response Team (NMRT)

Hospital Preparedness Program (HPP)

- Provides leadership and funding through cooperative agreements to States, territories, and eligible municipalities to improve surge capacity and hospital preparedness for public health emergencies
- Strengthens public health emergency preparedness:
  - Enhances planning
  - Increases integration
  - Improves infrastructure
- 85-90% of hospitals participate
- Emphasis on capabilities

Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP)

- Federal program created to support states and territories in establishing standardized volunteer registration programs for disasters and public health and medical emergencies
- Administered on the state level, verifies health professionals’ identification and credentials so that they can respond more quickly when disaster strikes
- By registering - volunteers’ identities, licenses, credentials, accreditations, and hospital privileges are all verified in advance, saving valuable time in emergency situations

Medical Reserve Corps (MRC)

- The mission of the MRC is to improve the health and safety of communities across the country by organizing and utilizing public health, medical and other volunteers.
- MRC units (973) are community-based and function as a way to locally organize and utilize volunteers who want to donate their time and expertise to prepare for and respond to emergencies and promote healthy living throughout the year.
- MRC volunteers supplement existing emergency and public health resources.
Emergency Prescription Assistance Program (EPAP)

- The purpose of the EPAP is to perform the activities related to processing prescription drug claims for medications and durable medical equipment (DME) for designated eligible individuals in a Federally-identified disaster area.

- EPAP allows any enrolled pharmacy in the United States and its territories to use existing electronic pharmacy systems as an infrastructure to efficiently process prescriptions and DME for individuals that are eligible for the Emergency Prescription Assistance Program (EPAP).

- This effort is performed under the authority cited in Sections 403 and 502(a) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 USC 5170b and 5192(a).

BARDA MISSION

Ensure the availability of countermeasures to address public health emergencies

- Three threat areas: Chem/Bio/Rad/Nuc, Pandemic Influenza, Emerging Infectious Diseases
- Comprehensive portfolio approach to development and acquisition of products
- Unique niche in USG biomedical R&D
  - Mid- to late-stage product development
  - Work with industry to progress product candidates through the pipeline
  - Staff with experience in product development and manufacturing

PROJECT BIOSHIELD 2004

Accelerated R&D:
Provided NIH/NIAD with new authorities for review and award of support for R&D of MCM.

Availability:
Established Emergency Use Authorization for medical products – use of unlicensed products, or alternative uses of licensed products.

Acquisition:
Established secure funding source from FY04-FY13 for purchase of CBRN security countermeasures.

Authorized the $5.6B Special Reserve Fund that had been established in the FY04 DHS Appropriations Bill (PL 108-90)

Virtually all risk placed on the manufacturer.
Pipeline of product candidates not as mature as had been envisioned.
Market guarantee attracted primarily small biotech firms.

ENTREPRISE MCM REVIEW 2010

Key Initiatives

1. Expand Product Pipeline through Concept Acceleration Program (CAP) at NIAID
2. Establish a Strategic Investment (Si) Fund to increase investments in commercial ventures with multi-use potential (BARDA & NIAID)
3. Establish Centers for Innovation in Advanced Development and Manufacturing (BARDA)
4. Investment in upgrading science capacity at FDA

MCM ENTERPRISE VISION

“Our Nation must have the nimble, flexible capacity to produce MCMs rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized naturally occurring emerging infectious disease”

If a product fails, it should only be the result of failure of the product to achieve the desired safety or efficacy thresholds, and not as a function of our inability to provide the proper support from a technical, business and regulatory perspective.
Emergency Use Authorization

- An Emergency Use Authorization (EUA) may be issued by the Food and Drug Administration (FDA) to allow either the use of an unapproved medical product or an unapproved use of an approved medical product during certain types of emergencies with specified agents.

- Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act), amended by the Project BioShield Act of 2004, permits authorization of such products for use in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agents, if certain statutory criteria are met.

What is required for an EUA?

- The Act requires that, before an emergency use may be authorized, the Secretary of the Department of Health and Human Services (HHS) must declare an emergency justifying the emergency use, based on one of the following grounds:
  - (1) The Secretary of the Department of Homeland Security determines that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
  - (2) The Secretary of the Department of Defense determines that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or
  - (3) The HHS Secretary determines that there is a public health emergency under the Public Health Service Act (PHS Act) that affects, or has a significant potential to affect, national security, and involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

On What basis is an EUA issued?

- The FDA Commissioner must conclude, as follows:
  - The agent specified in the declaration of emergency can cause a serious or life-threatening disease or condition;
  - Based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition;
  - The known and potential benefits of the product outweigh the known and potential risks of the product;
  - There is no adequate, approved, and available alternative;
  - An EUA may remain in effect for the duration (one year) of the declaration justifying the emergency use unless revoked.

Federal Public Health and Medical Services Support

- Federal Emergency Preparedness
- Federal Public Health Response
  - Emergency Support Functions
  - Medical Assistance
  - Medical Surge Capability
Federal Emergency Preparedness

- National Response Framework
  - Mandated by HSPD-5
  - Based on NIMS template

- National Incident Management System (NIMS)
  - System that provides consistent approach for Federal, State, Tribal and local government; the private sector; and NGOs to work together.

- HHS Concept of Operations Plan (CONOPS)
  - For ESF #8
  - The ASPR acts as the senior-level HHS liaison to DHS and other Federal departments

- Secretary’s Operation Center (SOC)
  - Focal point for command and control for all HHS components under non-emergency and emergency conditions

Emergency Support Functions

- ESF #8 Public Health and Medical Services
  - HHS the Lead for Health and Medical Response
  - Public health and medical care needs
  - Veterinary and/or animal health issues in coordination with the U.S. Department of Agriculture (USDA)
  - Potential or actual incidents of national significance
  - A developing potential health and medical situation

Federal Public Health Response

- First Response
  - IS ALWAYS LOCAL

- Federal Disaster Response
  - When incident overwhelms or anticipated to overwhelm State resources - the Governor may request Federal assistance

- Federal Public Health and Medical Services Response
  - Secretary of HHS leads all Federal public health and medical response covered by NRF

- Legal Authority of the HHS Secretary
  - Public Health Service Act
  - Federal Food, Drug, and Cosmetic Act
  - Social Security Act
  - Robert T. Stafford Act

Federal Medical Assistance

- USPHS Commissioned Corps (USPHS)
  - Rapid Deployment Force (RDF)
  - Applied Public Health Team (APHT)
  - Mental Health Team (MHT)

- National Disaster Medical System

- Strategic National Stockpile (SNS)
  - National repository
  - Designed to supplement and re-supply State and local public health agencies

- Federal Medical Stations (FMS)
  - Deployable healthcare platform
  - Team of approximately 100 personnel is needed to staff the FMS, with personnel provided primarily by the USPHS
  - Each FMS contains a three-day supply of medical and pharmaceutical resources to sustain 200 stable primary care-based patients who require bedding services

- Medical Reserve Corps (MRC)

Strategic National Stockpile

- Stockpiles strategically placed throughout US
- 12-Hour Push Packages
- Stockpile Managed Inventory (SMI)
- Vendor Managed Inventory (VMI)
- Shelf Life Extension Program (SLEP)
- Technical Assistance
- Training and Education
- Protected assets

Medical Surge Capacity and Capability

- The primary role of Federal resources in providing medical surge capacity and capability (MSCC) is to support, not supplant, State, Tribal, and jurisdictional response efforts.

- MSCC Handbook

Keynote Address—The Role of Clinical Pharmacy in Emergency Preparedness and Response
Your Role...Whole Community Preparedness

- Get involved...everyone has an important role
  - Personal/family preparedness
  - Community preparedness
  - Workplace resiliency
    - Generator
    - IT/Communications
    - Continuity of business plan
  - Joining a response organization
    - Federal
    - State
    - Local

http://www.ready.gov/  

Same Role...with Differences

- Medical Countermeasures...IS IT SAFE???
  - Product description
  - Dose/preparation
  - Indications/Use in special populations
  - Adverse events
  - Drug/food interactions
  - Expiry date...is it part of SLEP?
  - Regulatory status- does it require an EUA?

Where things go bad...

- Communication
- Coordination

- Anticipate what might go wrong and make your plans...
  - Know drug interactions and what combinations cannot be taken together
  - Know the alternative products (where feasible)

Everyone knows the easy stuff...prepare for the what if...

Decade of Challenges

- Complacency
- Failure of imagination
  - 9/11
  - Deep Water Horizon
  - Fukushima Daiichi nuclear plant
- Budgets
- Constant threat of terrorism

Decade of Progress

- Emergency Operations Centers
- Laboratory Response Network
- PAHPA
- Strategic National Stockpile
- PHEMCE Process
- Preparedness Grant Programs

“Volunteer for a career...
not for an individual event”  
Dr. Kevin Yuskey
Thank you!

Links

* http://www.phe.gov/about/aspr/Pages/default.aspx
* http://www.fema.gov/prepared/ppd8.shtm
* http://www.bt.cdc.gov/cri/
* http://www.phe.gov/Preparedness/responders/ndms/teams/Pages/recruitment.aspx
* http://www.medicalreservecorps.gov/HomePage
* http://www.fda.gov/emergencypreparedness/counterterrorism/ucm182568.htm
* http://www.cdc.gov/phpr/stockpile/stockpile.htm