**Capability 8: Medical Countermeasure Dispensing and Administration**

**Definition:** Medical countermeasure dispensing and administration is the ability to provide medical countermeasures to targeted population(s) to prevent, mitigate, or treat the adverse health effects of a public health incident. This capability focuses on dispensing and administering medical countermeasures, such as vaccines, antiviral drugs, antibiotics, and antitoxins.

**Functions:** This capability consists of the ability to perform the functions listed below.
- **Function 1:** Determine medical countermeasure dispensing/administration strategies
- **Function 2:** Receive medical countermeasures to be dispensed/administered
- **Function 3:** Activate medical countermeasure dispensing/administration operations
- **Function 4:** Dispense/administer medical countermeasures to targeted population(s)
- **Function 5:** Report adverse events

**Summary of Changes:** The updates align content with new national standards, updated science, and current public health priorities and strategies. Listed below are specific changes made to this capability.
- Revises the Capability 8 title, definition, and content to account for both the dispensing and the administration of medical countermeasures, such as vaccines, antidotes, and antitoxins
- Adds content and resources to account for potential radiological or nuclear exposure
- Broadens the network of dispensing and administration sites to include pharmacies and other locations

**For the purposes of Capability 8, partners and stakeholders may include the following:**
- emergency management agencies
- emergency medical services (EMS)
- environmental health agencies
- epidemiology programs
- federal groups and organizations
- government agencies
- health care coalitions
- health care organizations
- hospitals and health care facilities
- immunization programs
- jurisdictional office(s) of homeland security
- laboratory programs
- law enforcement agencies
- medical professional organizations
- mental/behavioral health services
- military installations and other federal facilities
- organizations representing persons with disabilities or persons requiring specialized access and functional accommodations
- pharmacies
- private organizations that may function as dispensing or vaccination sites
- public health agencies
- Public Health Service Commissioned Corps
- radiation control programs
- surveillance programs
- tribes and native-serving organizations
- volunteer groups

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7 For example, the U.S. Department of Health and Human Services regional emergency coordinators (RECs) and medical countermeasure specialists
Function 1: Determine medical countermeasure dispensing/administration strategies

Function Definition: Coordinate with partners to formulate jurisdiction-specific strategies for the timely provision of medical countermeasures based on incident needs.

Tasks

Task 1: Develop jurisdiction-specific strategies to prepare for medical countermeasure dispensing/administration. Coordinate with subject matter experts, partners, and stakeholders to develop strategies to dispense/administer medical countermeasures based on jurisdiction-specific risks, resource availability, and incident characteristics. Strategies should consider allocation methods for scarce resource scenarios.

Task 2: Establish a network of dispensing/administration sites. Identify dispensing/administration sites to activate when responding to a public health incident.

Task 3: Identify and assign required response roles. Identify and assign necessary medical countermeasure response roles and responsibilities in coordination with partners and stakeholders.

Preparedness Resource Elements

P1: (Priority) Multidisciplinary planning group(s), consisting of subject matter experts and key partners, to formulate and confirm medical countermeasure dispensing/administration strategies and roles.

(See Capability 1: Community Preparedness)

P2: (Priority) Procedures in place to identify medical countermeasures required to respond to current or projected incidents. Medical countermeasure needs may be determined by analyzing factors, which may include

- Number(s), location(s), and demographic information of people affected by the incident
- Types of available medical countermeasures
- Supplies and services necessary for individuals with access and functional needs
- Agent or cause of the incident
- Severity of the incident
- Projected timeline for establishing medical countermeasure dispensing/administration operations
- Pre-established activation triggers, indicators, and thresholds
- Types and numbers of personnel needed to provide medical countermeasures
- Types and numbers of dispensing/administration sites needed to provide medical countermeasures, whether a network of points of dispensing (PODs) or a network of vaccination sites in the community
- Federal or jurisdictional guidance for the prioritization of medical countermeasures, such as guidance for allocating vaccine to provider sites and patients during an influenza disease outbreak

P3: (Priority) Procedures in place to guide the dispensing/administration of medical countermeasures. Procedures may include

- Screening protocols to ensure an individual receives the appropriate medical countermeasures according to priority or target group status specific to the incident
- Procedures for pre-event and just-in-time event rapid enrollment, ordering and receiving, administration, documentation of medical countermeasures and vaccines dispensed/administered for a range of provider types and settings in public and private sectors
- Protocols to assure informed consent and communication of risks and benefits as outlined in emergency use authorization (EUA) or emergency use instructions (EUI)
- Protocols to track the interval between a first and second dose in cases when this information is necessary
- Procedures to communicate when subsequent doses are due, such as text message, e-mail, or other reminder or recall methods
- Medical countermeasure logistics and storage to maintain product integrity during the dispensing/administration process
- Security protocols to ensure facility safety, personnel safety, product security, and crowd management
- Protocols for use of medical countermeasures in cases when decontamination is needed, such as after chemical or radiological exposures
- Protocols for the disposition of unused medical countermeasures and potentially infectious waste
- Methods for documenting medical countermeasures dispensed/administered, such as immunization information systems (IISs) for vaccines, and procedures for training and on-boarding new providers on use of these information systems
- Strategies for providing medical countermeasures to critical workforce, health care providers, and public health responders to meet the needs of the incident, such as personal protective equipment (PPE), ventilators, vaccines or other medicines
- Multiple strategies to ensure access to medical countermeasures, such as direct contact with affected individuals or hotline contacts
- Contact information of key personnel assigned and trained to fill emergency response roles when medical countermeasures are dispensed/administered
- Strategies for providing medical countermeasures to households of critical workforce, if indicated as directed by the U.S. Government

P4: (Priority) Network of sites for dispensing/administering medical countermeasures. Sites may include points of dispensing (PODs), vaccination clinics, pharmacies, hospitals, health care facilities, school clinics, or temporary mass vaccination sites. Considerations for a network of sites may include

- Written agreements to share resources, facilities, services, and other potential support required when dispensing/administering medical countermeasures, such as contracts or memoranda of understanding (MOUs)
- Comprehensive list of public and private sector medical countermeasure dispensing/administration sites that includes addresses, phone numbers, and e-mail addresses
- Site-specific standard operating procedures and staffing plans for medical countermeasure dispensing/administration, such as processes to order and receive medical countermeasures, personnel training(s), and use of jurisdictional inventory management systems and immunization information systems
• Existing infrastructure and resources that may be available for use, such as the network of vaccine administration sites supported by the Vaccines for Children program or mail order pharmacy systems
• Alternate approaches for reaching tribal populations, including cross-jurisdictional agreements
• Alternate approaches for populations that may be difficult to reach, such as individuals who are undocumented, incarcerated, or experiencing homelessness and individuals who reside in long-term care or other congregate care facilities
• Alternate approaches for providing effective communication in multiple formats to account for the access and functional needs of at-risk individuals who may be disproportionately impacted by a public health incident or event, including children, pregnant women, older adults, and others with access and functional needs as well as communities that may be disproportionately impacted by a public health emergency
• Alternate approaches for providing medical countermeasures, such as direct to patient or home delivery
• Methods to track and monitor countermeasures dispensed, administered, or used across the network of sites

The selection of dispensing/administration sites should be adapted to the incident, and sites may include
• Open or closed PODs
• Vaccination clinics
• Hospitals, primary care, or other health care facilities
• Chain and independent pharmacies
• Public or private facilities
• Community or faith-based organization facilities
• Federal facilities, such as Department of Defense and Veterans Affairs facilities, as applicable
• School-based sites
• Workplace sites or occupational health clinics
• Temporary mass vaccination sites
• Doctor offices and other outpatient facilities

Skills and Training Resource Elements
S/T1: Personnel trained to dispense/administer medical countermeasures. Personnel considerations may include
• Requirements for licensing or certifying personnel providing medical countermeasures as determined by the jurisdiction
• Training to manage a potentially diffused network of dispensing/administration sites, such as vaccine administration through community pharmacies
• Necessary credentialing or background checks to assure personnel qualifications
• Training to ensure operational competence and familiarity with jurisdictional incident command structure
• Training to ensure adherence to clinical dispensing/administration protocols
• Training to communicate with and support those with access and functional needs, such as sign language interpreters

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**S/T2:** Personnel trained to conduct tabletop, functional, and full-scale exercises in accordance with the Homeland Security Exercise and Evaluation Program (HSEEP) in order to test and evaluate jurisdictional medical countermeasure strategies.

**Function 2: Receive medical countermeasures to be dispensed/administered**

**Function Definition:** Request and receive medical countermeasures at the jurisdictional level and ensure receipt of medical countermeasures at dispensing/administration sites based on incident characteristics.

**Tasks**

**Task 1:** Evaluate jurisdictional medical countermeasure inventories. Assess the ability of jurisdictional medical countermeasure inventories to meet the jurisdiction's needs based on the incident.

**Task 2:** Request medical countermeasures. Request or obtain medical countermeasures using established procedures from federal, jurisdictional, or private partners and stakeholders to meet supply needs.

**Task 3:** Receive medical countermeasures at dispensing/administration sites. Ensure all activated medical countermeasure dispensing/administration sites receive apportioned inventories according to incident requirements, logistics, infrastructure, and security strategies.

**Preparedness Resource Elements**

**P1:** (Priority) Procedures in place to assess medical countermeasure inventories and determine the need for additional medical countermeasures. Procedures to assess supply inventories may include

- Initial assessment of jurisdictional medical countermeasure inventories and supporting infrastructure prior to requesting mutual aid or federal assistance
- Inventory assessment and management throughout the incident response, for example, tracking inventory use and redeploying inventory to accommodate surges caused from under or overutilization of medical countermeasure dispensing/administration sites
- Assessments and procedures to identify and maintain ancillary medical countermeasure supplies

*(See Capability 9: Medical Materiel Management and Distribution)*

**P2:** (Priority) Procedures in place to request, order, and receive medical countermeasures at dispensing/administration sites, as applicable, in accordance with guidelines provided by the supply source, including the Strategic National Stockpile (SNS), jurisdictional immunization programs receiving vaccine from Biomedical Advanced Research and Development Authority (BARDA), or other applicable sources. These procedures should facilitate

- Assessment of local inventories and medical countermeasure caches to determine initial supply or resupply needs
- Identification of local pharmaceutical and medical supply wholesalers
- Decision tree to guide the process for requesting or ordering additional medical countermeasures and account for the status of emergency declarations
- Adherence to regulatory standards required for maintaining jurisdictional medical countermeasure caches, such as U.S. Food and Drug Administration (FDA) standards, including current good
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manufacturing practices, appropriate Drug Enforcement Administration (DEA) registrations, and the ability to track medical countermeasures rotation

P3: **(Priority)** Procedures in place for the storage and handling of medical countermeasures at dispensing/administration sites. Procedures may include

- Procedures for cold chain management
- Procedures to properly store and package unit-of-use doses according to pharmacy laws and manufacturer specifications
- Procedures for freeze-dried vaccine that must be reconstituted with a diluent
- Procedures to outline requirements for receiving vaccines when jurisdictional vaccine provider agreements are in place, such as the Vaccines for Children program
- Procedures to legally accept and manage controlled substances, including registration with the DEA
- Procedures to consider and incorporate other specific medical countermeasure dispensing/administration storage and handling needs

**Equipment and Technology Resource Elements**

E/T1: Information system(s) to track the medical countermeasures dispensed or administered for the purposes of informing resupply requests, understanding populations reached, and monitoring adverse events. Information systems may operate independently of the jurisdiction's inventory management system or be electronically networked to the system. Elements to track in information systems may include

- Targeted population(s)
- Name of the drug, generic or brand, or vaccine
- National Drug Code (NDC) number
- Lot number
- Expiration/manufacturing dates
- Site where medical countermeasure was dispensed/administered
- Inventory balance
- Interval between doses of a vaccine

E/T2: Equipment, supplies, and systems needed to support dispensing/administration, which may include

- Materiel-handling equipment, such as pallet jacks, handcarts or dollies, scissor-lifts, and forklifts
- Primary and backup cold chain management equipment, such as portable, insulated containers for transporting temperature-sensitive medical countermeasures, refrigerators, thermometers, and other equipment needed to meet storage and handling requirements
- Ancillary medical supplies and durable medical equipment
- Infrastructure supplies and systems, such as paper supplies, copiers, computers, printers, Internet/network access to support site inventory management, white boards, desks, vests, line tape, signage, and consent forms
Function 3: Activate medical countermeasure dispensing/administration operations

Function Definition: Coordinate with partners and stakeholders to ensure resources, including personnel, equipment, technology, and physical space, are activated to dispense/administer medical countermeasures.

Tasks

Task 1: Activate medical countermeasure dispensing/administration operations based on needs of the incident. Notify and then activate the participating network of sites that will dispense/administer medical countermeasures to achieve coverage goals commensurate with the incident.

Task 2: Notify and assemble personnel who will support medical countermeasure dispensing/administration. Alert and assemble personnel who will support medical countermeasure dispensing/administration according to the roles, responsibilities, and resources needed to achieve medical countermeasure coverage goals.

Task 3: Provide medical countermeasures to public health responders and critical workforce. Dispense/administer medical countermeasures to public health responders and critical workforce based on the incident needs and relevant guidance, such as targeting vaccine prioritization to certain population groups.

Task 4: Implement security measures for medical countermeasure dispensing/administration. Implement site-specific security measures to ensure facility safety, personnel safety, product integrity, and crowd management when dispensing or administering medical countermeasures.

Task 5: Provide information to the public. Inform the public about dispensing/administration site locations, operational periods (days and hours open), and populations targeted to receive medical countermeasures.

Preparedness Resource Elements

P1: (Priority) Procedures in place to guide the activation of dispensing/administration sites and the activation of trained personnel, volunteers, and skilled personnel to support those sites, which may include

- Activation procedures for dispensing/administration sites may specify elements, including
  - Site name or identifier
  - Demand estimate (number of people planning to visit the site)
  - Estimated throughput and vaccination capacity
  - Personnel required to operate one shift
  - Number of personnel and shifts required to operate the site throughout the incident
  - Personnel availability
  - Plan to accommodate access and functional needs of at-risk individuals who may be disproportionately impacted by a public health incident or event
• Mechanisms to address legal and liability barriers may include
  • Clinical standards of care
  • Licensing
  • Civil liability for volunteers
  • Liability for private sector participants
  • Property needed to dispense/administer medical countermeasures


P2: (Priority) Procedures in place to dispense/administer medical countermeasures to public health responders and critical workforce either pre-incident or during the early stages of an incident. Targeting of critical workforce groups would depend on severity of the threat, the risk of severe illness by age group, medical countermeasure supply, and the accompanying disruption to security, society, and the economy. Procedures may include dispensing/administering medical countermeasures to the household members of responders or critical workforce, as indicated in incident-specific targeting guidance.

(See Capability 14: Responder Safety and Health and Capability 15: Volunteer Management)

P3: Security measures, specific to each medical countermeasure dispensing and vaccine administration site, as necessary, to ensure personnel safety, product security, and crowd management during an incident. Security measures may include
  • Identifying and activating security personnel
  • Safeguarding site property
  • Protecting site personnel
  • Controlling traffic at and around sites
  • Implementing crowd management measures at and around sites
  • Collaborating with law enforcement and emergency management
  • Formulating evacuation plans
  • Developing security breach procedures

(See Capability 14: Responder Safety and Health and Capability 15: Volunteer Management)

P4: List of identified partners and stakeholders for private sector dispensing/administration and procedures to activate private sector partners, as applicable.

P5: Communication messages and procedures in place to develop tailored messages that address various threats and incidents, such as cases of a novel agent. Communication message strategies should be designed to account for individuals with sensory or mobility disabilities and individuals with cognitive, intellectual, developmental, mental, or other disabilities. Communication messages should include
  • Tailored messages to meet the specific information needs of the intended audiences, including target populations, at-risk populations, health care providers, and the public
  • Guidance from relevant federal or jurisdictional agencies
  • Information about site locations, operating hours, and known risks and benefits
  • Information that is standardized or harmonized within a jurisdiction or across jurisdictions, such as in cases where media outlets reach audiences across state lines
  • Information for populations that are specifically targeted to receive medical countermeasures
• Information for populations that are not targeted to receive medical countermeasures to ensure that the public understands priorities for allocating limited resources

(See Capability 4: Emergency Public Information and Warning)

**Equipment and Technology Resource Elements**

**E/T1**: Equipment for dispensing/administering medical countermeasures may include

- Materiel-handling equipment, such as pallet jacks, handcarts or dollies, and forklifts
- Equipment to ensure proper storage and handling of medical countermeasures, such as refrigerators and temperature tracking for cold chain management
- PPE
- Ancillary medical supplies
- Administrative supplies
- Specialized items, such as scales for weighing children, mixing equipment for pediatric portions, and Broselow tapes

**E/T2**: Information systems and communication tools to inform the community, target populations, and health care providers about key medical countermeasure information. Systems and tools may include jurisdictional health alert networks, social media, community outreach information network (COIN), or call center systems, such as poison control centers.

(See Capability 4: Emergency Public Information and Warning and Capability 6: Information Sharing)

**E/T3**: Information systems to support the development and maintenance of staffing models, such as RealOpt®.

**E/T4**: Equipment and Internet connection, as needed, to access an individual’s immunization status as found in an immunization registry, or information about medical conditions as found in an electronic health record.

(See Capability 15: Volunteer Management)

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**Function 4: Dispense/administer medical countermeasures to targeted population(s)**

**Function Definition**: Provide medical countermeasures to the target population in accordance with public health guidelines and recommendations appropriate to the incident.

**Tasks**

**Task 1**: **Dispense/administer medical countermeasures to target populations**. Identify, screen, and triage target populations to receive medical countermeasures and then to dispense/administer medical countermeasures according to appropriate protocols.

**Task 2**: **Provide essential information to those who receive medical countermeasures**. Provide product name, rationale for use and contraindications, point(s) of contact, and other information about the medical countermeasures provided.
Task 3: **Monitor and adjust medical countermeasure dispensing/administration throughput and coverage.** Monitor and adjust staffing and supplies to achieve and sustain throughput and coverage goals based on the remaining needs of the population, such as inventory level and remaining regimen use surge or decline.

Task 4: **Track medical countermeasures that are dispensed/administered.** Maintain inventory management systems to track medical countermeasure inventories and ancillary medical supplies.

**Preparedness Resource Elements**

**P1: (Priority)** Procedures in place to dispense/administer medical countermeasures to affected, targeted, and prioritized populations that align with current science, incident characteristics, and public health guidelines. Procedures and guidance may include

- Screening and triaging patients based on patient characteristics, such as age, weight, signs and symptoms, medical history, drug or food allergies, or assessment of exposure
- Ensuring that medical record or log or file of the recipient indicates the following information, as necessary
  - Date the medical countermeasure was provided to the individual
  - Product name, NCD number, lot number, expiration date, and other critical identifying information
  - Health care provider detail, such as name and contact information, prescription number, date of prescription, name of patient (if stated on prescription), directions for use, and cautionary statements
  - Version date of the information statement distributed
- Ensuring medical countermeasure recipients receive the information statement aligned to the medical countermeasure provided
- Ensuring data is recorded to report to state or federal entities, as necessary. Consideration should be given to potential priority status, population demographics, such as sex, age group, and risk factors, and characteristics of the medical countermeasure, such as product name, site, and date
- Ensuring that medical countermeasures are provided according to requirements of applicable state and federal laws or regulations, such as emergency use authorization, investigational new drug protocols, or expanded access to investigational drugs

**P2:** Drug or vaccine information available to the public and to persons receiving medical countermeasures. Drug and vaccine information may include

- Information for individuals receiving medical countermeasures, such as drug or Vaccine Information Statements (VISs), adapted for targeted populations and languages spoken
- Instructions for return visits, care of injection site, reporting of adverse events, and other key medical information
- Data forms required by federal regulation or other applicable regulations, such as the VISs prescribed by federal law for routine vaccines
- Information needed to ensure medical countermeasures compliance or adherence
- Information about product labeling or expiration, such as relevant consumer-focused information about Shelf Life Extension Program
- Emergency use instructions (fact sheets) developed by CDC about the conditions under which FDA has approved use

*(See Capability 10: Medical Surge)*
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**P3:** Procedures in place to request additional personnel and supplies based on incident characteristics. Procedures should describe how the jurisdiction will

- Assess inventory use rates to determine resupply intervals
- Access existing jurisdictional medical caches
- Implement national, regional, and intrastate mutual aid agreements, such as the Emergency Medical Assistance Compact (EMAC)
- Coordinate with relevant agencies, partners and stakeholders including jurisdictional emergency management agencies, HHS RECs, and SNS
- Deploy personnel and supplies to dispensing/administration sites based on public use
- Notify and allocate volunteers

**Skills and Training Resource Elements**

**S/T1:** Personnel trained on jurisdictional medical countermeasure tracking systems, such as immunization information systems, electronic health records, or other tracking databases.

**Equipment and Technology Resource Elements**

**E/T1:** Information statements, such as drug or vaccine information statements, for persons who receive medical countermeasures. Information statements should be adapted to the needs of target populations, such as accommodating different literacy levels and languages.

**E/T2:** Information system(s) for dispensing and administering medical countermeasures, such as inventory tracking systems to manage medical countermeasure supplies or state IISs to track vaccinations given to individuals. Backup system(s), such as other inventory management software, electronic spreadsheets, or paper-based systems, must be available in case of emergencies.

**Function 5: Report adverse events**

**Function Definition:** Monitor and report or facilitate the reporting of adverse events associated with a medical countermeasure.

**Tasks**

**Task 1: Prepare for adverse event reporting.** Assure jurisdictional procedures are in place for adverse event reporting and information dissemination to ensure persons who dispense, administer, or receive medical countermeasures are informed and understand actions to take in the instance of an adverse event.

**Task 2: Activate adverse event reporting procedures.** Activate adverse event reporting processes to accommodate reporting from any relevant source, including individuals, health care providers, or public health agencies.

**Task 3: Promote and facilitate reporting of adverse events.** Promote and facilitate reporting of adverse events, disseminate relevant trend data to applicable entities, such as federal agencies, jurisdictional government agencies, and health response partners, and monitor emerging data to inform potential modifications to medical countermeasure strategies.
Preparedness Resource Elements

P1: (Priority) Procedures in place to guide the reporting of adverse events including receipt of reports and dissemination of adverse event information, to include provisions for adverse event reporting at national and jurisdictional levels. Adverse event reporting procedures should specify

- When and how to use applicable national adverse event reporting systems, such as Vaccine Adverse Events Reporting System (VAERS) or FDA MedWatch Reporting System
- When and how to use adverse event reporting systems that are managed by the jurisdiction
- How to identify and analyze adverse event trends and modify medical countermeasure operations accordingly
- How to communicate emerging trends to health care providers and individuals receiving medical countermeasures
- Data elements to be collected, which may include
  - Name of person who received the vaccine or medication
  - Health care provider
  - Person reporting the adverse event
  - Adverse event being reported
  - Relevant diagnostic tests, laboratory data, and health status
  - Recovery status
  - Vaccine(s) or medications(s) received, date, lot number, dosage
- Written agreements, such as contracts or memoranda of understanding (MOUs), among relevant agencies and clinicians that specify how the jurisdiction will work together to investigate or report adverse events

P2: (Priority) Procedures in place to generate and disseminate pertinent information related to adverse event reporting. Information may include

- Information for persons receiving medical countermeasures regarding potential side effects; for vaccines, these messages are contained in the CDC VISs
- Information for health care providers or individuals to explain how to report adverse events, such as using VAERS or FDA MedWatch system

(See Capability 1: Community Preparedness)

Skills and Training Resource Elements

S/T1: (Priority) Personnel trained on federal and applicable jurisdictional adverse event reporting system procedures, including the designation of a vaccine safety coordinator.

Equipment and Technology Resource Elements

E/T1: Access to national and jurisdictional adverse event reporting systems, such as VAERS, FDA MedWatch, or local reporting systems.

(See Capability 4: Emergency Public Information and Warning and Capability 6: Information Sharing)