

2015-2016

NATIONAL REPORT

of

MEDICAL COUNTERMEASURE READINESS



Office of Public Health Preparedness and Response
Division of State and Local Readiness

This document was developed by Oak Ridge Associated Universities (ORAU) in collaboration with the Centers for Disease Control and Prevention (CDC)'s Division of State and Local Readiness (DSLRL).

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KEY ACRONYMS & TERMS

Cities Readiness Initiative (CRI)	CDC's federally funded program designed to enhance preparedness in the nation's largest population centers, where nearly 60% of the nation's population resides, to effectively respond to large public health emergencies needing life-saving medications and medical supplies.
Closed points of dispensing (PODs)	A point of dispensing site that serves a defined population and is not open to the general public.
Division of State and Local Readiness (DSLRL)	A division of CDC's Office of Public Health Preparedness and Response responsible for the management of the Public Health Emergency Preparedness (PHEP) program. DSLR's mission is to assure the nation's public health system is prepared to respond to and recover from a public health event or emergency.
Jurisdiction	Refers to the 50 states, four large localities, and eight U.S. territories and freely associated states funded and supported by CDC's Public Health Emergency Preparedness (PHEP) program
Public Health Emergency Preparedness (PHEP) cooperative agreement	A critical source of funding for state, local, and territorial public health departments which helps 62 PHEP jurisdictions strengthen their abilities to effectively respond to a range of public health threats and save lives when a public health emergency occurs.
Public Health Emergency Preparedness (PHEP) program	Provides state, local, and territorial public health departments with critical funding, guidance, and technical assistance to improve their ability to respond to any public health threat and save lives when an emergency occurs.
Medical countermeasures (MCMs)	Life-saving medicines and medical supplies regulated by the U.S. Food and Drug Administration (FDA) that can be used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear (CBRN) threats, emerging infectious diseases or natural disasters.
Medical countermeasure (MCM) dispensing	The ability to provide medical countermeasures (including vaccines, antiviral drugs, antibiotics, antitoxin, etc.) in support of treatment or prophylaxis (oral or vaccination) to the identified population in accordance with public health guidelines and recommendations.

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Medical countermeasure (MCM) distribution

The ability to acquire, maintain (e.g., cold chain storage or other storage protocol), transport, distribute, and track medical materiel (e.g., pharmaceuticals, gloves, masks, and ventilators) during an incident and to recover and account for unused medical materiel, as necessary, after an incident.

MCM operational readiness

The ability of a jurisdiction to execute their medical countermeasure distribution and dispensing plans during a public health response.

Open points of dispensing (PODs)

A dispensing site that serves the general public and does not have restrictions on who has access to the site; these PODs are open to everyone including residents, visitors, commuters, or anyone else in the affected area during an incident.

Points of dispensing (PODs)

Specific locations that can be used for distributing medicines or supplies to a large number of people in the event of a public health emergency.



EXECUTIVE SUMMARY

The *2015-2016 National Report of Medical Countermeasure Readiness* provides insights into the ability of the United States to plan and successfully execute a public health response requiring life-saving medical countermeasures. This report identifies key findings and recommended steps to advance our nation's health security.

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During a public health emergency, jurisdictions must be able to provide life-saving medicines and supplies, known as medical countermeasures (MCMs), to the right people in the right place at the right time. The Public Health Emergency Preparedness (PHEP) program, managed by Centers for Disease Control and Prevention (CDC)'s Division of State and Local Readiness (DSLRL), provides critical funding, support, and collaboration to ensure public health departments nationwide can successfully meet the MCM needs of their communities.

Governmental leaders at every level and the public need to be confident in the nation's ability to respond to a public health incident that requires life-saving MCMs.

CDC implemented a new process in 2014-2015 to evaluate how prepared jurisdictions are to execute plans for delivering MCMs in an emergency. This rigorous assessment process measures **MCM operational readiness** — the ability to plan and successfully execute a response requiring medical countermeasures during an incident such as an intentional release of anthrax or other public health threat.

From July 2015 to June 2016, CDC and PHEP program recipients conducted a national review of MCM operational readiness in 487 jurisdictions (figure 1) to identify key strengths and gaps using the new MCM operational readiness review (ORR) process. Using the results from the MCM ORR assessment, CDC works with jurisdictions to provide technical assistance and address any gaps identified.

WHAT ARE MEDICAL COUNTERMEASURES?

Medical countermeasures (MCMs) are medicines and medical supplies that can prevent or treat diseases related to public health emergencies including:

- Bacterial and viral diseases
- Radiation/nuclear emergencies
 - Chemical attacks
 - Natural disasters

MCMs include large quantities of antibiotics, chemical antidotes, antitoxins, medications, medical supplies, respirators, and personal protective equipment.



INTRODUCTION

BACKGROUND

Since 2004, CDC has designated about 8% of annual PHEP cooperative agreement funding to support the Cities Readiness Initiative (CRI). This dedicated CRI funding allows state and local CRI jurisdictions to increase their ability to rapidly and effectively receive, distribute, and dispense MCMs to their entire communities during large public health emergencies.

CRI funding supports PHEP program recipients including all 50 states and the four large localities, as well as more than 400 local CRI jurisdictions. In fiscal year 2016, 54 PHEP program recipients received approximately \$50 million in CRI funding to support MCM operational readiness.

AN INNOVATIVE APPROACH

For nearly a decade, CDC conducted technical assistance reviews (TARs) to assess MCM planning at state and local levels. By 2012, TAR scores had reached ceiling levels, with nearly half of states achieving the maximum possible overall score (100) and 94% of locals achieving a score of 90 or higher. In 2012, CDC identified the need for an enhanced approach to evaluate how prepared jurisdictions are to execute their plans for MCM distribution and dispensing during a public health emergency.

In 2012-2014, CDC, with input from PHEP program recipients, national public health partners, and CDC subject matter experts, designed a new process for measuring MCM operational readiness using a standardized assessment tool. The assessment tool, called the **Medical Countermeasure Operational Readiness Review (MCM ORR)**, evaluates both MCM planning capabilities and operational capacity for a public health incident requiring distribution and dispensing of MCMs, also known as a MCM mission.

WHAT IS THE PUBLIC HEALTH EMERGENCY PREPAREDNESS PROGRAM?

CDC's Public Health Emergency Preparedness (PHEP) program includes the PHEP cooperative agreement - a critical source of funding dedicated to building and sustaining public health preparedness. PHEP cooperative agreement funding and program support enhances the ability of communities nationwide to prepare for, respond to, and recover from any public health threat, and save lives when a public health emergency occurs.

62

PHEP program recipients include:

- **50 states**
- **4 large localities** (Chicago, Los Angeles County, New York City, and Washington, D.C.)
- **8 U.S. territories or freely associated states** (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Puerto Rico, Republic of Palau, and U.S. Virgin Islands)

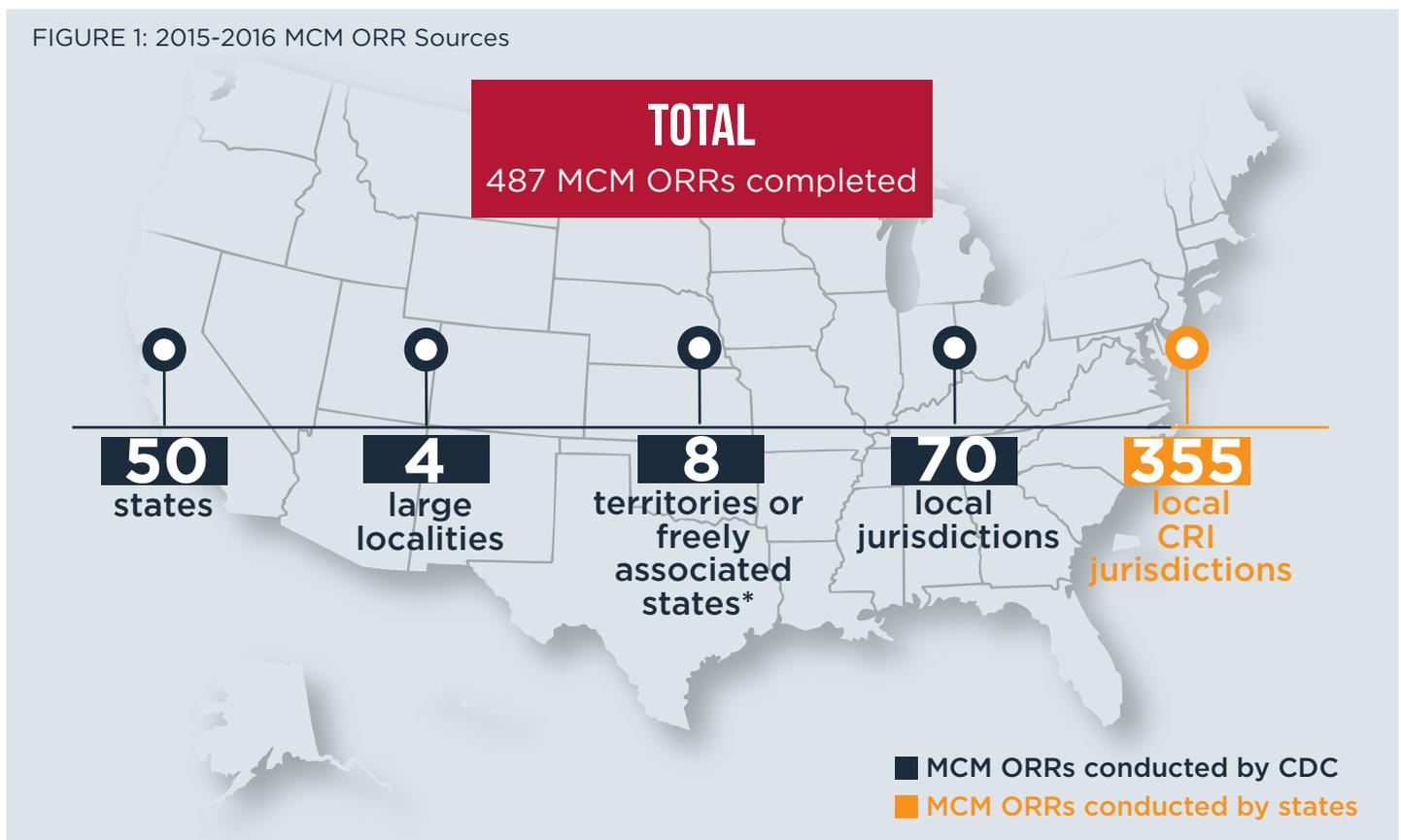
APPROACH REFINEMENT

CDC piloted and refined the MCM ORR process with 36 PHEP program recipients and 28 local CRI jurisdictions from 2014–2015. From July 2015 to June 2016, CDC implemented the new 2015-2016 MCM ORR assessment in 132 jurisdictions and state health departments implemented it in another 355 local CRI jurisdictions. The 2015-2016 MCM ORR consisted of 90 elements (54 planning and 36 operational). Reviewers assessed each jurisdiction’s MCM readiness status by evaluating each of the planning and operational elements outlined in the 2015-2016 MCM ORR using the criteria in CDC’s *Public Health Preparedness Capabilities: National Standards for State and Local Planning*¹, March 2011.

SOURCES

CDC compiled the *2015-2016 National Report of Medical Countermeasure Readiness* using MCM ORR results. CDC collected, reviewed, and analyzed data from 487* MCM ORRs to identify key findings that offer insight into our nation’s MCM operational readiness.

FIGURE 1: 2015-2016 MCM ORR Sources



* NOTE: MCM ORR data from the eight territories and freely associated states are not included in this report

¹ <https://www.cdc.gov/phpr/readiness/capabilities.htm>



MCM ORR 101

IMPLEMENTATION

The MCM ORR improves state and local readiness to respond to an emergency requiring the management of MCMs by helping CDC and jurisdictions complete the following implementation steps.



TRAINING

CDC trains all 62 PHEP Program jurisdictions on the MCM ORR assessment, providing instruction on how to document appropriate planning and operational status



SELF - ASSESSMENT

Jurisdictions complete self-assessments using the elements outlined in the MCM ORR and criteria from the public health preparedness capabilities



SITE VISIT EVALUATION

CDC and state public health personnel conduct site visits to review all relevant MCM plans and lead on-site discussions with public health department staff and relevant stakeholders



IMPROVEMENT

The findings from the MCM ORR assessment inform the development of action plans

MCM READINESS STATUS LEVELS

The four MCM readiness status levels range from “early” to “advanced” for each of the 90 planning and operational capacity elements outlined in the 2015-2016 MCM ORR. Reviewers assign an MCM readiness status level for each element based on the criteria outlined in CDC’s *Public Health Preparedness Capabilities: National Standards for State and Local Planning*, March 2011.

MCM READINESS STATUS LEVEL	DESCRIPTION
ADVANCED	All criteria met
ESTABLISHED	Majority of criteria met
INTERMEDIATE	Some criteria met
EARLY	Little to no evidence of criteria met

CDC’S MEDICAL COUNTERMEASURE OPERATIONAL READINESS REVIEW (MCM ORR) evaluates a jurisdiction’s MCM planning capabilities and operational capacity for distributing and dispensing MCMs during a public health emergency.



KEY FINDINGS

MCM ORR status levels of “advanced” or “established” are identified as strengths. MCM ORR status levels of “intermediate” or “early” are identified as gaps or areas of improvement.

For the purpose of this snapshot, each element that resulted in a 70% or more combined status level for strengths (“advanced” plus “established” status level) and gaps (“intermediate” plus “early” status level) have been included in the key findings.

STRENGTHS

“Advanced” or “Established” MCM ORR Status



States (n=50) and **large localities** (n=4) received an “advanced” or “established” MCM ORR status for 16 of the planning elements for distributing MCMs (figure 2).



Local jurisdictions (n=425) received an “advanced” or “established” MCM ORR status for five of the planning elements for dispensing MCMs (figure 3).

GAPS

“Intermediate” or “Early” MCM ORR Status



States (n=50) and **large localities** (n=4) received an “intermediate” or “early” MCM ORR status for three of the operational elements for dispensing MCMs (figure 4).



Local jurisdictions (n=425) received an “intermediate” or “early” MCM ORR status for three operational elements for dispensing MCMs (figure 5).

STRENGTHS

STATES AND LARGE LOCALITIES

States (n=50) and large localities (n=4) received an “advanced” or “established” MCM ORR status for 16 of the planning elements for distributing MCMs (figure 2). These results indicate a majority of states and large localities are planning for MCM management and distribution, including cold chain storage and maintenance, transport, tracking, receiving, and distribution of MCMs.

FIGURE 2: State and Large Locality Strengths

2015-2016

MCM ORR ELEMENTS

ADVANCED
Status Level

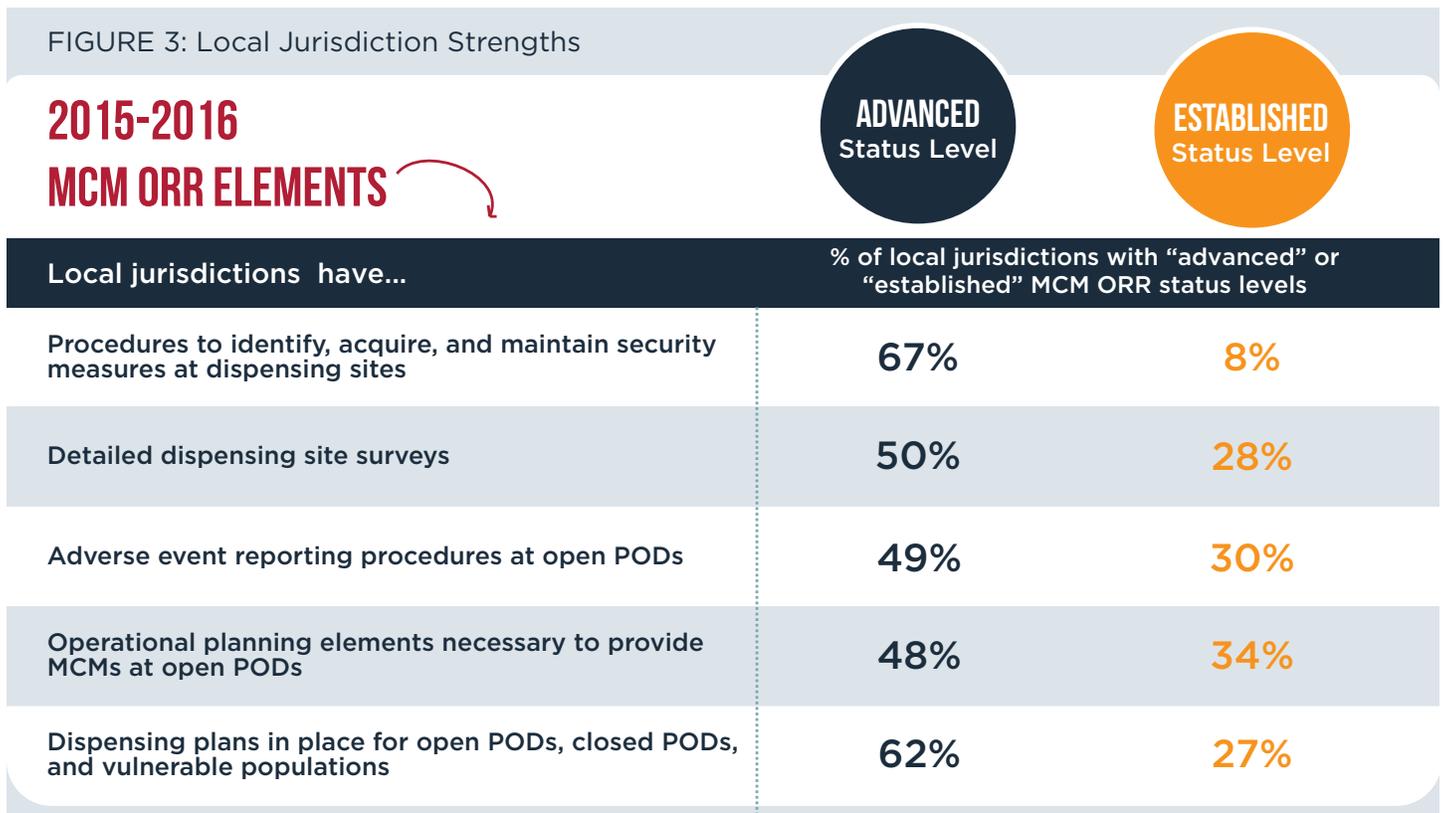
ESTABLISHED
Status Level

States and large localities have...	% of states and large localities with “advanced” or “established” MCM ORR status levels	
Recovery and waste disposal procedures in place	39%	31%
Exercised requesting materiel from jurisdictional, private, regional, or federal partners	50%	22%
Exercised transport of materiel from receiving sites to dispensing sites	61%	13%
Maintained integrity of medical materiel	48%	26%
Processes in place to track and report inventory levels	39%	35%
Detailed dispensing site surveys in place	52%	22%
Procedures in place to operate a primary or backup inventory management system	41%	37%
Identified personnel to staff receiving sites	41%	37%
Procedures in place to identify and maintain distribution site security	69%	13%
Procedures in place to request medical materiel from multiple partners	61%	20%
Plans in place for allocation and distribution strategies	56%	28%
Plans in place for secure transit of federal MCMs	56%	28%
Identified transportation assets	67%	17%
Plans in place for maintaining integrity of medical materiel	74%	15%
Identified receiving and distribution sites	81%	13%
Dispensing plans in place for open PODs, closed PODs, and vulnerable populations	57%	37%

STRENGTHS

LOCAL JURISDICTIONS

Local jurisdictions (n=425) received an “advanced” or “established” MCM ORR status for five of the planning elements for dispensing MCMs (figure 3). These results indicate more than half of local jurisdictions are planning for MCM dispensing, including having procedures to identify, acquire, and maintain security measures at MCM dispensing sites; detailed dispensing site surveys; adverse event reporting procedures; and dispensing plans for open PODs, closed PODs, and vulnerable populations.

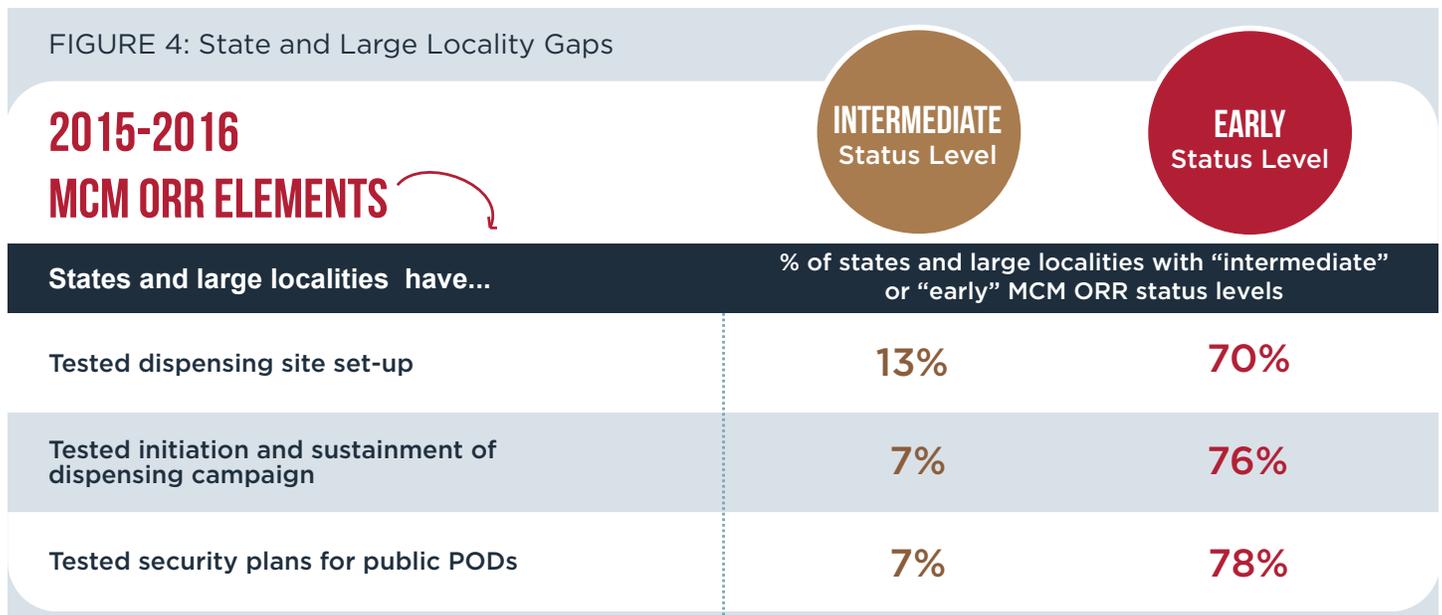


GAPS

STATES and LARGE LOCALITIES

States (n=50) and large localities (n=4) received an “intermediate” or “early” MCM ORR status for three of the operational elements for dispensing MCMs (figure 4). These results indicate a majority of states and large localities need to readily test and practice efforts to initiate, set up, and sustain MCM dispensing operations, including better testing of security measures at public dispensing sites.

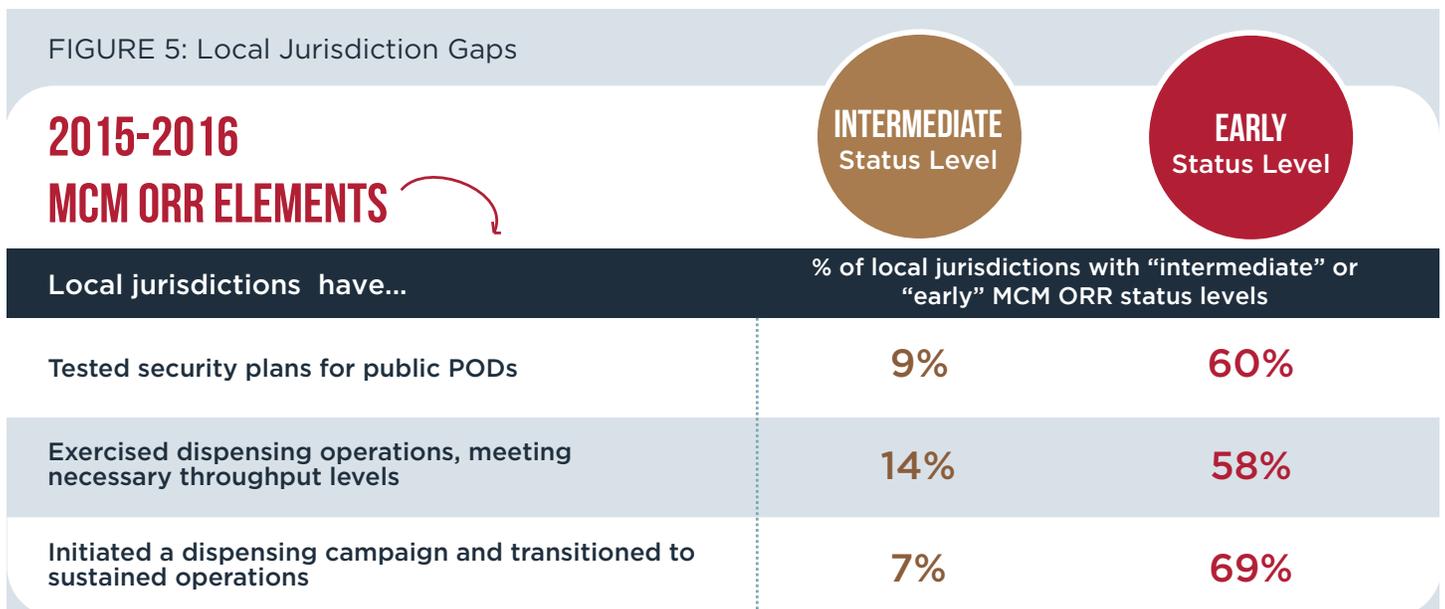
FIGURE 4: State and Large Locality Gaps



GAPS

LOCAL JURISDICTIONS

Local jurisdictions (n=425) received an “intermediate” or “early” MCM ORR status for three operational elements for dispensing MCMs (figure 5). These results indicate a majority of local jurisdictions require additional practice exercising and executing MCM dispensing operations, including testing security plans at dispensing sites, and initiating and sustaining a dispensing campaign.





LOOKING FORWARD

STEPS TO ADVANCE OUR NATION'S HEALTH SECURITY



IMPROVEMENT PLANNING AND IMPLEMENTATION

The findings from the 2015-2016 MCM ORR enabled state and local jurisdictions to identify MCM planning and operational gaps and develop and implement action plans. MCM ORR action plans guide the technical assistance provided by CDC MCM subject matter experts and help improve MCM planning and operations in support of national health security efforts.



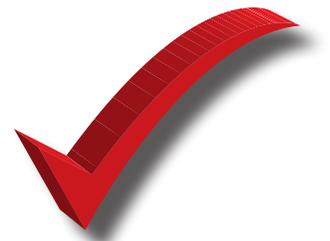
2016-2017 APPROACH REFINEMENT

To improve the MCM ORR assessment process, CDC refined the MCM ORR in 2016-2017 based on stakeholder and subject matter input. Key improvements to the assessment that were implemented in July 2017 include:

- Questions tailored for type of jurisdiction
- Real-time status updates as data are submitted
- Secure, 24-hour access for data entry and review



2022 MCM OPERATIONAL READINESS GOAL



By 2022, PHEP recipients will be fully capable of executing their MCM missions. CDC's 2022 MCM operational readiness goal strengthens our nation's critical growth in MCM operational capacity in support of national health security efforts.

CDC'S COMMITMENT

CDC is committed to the common defense of the country by safeguarding the nation's health security and advancing state, local, and territorial public health capability to distribute and dispense MCMs. To strengthen state and local MCM operational readiness, CDC will continue to:



TECHNICAL ASSISTANCE

Provide targeted technical assistance to address MCM gaps



TRAINING

Offer MCM coordinators ongoing training



CDC MCM REGIONAL STAFF

Place CDC MCM regional staff in each of the 10 U.S. Department of Health and Human Services regions to provide targeted technical assistance and support



INNOVATIVE PARTNERSHIPS

Support innovative partnerships and other strategies to identify staffing solutions for MCM operations

HEALTH SECURITY: A CDC PRIORITY

CDC plays a pivotal role in protecting the nation's health security. Through the PHEP program, CDC ensures public health departments are ready to respond to a diverse range of threats to protect communities and save lives.

MCM ORR TIMELINE



For more information, contact CDC
1-800-CDC-INFO (232-4636)
www.cdc.gov/phpr/readiness

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

