



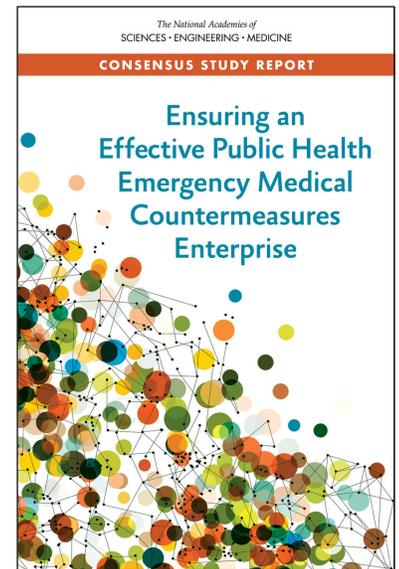
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Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise

The U.S. medical countermeasures (MCMs)¹ enterprise is interconnected, complex, and dynamic. It includes public and private entities that (1) develop and manufacture new and existing MCMs; (2) ensure procurement, storage, and distribution of MCMs; and (3) administer, monitor, and evaluate MCMs. The interagency group known as the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is the nation's sole coordinating body, based in the U.S. Department of Health and Human Services (HHS) with interagency participation, and is responsible for ensuring end-to-end MCM preparedness and response. An effective national MCM enterprise requires a mechanism to coordinate and integrate the activities and expertise of the diverse federal agencies and nonfederal and private-sector partners and stakeholders involved in these activities, and PHEMCE has the legislative mandate to serve that role.

This report provides recommendations from an expert committee—convened by the National Academies of Sciences, Engineering, and Medicine—for a re-envisioned PHEMCE. Four priority areas of improvement emerged from committee deliberations: (1) articulating PHEMCE's mission and role and explicating the principles guiding PHEMCE's operating principles and processes, (2) revising PHEMCE operations and processes, (3) collaborating more effectively with external public and private partners, and (4) navigating legal and policy issues.

¹ MCMs are biologics, drugs, or devices that can be used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear threats or emerging infectious diseases. MCMs may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material or a naturally occurring emerging disease.



DELIVERING ON PHEMCE'S MISSION THROUGH GUIDING PRINCIPLES

PHEMCE is a congressionally authorized coordinating body charged with advancing national preparedness for natural, accidental, and intentional threats by coordinating advanced research, development, procurement, stockpiling, deployment, distribution, and utilization. Its mission has evolved over the past two decades and now focuses on protecting the nation from chemical, radiological, biological, and nuclear threats and pandemics and emerging infectious diseases. PHEMCE has evolved through four distinct eras: foundational structures and policy (2001–2008), restructuring PHEMCE following the 2009 H1N1 experience (2009–2016), second restructuring (2017–2019), and COVID-19 and Operation Warp Speed (2020 and beyond).

These changes have left PHEMCE's role in MCM preparedness and response unclear. The committee called for clarifying the authorities, responsibilities, and roles of PHEMCE and its partners and stakeholders. The report proposes four sets of principles for redesigning the PHEMCE system: ethics, operations, strategic objectives, and budget alignment.

Recommendations:

- The Secretary of HHS and the Assistant Secretary for Preparedness and Response (ASPR) should recognize the critical functions of PHEMCE and reaffirm the PHEMCE mandate as the nation's major coordinating body for all aspects of U.S. MCM preparedness and response programs.
- PHEMCE should adopt a systems approach and conduct its business under the framework of clear ethical, operational, strategic, and budget goals.
- PHEMCE should ensure that the perspectives of its partners and stakeholders are incorporated into its Strategy and Implementation Plan and multiyear budget.

ENSURING DEFENSIBLE PHEMCE RECOMMENDATIONS

PHEMCE must develop and sustain the formal and informal processes required for effective business practices. PHEMCE faces challenges in establishing processes required for a predictable enterprise, including the need to coordinate the work of multiple organizations, accommodate personnel changes, shift priorities in response to emerging threats, and balance competing interests.

Priority Setting, Threat Assessments, and Needs Assessments

PHEMCE priority setting must consider the probabilities and potential impact of threats and the expected return on MCM investments. Priorities should be informed by assessments of threats, operational capacities, and MCM multifunctionality, and consider population vulnerabilities, life cycle costs, and time needed to meet goals and see return on investments.

Evaluation and Accountability

Regular monitoring and evaluation could be conducted through periodic performance assessments with key performance indicators (KPIs) representing various outputs in the MCM life cycle. Performance may be assessed through audits, exercises, and after-action reviews. Simulation exercises and table-top exercises provide opportunities to stress test organizational relationships.

Recommendations:

- PHEMCE processes should be metrics-driven with meaningful and measurable outcomes. PHEMCE should agree upon and articulate metrics in its Strategy and Implementation Plan and assess its progress toward strategic goals, outcomes, and processes across component agencies.
- PHEMCE should establish an integrated and accessible data system to support the monitoring, evaluation, and quality management of end-to-end MCM activities.

EXTERNAL PARTNERS AND THE PUBLIC HEALTH SUPPLY CHAIN SYSTEM

PHEMCE must sustain a high-performing network of nonfederal and private-sector partners and stakeholders. This requires transparent communication, internal processes that facilitate sustainable collaborations, and end-to-end engagement through the public health supply chain system.

Incorporating Nonfederal and Private-Sector Partners and Stakeholders into PHEMCE Decision Making

While its federal partners set policy, secure resources, orchestrate component functions, and manage programs, PHEMCE cannot achieve its mission without the performance, expertise, knowledge, experience, engagement, and support of its nonfederal and private-sector partners and stakeholders. To enhance transparency and communication, identify and close gaps, and build collaborative solutions, PHEMCE needs an advisory committee comprising representatives of these partners and stakeholders.

Recommendation:

- PHEMCE should establish an advisory committee of nonfederal and private-sector partners and stakeholders.

Transparency and Two-Way Communication

PHEMCE should be a transparent, reliable, and communicative partner in MCM priority setting, development, and distribution. PHEMCE must clarify roles and expectations with its partners and stakeholders through contracting, advance commitments, pricing agreements, and incentives, designed for routine and crisis operations.

Recommendations:

- PHEMCE should establish mechanisms for transparent communications across the government and with nonfederal and private-sector partners, stakeholders, and the public.
- PHEMCE should establish clear authorities, roles, and responsibilities for external partnerships.

Public Health Supply Chains and Stockpiling

PHEMCE should create appropriate incentives and commitments for private-sector engagement to promote a resilient and adaptable public health supply chain. These relationships should be designed to reveal vulnerabilities in scaling MCM provisions.

Recommendation:

- PHEMCE should commission an independent, evidence-based, root-cause assessment of lessons learned from COVID-19.

Global Considerations and Synergies

MCM preparedness and response involves a global network of resources, manufacturing, and distribution. PHEMCE must be engaged at the international level and leverage relationships with international governmental, nonprofit, and industry organizations.

Recommendation:

- PHEMCE should work synergistically with global and other national-level organizations with relevant missions and goals to benefit from their experiences.

LEGAL AND POLICY ISSUES

PHEMCE is bound and empowered by federal laws and policies. The enterprise faces regulatory challenges in several areas, including research support and procurement, research regulation and marketing authorization, and legal concerns facing nongovernmental partners in MCM manufacturing and distribution. The legal and regulatory landscape underpinning PHEMCE has evolved in response to public health emergencies like COVID-19. They have presented novel legal questions and actual and perceived regulatory barriers. Substantial legal and policy changes have come about as a result.

Recommendation:

- ASPR and HHS's Office of the General Counsel, in consultation with outside legal experts, should regularly identify, assess, and resolve the perceived or actual legal barriers that may continue to impede PHEMCE objectives.

CONCLUDING REMARKS

COVID-19 has created an urgent need to re-envision PHEMCE so that it can protect public health in both the current emergency and those to come. Given the public health threats facing the nation and the collaborative nature of MCM preparedness and response, a coordinating body is and will always be necessary. PHEMCE plays a critical coordinating role in all-of-government MCM preparedness and response. The recommendations set forth in this report provide the high-level strategic guidance that ASPR and all federal partners need to ensure PHEMCE fulfills its mission.

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To read the full report, please visit
<http://www.nationalacademies.org/re-envision-PHEMCE>

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