Consensus Study Report

MARCH 2022

HIGHLIGHTS

Building Resilience into the Nation's Medical Product Supply Chains

Over the past several decades, medical product supply chain disruptions and shortages have plagued the U.S. health care system—putting the lives of Americans at risk, costing medical facilities millions of dollars per year, and threatening the clinical research enterprise. The ongoing coronavirus disease 2019 (COVID-19) pandemic has laid bare the fragility of U.S. medical product supply chains and the profound impact supply chain disruptions have across society. Recognizing the need to strengthen the resilience and security of the nation's medical product supply chains, the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) requested the National Academies of Sciences, Engineering, and Medicine convene an expert committee to examine the root causes of medical product shortages and provide recommendations to address the most significant gaps in medical product supply chain resilience. The resulting report, *Building Resilience into the Nation's Medical Product Supply Chains*, presents recommendations to better enable stakeholders across U.S. medical product supply chains to prepare and plan for, absorb, recover from, or more successfully adapt to actual or potential adverse events.

FRAMEWORK FOR IMPROVING THE RESILIENCE OF MEDICAL PRODUCT SUPPLY CHAINS

To prioritize the myriad ways supply chains for critical medical products can be made more resilient, the committee invoked basic concepts of system reliability and supply chain management to create a framework that systematically enumerates the measures for providing a desired level of protection. The medical product supply chain resilience framework (see Figure 1) depicts how a potential trigger event (e.g., a surge in demand, capacity reduction, or coordination failure) may lead to public harm and how awareness, mitigation, preparedness, and response measures (represented as shields) provide successive layers of protection against supply disruptions and medical product shortages to prevent or reduce harm. The committee leveraged the framework to identify high-priority, high-impact recommendations that form the basis for an integrated strategy to build the resilience of critical medical product supply chains.

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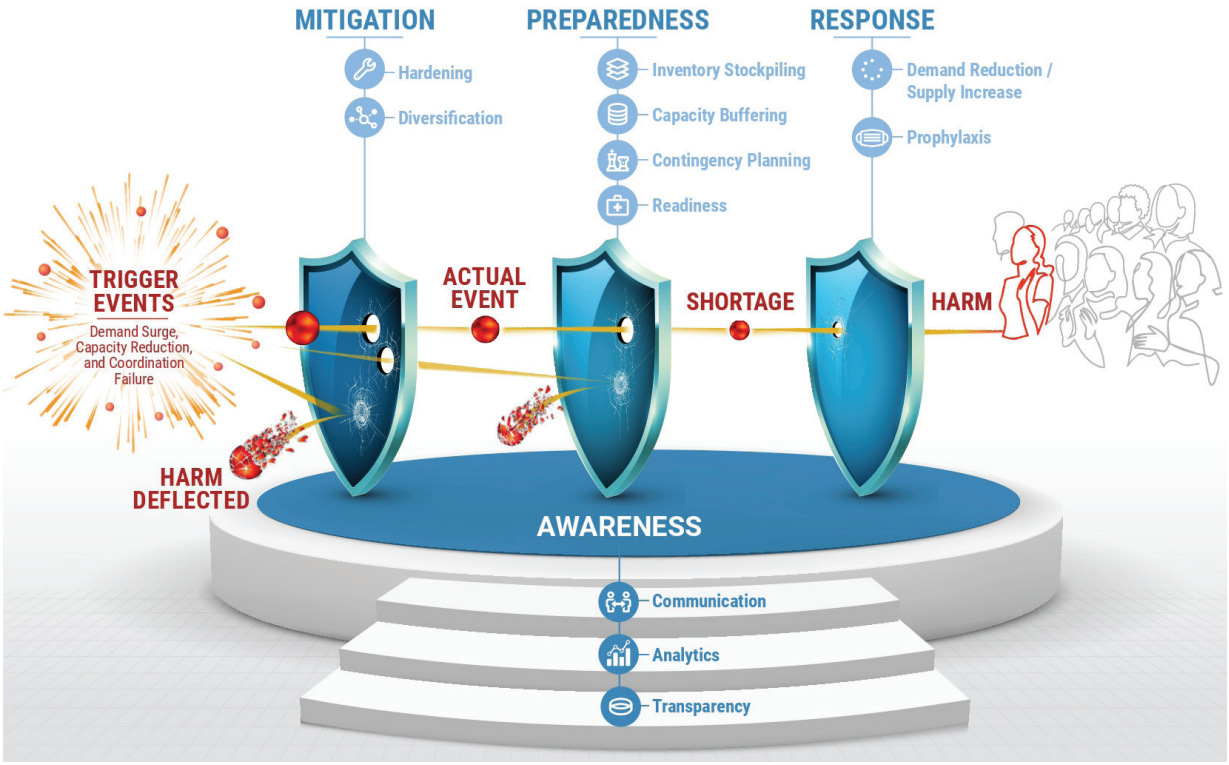

FIGURE 1 Medical product supply chains resilience framework: potential trigger events and resilience measures.

AWARENESS

Awareness is the foundation for medical product supply chain resilience, and it is achieved through transparency (i.e., visible data), analytics (i.e., processes for turning data into information), and communication (i.e., channels for sharing information with the relevant actors in the supply chain). The more visibility stakeholders have into medical product supply chains, the better positioned they will be to identify vulnerabilities and proactively mitigate, prepare for, and respond to potential supply chain disruptions.

Unfortunately, a lack of transparency in medical product supply chains has led to limited empirical evidence regarding best strategies for addressing supply chain issues. The current practice of keeping medical product supply chains confidential conflicts with public health needs and puts the public's health at risk. The lack of situational awareness across medical product supply chains was further highlighted during the COVID-19 pandemic.

Over the long term, efforts should be established to collect, compile, and disseminate medical product supply chain data from various stakeholders to increase end-to-end awareness to identify and mitigate risks. In the short term, the committee recommends that the U.S. Food and Drug Administration (FDA) should make sourcing, quality, volume, and capacity information publicly available for all medical products approved or cleared for sale in the United States (Recommendation 1), and should establish a public database to share this information and to promote analyses of these data by interested parties (Recommendation 2). Novel approaches to mitigation, preparedness, and response will come from these analyses.

MITIGATION

Mitigation measures include actions taken prior to a disruptive event that helps prevent the event altogether or reduce its magnitude. Types of mitigation measures include hardening to reduce the likelihood or magnitude of disruptive events within stages of the system and diversification to create parallel versions of stages to reduce the risk of catastrophic failure.

Medical product manufacturers currently have little incentive to harden their supply chains through updated techniques, processes, and controls that promote reliability and quality in medical products. A key place where action is needed is in the purchasing decisions by health systems. Given that a high percentage of medical

product shortages, particularly in generic drugs, are encountered during normal times as a result of process disruptions caused by problems with quality, the committee recommends tasking health systems with actions that incorporate reliability into their purchasing decisions, not just cost (Recommendation 3) to reduce the likelihood and magnitude of medical product supply shortages.

PREPAREDNESS

Preparedness measures include actions taken prior to a disruptive event that will reduce the risks to health and safety if the event occurs. These actions include inventory buffering and capacity buffering, in which stock or productive capacity are held in readiness to fill a supply shortfall; contingency planning, which establishes plans for dealing with specific scenarios; and readiness, which builds capabilities for dealing with scenarios without specific plans made in advance.

In the real world, problems with forecasting and monitoring stock levels, rotating stock to prevent expiration, and other practical details prevented inventory stockpiles from providing the intended level of protection in an emergency. Stockpiling is already part of the national preparedness strategy, primarily in the form of the Strategic National Stockpile, so the committee recommends refining and improving the ways inventory is held as protection against a medical product shortage (Recommendation 4). Specifically, ASPR should take steps to develop strategies to modernize and optimize inventory management to respond to medical product shortages at the national and regional levels. The committee also recommends that ASPR and FDA take steps to cultivate capacity buffering for supply chain critical medical products where such capacity is a cost-effective complement to stockpiling and as protection against long-lasting supply disruptions or demand surges (Recommendation 5).

RESPONSE

Response measures include actions taken after an event to minimize harm from medical product shortages and resolve the disruption. Response measures at the global and local level are required to close the supply gap through demand reduction and/or supply increase, and ensure medical products reach the end user.

At the global level, the health and well-being of the U.S. population is inextricably linked to the health and well-being of populations in other countries around the world. For this reason, international cooperation to facilitate global trade in medical products remains essential for maintaining the health security of the United States. The committee recommends an international treaty among major exporters of medical products, including the United States, under the World Trade Organization, to reframe from export bans or other interventions that would fragment or limit the global supply of critical medical products (Recommendation 6).

At the local level, or “last mile,” the distribution of critical medical products to end users, such as hospitals, clinicians, pharmacies, and patients, is vital for the protection of public health and safety. These end users have important roles to play in addressing supply chain disruptions and in developing and implementing contingency plans to reduce the impact of shortages on patient and community health. The committee advocates forming a working group of key stakeholders who represent end users of medical product supply chains to examine and identify effective last mile strategies to ensure end users are able to respond in the event of medical product shortages (Recommendation 7).

To read the full report, please visit
http://www.nationalacademies.org/supply-chain-resilience

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