# Defining and Measuring the Resilience, Criticality, and Vulnerability of Medical Product Supply Chains

**September 18, 2025**

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**Submitted to:**

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# Contents

# Tables



# Figures

## Acknowledgements

We thank the key informants and technical expert panelists for generously sharing their time, insights, and expertise. Their perspectives as supply chain experts and individuals from academia, industry, and government were invaluable in shaping the direction and depth of this work. We also thank Trinidad Beleche, Elizabeth Hussin, Elaina DiCorpo, and Oluwarantimi Adetunji from ASPE for their leadership and direction, and Michaela Vine from Mathematica for her careful quality assurance review.

# Executive Summary

## A. Introduction

Recent medical product supply chain disruptions—for example, Hurricane Helene's impact on intravenous (IV) saline availability—have highlighted the need for stronger, more coordinated approaches to ensuring reliable access to medical products (US News 2024, FDA 2025a). Medical products include pharmaceuticals, medical devices, and other healthcare supplies used to diagnose, treat, prevent, or manage health conditions. The supply chains for these products comprise the network of entities that source, manufacture, distribute, and deliver them to patients. Federal and private-sector leaders increasingly recognize the importance of building supply chain resilience—but lack shared definitions or measurement tools to guide investments, oversight, and preparedness. This report, prepared by Mathematica for the Office of the Assistant Secretary for Planning and Evaluation (ASPE), addresses that gap by synthesizing expert perspectives on how to define and measure three core concepts: resilience, criticality, and vulnerability.

## B. Key findings

This section summarizes how resilience, criticality, and vulnerability are defined and measured. It draws on insights from an environmental scan of recent literature, federal reports, and measurement tools; eight key informant interviews, and a technical expert panel representing (TEP) representing academia, industry, and government.

### 1. Definitions

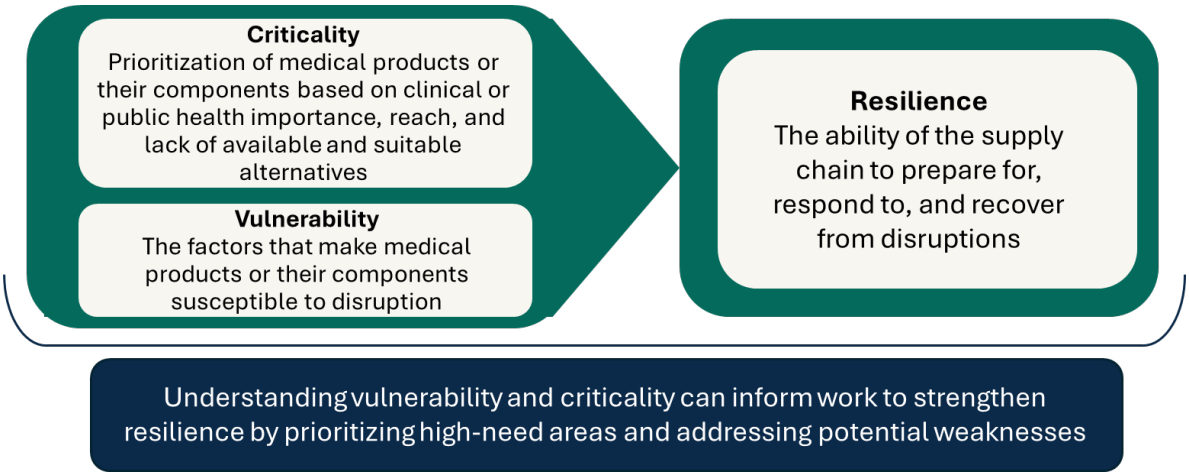
**Resilience** refers to the ability of supply chains to prepare for, respond to, and recover from disruptions in a way that ensures the continuous and reliable availability of medical products needed for patient care.

Resilience is most meaningful when considered alongside two related concepts:

- **Criticality** prioritizes medical products or their components based on their clinical or public health importance; their reach; and the lack of available and suitable alternatives (this often varies by context); and
- **Vulnerability** refers to factors that make medical products or their components more susceptible to disruption.

Figure ES.1 illustrates the relationship between resilience, criticality, and vulnerability.

**Figure ES.1.** Interplay between resilience, criticality, and vulnerability in medical products




### 2. Measurement approaches

Translating the concepts of resilience, criticality, and vulnerability into practice requires measurement tools, yet few have achieved broad consensus or adoption. Current efforts to assess resilience of medical product supply chains include self-assessments and surveys that evaluate organizations' capacity to prepare for, respond to, and recover from disruptions. Criticality is often operationalized through product lists that vary in scope and criteria. Vulnerability assessments typically integrate information on internal supply chain weaknesses and exposure to external disruptions. Several tools combine these dimensions, such as drug shortage lists, ranking systems, and internal assessments, which can help decision makers prioritize where resilience-building efforts are most needed.

### 3. Challenges and guiding principles

Experts agreed on the importance of measuring resilience but pointed to persistent challenges in generating the data needed to do so effectively. A central barrier is limited transparency: suppliers are often hesitant to disclose internal weaknesses due to concerns about reputational harm, competitive exposure, or uncertainty about how data will be used and protected. Contractual restrictions, operational silos, and gaps in information from upstream actors further obstruct efforts to build a shared evidence base. To address these challenges, experts emphasized several guiding principles for measuring resilience going forward:

- **Purpose-driven.** Metrics should be tied to specific use cases—such as regulatory oversight, procurement, investment, supply chain management, or patient care.
- **Tailored to level and product.** Effective metrics must be tailored to levels of the supply chain (for example, manufacturer versus provider) and to product characteristics (such as drugs or medical devices).
- **Informed by supply chain actors.** Approaches must involve those with operational knowledge and data access to ensure feasibility and usefulness, and to build trust in how data will be used and protected. Clearly articulating the purpose of measurement can further support transparency and trust in data sharing.

- **Coordinated.** Metrics should be aligned across public and private initiatives to support comparability, reduce duplication, and promote accountability.

The remainder of this report provides deeper discussion of these principles. It also discusses the importance of measures that are feasible, useful, and built through shared understanding and trust.

## C. Implications

Building more resilient medical product supply chains requires translating high-level frameworks into actionable tools that guide decision making and oversight. Key informants and the TEP emphasized the need for cross-sector alignment on shared measurement priorities, greater transparency in data practices, and coordination across initiatives to avoid duplication and promote consistency. Experts also highlighted the role of federal leadership to catalyze progress by supporting pilots, convening participants across the supply chain, and embedding resilience considerations into procurement, reimbursement, and regulatory frameworks.

# I. Introduction

## A. Background

Medical product shortages threaten both the quality of patient care and the integrity of work to ensure public health preparedness (HHS 2024). Drug shortages may put patients at direct risk by delaying or interrupting essential treatment and have been shown to increase staff workload and force last minute substitutions that can be costly (Vizient 2025).[1] Resilient supply chains for medical products require clear definitions and shared measurement frameworks to guide investments and resource decisions, prioritize risks, support data sharing and analytics, and align fragmented work in the public and private sector (HDA 2023). Currently, inconsistent terminology, absence of standardized frameworks, and siloed initiatives impede collaboration and informed decision making across supply chains.

This report, prepared by Mathematica for the Office of the Assistant Secretary for Planning and Evaluation (ASPE), aims to address these gaps by summarizing current thinking and expert perspectives on defining and measuring three key, interrelated concepts: supply chain **resilience**, **criticality,** and **vulnerability**.[2] Together, these concepts provide a framework for identifying medical products that should be prioritized for supply chain resilience efforts, understanding where disruptions would have the greatest impact, and guiding efforts to strengthen the resilience of medical product supply chains.

This report presents information about the dynamics, risks, and requirements of medical product supply chains. Medical products include pharmaceuticals and medical devices, such as personal protective equipment (PPE) and other healthcare supplies used to diagnose, treat, prevent, or manage health conditions (Box I.1). Both medical product supply chains and their market environments are distinct from those in other industries. They play a critical role in patient care and public health preparedness, and are shaped by unique regulatory oversight, specialized manufacturing requirements, global sourcing dependencies, and multiple federal and non-federal stakeholders and payors.

However, many core concepts and measurement challenges are shared across sectors. Insights from other sectors can help us understand the resilience of the medical product supply chain within a broader systems context. Therefore, although this report focuses on medical products, it was deliberately informed by insights from a broad set of sources including sectors other than health such as defense and commerce, where supply chain resilience has long been a strategic concern.

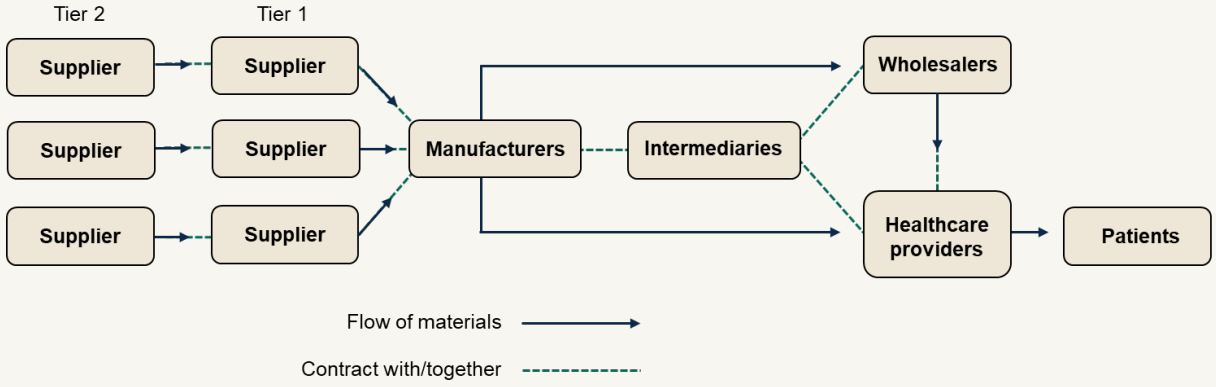
[1] Patients in this context refer to individuals under the care of a healthcare provider or in need of a medication.

[2] Other supply chain concepts such as reliability and robustness are closely related to resilience but are not examined explicitly in this report.

### Box I.1. Key terms: Medical products and their supply chains

- Medical products are items used to diagnose, treat, prevent, or manage health conditions. They include prescription and nonprescription pharmaceuticals[3] and medical devices such as diagnostics, PPE, and other healthcare supplies.
- A medical product supply chain is the network of entities responsible for sourcing, manufacturing, distributing, and delivering these products to patients. As shown in Figure I.1, supply chain participants typically include suppliers, manufacturers, intermediaries (such as group purchasing organizations or pharmacy benefit managers), wholesalers, healthcare providers, and patients.
- A medical product supply chain operates within a broader market environment shaped by policies, laws, and regulatory frameworks that influence how the supply chain functions.
- Although Figure I.1 shows a simplified linear pathway, real-world supply chains often involve more complex relationships, payors, multiple sourcing routes, and feedback loops between stages.

**Figure I.1.** Simplified figure of a medical product supply chain




## B. Overview of methods

To define and provide a comprehensive view of existing practices, frameworks, and measurement tools related to medical supply chain resilience, criticality, and vulnerability, Mathematica conducted an environmental scan, interviewed supply chain experts, and facilitated a technical expert panel (TEP).

### 1. Environmental scan

Mathematica conducted an environmental scan of key government, industry, and academic websites and reviewed literature from PubMed and Google Scholar. This scan helped reveal definitions, frameworks, and measurement tools currently in use, along with any gaps in the literature. Details on the search strategy and the websites Mathematica reviewed are in Appendix A, Tables A.1 and A.2.

### 2. Key informant interviews

Mathematica conducted eight key informant interviews with experts in academia, policy, and industry. The key informants had knowledge of medical product supply chains and supply chain resilience. They shared practical insights and valuable perspectives on how concepts of supply chain resilience are interpreted and applied in practice, including real-world experiences, challenges, and strategies for managing

[3] Biologics are also considered medical products.

uncertainty in supply chains. The key informants also discussed the availability of data sources to assess the resilience of supply chains and described how related concepts are defined and operationalized across various industries and research areas.

**3. Technical expert panel**

To validate and refine the preliminary findings, Mathematica convened a small TEP with a mix of governmental and non-governmental leaders. The four panelists reviewed the emerging themes from the literature and key informant interviews, assessed the proposed definitions and measurement frameworks, and provided feedback on ways to strengthen consistency, enhance generalizability, and address practical implementation considerations.

### C. Structure of report

The rest of this report is organized into three chapters. Chapter II outlines findings on **resilience**, including a framework of core capabilities, cross-cutting enablers, and outcomes specific to medical product supply chains. Chapter III examines **criticality** and **vulnerability**, defining key concepts, reporting influencing factors, and showing how these elements can be combined to reveal the products most in need of resilience-building. Chapter IV discusses **implications**, highlighting persistent challenges, principles for measurement, and opportunities for coordination and policy action.

## II. Findings on Supply Chain Resilience

This chapter introduces key concepts, frameworks, and tools related to the resilience of medical product supply chains. Section A gives a working definition of resilience and highlights capabilities, enablers, and outcomes of resilient supply chains. Section B reports insights from key informant interviews, including principles for measuring resilience, existing measurement approaches, and the challenges and limitations of using existing data sources.

### A. Defining resilience

Resilience is the ability of supply chains to prepare for, respond to, and recover from disruptions in a way that ensures the continuous and reliable availability of medical products needed for patient care (Box II.1). This definition frames resilience as a process and centers its purpose on supporting patient care. It reflects consensus aspects found across a range of existing definitions, while other elements emphasized in the literature are integrated below in our discussion of the capabilities, enablers, and outcomes of resilient supply chains.

### Box II.1. Resilience at a glance

**Definition**

The ability of supply chains to prepare for, respond to, and recover from disruptions in a way that ensures the continuous and reliable availability of medical products needed for patient care.

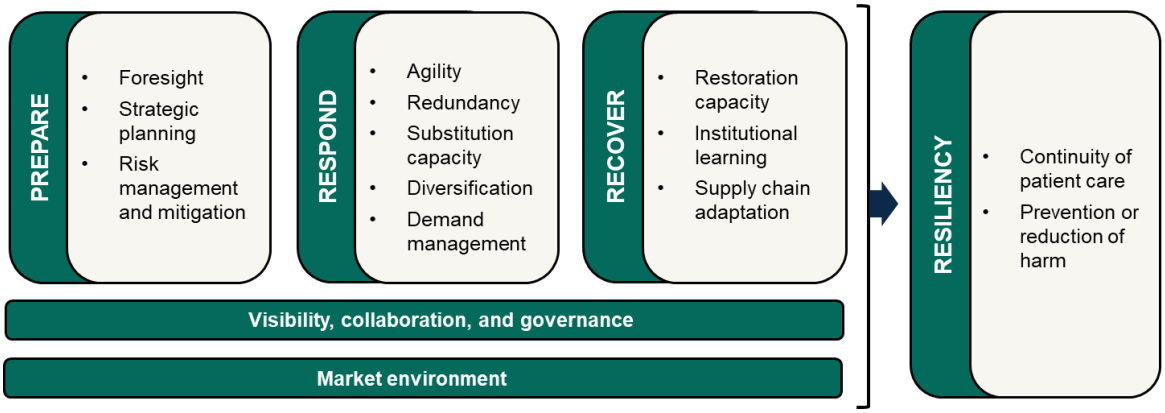
**Core elements of resilience**

- **Prepare for** highlights proactive planning to manage supply chain risks and prevent disruptions.
- **Respond to and recover from** reflect the ability to manage disruptions and restore operations.
- **Continuous and reliable availability** underscores the goal of sustained access throughout a disruption.
- **Patient care** anchors the definition in the goal of supporting favorable health outcomes for patients.

## 1. Capabilities, enablers, and outcomes of resilient supply chains

Figure II.1 is a framework for achieving resilience in medical product supply chains. This figure organizes core capabilities into phases that guide supply chain participants in preparing for, responding to, and recovering from disruptions. These capabilities are supported by cross-cutting enablers—including governance, visibility, collaboration, and market environment—that influence how effectively the capabilities can be implemented. Together, these capabilities and enablers support the overarching goal of resilience: maintaining continuity of patient care and reducing or preventing harm to the population and the broader healthcare system caused by supply chain hazards. The framework synthesizes insights from the supply chain resilience literature (Han et al. 2020; Pettit et al. 2010; Ponomarov & Holcomb 2009) and work by the Office of the Assistant Secretary for Preparedness and Response and the Food and Drug Administration (FDA 2023) and the National Academies of Sciences, Engineering, and Medicine (NASEM 2022), with adaptations to reflect the unique characteristics and policy context of U.S. medical product supply chains. The capabilities and cross-cutting enablers within each phase are described below the figure.

**Figure II.1.** Capabilities, enablers, and outcomes of resilient supply chains




Source: Adapted from the Critical Infrastructure Partnership Advisory Council Healthcare and Public Health Joint Supply Chain Resilience Working Group, September 2023: Critical Medical Device List: Summary and Recommendations and the National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Security of America's Medical Product Supply Chain: Building Resilience into the Nation's Medical Product Supply Chains, edited by C. Shore, L. Brown, and W.J. Hopp.

*a. Prepare*

Preparedness capabilities are proactive efforts that strengthen supply chains by anticipating potential disruptions and reducing their likelihood. Key preparedness capabilities include **foresight**, or the ability to anticipate potential disruptions through monitoring and scenario planning; **strategic planning**, which involves designing supply chain structures and governance to support resilience; and **risk management and mitigation**, which includes assessing vulnerabilities and deploying strategies—such as buffer stock, contractual safeguards, and regulatory tools—to reduce exposure. Together, these capabilities ensure that resilience is not purely reactive but embedded into the foundation of supply chain operations.

At the federal level, these capabilities can inform decision-making on procurement prioritization, industrial base investments, and stockpile management. For example, recent federal efforts to prioritize active pharmaceutical ingredients (APIs) for domestic manufacturing, guided by critical medicines lists, illustrate how preparedness principles are being operationalized as a policy priority (USP, 2025a).

*b. Respond*

Response capabilities reflect how supply chains function during a disruption. These capabilities determine the system's ability to absorb challenges, pivot operations, and sustain the flow of critical products despite constraints. Key response capabilities include **agility**, or the ability to reconfigure production, sourcing, or distribution rapidly in reaction to emerging conditions; **redundancy**, such as maintaining alternate suppliers or inventory reserves that can be activated when primary sources fail; **substitution capacity**, which allows supply chain participants to switch to functionally equivalent products, if available, when needed; **diversification**, which spreads risk across multiple suppliers, geographies, and transportation modes; and **demand management**, which refers to the ability to anticipate, prioritize, or reallocate demand—for example, through conservation protocols, temporary formulary adjustments, or coordinated redistribution strategies While our findings emphasized supply-side strategies, the literature also highlights demand-side approaches as an important aspect of resilience (Guo et al. 2025). When deployed effectively, these capabilities can mitigate the impact of disruptions and maintain continuity of supply.

*c. Recover*

Recovery capabilities support the system's ability to stabilize and improve after a disruption. These capabilities are not only designed to restore supply chain operations to baseline but also to enable learning and adaptation that reduces risk going forward. Key recovery capabilities include **restoration capacity**, which refers to the ability to return to normal or stable operations in a timely and efficient manner; **institutional learning**, which involves systematically capturing lessons from disruption events and integrating them into future planning and response; and **supply chain adaptation**, which refers to making structural or strategic changes—such as reconfiguring sourcing strategies, updating contracts, or investing in domestic manufacturing—based on insights gained during recovery. Together, these capabilities help transform recovery into an opportunity for long-term system strengthening.

**2. Cross-cutting enablers**

**Visibility, collaboration, and governance** influence how effectively supply chain actors can prepare for, respond to, and recover from disruptions. ***Visibility*** refers to the ability to monitor supply chain

conditions, interdependencies, and risks in a timely manner. Achieving adequate visibility often requires investments in data infrastructure and analytics tools that generate situational awareness and function as early warning systems, enabling proactive identification of emerging issues and supporting timely decision making. ***Collaboration*** includes the relationships, communication channels, and trust that supply chain actors need to share information, align responses, and act collectively during disruptions. ***Governance*** provides the leadership, accountability, and structures needed to support visibility and collaboration and invest in other capabilities.

**The market environment** plays a critical role in shaping whether and how resilience strategies are adopted. It includes the policies, laws, incentives, payment structures, regulations, competitive dynamics, and purchasing practices that influence supply chain behavior. In many cases, market forces prioritize efficiency—such as just-in-time inventory or lowest-cost sourcing—over investments in redundancy, diversification, or surge capacity.

### 3. Outcomes

Resilient supply chains will ensure continuity of patient care, and prevent or reduce harm during and after disruptions. Not all disruptions can be avoided, but resilient supply chains minimize the consequences of such disruptions, both for patients and the broader system.

## B. Measuring resilience: Approaches, data sources, and challenges

### 1. Measurement approaches and tools

Although many frameworks articulate the core elements of supply chain resilience, few provide practical methods for measuring it—particularly in the context of medical product supply chains. The literature identifies four main approaches for measuring resilience—case studies, surveys, modelling, and simulation-based methods (Piffari et al. 2024)—each with distinct strengths and limitations. Key informants discussed a few tools currently in use or development that measure resilience through a combination of surveys and in-depth data review and collection (Box II.2).

Additional efforts to measure and assess supply chain resilience include a systematic review of resilience indicators used in academic literature (Han et al. 2020) and several descriptive self-assessment tools developed by public and private entities. These include the SMI Resilience Maturity Model (SMI 2022), Deloitte's Supply Chain Resilience Matrix (Deloitte 2022), the Department of Homeland Security and Federal Emergency Management Agency's Supply Chain Resilience Guide (DHS 2019), and ASPR's Risk Identification and Site Criticality (RISC) Toolkit (ASPR 2025). Together, these examples illustrate a range of approaches and levels of rigor, but they also highlight the need for more standardized and scalable solutions. Few have been widely adopted or proven scalable across product types or supply chain segments. Illustrative metrics include measures of supplier diversification, inventory management, continuity-of-operations planning, recovery times, surge capacity, structural adjustments after disruptions, and geographic concentration of supply sources.

### Box II.2. Examples of tools to assess resilience

**Healthcare Industry Resilience Collaborative (HIRC) Resiliency Badge**

A voluntary, industry-led program that recognizes healthcare suppliers—including pharmaceutical, medical device, and med tech manufacturers—for adopting practices that promote supply continuity. HIRC evaluates areas such as risk mitigation planning, dual sourcing, and transparency with downstream stakeholders (HIRC 2025).

**FDA Quality Management Maturity (QMM) Program**

The QMM Program is a voluntary regulatory initiative focused on drug manufacturers that assesses the robustness of a facility's quality management practices beyond baseline compliance. Higher QMM scores reflect more mature manufacturing practices, including proactive monitoring, risk management, and continuous improvement (FDA 2025b).

**USP Drug Supply Chain Resilience Initiative (DSCRI)**

The DSCRI aims to develop a benchmark program in consultation with manufacturers and other supply chain actors to measure the resiliency of generic drug manufacturers. The DSCRI would evaluate areas such as resilience and reliability of manufacturers, promote sustainable pricing, and incentivize reforms to purchasing practices (USP 2025b).

## 2. Common challenges or limitations in measuring supply chain resilience

Key informant interviews revealed two major categories of challenges that hinder efforts to measure resilience in medical product supply chains: (1) limitations in data availability and visibility and (2) the absence of clear, trusted norms for data sharing.

Critical data on suppliers, inventory levels, and production capacity are often proprietary and inaccessible to the public. Even within the federal government, access may be constrained by contractual arrangements or siloed systems across agencies. Manufacturers frequently know little about the practices of their lower-tier suppliers, making it difficult to identify upstream risks. Inventory and production data can also change quickly, so point-in-time metrics can be outdated or misleading. Efforts to share information across supply chain actors are hindered by poor interoperability between data systems and inconsistent reporting standards, and laws protecting certain types of data from being shared by government partners.

The lack of clear, trusted data-sharing norms further complicates measurement. There is no widely accepted guidance on why, how, and with whom data should be shared. As a result, trust is limited among supply chain actors based on concerns about how data will be used, interpreted, or disclosed. Key informants cited persistent concerns about confidentiality, reputational damage, and competitive risk as key deterrents to transparency —whether sharing information with government agencies, industry partners, or competitors. They also noted potential unintended consequences of limited data transparency, such as hoarding or increased purchasing and demand. Without greater clarity and assurance around data governance, many organizations remain reluctant to collaborate on assessing resilience. Relatedly, the TEP discussed one resilience metric that may have been discontinued because it was not adopted widely enough—underscoring the importance of building trust and buy-in for measurement initiatives. To support more consistent and actionable measurement, key informants shared several guiding principles, summarized in Box II.3.

### Box II.3. Principles for measuring supply chain resilience

- **Purpose-driven**

  Begin with a clear understanding of how the results will be used—whether for policy, regulatory oversight, procurement, supply chain management, risk monitoring, response, investment decisions, or patient care.
- **Tailored to level and product**

  Tailor metrics to the entity being assessed (such as manufacturer, provider, or medical product) and the product type. What defines resilience in pharmaceuticals may differ from what defines it in diagnostics, other medical devices, or PPE.
- **Informed by supply chain actors**

  Involve people with operational knowledge, data access, and implementation responsibility to ensure the metrics are feasible and useful.
- **Coordinated**

  Ensure alignment and continuity across public and private measurement initiatives to support comparability, reduce duplication, and sustain accountability and progress over time. A whole-of-government approach that aligns efforts across federal agencies can strengthen coordination with the private sector.
- **Feasible and useful**

  Balance simplicity and interpretability with analytical rigor. Metrics should be practical to implement and provide meaningful insights.
- **Built on trust and shared understanding**

  Be transparent about how data will be used. Address concerns about burden, data misuse, or unintended consequences.

# III. Findings on Supply Chain Criticality and Vulnerability

This chapter introduces key concepts, measurement approaches, and gaps related to the criticality and vulnerability of medical products and their components. The concepts of criticality and vulnerability are discussed together because they are closely related and are often used in combination to inform decision making about supply chain resilience. Sections III.A and III.B present definitions of criticality and vulnerability. Section III.C explains how these concepts are measured and how approaches to measuring both can be used to direct resilience efforts. Section III.D discusses gaps in existing data sources and approaches for measuring criticality and vulnerability.

## A. Defining criticality

Medical product criticality can be defined as prioritization of medical products or their components based on their clinical or public health importance, reach, and a lack of available and suitable alternative products. This report focuses on criticality of medical products and their components, recognizing that criticality can also be applied more broadly to infrastructure, sectors, or functions within supply chains (Erkose 2024; Boyens et al. 2022).

### Box III.1. Criticality at a glance

**Definition**

Prioritization of medical products or their components based on their clinical or public health importance; reach; and a lack of available and suitable alternative products. The products determined to be critical often vary by context.

**Core elements of criticality**

- **Factors for determining criticality**
  - **Clinical or public health importance.** The product's role in treating, diagnosing, or monitoring, or preventing conditions or diseases for patients or specific groups (such as children) or for the population as a whole (including during emergency situations).
  - **Reach.** How much a disruption in the supply chain of a product could affect the population or broader health systems.
  - **Lack of available and suitable alternatives.** The absence of other products that can serve the same function with comparable safety, efficacy, and availability.
- **Context.** The setting in which criticality is determined; what is considered critical will vary by context—for example, by patient population served, type of care delivered, etc.

- **Clinical or public health importance** refers to a product's role in diagnosing, treating, or monitoring serious diseases or medical conditions or its role in preventing disease or protecting the health of the population as a whole (FDA 2023; SMI 2023). Clinical or public health importance also includes factors such as (1) the importance of a product among special populations, like children or pregnant people (FDA 2023), (2) the possibility for increased demand for a product in emergency situations, and (3) the potential to impact public health or safety if the product were not available in an emergency (for example, a lack of PPE putting healthcare workers at risk during a pandemic) (Boyens et al. 2022; FDA 2023; NASEM 2022; Yang and Zelbst 2024).
- **Reach** is closely related to clinical or public health importance, but is focused on assessing the magnitude of impact, or how much a disruption in the supply chain of a particular product could affect the population or broader health systems (Wosińska et al. 2023). For example, reach can be measured by the number of patients who would be affected if a product were unavailable, the impact on multiple products if a specific component or material were not available, or the magnitude of spillover effects on people who do not use the product itself.
- **Lack of suitable alternatives** refers to the absence or limited number of other products that can provide the same function with comparable safety, efficacy, and availability. Products should only be considered critical if there are no available and suitable alternative products that could fill gaps (and not adversely impact supply of the alternative product for other needed clinical uses) in the case of a shortage or supply chain disruption (FDA 2023).

Although definitions and assessments of criticality generally incorporate the above elements, determination of a medical product's clinical or public health importance and its reach can vary based on the context and purpose of the assessment. For example, factors considered critical in a public health context often differ from those critical to clinical care. As one key informant put it, "A product essential during a disease outbreak may not be critical for routine care like oncology, and vice versa."

In addition, clinical settings may prioritize different products based on the type of care they deliver and their patient populations. For example, one key informant shared: "It is very subjective because a Level 1 academic trauma center [or an] academic medical center is going to have a different list of what they view as critical than a very rural, small hospital." TEP participants noted the importance of distinguishing between critical products for acute care and products needed for chronic care. Failing to distinguish between acute and chronic needs when determining criticality may mean that important products for sustaining lives and protecting health are overlooked.

## B. Defining vulnerability

Vulnerability refers to the factors that make medical products or their components more susceptible to disruption. These factors can include events that initiate a disruption (triggers), conditions that amplify a disruption's impact (potentiators), and the absence or weakness of elements that mitigate disruptions (buffers) (Wosińska et al. 2023).

### Box III.2. Vulnerability at a glance

**Definition**

The factors that make medical products or their components more susceptible to disruption.

**Core elements of vulnerability**

- **More susceptible to disruption.** Higher likelihood that a disruption will occur or increased severity and intensified effects when a disruption does occur.
- **Factors that increase susceptibility to disruption.** Include events that initiate a disruption (**triggers**), conditions that amplify a disruption's impact (**potentiators**), and the absence or weakness of elements that mitigate disruptions (**buffers**).

In contrast with resilience, which is more widely and consistently defined, relatively few formal definitions of vulnerability exist in literature or government sources. Key informants noted the lack of consensus around definitions of vulnerability and provided different interpretations of the concept. The definition in this report aims to capture the various ways of understanding vulnerability across the literature and among key informants.

When discussing vulnerability, literature and key informants emphasized different factors. Some emphasized factors within the control of businesses or actors in supply chains (FDA 2023; NASEM 2022; Yang and Zelbest 2024). Others emphasized factors involving communication between supply chain actors, or events external to supply chains, such as natural disasters (NASEM 2022; Resilinc 2024; Yang and Zelbest 2024). One framework proposed by Wosińska et al. (2023) summarizes these key components of vulnerability and classifies them as triggers, potentiators, and buffers.

- **Triggers** are events external to supply chains or shocks that initiate disruption and impact both supply and demand (Wosińska et al. 2023). These include public health emergencies such as pandemics, which can increase the demand for specific products and lead to shortages. They also include natural or man-made disasters, geopolitical conflict, and trade policies or tariffs, which can disrupt supply. Trigger events are often outside the control of actors within supply chains.

- **Potentiators** are conditions within supply chains that amplify the effects of a disruption once a trigger occurs (Wosińska et al. 2023). Examples include high supplier concentration, limited visibility across tiers of supply chains (such as between suppliers, manufacturers, and providers), just-in-time inventory practices, and over-procurement or hoarding by providers when product shortages are announced. Unlike trigger events, these conditions are often within the control of actors in supply chains.
- **Buffers** can be conceptualized as the reverse of potentiators because they help mitigate the impact of supply chain disruptions. Buffers include things like sourcing redundancy, strategic stockpiles or buffer stocks, and robust business continuity planning.

Table III.1 highlights potentiators that impact the vulnerability of supply chains, and buffers that can be used to address them, with examples mentioned by key informants and in the literature that are particularly important to consider for medical products. The IV fluid shortage following Hurricane Helene also highlights an example of the relationships between triggers, potentiators, and buffers. A trigger event (hurricane) caused the closure of the largest IV manufacturer in the U.S., exacerbating existing potentiators (such as a limited number of suppliers) (US News 2024). Following the hurricane, organizations began to build buffers, such as expanding manufacturing capacity and regulatory action to allow imports of IV fluids from new suppliers (FDA 2025a).

**Table III.1.** Examples of potentiators and buffers relevant to medical products

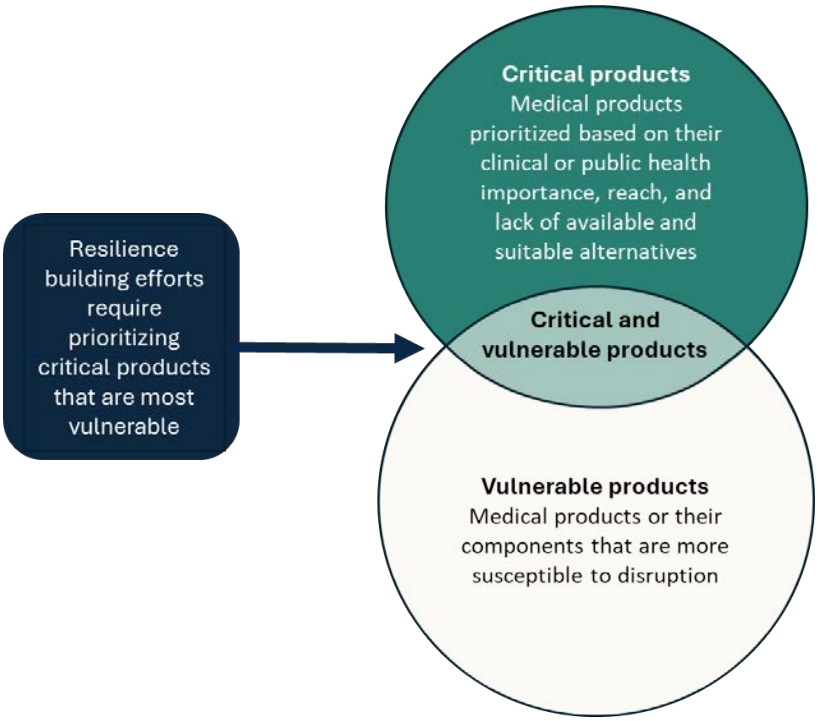
| Potentiator | Buffer |
|---|---|
| **Geographic concentration.** Heavy reliance on production in a limited number of regions or countries creates exposure to localized shocks—such as natural disasters, political instability, or export restrictions—with few alternatives for rapid substitution. | **Geographic diversification.** Supply chain mapping helps proactively identify geographic risks and allows sourcing from multiple regions. |
| **Low profit margins**. Medical products such as generics and sterile injectables with low profit margins may be less attractive to manufacturers, leading to limited production capacity and fewer interchangeable suppliers if one supplier experiences a failure. | **Incentive alignment**. Financial and regulatory mechanisms, such as guaranteed purchasing contracts, subsidies, or premium pricing for resilience investments could help sustain manufacturer participation. |
| **Hard-to-scale production.** Specialized or capital-intensive manufacturing processes, such as those needed for sterile injectables, can delay recovery after a disruption. | **Adaptable production.** Adaptable manufacturing lines and multi-product facilities can be repurposed quickly. |
| **Overreliance on a single manufacturer or dependence on proprietary components.** Even when other manufacturers exist, exclusive or primary sourcing contracts can leave healthcare systems dependent on one supplier. In addition, some medical products require brand-specific or patented parts that are not easily substituted. These dependencies reduce supply chain flexibility and increase the risk of cascading disruption. | **Multi-sourcing and standardization**. Using interchangeable components, engaging with multiple suppliers, and developing alternative sources can mitigate the impacts of disruptions. |
| **Inefficient inventory management.** Minimal or poorly coordinated stockpiles can lead to rapid depletion during a disruption, while overstocking can cause waste or shortages elsewhere. | **Strategic inventory management.** Right-sized buffer stock, rotation systems, and visibility into inventory across supply chains help relevant actors anticipate and appropriately respond to shortages. |

Sources: Key informant interviews; USP 2025c; Wosińska et al. 2023.

## C. Approaches and data sources for measuring criticality and vulnerability

Criticality and vulnerability are closely connected and, when measured together, can help direct and inform work to build resilience (Figure III.1). Identifying products that are critical within a particular context (such as for a specific care setting, to prepare for a public health emergency, etc.) and incorporating information about potential vulnerabilities can help reveal the products that would have the most significant impact on health outcomes if their supply chains were disrupted, and the ones that are most likely to experience disruption.

**Figure III.1.** Measuring criticality and vulnerability to inform work on resilience




Decision makers can use a variety of data, tools, and strategies to support measurement of criticality and vulnerability. For example, medical product lists help to identify critical products; mapping tools and drug shortage lists help to reveal products at risk of disruption or experiencing shortages due to vulnerabilities; and ranking systems and internal assessments help identify products that are both critical and vulnerable within organizations' specific contexts.

### 1. Critical medical product lists

Critical or essential medical product lists are common tools for understanding which products are most important to maintain during a disruption, but their scope and criteria vary widely. For example, some lists focus on inpatient acute care needs for a certain period of time (e.g., 2 weeks) or focus on care of chronic conditions, and some emphasize medical countermeasures needed for a public health emergency response. Several lists also assess reach (including the number of affected patients, spillover effects in the health system, and use of one active ingredient or raw material across multiple products) or look at the importance of a product to vulnerable populations. Table III.2 below presents a few examples of critical

medical product lists, focusing specifically on lists developed for the U.S. healthcare and public health sectors.

Some essential medicine or device lists layer on vulnerability data to identify critical products at risk of shortage or disruption (ASPR 2022; NAEMSP 2024; USP 2024; Vizient 2024). TEP participants noted the value of lists that combine criticality and vulnerability data, as well as those that do not include vulnerability data.

The latter can serve as a reference point for decision makers, whereas the former, when regularly updated to incorporate changes in data on vulnerabilities, can provide a more real-time estimate of products at risk of disruption.

**Table III.2.** Examples of critical medical product lists

| Name of list | Type of product | | Type of care (if specified) | | | Considerations for determining criticality | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Medical device | Pharma | Acute or urgent | Chronic | Pre-hospital | Reach | Clinical or public health importance | Needs of vulnerable population[a] | Lack of available and suitable alternatives |
| Essential Medicines Needed for Acute Patient Care (ASPR 2022) | | X | X | | | | X | X | X |
| Executive Order (E.O.) 13944 List of essential medicines, medical countermeasures and critical inputs (FDA 2020) | X | X | X | | | X | X | X | |
| HHS Critical Medical Device List (FDA 2023) | X | | | | | X | X | X | X |
| National Association of Emergency Medical Services= Physicians Medications for EMS and Critical Care Transport Patients (NAEMSP 2024) | | X | | | X | X | X | | X |
| USP 2024-2025 Vulnerable Medicines List (USP 2024) | | X | X | X | | X | X | | X |
| Vizient Essential Medications List (Vizient 2024) | | X | X | X | | X | X | X | X |

a. This column includes (1) lists that mentioned taking into account the needs of special patient populations as part of their criteria, and (2) lists that were specifically tailored to special populations (such as children) were included in this column.

### 2. Mapping tools and drug shortage lists

A range of publicly available tools exist to map vulnerabilities across supply chains, often incorporating advanced analytics and supplier assessments. These tools can be used to "stress test" supply chains by

estimating the likelihood of disruptions in particular regions and pinpointing products, suppliers, manufacturers, and others most likely to be affected. They can also inform mitigation strategies and help build buffers before disruptions occur. Two examples of such tools are summarized in Box III.3.

### Box III.3. Examples of tools for identifying supply chain vulnerabilities

**USP Medicine Supply Map.** An interactive analytics platform that aggregates data on pharmaceutical supply chains to highlight potential weaknesses. The map tracks where ingredients and finished drugs are made, links products to specific manufacturing sites, and incorporates regulatory and quality data. The tool supports early detection of supply risks by using machine learning to flag vulnerabilities that may lead to shortages. It also generates a vulnerability score for pharmaceuticals, which key informants noted is helpful for prioritizing resilience-building efforts (USP n.d.).

**Resilinc Disruption Vulnerabilities Index.** A commercial monitoring system that provides visibility into global supply chain threats. The index analyzes suppliers' exposure to external shocks (such as natural disasters or cyber events) and internal risk factors (such as compliance issues or operational fragility). It also produces supplier ratings, which reflect historical responses to disruption (for example, if a supplier previously had buffers in place to withstand a disruption). It helps reveal which nodes within the supply chain may be most at risk in future crises (Resilinc 2024).[4]

Reports on drug shortages and vulnerability assessment guides also support decision makers as they determine product and supplier vulnerability. For example, key informants have tracked current and historical drug shortages by using the FDA Drug Shortage website (FDA 2025c) or the American Society of Health System Pharmacists (ASHP) Drug Shortage List (ASHP 2025) to identify which pharmaceuticals were most vulnerable and to target their organizations' work on building resilience. [5]

### 3. Ranking systems and internal assessments

Ranking systems can help decision makers identify the most critical and vulnerable products in their specific contexts, enabling them to target resilience-building efforts where they will have the greatest impact. For example, the SMI Critical Product Attributes Framework (SMI 2023) outlines criteria organizations can use to rank products from "not critical" (no threat to patient safety if the product were not available) to "extremely high severity" (a threat to patient safety if the product were not available) based on their clinical importance and their vulnerability to supply chain disruptions. Similarly, the NASEM framework (2022) proposes a quantitative model to rank products with the highest likelihood of disruption and those that would cause the most severe impact on patient health if they were not available. The framework allows flexibility to incorporate contextual considerations such as preparedness and national security.

[4] Although Resilinc incorporates indicators of how well suppliers have performed during past disruptions—an aspect of resilience—we categorize it here as a vulnerability assessment tool because its primary function is to identify and monitor risk exposure across the supply chain.

[5] Organizations may use different definitions of shortages. As an example, see "FDA and ASHP Shortage Parameters" for more information about the differences between the FDA and ASHP drug shortage definitions.

Organizations may also conduct their own internal assessments, often combining internal data with existing lists or frameworks to identify priority products. For example, some use essential medicine lists in combination with purchasing and shortage-tracking data to flag sole-source drugs with a history of shortages. Several practical tools are designed to guide these assessments. The Supplier Risk Assessment Scorecard (Yang and Zelbst 2024) provides a structured, step-by-step process for determining which products should be prioritized for resilience efforts. Key steps include conducting a risk assessment, analyzing historical usage data, consulting with healthcare professionals, prioritizing based on impact and patient care, reviewing supply chain vulnerabilities, considering legal and regulatory requirements, implementing a tier system, continuously evaluating the work, and planning a variety of scenarios.

### D. Gaps in criticality and vulnerability data

A lack of standardization, transparency, and data availability are key barriers to measuring both criticality and vulnerability.

For criticality, there are no standardized, widely adopted metrics across the health care sector—likely due in part to the context-specific nature of what is considered critical. This variation can make it difficult to determine where to focus resilience-building efforts. Some organizations struggle to find critical product lists that are relevant and aligned with their needs, given that lists are often developed for different contexts. Existing lists also have notable gaps; for example, there are no published, U.S.–specific lists of medicines tailored for chronic diseases, or oncology treatment. In addition to tracking key source materials (KSMs) and APIs, it is also important to track inactive ingredients used in oral forms of medications. As described by Wosińska et al. (2023), some inactive ingredients, such as Magnesium Stearate, are used across multiple critical medications. However, only one list in the U.S., developed by the Department of Commerce (ITA 2022), includes these ingredients.

In addition, some lists include criteria such as a lack of suitable and available alternatives, which can vary based on vulnerability data, or prioritize critical products experiencing shortages. Vulnerability is a dynamic and difficult-to-measure concept, which makes it challenging to maintain accurate lists of critical and vulnerable medical products. One challenge is the difficulty of anticipating trigger events, which by nature are uncertain. A second challenge is assessing supplier vulnerabilities: even when risks are more apparent, suppliers are often reluctant to disclose internal weaknesses or threats. One respondent emphasized, "Vulnerability is the most difficult [concept] to assess and has the least amount of public data available."

## IV. Implications

This report is a foundational summary of how resilience, vulnerability, and criticality are defined and measured in the context of medical product supply chains. Definitions referenced in the report are grounded in the literature and expert input, and tailored to reflect the demands of the U.S. medical product system. Clarifying these terms—and developing meaningful ways to measure them—is essential to guiding future investments, monitoring risk, and ensuring cross-sector coordination to support resilient medical product supply chains. Recent evidence shows that medicines identified as critical remain in shortage, underscoring the need to strengthen our measurement and resilience-building efforts (Janvrin at al. 2025)

**Balancing efficiency and resilience.** A key barrier to building resilient medical product supply chains is the misalignment between resilience-oriented practices and prevailing market incentives. Current supply chain strategies—such as just-in-time inventory, lowest-cost sourcing, and lean operations—often prioritize efficiency but discourage investments in redundancy, diversification, and surge capacity. Moreover, resilience-enhancing practices typically require upfront costs but yield benefits that are systemwide and long term. Without financial or regulatory mechanisms to offset these costs manufacturers and other supply chain participants—especially those producing low-cost generics and sterile injectables— may not have the motivation or capacity to adopt them (ASPE 2024).

**Leveraging measurement to support resilience.** Measurement can help shift market dynamics by making resilience more visible and actionable. Well-designed metrics for resilience, vulnerability, and criticality can inform multiple strategies such as investment decisions, payment policies, contracting decisions, and risk mitigation strategies. For example, manufacturer- or facility-level resilience metrics could support certification or rating systems linked to procurement decisions, thus creating incentive and accountability for these players to incorporate best practices to bolster resilience (ASPE 2024, DOC 2024, U.S. Senate 2024).

However, to be effective, metrics must be fit for the purpose and tailored to the context. What to measure, how to measure it, and who is responsible will depend on the product, the actor's role in supply chains (such as manufacturer, distributor, provider), and the intended application of the metric. Key informants emphasized that metrics suitable for pharmaceuticals may not apply to medical devices or diagnostics. Without shared frameworks or guidance, efforts may be fragmented or misaligned.

**Coordinating within and across actors to advance measurement.** Developing common measurement guidelines could help promote comparability and broader adoption, but doing so will require coordination across agencies and actors to ensure alignment and accountability. Without shared governance, new tools and approaches risk being duplicative, incompatible, or unevenly applied.

The TEP emphasized the need for a whole-of-government approach to measuring resilience, with coordinated action across federal agencies to ensure that measurement strategies and resilience initiatives are aligned and mutually reinforcing. Recent federal analyses, including a 2025 GAO report on drug shortages, underscored the risks of fragmented efforts and recommended establishing sustained mechanisms for interagency coordination (GAO 2025). In this context, the federal government could play a central role in developing or endorsing shared measurement frameworks that support comparability while allowing for flexibility across use cases.

**Overcoming data challenges.** Efforts to measure supply chain resilience and vulnerability in particular face persistent barriers related to data access and trust. Much of the information needed to assess resilience and vulnerability—such as supplier relationships, production capacity, and inventory levels—is proprietary or siloed. When data exist, organizations may be reluctant to share them due to concerns about confidentiality, reputational risk, or competitive exposure. According to the TEP, without stronger norms and safeguards for data governance, efforts to develop shared metrics or tools will remain fragmented. Building trust will require clear protections for sensitive information and transparency around how data will be used.

Measurement is also technically complex and often involves highly dynamic concepts. Vulnerability, for example, is shaped by real-time shifts in supply, demand, policy, and geopolitics. Developing tools that can capture and analyze such changes in a timely manner is essential to provide decision makers with actionable information.

**Gaps and future research needs.** This study surfaced several areas where further research is needed to support effective resilience measurement and policy. First, this study identified broad tools and approaches for measuring resilience, vulnerability, and criticality. However, more work is needed to catalog the specific data sources that are currently used to inform existing tools, or that could be leveraged to inform metrics in the future. Second, findings suggest that assessing the resilience of pharmaceuticals and medical devices likely requires different strategies, but we found limited detail on how strategies should differ. Third, while our findings emphasized supply-side strategies, other literature suggests demand-side factors are also important in building resilience (Guo et al. 2025). Future research could focus on demand-side approaches—such as conservation protocols, tiered allocation frameworks, substitutions, and other provider- or patient-facing strategies—to better understand their role in maintaining access during shortages and crises. Finally, although we identified multiple definitions of criticality, vulnerability, and resilience, the available literature provided limited information on the relative strengths and weaknesses of those definitions to support the development of standards or guidelines. While key informant interviews and the TEP provided valuable insight to refine the definitions presented in this report, further work is needed to translate them into practical standards and guidelines for industry and policymakers.

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# Appendix A. Methods for the Environmental Scan

**Table A.1.** Search strategy for the environmental scan and literature review

| Search strategy | Search targets | Resources extracted |
|---|---|---|
| 1. **Website review:** Searched public- and private-sector entities' websites for definitions, tools, and frameworks in March 2025. | **Websites:** U.S. government federal agencies, international organizations, healthcare coalitions, industry associations, and healthcare supply chain organizations in the private sector<br>**Search key terms:** Medical supply chain, resilience/resiliency, criticality and vulnerable/vulnerability | **Types of definitions:** Conceptual, regulatory, industry standards<br>**Types of tools or frameworks:** Industry metrics, toolkits, badges, frameworks |
| 2. **Database search:** Performed targeted searches for peer-reviewed U.S.-centric sources in PubMed and Google Scholar in April 2025. | **Databases:** PubMed search terms yielding 78 articles in the last 10 years (January 2015-April 2025):<br>• **Resilience:** ("Medical Supply Chain" OR "Healthcare Supply Chain" OR "Pharmaceutical Supply Chain" OR "Medical Product Supply Chain" OR "Medical Device Supply Chain") AND (Resilien*)<br>• **Criticality:** ("Medical Supply Chain" OR "Healthcare Supply Chain" OR "Medical Product Supply Chain" OR "Medical Device Supply Chain") AND (Critic*)<br>PubMed search yielded 78 articles in the last 10 years.<br>• **Vulnerability:** ("Medical Supply Chain" OR "Healthcare Supply Chain" OR "Pharmaceutical Supply Chain" OR "Medical Product Supply Chain" OR "Medical Device Supply Chain") AND (Vulnerab*)<br>Google Scholar search terms yielding 40 relevant articles in the last five years:<br>• ("Medical Supply Chain resilience" OR "Medical Supply Chain Criticality" OR "Medical Supply Chain Vulnerability) | **Types of definitions:** Conceptual, research-based<br>**Types of tools or frameworks:** Measurement approaches, frameworks |

**Table A.2.** Reviewed websites for the environmental scan

| U.S. federal agencies | Website |
|---|---|
| Administration for Strategic Preparedness and Response | aspr.hhs.gov |
| Centers for Medicare & Medicaid Services | cms.gov |
| Congress | congress.gov |
| Council of Economic Advisers | whitehouse.gov/cea |
| Cybersecurity and Infrastructure Security Agency | cisa.gov |
| Executive Office of the President | whitehouse.gov/administration/eop (inactive), bidenwhitehouse.archives.gov (archived EOP) |
| Federal Emergency Management Agency | fema.gov |
| Food and Drug Administration | fda.gov |
| National Academies of Sciences, Engineering, and Medicine | nationalacademies.org |
| National Institute of Standards and Technology | nist.gov |
| Office of Management and Budget—Made in America Office | whitehouse.gov/omb |
| Office of the Director of National Intelligence | dni.gov |
| Office of the United States Trade Representative | ustr.gov |
| United States Census Bureau | census.gov |
| United States Department of Agriculture | usda.gov |
| United States Department of Commerce | commerce.gov |
| United States Department of Defense | defense.gov |
| United States Department of Energy | energy.gov |
| United States Department of Health and Human Services | hhs.gov |
| United States Department of Homeland Security | dhs.gov |
| United States Department of the Interior | doi.gov |
| United States Department of Transportation | transportation.gov |

| International organizations | Website |
|---|---|
| Directorate-General for Health and Food Safety | ec.europa.eu/health |
| European Centre for Disease Prevention and Control | ecdc.europa.eu |
| European Medicines Agency | ema.europa.eu |
| Health Emergency Preparedness and Response Authority | health.ec.europa.eu/health/agency/hero_en |
| International Federation of Pharmaceutical Manufacturers & Associations | ifpma.org |
| International Organization for Standardization | iso.org |
| International Pharmaceutical Federation | fip.org |
| International Society for Pharmaceutical Engineering | ispe.org |
| The Organization for Economic Co-operation and Development - Resilient supply chain | OECD |
| World Health Organization | who.int |

| Industry actors (associations and private sector) | Website |
|---|---|
| Advanced Medical Technology Association | advamed.org |
| Association for Accessible Medicines | accessiblemeds.org |
| Association for Health Care Resource & Materials Management | ahrmm.org |
| Biotechnology Innovation Organization | bio.org |
| Council of Supply Chain Management Professionals | cscmp.org |
| Healthcare Distribution Alliance | hda.org |
| Healthcare Industry Resilience Collaborative | hircstrong.com |
| Healthcare Supply Chain Association | supplychainassociation.org |
| International Society for Pharmaceutical Engineering | ispe.org |
| MedTech Europe | medtecheurope.org |
| National Academies of Sciences, Engineering, and Medicine | nationalacademies.org |
| National Association of Chain Drug Stores | nacds.org |
| National Association of Manufacturers | nam.org |
| Pharmaceutical Research and Manufacturers of America | phrma.org |
| Supply Chain Resource Cooperative | scm.ncsu.edu |
| U.S. Chamber of Commerce Global Supply Chain Initiative - Resilient Supply Chain | uschamber.com/security/supply-chain |
| Resilinc | resilinc.com |

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