BUILDING SUPPLY CHAIN RESILIENCE IN THE ARIZONA HEALTHCARE SYSTEM

ASU – AzCHER Study of the Needs of the Arizona Healthcare Ecosystem

June 2022

A report commissioned by the Arizona Coalition for Healthcare Emergency Response (AzCHER), administered by the Arizona Hospital and Healthcare Association.





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The Arizona Coalition for Healthcare Emergency Response (AzCHER) understands how crucial the availability of critical medical supplies and equipment are to ensure the ongoing delivery of patient care services. This has been a focus for AzCHER and its members prior to and during their response to COVID-19. As members continued to provide critical patient care during a global pandemic, AzCHER worked closely with county public health departments, hospitals, and healthcare facilities across the state to provide resources and means to access medical supplies and equipment.

AzCHER is a federally funded program administered by the Arizona Hospital and Healthcare Association (AzHHA) through a grant with the Arizona Department of Health Services. In 2016, The U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) released the 2017-2022 Health Care Preparedness and Response Capabilities guidance to describe what the healthcare delivery system, including healthcare coalitions (HCCs), hospitals, and emergency medical services (EMS), must do to effectively prepare for and respond to emergencies that impact the public's health. A part of these capabilities is the objective to Maintain Access to Non-Personnel Resources During an Emergency, including the Assessment of Supply Chain Integrity.

To achieve this objective, AzHHA engaged faculty from the W.P. Carey School of Business at Arizona State University (ASU) and the Healthcare Transformation Institute to complete the Assessment of Supply Chain Integrity for AzCHER. The team of ASU undergraduate, graduate, and doctoral students along with staff from the ASU-affiliated Healthcare Transformation Institute were led by Eugene Schneller (Professor), Jim Eckler (Adjunct Faculty), and Mikaella Polyviou (Assistant Professor), in the Department of Supply Chain Management at the W. P. Carey School of Business at Arizona State University. Together, the team surveyed members (hospitals, long-term care facilities, medical clinics, dialysis centers, and other medical care providers) of AzCHER, and interviewed medical supply manufacturers, distributors, and government agencies to determine supply chain vulnerabilities for the following categories:

- Blood
- Medical gas
- Fuel
- Pharmaceuticals and nutritional products
- Leasing entities for biomedical (e.g., monitors, ventilators, etc.) and other durable medical equipment
- Disposables supplies, including personal protective equipment (PPE)

Documented in the full report, Building Supply Chain Resilience in the Arizona Healthcare System, are clear and significant vulnerabilities along with a wide range of mitigation strategies, the capabilities required to engage in mitigation activities and the required business structure. AzHHA and AzCHER will utilize this information to coordinate effectively within the state, in collaboration with ESF-8 (Public Health and Medical Service) agencies, to develop a joint understanding and strategies to address vulnerabilities in the medical supply chain. These strategies will provide AzCHER a pathway to enhance its efforts in meeting its mission to build a more resilient healthcare system so that it is prepared to respond to and recover from a large-scale emergency or disaster.

Ann-Marie Alameddin
President and CEO
Arizona Hospital and Healthcare Association

Research Leaders

Jim Eckler, Adjunct Faculty Member
Department of Supply Chain Management
W.P. Carey School of Business
Arizona State University
jim.eckler@hscxi.com

Eugene Schneller, Professor
Department of Supply Chain Management
W.P. Carey School of Business
Arizona State University
gene.schneller@asu.edu

Mikaella Polyviou, Assistant Professor
Department of Supply Chain Management
W.P. Carey School of Business
Arizona State University
mikaella.polyviou@asu.edu

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This report was prepared for the Arizona Coalition for Healthcare Emergency Response through the sponsorship of the U.S. Department of Health and Human Services (HHS). The work was conducted by faculty of the Department of Supply Chain Management in the W.P. Carey School of Business at Arizona State University (ASU). Supporting the work were undergraduate, graduate, and doctoral students at ASU together with staff from the ASU-affiliated Healthcare Transformation Institute (HTI) and Healthcare Supply Chain eXcellence. Names of the study investigators are listed in Appendix B.

We thank the ASU and HTI teams for their excellent contributions to the work. We also thank the AzCHER leadership (Robin Oothoudt, Shawna Murphy, and others) for their insights and their support in conducting the research. We also thank the AzCHER provider members and the executives from manufacturers/suppliers, distributors, group purchasing organizations, and government for participating in the research and sharing their insights. Without their insights, this work would not be possible.

Many subject matter experts, from provider, supplier, distributor, group purchasing, and government organizations contributed to this effort. In an industry that is characterized by highly competitive organizations, we generally experienced great openness and transparency. They responded to our inquiries regarding products, experiences in meeting their mission during the first two years of COVID, their vulnerabilities, and their resilience strategies. We are grateful for their commitment to engage in hour-long interviews, openness, willingness to share information, and concern for their organizations, their sectors of the healthcare industry, and, perhaps most important, their commitment to assuring a sustainable healthcare delivery system. Adhering to our promise of anonymity during interviews, we have not listed the names of the organizations interviewed. We hope that this report will provide all with insights that will help them to build their own resiliency and preparedness and develop ongoing efforts to assure the public that, in a future disruption, there is a high level of preparedness to provide care to patients and the public.

Finally, we congratulate AzCHER for its foresight and commitment to this effort. During the investigation, we sought to identify similar efforts across the country to examine supply chain disruption impacts on the healthcare system and to develop mitigation solutions. We did not find any other initiative of this type. The Arizona research, while of direct value to the state's healthcare system, applies to every other state in the country. We hope that this work provides value to all.

EXECUTIVE SUMMARY

This report, and the research that underpins it, was prepared to familiarize the Arizona healthcare community with the need for resilient supply chains and to propose solutions for the design and sustenance of a <u>resilient</u> and <u>prepared</u> supply chain. It provides both a framework for understanding the supply chain challenges and guidance for managing them. The report focuses on the perspectives of Arizona providers of care but also considers other key stakeholders: manufacturers/suppliers, distributors, group purchasing organizations (GPOs), and governments. While the focus in this study was on Arizona providers and suppliers, most of the findings, conclusions, and recommendations are applicable to providers in other parts of the U.S.

During the recent COVID-19 pandemic and other abnormal events, the supply chain for critical healthcare products was disrupted, causing healthcare providers to modify their standards of practice. Increasingly we are incurring more frequent and significant disruptions that have a deleterious effect on patients and healthcare workers. These disruptions make the systems and their services vulnerable to failure. Due to the highly fragmented structure of the U.S. healthcare system, many providers learn too late about the problems and have insufficient time to properly adjust to the situation.

The research was focused on disruptions characterized by uncertainty in their depth and breadth of impact and uncertainty regarding the pattern of recovery and, perhaps of most importance, high levels of uncertainty regarding reoccurrence. It focuses on preparation for the "long game." Thus, the report focus is different from other efforts to mitigate and respond to disruptions of relatively short duration, such as hurricanes and fires.

Remarkably we found that virtually no provider organization and few suppliers have the term "preparedness" within their mission statement or in their budget to support preparedness. Consequently, our documentation of the many mitigation strategies we identify is accompanied by a concern for the "stickiness" of such strategies. With uncertainty for what some describe as "black swan" events, it is easy to revert to old ways of working.

Further, much discussed in the early days of COVID-19 was criticism of the focus on managerial practices (especially lean and just-in-time), a delivery system inordinately focused on price, and a dwindling redundancy due to a drive for sole sourcing. These are important managerial strategies that will likely be continued but require to be practiced alongside strategies that are more aligned with the "long game." Also considered has been the observation of the dependency of the medical product supply chain on manufacturing from across the globe. Over half of protective garments, respirators, surgical masks, and medical garments are imported from China.¹ An extensive assessment of the uncertainties surrounding PPE and supply issues in the U.S. environment reveals overlapping entities and multiple networks. In many cases, these were rivals, resulting in the absence of cohesive leadership, agile strategies, and visibility into product availability. While such dependencies cannot be fully eliminated, strategies to buffer against such dependencies are quickly evolving.

A. RESEARCH GOALS

The report provides both a framework for understanding the supply chain challenges and guidance for managing them. In our research we:

¹ Bradsher, K. (2020). China Dominates Medical Supplies, in This Outbreak and the Next. *The New York Times* (May 5. 2020). URL: https://www.nytimes.com/2020/07/05/business/china-medical-supplies.html

- Assessed the major disruptions experienced by providers of care and the need for greater resiliency within the full ecosystem of providers of health care services within Arizona
- Documented and assessed the mitigation strategies undertaken by providers of care, their suppliers, and government
- Put forth a framework to understand the nature of the disruptions
- Outlined a set of steps that leads to a roadmap for the healthcare community to apply to improve their resilience to disruptions. We also provide suggestions for moving forward.
- Identified capabilities that healthcare providers should develop to ensure appropriate preparation for and response to emergencies, such as the COVID-19 pandemic, and a quick recovery from them.

Succinctly this work addresses supply chain resilience and preparedness needs for healthcare providers to meet long-term disruptions in the supply chain — to what we refer as the "long game."

B. METHODOLOGY

The report draws on a (1) survey of AzCHER members to assess their vulnerabilities, principal suppliers, likely triggers and disruptions, and actions impacting product shortages, management, and patient care, (2) interviews with over 75 suppliers, GPOs, distributors, and other key stakeholders, (3) reviews of literature both academic and grey, and (4) advice from an expert panel for both the supplier and provider communities. Over 600 observations were documented, focusing on both vulnerabilities and mitigation strategies.

This report considers a specific set of categories of supplies that may impact the capability of a healthcare provider to respond to long-term disasters, including (1) pharmaceuticals and nutritional products, (2) disposable supplies, including PPE, (3) Medical gases (4) Blood banks, (5) Leasing entities for biomedical (e.g., monitors, ventilators) and other durable medical equipment and beds, (6) Hazardous waste removal services, and (7) Fuel. The full report contains an extensive analysis of each of these categories. Of note is the extent to which both the pharmaceuticals and disposable medical device categories were impacted in terms of product availability, quality, cost, and management.

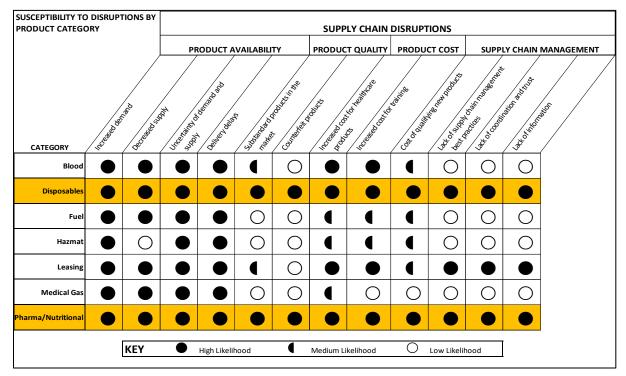
C. SUPPLY CHAIN VULNERABILITIES

Vulnerability is the susceptibility of exposed assets to damage or impact from a trigger action causing a disruption. It is a function of the physical, social, economic, and environmental factors or processes that make a system susceptible to disruptions² and relates to deficiencies, weaknesses, or lack of capabilities that allow the adverse effects of a trigger to influence these assets.³ In this report, we focus on supply chain vulnerabilities that lead to disruptions to the healthcare system. Exhibit 1 below identifies the key 12 supply chain disruptions that we identified impacting the studied product categories as they relate to product availability, quality, cost, and supply chain management. The rating indicates susceptibility to disruption. We found that two product categories (disposables and pharma/nutritional products) are more susceptible to supply chain disruptions than others. Consequently, more attention to these products is warranted.

² United Nations Office for Disaster Risk Prevention. (2022). *Understanding Disaster Risk*. URL: https://www.preventionweb.net/understanding-disaster-risk.

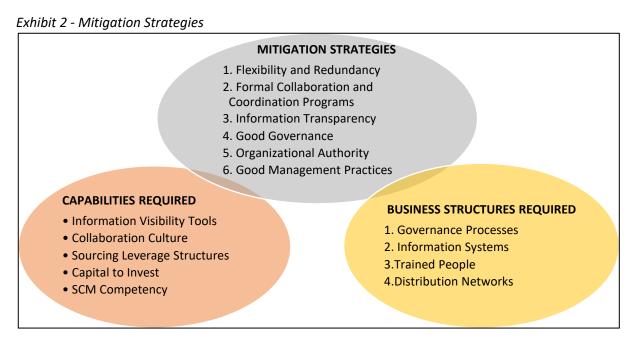
³ Ibid.

Exhibit 1 - Susceptibility to Disruptions by Product Category



D. MITIGATION OF VULNERABILITIES

Considered in the full report are a wide range of mitigation strategies, the capabilities required to engage in mitigation activities, and the business structures required. Such strategies are being carefully considered by the full range of organizations across the healthcare ecosystem, as reflected in Exhibit 2. Not all healthcare organizations across the ecosystem are incorporating these mitigation strategies in their business practices. To mitigate against future supply chain disruptions, they need to adopt these practices and develop the recommended capabilities.



Together, these strategies are designed to manage risk and disruption and shift from traditional risk management to a "manage for resilience practice." This involves:

- anticipating and preparing for disruptions,
- restoring operations after a disruption,
- adapting to transform operations in response to disruptions,
- ensuring the continuity of operations and service to customers.⁵

In the report, we describe each of the strategies, capabilities needed, and structures in greater detail.

E. THE ROLE OF A HEALTH CARE COALITION

The Office of the Assistant Secretary for Preparedness and Response (ASPR) of the U.S. Department of Health & Human Services established Health Care Coalitions (HCC) across the country to develop capabilities for response to health emergencies. An important and articulated role for an HCC is to examine its supply chain and, as part of its HCC role, to develop and coordinate⁶ a Health Care Coalition Response Plan that is aware of each individual member's resources and responsibilities.⁷ Indeed, it is envisioned that an HCC has the ability to collaborate with stakeholders to develop a joint understanding and strategy. This includes:

- Mitigating strategies associated with vendor-and/or distributor-managed inventory stockpiles
- Establishing secondary vendors
- Developing "push" or pre-event disaster supply procedures and triggers for activation.8

AzCHER, as the Arizona HCC, has begun this role through a strong commitment to understanding and acting on supply chain management issues. We believe that even more can be done. HCCs can play one or more of four roles ranging from convenors to advisors to coordinators and operators for preparedness and response.

In Appendix A, we present four areas of focus for an enhanced HCC role in the area of supply preparedness including:

- 1. Information competencies and capabilities.
- 2. Enhanced partnerships.
- 3. Training for preparedness.
- 4. Development of a common pool resource organization.

We believe that HCCs can develop these important capabilities.

F. IMMEDIATE NEXT STEPS

In accordance with the expanded role for an HCC and supplementing the ASPR guidelines, we have proffered strategies for enhancing an HCC's role in the supply chain for emergency preparedness efforts beyond their typical role as a convenor and advisor. We believe that HCCs can take on a more

⁴ Fiksel, J., Polyviou, M., Croxton, K. L., & Pettit, T. J. (2015). From Risk to Resilience: Learning to Deal with Disruption. *MIT Sloan Management Review* 56(2), 79–86.

⁵ Wieland, A., & Durach, C. F. (2021). Two Perspectives on Supply Chain Resilience. *Journal of Business Logistics*, 42(3), 315-322.

⁶ Ibid., p. 25

⁷ Ibid., p. 27

⁸ Ibid., p.34

coordinative, facilitative, and operational role. This expanded role is described in more detail in Appendix A to this report.

It is our hope that this report will help advance AzCHER, in its quest to support preparedness to reduce the impact of coming disruptions. Details of this are fully described and explored in the following pages of this report.

I. INTRODUCTION

A. THE PROBLEM DEFINED

During the years of the COVID-19 pandemic, the U.S. healthcare supply chain has experienced extraordinary challenges in meeting the needs for patient care, healthcare workforce protection, and the public. This report was prepared to familiarize the Arizona healthcare community with the need for resilient supply chains and proposed solutions to design and sustain a resilient and prepared supply chain for forthcoming disruptions, especially disruptions of great magnitude. It provides both a framework for understanding the supply chain challenges and guidance for managing them. The report focuses on the perspectives of Arizona providers of care but also considers other key stakeholders: manufacturers/suppliers, distributors, group purchasing organizations (GPOs), and governments. Specifically, this work addresses supply chain resilience and preparedness needs for healthcare providers to meet long-term disruptions in the supply chain – to what we refer as the "long game." While the focus in this study was on Arizona providers and suppliers, most of the findings, conclusions, and recommendations are applicable to providers in other parts of the U.S.

During the recent COVID-19 pandemic and other abnormal events, the supply chain for critical healthcare products was disrupted, causing healthcare providers to modify their standards of practice. Often these modifications have had a minor impact on the delivery of care or patient outcomes. However, increasingly we are incurring more frequent and significant disruptions that have a deleterious effect on patients and healthcare workers. These disruptions make the systems and their services vulnerable to failure. Due to the highly fragmented structure of the U.S. healthcare system, many providers learn too late about the problems and have insufficient time to properly adjust to the situation.

Writing about the importance of preparedness for preventing the next pandemic, Bill Gates reflected on our need for strategies for test and vaccine development that are both clear and rigorous, much like the military focus on preparedness for events that threaten national security. Needed, he posits, are better tools, an organized team, improved surveillance, and a strengthened health system. Preparedness for future supply chain disruptions will require such clarity and commitment. Also needed will be tools, especially those that will provide transparency and visibility into the supply chain during such events. Without such tools, surveillance for supply chain integrity and the need for impact mitigating adjustments and innovation will not be possible.

Fortunately, the impacts created by these disruptions can be avoided. There are steps that can be taken to reduce or eliminate the negative impacts of these disruptions. In this report, we build a framework to understand the types and nature of the disruptions. Then we outline a set of steps that will lead to a roadmap that the healthcare community can apply to improve their resilience to disruptions. We also provide suggestions for moving forward.

1) THE FOCUS ON SUPPLY CHAIN MANAGEMENT

In the healthcare sector, supply chain management is the business process of integrating products, processes, and organizations, including the coordination of goods, data, and investments to deliver needed goods and value to the customer that will assure positive clinical outcomes and cost control. The goal of a supply chain is to synchronize the requirements of the customer with the flow of materials from suppliers in order to achieve a balance between what

⁹ Gates, B. (2022). How to Prevent the Next Pandemic. Alfred A Knopf.

are often seen as conflicting goals of high customer service, low unit cost, and lean inventory management. Simply stated, as often cited by supply chain professionals, good supply chain management should get the right goods from the right sources to the right place at the right time and at the right cost.

In the public health arena, the U.S. Department of Health & Human Services (HHS) states that:

The public health supply chain systems produce and deliver medical supplies to support the healthcare and public health sector and includes both domestic and international suppliers and manufacturers. It provides PPE, DME, diagnostics, other medical devices, and pharmaceuticals (therapeutics and vaccines) to the American people. The public health supply chain and industrial base are primarily within the purview of the private sector.¹⁰

This report focuses on a specific set of categories of supplies identified by HHS and the Arizona Coalition for Healthcare Emergency Response (AzCHER) that are key to pandemic preparedness. Specifically, we address challenges and paths to resilience associated with the supply of seven distinct product categories:

- Pharmaceuticals and nutritional products
- Disposable supplies, including PPE
- Medical gases
- Blood banks
- Leasing entities for biomedical (e.g., monitors, ventilators) and other durable medical equipment and beds
- Hazardous waste removal services
- Fuel

These categories represent many supplies that may impact the capability of a healthcare provider to respond to long-term disasters (e.g., increased demand for ventilators). As discussed in the subsequent method section, we gathered information from AzCHER members to determine their vulnerability to supply chain disruptions and, in conjunction with suppliers, providers, and other stakeholders, developed proposed mitigation strategies to address these vulnerabilities.

2) THE NEED FOR STICKINESS

Supply chain disruptions that impact healthcare delivery are not new. They have been and continue to be a perennial condition facing clinicians and administrators. Despite frequent warnings and actual disruptions, management for preparedness for major disruptions has not been "top of mind" for many healthcare organizations. And for disruptions that have longevity, in many respects, management for such occasions has not even been a thought. It is easy to forget about preparedness when organizations return to business as usual.

For example, when the COVID-19 pandemic occurred, preparedness for a disruption of this magnitude was not present. The larger healthcare organizations had some plans, but even they were insufficient. The challenge for healthcare system leaders is to develop this preparedness capacity and keep it top of mind. We call this "stickiness."

Only two years before the COVID-19 pandemic hit, the healthcare community had faced a different disruptive event with similar long-term consequences. Hurricane Maria hit Puerto Rico

¹⁰ Department of Health and Human Services. (2022). *One-Year Report in Response to Executive Order 14017* (February 2022). URL: https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx

in September 2017. Puerto Rico was home to over 70 healthcare supply manufacturers, including manufacturers of needed intravenous solutions. Following the hurricane, recovery for some of these manufacturers was slow and, in the absence of redundancy in manufacturing sites, impactful for months on surgical procedures in U.S. hospitals. Yet, only two years later, the learnings from this disruption were insufficient to lead to widespread scrutiny, mitigation, and action by healthcare industry stakeholders when the COVID-19 pandemic emerged in late 2019. This approach reflects a lack of stickiness. Such disruptions, especially those occurring globally, can impact the delivery of care to our population. For healthcare systems to maintain resilience, they need an ongoing commitment to preparedness and stickiness.

Much discussed in the early days of COVID-19 was a focus on managerial practices (especially lean and just-in-time), a delivery system inordinately focused on price, and a dwindling redundancy due to a drive for sole sourcing. These are important and managerial strategies that will likely be continued but require to be practiced alongside strategies that are more aligned with the "long game." Also considered has been the observation of the dependency of the medical product supply chain on manufacturing from across the globe. Over half of protective garments, respirators and surgical masks, and medical garments are imported from China.¹¹ An extensive assessment of the uncertainties surrounding PPE and supply issues in the U.S. environment reveals overlapping entities and multiple networks. In many cases, these were rivals, resulting in the absence of strong leadership, agile strategies, and visibility into product availability. While such dependencies cannot be fully eliminated, strategies to buffer against such dependencies are quickly evolving.

The global COVID-19 pandemic caused the healthcare ecosystem to wake up to these issues. The supply chain disruptions that occurred due to the pandemic emphasized, more powerfully than any other recent event, that we need to sustainably manage the vulnerabilities caused by supply chain disruptions. With that in mind, AzCHER has encouraged that investigation into this perennial problem. This report is the beginning of that effort on behalf of the healthcare providers in Arizona.

The components of response and mitigation of vulnerabilities we outline in this report are the components of a roadmap to build stickiness for long-term solutions. For the healthcare community, it will require commitment and a change in outlook for that to occur.

3) THE NEED TO FOCUS ON THE LONG GAME

It is noteworthy that the words "resilience" and "preparedness" are largely absent from the mission statements of most providers of care, their supply chain departments, and their suppliers. Preparedness, however, is not a new problem for the healthcare provider system or the organizations that comprise what we will describe later in this report as the healthcare supply chain ecosystem. Hospitals always stand ready to meet the demands of illness as it occurs and to meet extraordinary demand in times of emergencies such as hurricanes, school bus crashes, and demand due to multiple sets of twins' deliveries. While these are not regular events, they are relatively short. Most healthcare organizations are designed and equipped to meet the needs of these short-duration events, but they are less prepared when a long-duration event occurs.

¹¹ Bradsher, K. (2020). China Dominates Medical Supplies in This Outbreak and the Next. *The New York Times* (May 5. 2020). URI: https://www.nytimes.com/2020/07/05/business/china-medical-supplies.html.

¹² The Defense Health Agency of the Department of Defense is one of the only healthcare systems which has explicitly added preparedness to its mission statement.

Emergency services by first responders are by definition designed to meet the challenges associated with events of relatively short duration. Despite this, full-time permanent fire departments exist solely to meet the needs for community emergencies and disruptions — both short and increasingly for long durations. A similar entity does not exist in the healthcare system. When a long-duration disruption occurs, there is no effective backstop.

While manufacturers/suppliers and distributors of medical products recognize that disruptions occur — and in the past have worked to have in place sourcing and contracting strategies to secure products for their customers — they alone were unable to meet the demand levels created during the COVID-19 pandemic. Consequently, in response to the pandemic, the need to manage preparedness has recently become top of mind for entities across the supply chain. Some states have mandated requirements for pools of inventory to be held by providers of care. Governments have engaged suppliers to increase their own inventories. The extent to which these efforts will be successful and/or sustained remains uncertain.

To manage future short- and long-duration disruptions, the healthcare system must establish a form similar to that of a fire department. This form could be a standalone organization or a coalition of providers positioned to stand up an operational entity to support emergency supply chain needs. That would require a view and a commitment to the long game. Proactively investing in supply chain resilience will improve performance and outcomes in times of disruption. Managers, however, may be reluctant to make the necessary commitments. What is needed is the development of a business case for such investment and actionable strategies that integrate preparedness and resilience¹³ with other organizational processes and systems.

B. SUPPLY CHAIN MANAGEMENT IN THE HEALTHCARE SYSTEM

In recent years, the media has regularly mentioned the "supply chain" when discussing the healthcare delivery system problems. But what is a "supply chain," and how does it affect our healthcare system? Simply stated, a supply chain comprises all parties related to a commercial transaction that involves the purchase and sale of goods or services (e.g., raw material suppliers, manufacturers, transportation providers, warehouses, distributors, retailers, and customers) and, within each of these organizations, all the functions directly or indirectly involved in fulfilling a customer request. Supply chain management involves managing the relationships across these parties to source and secure products or services effectively and efficiently. It requires the engagement and collaboration amongst these parties, the financial resources to assure the sustainability of these relationships, a strong focus on product quality to meet specifications and satisfy end-users, and information needed to reduce risk by monitoring and assessing the environment in which supplies are secured.

While supply chains exist in every industry, healthcare supply chains are, due to the importance of products used with a wide range of patient characteristics, uniquely complex and mission-critical. Healthcare operates in a highly complex supply chain ecosystem. We define the healthcare supply chain ecosystem as a group of interacting organizations and institutions that impact the healthcare

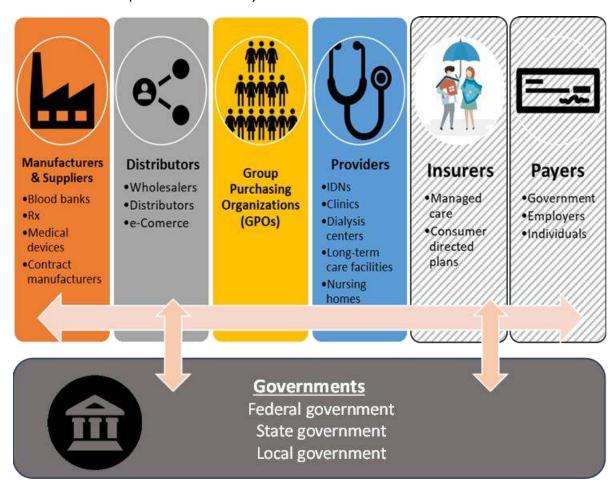
¹³ Throughout this report we refer to resilience and preparedness. Resilience is the ability to anticipate and prepare, recover, and transform from disruptions. Resilience is evaluated based on the three phases of a disruption: (A) anticipation and preparedness (pro- active, before an event), (B) response (during an event), and (C) recovery and adaptation to the new normal (re-active, after an event) (Pettit et al. 2010). Preparedness is the state of being ready to act.

¹⁴ Chopra, S., & Meindl, P. (2001). Strategy, Planning, and Operation. *Supply Chain Management*, 13-17.

¹⁵ Lambert, D. M. (2008). *Supply Chain Management: Processes, Partnerships, Performance*. Supply Chain Management Institute, Sarasota, FL.

provider's ability to source supplies and provide effective care. Essentially, this ecosystem represents the supply chain environment to which a healthcare provider must monitor and react. It includes manufacturers/suppliers, distributors, purchasing intermediaries, such as GPOs, and providers of care, which operate relatively independently, as detailed in Exhibit 3.¹⁶ It is noteworthy that there are relatively few points where these organizations interface and that, in many ways, they only interface in a highly competitive commercial environment. Further, unlike other industries, the distributors and GPOs act primarily as buffers between those who supply goods and those who actually purchase. Thus, in times of stress in the system, providers have relatively few strong relationships, especially upstream to manufacturers and suppliers. Finally, and worthy of mention, is the relative distance between those who actually pay for services (i.e., government and insurance) and the other supply chain stakeholders.

Exhibit 3 – The Complex Healthcare Ecosystem



In this next section, we provide an overview of the healthcare supply chain and introduce the reader to fundamental aspects of supply chain risk management and resilience.

¹⁶ Adapted from: Burns, L. R. (Eds.). (2012). The Business of Healthcare Innovation. Cambridge University Press.

1) OVERVIEW OF HEALTHCARE SUPPLY CHAIN MANAGEMENT

In many ways, the healthcare sector shares many supply features with other industry sectors – such as an increased concern with supply costs, quality of products, and increased dependency on global markets. Similarly, the health sector has adopted supply chain strategies, such as lean, just-in-time product access, and global sourcing to reduce costs. In many ways, the manufacturing of healthcare goods adheres to the manufacturing practices and risks displayed by other industries. However, the health sector is unique, leading some to invoke the idea of supply chain "exceptionalism" due to several factors:¹⁷

- Provider organization diversity,
- Mission surrounding patient care,
- Supply chain intermediation in the use of GPOs, distributors, and the role of external payers,
- The significant range and criticality of products,
- Physician involvement in supply selection,
- The level of customization of services provided to patients,
- The degree of participation of those who consume products as a "partner"
- Payment by third-party agents
- A high level of regulation.

For these reasons, the provider sector of health is often cited as one of the most resource-dependent sectors in our economy – making little of what goes into the production of care. ¹⁸ The management of healthcare supply chains, however, is a pivotal function for organizational sustainability and service to the healthcare workforce and patients. Without adequate supplies, life-sustaining surgical and emergency procedures cannot be performed, patient and clinician safety is compromised, and income for organizations, professionals, and others involved in the care process is jeopardized. Moreover, in recent years, healthcare supply chains have been subjected to significant supply chain disruptions due to a range of external causes, including environmental, political, and man-made. Due to these disruptions, the ability of healthcare systems to deliver care appropriately has suffered. With the COVID-19 pandemic, we have recently seen these disruptions skyrocket.

In this report, we scrutinize the causes of these supply chain disruptions and the need for greater resiliency within the full ecosystem of providers of healthcare services within Arizona. This review is not only about the recent COVID-19 pandemic issues but about supply chain disruptions in general. Selected product categories, originally defined by the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) as critical in emergencies, were explicitly examined, under contract with AzCHER, concerning their contributions to the health sector market, healthcare delivery vulnerabilities, and strategies to mitigate and improve resilience.

2) INTRODUCTION TO SUPPLY CHAIN RISK MANAGEMENT

Supply chains have become more global and, as a result, more complex, creating blind spots for supply chain managers and increasing the exposure of organizations to numerous events occurring worldwide that can disrupt normal operations. Over recent years, this exposure has become apparent as various natural or man-made events disrupted supply chains and adversely

¹⁷ Abdulsalam, Y., Gopalakrishnan, M., Maltz, A., & Schneller, E. (2015). Healthcare Matters: Supply Chains in and of the Health Sector. *Journal of Business Logistics*, 36(4), 335-339.

¹⁸ Ibid.

affected organizations and their stakeholders. Indeed, events disrupting supply chains have become more frequent and have had adverse financial consequences.¹⁹ For example, when Hurricane Katrina hit Louisiana in 2005, it shut down crude oil and natural gas production in the Gulf of Mexico. Likewise, when the aforementioned Hurricane Maria hit Puerto Rico in 2017, it disrupted the production of intravenous bags and resulted in a severe shortage in the mainland U.S. More recently, the COVID-19 pandemic exposed the dependency of countries and organizations, such as healthcare providers, on Asian suppliers and manufacturers of masks, gowns, other protective equipment, and pharmaceuticals. Finally, the semiconductor shortage has threatened the production of critical medical devices. As a result, the importance and consequences of not managing supply chain risks and not improving the resilience of global healthcare supply chains have become clear to nations, public and private enterprises, and consumers.²⁰

Below, we define some key terms that we will use throughout the report and that are essential in the areas of supply chain risk management and resilience.

i) Definitions

TRIGGER OR HAZARD – A trigger or hazard is a natural or man-made event that can adversely affect the normal flow of materials, services, information, and financial assets in a supply chain. Triggers directly affect buildings, infrastructure, other assets, people, or commodities and are evaluated based on (a) their source, (b) their frequency or probability of occurrence, and (c) their magnitude or severity of impact.²¹ Exhibit 4 presents examples of triggers that can disrupt supply chains.

¹⁹ Resilinc (2019, 2020). *The Road to Supply Chain Resiliency*. URL: https://www.resilinc.com/learning-center/white-papers-reports/resilinc-annual-report-2019-2020/

²⁰ Office of the Assistant Secretary for Preparedness and Response. (2022). URL: https://aspr.hhs.gov/newsroom/Pages/SupplyChain-9Mar2022.aspx.

²¹ FEMA. Introduction to Hazard Mitigation. URL: https://training.fema.gov/emiweb/is/is393a/is393.a-lesson3.pdf.

Exhibit 4 – Examples of Triggers (Or Hazards) That Can Disrupt Supply Chains²²

Natural Disasters	Accidents	Deliberate Attacks	Government Compliance and Political Uncertainty	Financial Viability
 Epidemics Earthquakes Tsunamis Volcanoes Weather disasters (hurricanes, tornados, storms, blizzards, 	 Fires Explosions Structural failures Hazardous spills 	 Computer attacks Product tampering Intellectual theft Physical theft Bombings Biological and chemical 	 War Political unrest Boycotts Tariffs and other export regulations 	BankruptcyWithdrawal from the market
floods, droughts)		weapons • Blockades		

EXPOSURE – Exposure assesses what is at risk from the occurrence of the trigger, including buildings, infrastructure, other assets, people, or commodities.²³ Exposure is evaluated based on the attributes and location of each of these elements that are at risk. For example, healthcare providers in Arizona are exposed to wildfires due to facilities in areas of the state prone to wildfires. Importantly, however, exposure is a necessary but not a sufficient determinant of risk.²⁴ For example, healthcare providers may have sufficient means and have taken sufficient measures to protect their physical and human assets from wildfires.²⁵

VULNERABILITY – The susceptibility of the exposed assets to damage or impact from a trigger. Vulnerability is a function of the physical, social, economic, and environmental factors or processes that make a system susceptible to disruptions.²⁶ It relates to deficiencies, weaknesses, or lack of capabilities that allow the adverse effects of a trigger to influence these assets.²⁷ Examples of inherent vulnerabilities in supply chains are:²⁸

²² Supply Chain Risk Leadership Council. (2011). Supply Chain Risk Management Practices.

²³ United Nations Office for Disaster Risk Prevention. (2022). *Understanding Disaster Risk*. URL: https://www.preventionweb.net/understanding-disaster-risk.

²⁴ Cardona, O. D., van Aalst, M. K., Birkmann, J., Fordham, M., McGregor, G., Perez, R., Pulwarty, R. S., Schipper, E. L. F., & Sinh, B. T. (2012): *Determinants of Risk: Exposure and Vulnerability*. In: Managing the Risks of Extreme Events and Disasters to Advance Climate Change Adaptation [Field, C.B., Barros, V., Stocker, T. F., Qin, D., Dokken, D. J., Ebi, K. L., Mastrandrea, M. D., Mach, K.J., Plattner, G-. K., Allen, S. K., Tignor, M., & Midgley, P. M. (Eds.)]. A Special Report of Working Groups I and II of the Intergovernmental Panel on Climate Change (IPCC). Cambridge University Press, Cambridge, UK, and New York, NY, USA, 65-108.

²⁵ FEMA. *Introduction to Hazard Mitigation*. URL: https://training.fema.gov/emiweb/is/is393a/is393.a-lesson3.pdf.

²⁶ United Nations Office for Disaster Risk Prevention. (2022). *Understanding Disaster Risk*. URL: https://www.preventionweb.net/understanding-disaster-risk.

²⁷ United Nations Office for Disaster Risk Prevention. (2022). *Understanding Disaster Risk*. URL: https://www.preventionweb.net/understanding-disaster-risk.

²⁸ Pettit, T. J., Fiksel, J., & Croxton, K. L. (2010). Ensuring Supply Chain Resilience: Development of a Conceptual Framework. *Journal of Business Logistics*, 31(1), 1-21; Pettit, T. J., Croxton, K. L., & Fiksel, J. (2013). Ensuring Supply Chain Resilience: Development and Implementation of an Assessment Tool. *Journal of Business Logistics*, 34(1), 46-76.

- Availability of raw materials
- Availability of natural resources
- Restricted materials
- Fragility of handling
- scale of the supply chain network
- degree of outsourcing
- Reliance on specialty sources

RISK – The combination of triggers (or hazards), exposure (i.e., what elements are at risk), and vulnerability (i.e., how each exposed element responds to the level of hazard).²⁹

SUPPLY CHAIN DISRUPTION – The manifestation of a risk, which results in some interruption in the flow of materials, services, information, or financial assets from a seller to a customer or a customer to a seller.³⁰

ii) Risk Mitigation and Resilience

The traditional approach to mitigating supply chain risks follows the process of identifying risks, assessing risks, managing the most important risks as determined by the organization, and monitoring risks.³¹ While this approach can help organizations reduce the likelihood or the severity of a specific event disrupting supply chain operations, it also has some limitations, as listed below:³²

- It relies heavily on risk identification. In complex supply chains, there are triggers that an organization cannot anticipate. These are highly unlikely events with severe consequences, regarded as "black swans." They may also be inconceivable by management, regarded as "unknown-unknowns."
- It relies on accurate risk assessment, which can often be difficult due to the unavailability of good data and subjectivity in the data.
- It focuses on strategies that manage specific risks, overlooking how risks might inter-relate or how complexities in the supply chain might create "hidden" risks.
- It focuses on returning a supply chain to normal operations, as risks represent possible deviations from this "normal" state. Nonetheless, once a disruption occurs, the organization or supply chain might need to adapt to the new normal and change how they have been conducting business.

Organizations, therefore, need to shift from this traditional risk management approach to a resilience approach in managing and responding to supply chain disruptions.³⁵

²⁹ United Nations Office for Disaster Risk Prevention. (2022). *Understanding Disaster Risk*. URL: https://www.preventionweb.net/understanding-disaster-risk.

³⁰ Polyviou, M., Rungtusanatham, M. J., Reczek, R. W., & Knemeyer, A. M. (2018). Supplier Non-Retention Post Disruption: What Role does Anger Play? *Journal of Operations Management*, 61, 1-14.

³¹ Zsidisin, G. A., & Ellram, L. M. (2003). An Agency Theory Investigation of Supply Risk Management. *Journal of Supply Chain Management*, 39(2), 15-27.

³² Fiksel, J., Polyviou, M., Croxton, K.L., & Pettit, T.J. (2015). From Risk to Resilience: Learning to Deal with Disruption. *Sloan Management Review* 56(2), 79–86.

³³ Taleb, N. N. (2007). The Black Swan: The Impact of the Highly Improbable (Vol. 2). Random House.

³⁴ Ramasesh, R. V., & Browning, T. R. (2014). A Conceptual Framework for Tackling Knowable Unknown Unknowns in Project Management. *Journal of Operations Management*, 32(4), 190-204.

³⁵ Fiksel, J., Polyviou, M., Croxton, K. L., & Pettit, T. J. (2015). From Risk to Resilience: Learning to Deal with Disruption. *MIT Sloan Management Review* 56(2), 79–86.

<u>Resilience</u> is the ability of organizations (and systems, more generally) to anticipate and prepare for disruptions, restore their operations after a disruption, and adapt and transform their operations in response to disruptions to ensure continuity of operations and service to their customers.³⁶ Hence, resilience has a proactive component, reflecting an organization's ability to resist disruptions. Here, the capabilities of anticipation of future disruptions and preparedness for them are key. Resilience also comprises a reactive component, which reflects an organization's ability to recover from disruptions. Agility and adaptation are key capabilities that facilitate this component.

iii) Strategies that Enhance Supply Chain Resilience

The literature has identified numerous *capabilities* organizations can develop to anticipate and overcome supply chain disruptions, as summarized below:^{37,38,39,40}

- Sourcing flexibility: multiple suppliers; finding the optimal mix of domestic and international sourcing; flexible contracts with suppliers
- Manufacturing flexibility: insourcing, outsourcing, offshoring, and nearshoring; production scalability; postponement
- Distribution and transportation flexibility: multiple carriers or distributors; flexible transportation network; alternative distribution modes
- Product flexibility: standardization of parts; product substitution lists
- Redundancy: buffer stock; extra assets, capacity, equipment, and workforce
- Collaboration: collaborative forecasting; resource-sharing or risk-sharing with trading partners; communication with trading partners
- Visibility: information technology; market intelligence into supply chain risks; inventory tracking and visibility systems; shipment visibility systems; consumption visibility systems; supply chain mapping tools that allow a visual representation of the supply chain network, including several tiers upstream and downstream
- Anticipation: demand forecasting; monitoring of early warning signals; business continuity plans; contingency plans
- Recovery: quick mobilization of assets and people; crisis management; communication strategy
- Efficiency: asset utilization; quality management; process standardization; preventive maintenance

iv) Balancing Vulnerabilities and Capabilities for Resilience

Excessive vulnerabilities relative to capabilities result in higher exposure to risk; therefore, organizations need to improve their capabilities. Conversely, excessive investments in capabilities relative to vulnerabilities can erode profitability and service quality. Therefore, organizations must balance their vulnerabilities and capabilities to ensure

³⁶ Wieland, A., & Durach, C. F. (2021). Two Perspectives on Supply Chain Resilience. Journal of Business Logistics, 42(3), 315-322.

³⁷ Sheffi, Y., & Rice Jr, J. B. (2005). A supply chain view of the resilient enterprise. MIT Sloan management review, 47(1), 41.

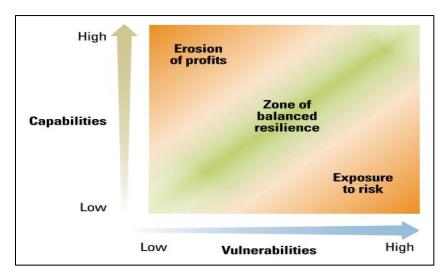
³⁸ Fiksel, J., Polyviou, M., Croxton, K. L., & Pettit, T. J. (2015). From Risk to Resilience: Learning to Deal with Disruption. *Sloan Management Review* 56(2), 79–86.

³⁹ Handfield, R., Finkenstadt, D. J., Schneller, E. S., Godfrey, A. B., & Guinto, P. (2020). A commons for a supply chain in the post-COVID-19 era: the case for a reformed strategic national stockpile. *The Milbank Quarterly*, *98*(4), 1058-1090.

⁴⁰ Wiedmer, R., Rogers, Z. S., Polyviou, M., Mena, C., & Chae, S. (2021). The dark and bright sides of complexity: A dual perspective on supply network resilience. *Journal of Business Logistics*, *42*(3), 336-359.

balanced resilience.⁴¹ Exhibit 5 depicts the zone of balanced resilience that organizations should seek.

Exhibit 5 - Zone of Balanced Resilience⁴²



Never has the requirement for resilient supply chains been more evident than in the COVID- 19 pandemic era. This is especially true for healthcare supply chains, which struggled to manage the surge in sick patients, allocate their limited capacity, and find the necessary products, including personal protective equipment (PPE), to protect their patients and workforce. These disruptions also impacted the Arizona healthcare supply chain. AzCHER has tasked the ASU team to identify capabilities that healthcare providers should develop to ensure appropriate preparation for and response to emergencies, such as the COVID-19 pandemic, and a quick recovery from them.

In this report, we are focused on the long-term issues of healthcare supply chain risk. These address a wide array of risks and the associated mitigation strategies and resilience capabilities that manage the long-term consequences. While COVID-19 was a single event that triggered severe supply chain disruptions, it has ably demonstrated the issues associated with risk management. Hence, throughout this report, while focusing on the long term, we will draw real-life, practical examples from the COVID-19 pandemic experience.

C. THE ROLE OF THE FEDERAL GOVERNMENT TO AID SUPPLY CHAIN RESILIENCE

Supplementing the actions that healthcare suppliers and providers take to mitigate supply chain disruptions, the federal government diligently tries to soften the impact on the healthcare system. These efforts have not always succeeded, but given the size and breadth of the federal government footprint, they play a very important role as a stakeholder.

⁴¹ Pettit, T. J., Fiksel, J., & Croxton, K. L. (2010). Ensuring Supply Chain Resilience: Development of a Conceptual Framework. *Journal of Business Logistics*, 31(1), 1-21.

⁴²Fiksel, J., Polyviou, M., Croxton, K. L., & Pettit, T. J. (2015). From Risk to Resilience: Learning to Deal with Disruption. *Sloan Management Review* 56(2), 79-86.

This report was written during the waning days of the COVID-19 omicron variant, in the presence of new sub-variants, and in the midst of great activity and concern for preparedness. During this time, the government undertook many specific initiatives. This section highlights some of these programs.

1) STRATEGIC NATIONAL STOCKPILE

In the late 1990s, the United States government, in response to terrorism concerns, established the Strategic National Stockpile (SNS). This program, administered by the CDC, was aimed at stocking critical medical products for use by the civilian population in the event that private commercial programs were unable to fulfill the country's needs during an emergency health situation. Primarily focused on responding to terrorism events, the SNS has been used for broader emergencies such as hurricanes, flu epidemics, and, most recently, COVID-19.

During the past two years, there have been numerous discussions regarding the healthcare supply chain's inability to meet the demands for supplies, both pharmaceutical and medical/surgical supplies. Many had believed that the SNS was a resource of capability – the capability to meet the needs of a medical care system under stress. In November 2019, when it was clear that the SNS would not meet the needs of a nation under surge, a request for information (RFI) was issued to seek detailed information from product manufacturers and distributors on their experiences in securing critical supplies.⁴³

Only after discovering the lack of product availability and the poor quality of products provided by the SNS did the SNS seek to identify the constraints encountered in their ability to meet demand. Requested were a detailing of what products should be procured and an inquiry regarding the investments needed to increase availability and reduce lead times. Also requested was an assessment of the factors that might buffer manufacturing from the global dependency for products. Furthermore, the RFI revealed the U.S. Government's lack of visibility into its pools of products and only after the fact, invested in a Supply Chain Control Tower to create visibility, provide insights, and orchestrate a disruption response. Clearly, there was insufficient preparedness for the emerging pandemic.⁴⁴ Importantly, while there have been many criticisms of the SNS, changes in administrations over the years did not respond to funding requests or operational improvements. Forthcoming have been analyses of the SNS and calls for its reform, including its development into a stronger pool resource.⁴⁵

2) EXECUTIVE ORDERS TO IMPROVE THE HEALTHCARE SUPPLY CHAIN

In the absence of periods of stress, a focus on preparedness is difficult to sustain!

Beyond government, assessments of the lack of preparedness by suppliers and providers of care were frequent. Considered early on was a focus on managerial practices (especially lean and just-in-time), a delivery system inordinately focused on price, and a dwindling redundancy due to a drive for sole sourcing. Much considered has been the observation of the dependency of the medical product supply chain on manufacturing from across the globe. Over half of protective garments, respirators and surgical masks, and medical garments are imported from China.⁴⁶ An

⁴³ Office of the Assistant Secretary for Preparedness and Response (HHS). (2020). Request for Information (RFI) – Strategic National Stockpile (May 14, 2020). URL: https://govtribe.com/file/government-file/20200512-sns-rfi-vfinal-dot-pdf
⁴⁴ Ibid.

⁴⁵ Op, cit. Handfield et al.

⁴⁶ Bradsher, K. (2020). China Dominates Medical Supplies in This Outbreak and the Next. *The New York Times* (May 5. 2020). URL: https://www.nytimes.com/2020/07/05/business/china-medical-supplies.html.

extensive assessment of the uncertainties surrounding PPE and supply issues in the U.S. environment reveals overlapping entities and multiple networks. In many cases, these were rivals, resulting in the absence of strong leadership, agile strategies, and visibility into product availability.

It takes an ecosystem of providers, suppliers, distributors, and government to build a sustainable and prepared supply chain!

These vulnerabilities are to be understood by the recognition that bringing manufacturing to the U.S. or nearby locations would be both costly and, in many cases, infeasible as access to needed resources is not available domestically. Depicted as a root cause were poor data tracking, paucity of inventory management capabilities, and a governance strategy to provide visibility into the supply chain and its performance.⁴⁷ Importantly, just-in-time was not the villain but a best supply chain management practice that, in normal times, appears to have served the system well. Not considered was a parallel concern for "just-in-case," an approach to the supply chain which requires a very different way of thinking, managing, sourcing, manufacturing, and financing.

Good supply chain management practice requires situational awareness!

There has been much consideration regarding how to approach and prepare for future disruptions. Executive orders by President Biden and the January 2021 publication of the National Strategy for the COVID-19 Response and Pandemic Preparedness identified a large number of gaps and strategies, including greater engagement between the public and private sector, a need for strengthening the supply chain through increasing domestic manufacturing and advanced purchases, coordination, and tracing of suppliers and their inventories. While it is clear that there is a concern for pandemic preparedness, it is not clear how and when efforts (as discussed below) will materialize.

A February 2022 report to update Executive Order (EO) 14017, "On America's Supply Chains," reveals the progress on strategies to help our public health supply chain become more resilient, diverse, and secure. It builds on the Biden Administration's ongoing efforts to build and sustain U.S. preparedness and response capabilities for future pandemics. 48,49,50

In addition to the White House-driven initiatives, the Department of Health and Human Services plays several roles in assisting with mitigating supply chain disruptions. The Centers for Medicare & Medicaid Services published an emergency preparedness rule⁵¹ which established national emergency preparedness requirements to ensure planning for both natural and man-made disasters and coordination with federal, state, tribal, and local emergency preparedness systems. It importantly recognizes an "all hazards" approach for preparedness, including earthquakes, hurricanes, severe weather, flooding, wildfires, fires in general, homeland security threats, as well as influenza and virus.

⁴⁷Finkenstadt, D. J., & Handfield, R. (2021). Blurry Vision: Supply Chain Visibility for Personal Protective Equipment During COVID-19. *Journal of Purchasing and Supply Management*, 27(3), 100689.

⁴⁸ Lander, E. S., & Sullivan, J. J. (2021). *American Pandemic Preparedness: Transforming Our Capabilities*. The White House: Washington, DC, USA.

⁴⁹ Biden, J. (2022). *The Biden-Harris Plan to Revitalize American Manufacturing and Secure Clinical Supply Chains in 2022* (February 24, 2022).

⁵⁰ Biden, J. (2021). Executive Order on America's Supply Chains (February 24, 2021).

⁵¹ Centers for Medicare and Medicaid Services (2016). *Emergency Preparedness Rule* (November 2016); Centers for Medicare and Medicaid Services (2021). CMS Emergency Preparedness Guidance (March 2021). URL: https://www.cms.gov/files/document/qso-21-15-all.pdf

The Centers for Disease Control and Prevention (CDC) leads the emergency preparedness and response activities by providing strategic coordination for activities across local, state, national, and international public health partners. However, little attention is given by CDC to events with the proportions of a pandemic, characterized by uncertainty in depth, breadth, recovery pattern, and duration. Indeed, in its discussion of similarities and differences between flu and COVID-19, the CDC emphasizes the clinical aspects of COVID-19 rather than preparedness and mitigation.

The public health system recognizes that the flu, while changing in severity over time, can raise its head on an annual basis. While such events are characterized by a level of uncertainty, they have lent themselves to a fairly high level of preparedness to mitigate interruptions. Importantly, the manufacturers of products needed for the delivery of healthcare are also aware of the risks associated with their own supply chains, and many have implemented mitigation strategies.

The Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response (ASPR), has a mission that comprises preparedness, response, partnerships, and workforce into a portfolio of medical countermeasures (MCM). BARDA provides a systematic approach to developing and purchasing the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies. BARDA's 2022-2026 Strategic Plan⁵² recognizes that COVID-19 spotlighted "new and known challenges in the nation's pandemic preparedness and response strategy." Its strategies included increasing the availability of MCMs, establishing domestic-based manufacturing for COVID-19 MCMs (such as syringes or needles), and de-risking development through advanced purchasing agreements. BARDA is aware of the challenges associated with supply chain business processes as reflected in its 10-year commitment to scale new communications, data, and technology applications, including investments in data management and architecture, business process automation, and accurate analytics to strengthen response posture.

Adopting modern business, analytics, and communications tools to enhance efficiency is a foundation of the BARDA efforts. BARDA repurposed existing capabilities under BARDA Digital Resources (BDR) to build a real-time system during the pandemic to plan, track, and accept over 900 million COVID-19 vaccine doses. BARDA must learn from this experience and build on the capabilities needed to ensure there are agile systems capable of supporting future public health emergency response. It is noteworthy that BARDA also increased the availability of information about MCMs to the public, including expanding its presence on social media and publishing interactive timelines, portfolios, and explanatory articles.

3) SUMMARY OF GOVERNMENT INITIATIVES

This report identifies the successes that government has had in bringing vaccines to market in the U.S. and supporting vaccine administration in other nations. Yet it reiterates the challenges associated with foreign dependencies, barriers to entry and expansion, and plans to grow the public health supply chain through better supply chain management and collaboration with academia and industry. An annual report on the plethora of efforts is expected in July 2022. Notwithstanding the above, the role of the federal government is critical yet evolving. The government needs to give this role careful consideration. Healthcare leaders, associations, and HCCs need to be observant and appropriately responsive.

⁵² U.S. Department of Health and Human Services. (2022). BARDA Strategic Plan 2022-2026 (May 2022).

4) NON-GOVERNMENT EFFORTS OF NOTE

Despite these significant strides towards a more resilient public health supply chain, challenges remain. Consulting organizations, GPOs, and distributors all recognized the need for a stronger focus on preparedness. COUPA, for example, enhanced its focus on risk, resiliency, and supply chain modeling.⁵³ Premier, for example, put forth an extensive document focusing on the stabilization of the supply chain.⁵⁴ The Health Industry Distributors Association provided a set of industry recommendations for building a pandemic infrastructure and for allocating medical supplies.⁵⁵ In addition, the Healthcare Industry Resilience Collaborative (HIRC)⁵⁶ has brought together a large number of providers and suppliers to champion and lead standards and best practices in healthcare supply chain resiliency. We believe that HIRC's activity to develop resiliency score-carding, KPIs, risk assessment, and peer learning deserve following. Notably, several Arizona providers of care (e.g., Banner Health, Honor Health, and Mayo Clinic) and key intermediaries serving the state (e.g., Cardinal Health, O&M, Vizient, and Premier) and suppliers serving providers (e.g., Johnson & Johnson, Baxter, GHX, Philips, Stryker) are important HIRC participants. Aforementioned are only illustrative of the many assessments uncovered during the course of this research

The Strategic Management Initiative (SMI),⁵⁷ a coalition of suppliers in the health sector, has carried out surveys to assess priorities for a resilient supply chain and, with the assistance of Professor Rob Handfield of NC State, developed a resiliency model to assess organizational maturity towards resilience⁵⁸ How organizations across the healthcare supply chain ecosystem implement this model deserves ongoing scrutiny.

D. THE ARIZONA SITUATION

The Arizona healthcare system is a microcosm of the entire country. It has large urban areas and small remote rural communities. Population demographics are similar to the national averages, and the range of healthcare delivery providers is representative of the national pattern, with large acute care centers through to small clinics, long-term care facilities, hospices, and dialysis centers spread across the state. Consequently, the supply chain ecosystem concept introduced in the previous section applies directly to the stakeholders in Arizona. As with all other providers in the country, Arizona providers were significantly impacted by recent pandemic-related supply chain disruptions and are keenly interested in ways to improve their resiliency in anticipation of future disruptions. This section identifies the stakeholders in Arizona and their interests in resilience improvement in the state.

⁵³ COUPA (2021). *Risk, Resiliency and Supply Chain Modeling* (September 2021). URL: https://get.coupa.com/rs/950-OLU-185/images/21-Risk-Resiliency-SC-Modeling.pdf# ga=2.126918542.201720871.1655591981-773911264.1655591981& gac=1.217786914.1655592200.EAlalQobChMlk-uD34i4-AIVIQ nCh3R4gftEAAYAiAAEgIn8 D BWE

⁵⁴ Premier (2021). *Reflections and Recommendations on Preparing for the Next Surge or Pandemic* (January 2021). URL: https://www.premierinc.com/downloads/Supply-Chain-Improvement-Ideas-January-2021.pdf

⁵⁵ Health Industry Distributors Association (2021). *Allocations: Best Practices for Conserving Medical Supplies During Shortages*. 2021. https://www.hida.org/uploadedfiles/resources/whitepapers/allocations-best-practices-conserving-medical-supplies-shortages.pdf.

⁵⁶ Healthcare Industry Resilience Collaborative. URL: https://hircstrong.com/

⁵⁷ Strategic Marketplace Initiative. URL: https://www.smisupplychain.com/

⁵⁸ SMI. (2022). *Planning for a Resilient Supply Chain for Healthcare in a Post-Covid World* (May 2022). URL: https://smi.memberclicks.net/assets/docs/tools/rmm playbook-2022.pdf.

1) SUPPLIERS AND PROVIDERS

With a population of over seven million, Arizona is the 14th most populous state in the country. As such, healthcare providers have access to a wide array of medical products and supplies. All of the major distributors and manufacturers provide products throughout the state. Some of the distributors have product warehoused in the state. To support the providers, all of the major GPOs operate within the state. For the smaller providers, specialized mid-market GPOs also offer services to providers in Arizona.

During the COVID-19 pandemic, providers and those who provide support faced shortages of key medical supplies. While PPE shortages gained the most notoriety, other products, including pharmaceuticals, medical gases, and disposable supplies, were also in a serious shortage. Non-disposable supplies, such as ventilators, stethoscopes, and tanks for oxygen, were also scarce. All suppliers worked diligently to satisfy the increased demand, but the supply chain system was not designed for such a large unanticipated increase in demand. Consequently, there was insufficient product available to meet the needs of healthcare providers. This caused providers to take remedial action, such as postponing elective procedures and rationing access to certain supplies. As a result, the delivery of healthcare services during this time was below an acceptable standard of care. Going forward, providers (and suppliers) in the state do not want that to happen again and are committed to improving their resiliency to such future conditions.

2) **GOVERNMENTS**

The interest and the role of the federal government were discussed above. At the state, county, and local levels, government agencies have had an active but limited role in contributing to healthcare supply chain resilience improvement. While their interest is strong, government agencies are limited by available resources and legislative mandates. In Arizona, dealing with the impact of healthcare-related supply chain disruptions falls between the cracks with the state Department of Public Safety and Department of Health sharing jurisdiction. During normal times, the state's role in healthcare is primarily regulatory. They have little operational capability when it comes to supporting supply chain needs. At the county and local levels, the relevant health departments also take a strong interest in disruptions to healthcare delivery but have even fewer resources and capabilities to make a meaningful contribution.

3) THE ROLE OF AZCHER

A Healthcare Coalition (HCC) is a group of individual healthcare response organizations in a defined geographic area playing the critical role in developing healthcare delivery system preparedness and response capabilities.⁵⁹ Over 400 such coalitions exist across the U.S.,⁶⁰ with a good deal of diversity in their structure, collaboration, and organization but with self-defined boundaries in terms of their advisory and/or operational roles. The role of HCCs and the importance of member autonomy and relationships to governmental agencies are specified in the Medical Surge Capacity and Capability (MSCC) handbook.⁶¹ The four ASPR capabilities stated for

⁵⁹ Office of the Assistant Secretary for preparedness and Response, 2017-2022, November 2016, 2017-2022 Healthcare Preparedness and Response Capabilities.

⁶⁰ List of awardee coalitions by state can be found at:

https://cdn.ymaws.com/www.ahepp.org/resource/resmgr/Resource Center/CMS/By-Name-by-State-Healthcare-.pdf

⁶¹ U.S. Department of Health and Human Services. (2021). *MSCC Handbook*. (February 14, 2012). URL: https://www.phe.gov/Preparedness/planning/mscc/healthcarecoalition/chapter2/Pages/overview.aspx#2.1.2

an HCC are (1) providing a foundation for healthcare and medical readiness, (2) providing healthcare and medical response coordination, (3) supporting uninterrupted, optimal medical care to all populations in the face of a damaged or disabled healthcare infrastructure, and (4) coordinating information and available resources for its members to maintain conventional surge response.⁶²

The Arizona Coalition for Healthcare Emergency Readiness (AzCHER) was established to build resilience in the state's healthcare delivery system. While initially primarily focused on emergency response to large-scale disasters, the experience of healthcare organizations in Arizona during the pandemic, which was a widespread emergency in part driven by supply shortages, caused AzCHER to expand its focus to the broad supply chain needs of all providers. This expansion of its focus is in accordance with the 2017-2022 Healthcare Preparedness and Response Capabilities established by the Assistant Secretary for Preparedness and Response (ASPR). This document will be elaborated upon in Chapter IV as we craft some future options for AzCHER in supporting the supply chain in times of disruption. Importantly, we focus on AzCHER's efforts to collaborate to ensure each member has what it needs to respond to emergencies and planned events, including medical equipment and supplies, real-time information, communication systems, and educated, trained healthcare personnel.⁶³

Across the state, AzCHER has over 900 member facilities operated by over 500 healthcare organizations. Much of the funding to resource AzCHER is derived from grants from ASPR to the state which directs the funds to support the AzCHER organization. Amongst healthcare providers that are members of AzCHER, there are many types. They range from very large organizations with thousands of employees down to small clinics with less than 10 employees. Some provide inpatient services, others are limited to outpatient services, and some are state, county, or municipally operated in the case of emergency response and public health services. These facilities are highly diverse, not just in size but in their geographic dispersion across both urban and rural communities. We limited our research to these provider types, including:

- Skilled Nursing & Long-Term Care Facilities
- Ambulatory Surgical Centers
- Acute Care Hospitals
- Hospices
- End-Stage Renal Disease Facilities
- Home Health Agencies
- Behavioral Health Facilities
- Community Health Centers / Federally Qualified Health Centers
- Public Health Agencies
- Healthcare Clinics in the non-government sector
- Healthcare Clinics and facilities associated with government (e.g., the VA and HIS)
- Emergency Management Organizations
- Critical Access Hospitals
- Rehabilitation Hospitals
- Emergency Medical Services
- Professional Association or Organizations

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⁶² Op., cit. Office of the Assistant Secretary for preparedness and Response, 2017-2022, November 2016, 2017-2022 Healthcare Preparedness and Response Capabilities. p.7.

⁶³ Ibid., p.8.

- Specialty Hospitals
- Long-Term Acute Care Hospitals
- CERT or MRC Organizations
- Correctional Health Facilities
- Non-Governmental Organizations

Consistent with its mandate, AzCHER sought to examine opportunities for all providers in the state to improve the resilience of their supply chains. This report focuses on seven product categories specified by ASPR as critical and susceptible to supply chain disruptions.

E. RESEARCH METHOD

The overarching goal of our method was to identify supply chain vulnerabilities and develop related mitigation strategies within and across healthcare organizations in Arizona. While our primary focus was the provider community (AzCHER members), we extended our assessment to suppliers supporting Arizona providers and other stakeholders within the healthcare supply chain ecosystem given that the vulnerabilities that can affect any of these stakeholders will influence the ability of providers to access supplies and deliver good-quality care.

Within our study, the assessment addressed many factors affecting resiliency, including flexibility, redundancy, the extent to which systems supported traceability and information transparency, their collaboration within and across their activities, the extent to which they were persistent and responsive to disruptions, and, finally, the impact on Arizona. To achieve these goals, we used a multimethod approach. We administered a survey with AzCHER members, conducted in-depth interviews and corresponded in writing with stakeholders from the healthcare supply chain ecosystem, administered two expert panel discussions, and thoroughly reviewed the literature. We outline these methods below.

1) **SURVEY OF AZCHER MEMBERS**

For the first step in the process, we developed and administered a survey (determined as "exempt" by the Arizona State University Institutional Review Board (IRB)) to understand the following about Arizona providers:

- Triggers of disruptions to their supply chains that they considered most relevant
- Their dependence on the SNS during the COVID-19 pandemic and their view of the quality of products received from the SNS
- Their primary and secondary suppliers across the eight product categories of interest, as well as their distributors
- The consequences of COVID-19 in terms of supply-related and patient-care-related challenges
- The strategies that they have started to employ to mitigate supply chain disruptions

AzCHER consists of members with dedicated supply chain managers as well as organizations where supply chain decisions are made by individuals who have multiple functions. As some AzCHER members belong to larger systems, where the supply chain function is centralized, it was important to identify the most appropriate respondents. AzCHER supported our work by asking members to identify the most relevant respondents, providing confidence that respondents would be knowledgeable about their supply chain practices, vulnerabilities, and mitigation strategies. Once this was completed, we sent out the survey to the 500 AzCHER identified principal contacts requesting them to respond. We followed survey research best practices, including

sending biweekly reminders and having AzCHER send reminders to their member organizations. After removing incomplete responses, the final sample was 140 Arizona providers. Exhibit 6 shows the types of providers represented in the sample, while Exhibit 7 shows the type of care they provide. This analysis of members indicates that the sample we obtained fairly represents the total membership of AzCHER. According to Exhibit 7, most survey respondents represent outpatient treatment providers and include ambulatory surgical centers, emergency medical services, end-stage renal disease facilities, home health agencies, and hospices. The second-largest category is chronic inpatient treatment providers and includes behavioral health facilities, community health centers / federally qualified health centers, and healthcare clinics. The third-largest category is acute care hospitals, which primarily includes the large IDNs.

Exhibit 6 - Survey Respondents by Organization Type

AzCHER Member Type	Frequency	Percent of Sample
Acute Care Hospital	19	14%
Chronic Inpatient Treatment ^a	23	16%
Healthcare Center – Outpatient ^b	11	8%
Other Acute Inpatient Treatment ^c	7	5%
Outpatient Treatment ^d	67	48%
Public Health Agency/ Other ^e	13	9%
Total	140	100%

^a Includes Rehabilitation Hospitals and Skilled Nursing or Long-Term Care Facilities

Exhibit 7 - Survey Respondents by Type of Care

		Home care (No)	Home care (Yes)	Total
Innationt care (No)	Outpatient care (No)	16	26	42
Inpatient care (No)	Outpatient care (Yes)	43	1	44
	Total	59	27	86
Innationt core (Ves)	Outpatient care (No)	21	2	23
Inpatient care (Yes)	Outpatient care (Yes)	21	10	31
	Total	42	12	54

Other demographic information about the provider organizations is presented in Exhibit 8. Forty-five percent of the organizations are in Central Arizona, and 46% represent a multi-location system. The majority are small organizations, with 53% employing less than 100 people, 24% employing between 101 and 500 people, and 23% employing more than 501 people.

^b Includes Behavioral Health Facilities, Community Health Centers / Federally Qualified Health Centers, and Healthcare Clinics

^c Includes Critical Access Hospitals and Specialty Hospitals

^d Includes Ambulatory Surgical Centers, Emergency Medical Services, End-Stage Renal Disease Facilities, Home Health Agencies, and Hospices

^e Includes Public Health Agencies and Others

Exhibit 8 - Other Demographics of Survey Respondents

Arizona Region	Percent of Sample
Central	45%
South	28%
North	17%
West	10%

Number of Employees	Percent of Sample
Small (1-100)	53%
Medium (101-500)	24%
Large (501+)	23%

Multi-location System	Percent of Sample
Yes	46%
No	51%
Not applicable	3%

Purchase Supplies	Percent of Sample
Yes	96%
No	4%

2) CORRESPONDENCE WITH SUPPLIERS AND DISTRIBUTORS

We have also had written correspondence with a major supplier of disposable supplies and a key distributor. Our team had sent out a set of open-ended questions for which we received written responses. Once we received the responses, we followed up with additional questions and then received additional clarification.

3) INTERVIEWS WITH STAKEHOLDERS IN THE HEALTHCARE SUPPLY CHAIN ECOSYSTEM

We interviewed over 70 experts representing different stakeholders in the healthcare supply chain ecosystem, as shown in Exhibit 9. Each interview was recorded and transcribed. We then coded each transcript following established coding procedures from the literature^{64, 65} to identify the emerging themes in terms of vulnerabilities, mitigation strategies, and the structures that support implementing these mitigation strategies. To supplement and triangulate the information received from the interviews, we collected, when possible, internal documents from these organizations that outline their challenges/vulnerabilities and mitigation strategies.⁶⁶

⁶⁴ Strauss, A., J. Corbin. (1998). *Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory*, 2nd Ed. Sage Publications, Thousand Oaks, CA.

⁶⁵ Gioia, D. A., Corley, K. G., & Hamilton, A. L. (2013). Seeking Qualitative Rigor in Inductive Research: Notes on the Gioia Methodology. *Organizational Research Methods*, 16(1), 15-31.

⁶⁶ Jick, T. D. (1979). Mixing Qualitative and Quantitative Methods: Triangulation in Action. *Administrative Science Quarterly*, 24(4), 602-611.

Exhibit 9 - Interviews with Stakeholders Across the Healthcare Supply Chain Ecosystem

Stakeholder Type	Number of Experts Interviewed
Arizona Providers	10
GPOs	16
Distributors	6
Manufacturers	20
Governments (Federal, State, & Local)	9
Other organizations outside Arizona (e.g., other providers, coalitions)	13
Total	74

4) EXPERT PANELS

We also administered two panels with experts from academia and the healthcare industry. The purpose of these panels was to obtain independent insight into the research findings, conclusions, and recommendations. These experts provided a validation role in the process.

The first expert panel was held on April 28, 2022. It included three presentations from our team reporting on current progress and four presentations from four industry experts:

- Jimmy Chung, M.D., MBA, Chief Medical Officer, Advantus Health Partners, Bon Secours Mercy Health
- Denis Cortese, former CEO of Mayo Clinic and now a professor at ASU
- Doug Bowen, Senior Vice-President for Supply Chain Services, Banner Health
- Gerry Collins, Vice President, Supply Chain Resilience Development, Johnson & Johnson
- Devendra Mishra, Executive Director and Founder, Bio Supply Chain Management Association
- Bindiya Vakil, Founder and CEO, Resilinc

Other attendees were other experts from ASU and industry, as well as AzCHER representatives. This panel provided insight into the challenges healthcare supply chains faced, especially during and after the COVID-19 pandemic, and important mitigation strategies.

The second panel was held on June 1, 2022. It included a presentation from our team, which highlighted the emerging vulnerabilities and mitigation strategies. It also included presentations from industry experts and several discussion sessions on the feasibility of mitigation strategies and their stickiness for the long term:

- William Abrams, President of Distributed Products Division, Medline Industries
- Gerry Collins, VP of Supply Chain Resilience Development, Johnson & Johnson
- Kevin Cook, VP of Supply Chain, Sandoz
- Dr. Erich Heneke, Director of Business Integrity & Continuity, Mayo Clinic
- Bindiya Vakil, Founder and CEO, Resilinc

5) LITERATURE REVIEW

Our final data collection phase involved an in-depth review of the literature to develop profiles of the ten product categories with a focus on their use, the market in which suppliers in a category operate, the impact of COVID-19 on these categories, the vulnerabilities faced in this supply chain, and the mitigation strategies that organizations in this supply chain have implemented. As we progressed through this phase, we recognized that there was considerable overlap in the characteristics of some of these categories. Consequently, with AzCHER's acknowledgment, we merged several categories to rationalize the list to seven product categories, as listed below:

- Blood Products
- Medical Gases
- Fuel
- Leasing Entities
- Pharmaceutical & Nutritional Products
- Disposable Products (including PPE)
- Hazardous Waste Removal Services

As requested by AzCHER, we also identified relevant federal and state government mandates and strategies and published descriptions of initiatives undertaken by other stakeholders, including providers, GPOs, distributors, and manufacturers, to improve resilience in healthcare supply chains. Chapter II, Section B contains synopses of the industry profiles.

6) OBSERVATIONS ANALYSIS

We compiled the observations from the survey, interviews, expert panels, and literature review into a database coded by vulnerability and mitigation strategy. We assembled over 600 observations from this data collection process. This analysis enabled us to establish a comprehensive data set that provides a complete picture of the drivers and solutions employed by providers, suppliers, and others to strengthen healthcare supply chain resiliency.

As we analyzed the data, we identified 12 themes that increase supply chain vulnerability. Building on this analysis, we identified six additional themes that characterized the successful mitigation strategies. However, these mitigation strategies are ineffective without five core supply chain management capabilities. We identified these needed capabilities and examined their applicability. While these capabilities are critical for supply chain disruption mitigation measures, they cannot function without four core business structures. Hence, we also identified a set of core business structures to support the resiliency efforts. For each, we identified the requirements. These are discussed in considerable detail in Chapters II and III.

II. ASSESSMENT OF THE ARIZONA HEALTHCARE SUPPLY CHAIN'S SUSCEPTIBILITY TO SUPPLY CHAIN DISRUPTIONS

A. ARIZONA HEALTHCARE PROVIDERS' SUSCEPTIBILITY TO SUPPLY CHAIN DISRUPTIONS

The healthcare supply chain can be described as highly resource-dependent, fragmented, diverse, and decentralized. Whereas in some nations, the government conducts operational tasks, such as sourcing and inventory management, acute care organizations in the U.S. primarily outsource key supply chain functions to GPOs and commercial distributors. Other providers utilize a wide range of suppliers to secure the product categories we have scrutinized.

In our survey of providers, the following events triggering disruptions were identified, as shown in Exhibit 10. Pandemics and labor shortages were top of mind for Arizona providers, as were price increases in supplies and transportation. Bottlenecks at ports were considered the fifth most likely source of disruption. The events shown in Exhibit 11 were considered the least likely by Arizona providers to trigger disruptions in the supply chain. Deliberate threats, such as sabotage and terrorism, and natural disasters, such as earthquakes, tornados, and hurricanes, were considered the least likely triggers. These latter results are surprising given that Hurricane Maria only happened in 2017 and adversely affected healthcare supply chains, especially the production and delivery of intravenous bags.

Exhibit 10 - The Three Most Important Disruption Triggers for Arizona Providers

Five most likely triggers of disruptions to the supply chain		
	Average likelihood	
Pandemics/ epidemics	3.7	
Labor shortages	3.6	
Price increases in supplies	3.5	
Price increases in transportation	3.4	
Bottlenecks at ports 3.2		
1 = Not likely at all; 2 = Somewhat likely; 3 = Likely; 4 = Very likely; 5 = Extremely likely		

Exhibit 11 - The Three Least Important Disruption Triggers for Arizona Providers

Five least likely triggers of disruptions to the supply chain	
	Average likelihood
Sabotage	2.0
Terrorism	2.0
Earthquake	1.8
Tornado	1.8
Hurricane	1.8
1 = Not likely at all; 2 = Somewhat likely; 3 = Likely; 4 = Very likely; 5 = Extremely likely	

Exhibit 12 shows the percentage of respondents who considered the following supply-related problems to be "very important" or extremely important" challenges they faced during COVID-19. As shown in the exhibit, 76% and 70% of the survey respondents considered, respectively, long replenishment times from suppliers and long turnaround times from other external providers, such as laboratories, to be a very important or extremely important supply challenge during COVID-19. Other important challenges were the lack of PPE (72% of respondents), unreliable deliveries from suppliers (69% of respondents), lack of other products except for PPE (69% of respondents), and higher prices for both PPE (62% of respondents) and medical equipment (60% of respondents).

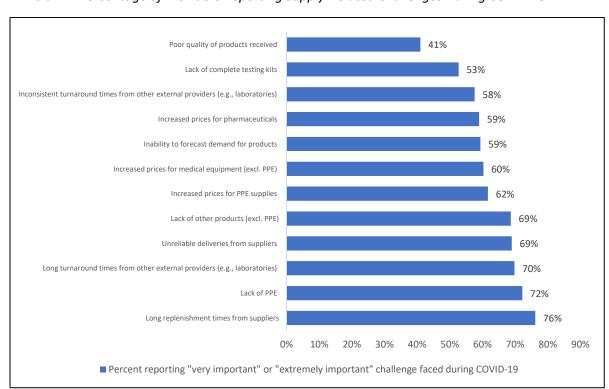
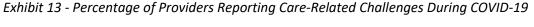


Exhibit 12 - Percentage of Providers Reporting Supply-Related Challenges During COVID-19

Exhibit 13 shows the percentage of respondents that had to take or, at the time of the survey, intended to take care-related actions as a result of insufficient access to products during COVID-19. As shown in the exhibit, 60% of respondents had to or intended to postpone elective surgeries, a consequence we have observed very often during the pandemic. Forty-five percent of respondents had to or intends to prioritize care for COVID-19 patients, while 37% had to send COVID-19 patients elsewhere. We had observed the latter when smaller hospitals, hospices, and other clinics had to send their COVID-19 patients to large IDNs to receive care.



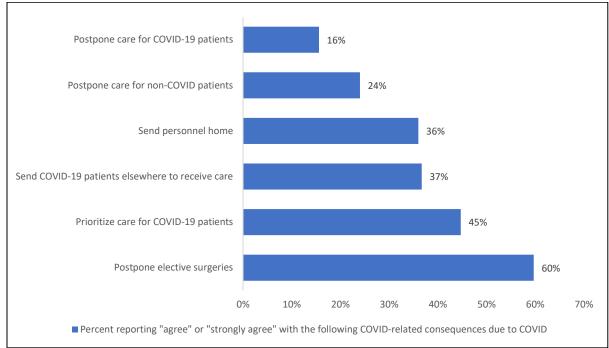
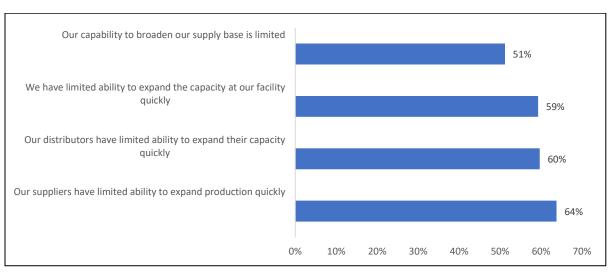


Exhibit 14 shows the percentage of respondents who agreed or strongly agreed with the following statements about their ability or their suppliers' ability to expand capacity quickly. As shown in the exhibit, 64%, 60%, and 59% of respondents agreed, respectively, that their suppliers, distributors, and they, themselves, have limited ability to expand the capacity of their facilities quickly. These high percentages demonstrate that providers do not believe that their suppliers/distributors or they have sufficient capability to be flexible during disruptions by adjusting the capacity they can handle upward. Therefore, as we observed during COVID-19, any surges in demand are likely to crumble the system.

Exhibit 14 - Percentage of Providers Reporting Their Ability or Their Suppliers' Abilities to Expand their Facilities and Supply Base Quickly



Finally, sixty providers from our sample indicated that they had received products from the SNS. When asked to evaluate the quality of those products, they indicated that the quality was not always acceptable. Exhibit 15 shows the percentage of respondents who had received a specified product from the SNS and indicated that the quality of that product was poor or fair. For example, 41% of those who had indicated they received gowns from the SNS stated that their quality was poor or fair. Likewise, 24% of those who had indicated they received gloves and N-95 respirators stated that their quality was poor or fair. These results would be unacceptable in most commercial supply chains where zero defects are the expectation. Given that the SNS was created to serve as a backup in stocking critical medical products for use in the event that commercial supply chains would be unable to fulfil the population's needs, it did not serve its purpose effectively with this kind of product quality.

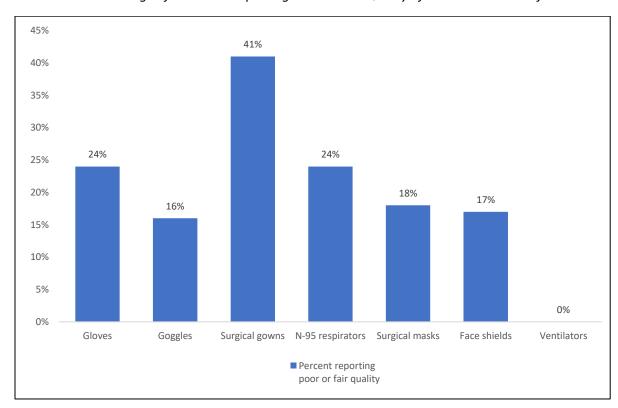


Exhibit 15 – Percentage of Providers Reporting Poor or Fair Quality of Products Received from the SNS

The supplier categories scrutinized for this study are likewise susceptible to a wide range of disruptions. Greater insight into the vulnerabilities of each category and the respective mitigation efforts are presented in the following section.

B. SUPPLIERS' SUSCEPTIBILITY TO SUPPLY CHAIN DISRUPTIONS

COVID-19 impacted organizations across the full range of suppliers for products for the provision of care. Impacted was their ability to meet initial surge-related demand from current inventories and their ability to replenish inventories. As demand for products increased, suppliers found challenges in securing products and expanding production due to disruptions in their upstream supply chains. Many of the disruptions were related to reliance on suppliers across the globe, who themselves faced disruptions. This was clearly the case for PPE, much of it sourced from Asia. In other instances, as

discussed below for blood, disruptions had to do with the reluctance of their donors, the source of their supply, to visit domination sessions. In this next section, we provide insight into the industries and their products identified by AzCHER as critical to emergency response. Our focus is on their resiliency, mitigation efforts, and, in several cases, how Arizona fared.

1) <u>BLOOD</u>

The blood industry relies upon blood donors to give blood and other blood products. Each year approximately 6.8 million Americans donate blood, who are the supply source. Blood is highly perishable, with red blood cells needing to be used within 42 days and platelets needing to be used within five days. Therefore, any event that keeps donors from visiting blood donation sites during a disruption, such as a pandemic (where donors may feel unsafe visiting donation sites) or during an earthquake or storm (where donors may not have physical access to a donor site), yields a disruption.

COVID-19 raised questions about the resiliency of the blood supply, as donations decreased by 10%, causing shortages. Blood drives located in large organizations and universities suffered as these organizations moved to online participation. In January 2022, at the omicron variant's height, one of the nation's largest blood banks reported the worst shortage of blood that they had seen in over a decade. As a result, some doctors needed to delay treatment. Some blood donation centers closed or reduced capacity, and many potential donors stayed home due to fear of transmission of COVID-19.

The blood industry is highly concentrated in a few large donor suppliers, with the top five owning about 70% of the nation's supply. The industry has consolidated with some of the smaller blood centers that could not compete from a price standpoint being acquired by some of the larger ones.

Many donation facilities saw staffing shortages limiting the donations they could accept. To address the shortage in donations that came with COVID-19, a major blood bank urged individuals to donate by emphasizing the importance of blood supply, especially in January during National Blood Donor Month, partnering with organizations such as the NFL for publicity and incentives such as giveaways to encourage.

As stated above, blood suppliers are highly dependent on upstream suppliers to provide the disposable medical products used in blood collection including needles, tubing, blood tubes, etc. The blood banks work with major distributors and GPOs to secure these needed disposables. Reflecting shortages is a comment by one of the suppliers:

"One company is the largest and frequent sole supplier of blood tubes and was thus trying to supply everybody. And so, once they have an issue, there are no alternatives. So, you couldn't go to other manufacturers mainly because they didn't exist, or if they did exist, hospitals get these products from the same sources."

A blood bank that we interviewed demonstrated great acuity in managing its supply base, both pre-pandemic and beyond. As one respondent commented:

"We made it very clear to any potential supplier that in order to be considered, they needed to provide very specific data, so we could do a more in-depth vetting of that supplier. There are a number of cases where we believed that the risk associated with a specific supplier or engaging in a specific supplier was too high, and we gracefully declined."

"And some of the blood centers, the smaller ones were actually very nimble. So, they had small vehicles, and they had the ability to run small blood drives, not as efficiently and not as less costly as they would like, but they were getting product."

It also demonstrated its acuity in managing risk, as reflected in the following comment regarding vetting new contracts:

"Whenever we're [developing] a new strategy or new contract or contract amendment with a major supplier (and we define "major" [or] "strategic" as [those] with [whom we] spent 250 thousand or more), we're conducting a rigorous risk assessment at that time. And we're talking about the pros and cons and options and issues to raise."

Respondents to the AzCHER survey listed multiple blood supplier companies, with two companies dominating the supplier terrain. Suppliers and GPOs, which provide the materials needed to collect and process blood, are highly aware of the challenges posed by a surge in demand and appear to have learned a good deal during the first two years of the COVID-19 surge in Arizona. Challenges associated with donor recruitment during periods of emergency remain a concern.

2) MEDICAL GASES

Medical gas production requires supplies to harvest gasses. The increase in demand, especially for oxygen, was principally due to the respiratory nature of the disease as patients became hospitalized and required supplemental oxygen. Other medical gases are important for anesthesia, therapeutic, and diagnostic purposes.

Without doubt, the level of disruption was significant, as reported by a major supplier of medical gas that we interviewed, reflecting on the early surge in New York:

"There was nowhere in the world enough cylinders to supply what just New York City wanted If available. It didn't matter... I could have shipped thousands of cylinders from all over the country. I had trucks and I got guys on the road 24 hours a day. We were filling cylinders 24 hours a day; we were picking up cylinders taking them back to our plant filling them putting them back on the road."

From a national perspective, oxygen demand went up significantly. A respondent from a major supplier of oxygen explained:

"Hospitals were standing up beds outside the hospital, repurposing rooms that weren't for surgical patients, additional triage areas - required changing O_2 cylinders all the time. It was difficult to assess demand and to keep up with usage. ... A good average was probably seven times higher oxygen usage."

Many of the issues faced by acute care organizations had to do with the high flow of oxygen through oxygen systems causing liquid oxygen vaporizers to freeze and, thus, the inability to accommodate the demand. Additionally, small machines used to convert oxygen were in short supply during the pandemic. It is noteworthy that delivery of oxygen requires not only tanks (especially for non- acute care settings) but also a variety of disposable medical supplies, such as nasal cannula humidifier kits as well as tanks, air-oxygen blender flowmeters and concentrators – all key to the delivery of oxygen to patients.

Respondents to the AzCHER survey listed multiple medical gas companies, with two companies dominating the supplier terrain. Medical gas companies and GPOs are highly aware of challenges

posed by a surge in demand and appear to have learned a good deal during the first two years of the COVID-19 surge in Arizona. A major supplier explained:

"... we can exchange products, that's a big part of the resiliency ... redundancy of production and distribution are really essential so that, if we have a piece of equipment that fails in San Francisco, well that's okay. Sacramento is going to pick it up."

Impressive was the high level of suppliers collaborating and their ability to convert from manufacturing-grade to medical-grade oxygen. Arizona was less challenged than many other states, with key issues being, rather than the ability to produce oxygen, a shortage of qualified drivers and a shortage of oxygen tanks of all sizes. It is noteworthy that there are no substitutes for oxygen. Suppliers being able to convert manufacturing from the production of non-healthcare grade to medical-grade oxygen reflects important flexibility in the system.

3) **FUEL/ENERGY**

Healthcare facilities in need of fuel and energy include physicians' offices, dentists' offices, outpatient and inpatient centers, medical laboratories, home healthcare facilities, general medical and surgical hospitals, and community care facilities. Healthcare facilities account for 4.8% of the total area of commercial buildings in the United States and are responsible for 10.3% of total energy consumption in this sector.⁶⁷ Healthcare organizations require electricity, petroleum, and natural gas to power generators during times of disruption. Historically, healthcare has been resilient to short-term fuel supply shifts, but this resilience may deteriorate with longer-term supply contraction. In such an event, disruption impacts will be felt on local, regional, and national scales, and the system's organizational structure may be challenged. Fuel, especially gasoline, is necessary for healthcare workers and patients to get to their jobs and for emergency services to reach their destinations.

Our interviews revealed that fuel shortages were not a significant issue. Given reduced personal travel, there was an excess of gasoline. However, with virtually all petroleum fuel coming to Arizona via two pipelines (one from California and one from Texas), dependency on dual sources can be seen as a significant dependency that might be more pronounced in the case of a disruption in California or Texas. Similarly, with ethanol, a required additive to gasoline, interruptions with rail services from sources in the Midwest expose an important dependency.

Arizona's Palo Verde Nuclear Generating Station, the largest nuclear power plant in the U.S., poses a significant dependency. In 2021, 99% of Arizona's total electricity net generation was provided from six sources: natural gas (43%); nuclear power (28%); coal (13%); solar energy (9%); hydroelectric power (5%): and wind (1%). Hydroelectric pumped storage, petroleum, and biomass supply the rest.⁶⁸

4) PHARMACEUTICALS AND NUTRITION

Pharmaceuticals are critically important to the successful delivery of healthcare in the U.S. They are used daily both to save lives and to improve quality of life. Medications are used in emergencies, management of chronic conditions, palliative care, infection, immunosuppression, and many other aspects of care. Even before the COVID-19 pandemic, obtaining certain

⁶⁷ Bawaneh, K., Ghazi Nezami, F., Rasheduzzaman, M., & Deken, B. (2019). Energy Consumption Analysis and Characterization of Healthcare Facilities in the United States. *Energies*, 12(19), 3775.

⁶⁸ Energy Information Administration, State Energy Data System.

pharmaceutical and nutritional products could be challenging. In fact, over the past 15 years, a significant number of new and ongoing, drug shortages have been identified each year. ^{69, 70} These shortages were caused by a range of issues, with supply/demand fluctuations and manufacturing problems leading to almost 50% of new shortages. However, another 42% of shortages were caused by unknown factors, indicating that there is still much work to be done to achieve supply chain visibility, transparency, and resiliency in this industry, even before accounting for a global pandemic. ⁷¹ The recent closing of factories producing baby formula from a single source reflects the vulnerability to infant nutrition.

The large number of patients on ventilators during COVID-19 put additional pressure on certain key areas, such as the demand for propofol, a common sedative used during intubation procedures. This pharmaceutical is in high demand and difficult to secure in Arizona. Even before the spring and summer of 2022 disruption in infant nutrition, products such as Similac and Enfamil, along with electrolyte solutions such as Pedialyte, became difficult to obtain at various times.

The distribution of pharmaceuticals is largely facilitated by three major wholesalers, which operate extensive national distribution networks. Collaboration in the pharmaceutical network was noted by one of the GPOs, we interviewed, as important to averting issues during the first two years of COVID.

"Having manufacturers come to the table in response to a steady demand signal and consistent forecast has resulted in a seamless receipt of vital medications that used to be a top-of-mind supply and safety concern."

Importantly, distributors leveraged their strong relationships, logistics expertise, and emergency response expertise to establish a "fair allocation" program to meet demand. This was facilitated by the existence of regular updates of a number of COVID admissions and ICU capacity.

It is noteworthy that Arizona did not see a notable difference in impact from the COVID-19 pandemic as compared to other parts of the U.S. Some geographic factors could conceivably affect the demand for certain categories of medications, however, and could therefore disproportionately affect Arizona if these types of medications became difficult to obtain. Examples include certain antivenoms, as well as treatments used to combat severe dehydration, both of which would be in higher demand in Arizona than in many other states. As recently as May 2022, more than half of infant formula products were out of stock in Arizona as the nationwide formula shortage worsened.

Respondents to the AzCHER survey listed multiple pharmaceutical suppliers. Our expert panel reflected on shortages and the challenges associated with increasing supply, bringing manufacturing closer to the U.S., and allocating resources by both the SNS and distributors. These concerns are considered at the national level.

⁶⁹ Statista (2021). *Number of Drug Shortages in the United States from 2001 to 2021*. URL: https://www.statista.com/statistics/288876/number-of-drug-shortages.

⁷⁰ U.S. Food & Drug Administration. (2020). *Drug Shortages for Calendar Year 2020*. URL: https://www.fda.gov/media/150409/download.

⁷¹ Accenture. (2021). *The Pharmaceutical Supply Chain: Closing the Visibility Gap – The State of Pharmaceutical Supply Chain: Industry Report*. URL: https://www.accenture.com/ acnmedia/PDF-166/Accenture-Pharmaceutical-Supply-Chain.pdf.

5) LEASING ENTITIES

Leasing entities provide medical equipment and related medical equipment and services to healthcare providers throughout the U.S. The products they rent include ventilators, defibrillators, intravenous pumps, patient monitors, and other lifesaving products. Large national companies maintain thousands of pieces of equipment, keeping such equipment on hand in their warehouses nationwide. Leasing companies frequently maintain a transportation network to deliver equipment to healthcare providers. The medical equipment rental market divides into durable medical equipment that is further divided into acute care, long-term care, and emergency and trauma care.

Leasing companies offer rentals for both short and long term. Healthcare providers may tum to a rental supplier in the face of an unanticipated equipment shortage when there is a sudden surge of patients needing care and insufficient equipment on-hand to meet the need.

Leasing entities are especially important during times of disaster. For example, in the wake of the September 11, 2001, terrorist attacks, the number of patients surged in New York City and Washington, D.C. area hospitals. Rental agencies transport and deliver warehoused products, including defibrillators, ventilators, breathing pumps, and cardiac monitors - to affected hospitals the same day. In August 2005, rental agencies mobilized equipment to assist in areas affected by Hurricane Katrina. Again, in September 2008, Freedom joined other first responders after Hurricane Ike devastated Galveston Island.

Such entities were not well equipped for a pandemic of the proportion of COVID-19. While leasing entities work to meet demand during periods of spike, the magnitude of a number of cases early in the pandemic stressed the leasing industry's goal to provide "peak use" back-up. Early in the pandemic, one major rental company, US Med-Equip, had rented 60 percent more ventilators, monitors, and other equipment over the past few weeks than at any time during the previous year.

These entities, the larger of which are frequently sourced via GPOs, are susceptible to the same disruptions as provider organizations for newly manufactured products. Importantly, there are significant barriers to market entry to expand the backup role of leasing organizations due to the amount of capital needed and high concentration in the market as UHS has well over half of the national rental market and, along with Hill-Rom, constitute at least 75% of the rental market. Other major companies include MedOne Group, AGITO Medical Equipment, Siemens Financial Services, Westside Medical Supply, and Nunn's Home Medical Equipment.

Respondents to the AzCHER survey listed multiple leasing companies, with two companies dominating the supplier terrain. Leasing companies frequently provide their services via GPO contracts and are not designed to meet the demands of large-scale disruptions. These companies have capabilities in maintaining backup inventory and could be considered candidates for collaboration with AzCHER members. However, exactly which products to maintain for reserves, given the demand for different kinds of products for different disruptions, remains a challenge. In many ways, leasing companies are part of the "stand-by" supply rather than a major supplier category.

6) MANUFACTURERS AND DISTRIBUTORS OF DISPOSABLE SUPPLIES AND PPE

Disposable medical supplies consist of medical apparatuses, devices, or consumables intended for one-time or temporary use in medical settings. These supplies are an essential component in hospital settings, as they save staff time, reduce risk to employees and others within the walls of

the care setting, and reduce healthcare-associated costs. A few examples of disposable medical supplies include bandages and wraps, drug tests' disposables, exam gowns, face masks, gloves, suction catheters, surgical sponges, hypodermic needles, syringes, and applicators, among others. The disposable medical supplies market is segmented based on diagnostic supplies, dialysis consumables, radiology consumables, infusion products, intubation and ventilation supplies, hypodermic products, sterilization consumables, nonwoven medical supplies, wound care consumables, and other medical supplies.

During the COVID-19 pandemic, a group of disposable medical supplies, referred to as personal protective equipment (PPE), were in great demand. The inability to meet this demand, for healthcare organizations and the citizenry at large, received great publicity — especially for masks, gloves, hand sanitizer, and other disinfectants. These supplies, long considered commodities, are frequently sourced out of the U.S, were in short supply and took on a strategic value as their demand skyrocketed as COVID-19 surged. It has been estimated that the demand surge during COVID-19 was 300% to 400% from 2019-to 2021. For masks, perhaps the most prominent category of PPE, demand increased from 5% to 40%, with consumer and non-healthcare demand accounting for 60% to 70% of the demand.

Disposable medical equipment is generally sourced through GPOs and purchased through distribution channels. 3M, the dominant manufacturer of N95 masks, sells exclusively through distribution. During COVID-19, they worked to understand the needs of nursing homes and other provider organizations that had never used traditional distribution channels. Perhaps unrecognized is the fact that hospitals did not use many respirators before COVID-19.

A 2021 survey of Arizona acute care provider organizations⁷² revealed twenty disrupted products, rank-ordered in Exhibit 16. High on the list were PPE, including masks, gowns, caps, gloves, and face shields, as well as other disposable devices, including tubing, ventilators, cannulas, syringes, and products that would be considered medical devices – but not disposable, such as a thermometers, stethoscopes and ventilators, telemetry monitory units, IV pumps, and blood pressure monitoring machines. While some of these supplies were judged to have substitutes if unavailable (e.g., switching from paper to cloth gowns), many have no substitutes.

Exhibit 16 - Products in Short Supply in Arizona During COVID-19

1. Masks	11. Face shields		
2. Gowns	12. Fluids		
3. Caps	13. Linen		
4. Disinfectant	14. Stethoscopes		
5. Gloves	15. Thermometers		
6. Shoe covers	16. Ventilators		
7. Tubing	17. Cannulas		
8. Viral transport media	18. Reagents		
9. Eye protection	19. Syringes		
10. Filters	20. Oxygen		

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⁷² Eckler, J. & Schneller, E. (2021). *AZ Healthcare Emergency Planning: An After-Action Report: Supply Chain Management* (June 2021). Presented to leadership, Arizona acute care hospitals.

Respondents to the AzCHER survey listed multiple suppliers of disposable medical supplies. Supplies are secured both through direct contracting with manufacturers as well as through GPO contracts and distributor contracts. All entities worked tirelessly to secure products, but with the large proportion of these products produced from global sources, especially Asia, securing additional goods in a time of surge was not possible. An earlier survey identified the principal products in shortage during the first two years of COVID-19, many of which were disposable and, in many instances, had no substitutes (see Exhibit 17).

Exhibit 17 - Survey of Maricopa County Healthcare Systems' Product Shortages⁷³

CATEGORY	EXAMPLES	SUBSTITUTABILITY		
PPE	Masks, Gowns, Gloves, Wipes	Limited		
Critical Care Supplies	Cannulas, Tubing, Ventilators	Limited		
HVAC	HEPA Filters	Yes		
MED/SURG	Stethoscopes, Syringes, Linen	Limited		
LAB	Swabs, Tubes, Pipets	Limited		

These supplies, especially PPEs, remain the focal point for discussion, policy, and sourcing. Some states, notably California and New York, have mandated reserve levels for PPE. The size of such reserves, and the strategies to maintain them, remain uncertain. In addition, there is concern that the products in reserves, based on an air-borne virus, may not be the products most appropriate for a wider range of disruptions identified by AzCHER members. AzCHER was able to serve as a "clearing house" for its members as they identified needs. As elaborated upon in Chapter IV, AzCHER could continue providing visibility and transparency into inventories.

7) HAZARDOUS WASTE

There is not a single comprehensive list of hazardous waste that is continuously updated. For a material to be a hazardous waste, the material must first be a "solid waste." Regulated medical waste (RMW), also known as 'biohazardous' waste or 'infectious medical' waste, is the portion of the waste stream that may be contaminated by blood, body fluids or other potentially infectious materials, thus *posing a significant risk of transmitting infection*. Every year, approximately 2.6 million tons of medical waste is generated, with a large majority coming from healthcare facilities, such as hospitals, doctors' offices, dentists, research facilities, veterinarians, and surgery centers. And healthcare facilities are not alone. Tattoo parlors and funeral homes also generate biohazardous waste, as do pharmacies, nursing homes, and stand-up vaccine and testing clinics.

⁷³ Ibid.

⁷⁴ BCC Research (2012). US Medical Waste Treatment, Containment, Management and Disposable Market (December 10, 2012). URL: https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx.

https://www.bccresearch.com/pressroom/env/arket-medical-waste-treatment-containment-management-disposal-reach-nearly-\$3.2-billion-2017

Regulations are in place to help reduce the risk of injury and infection during handling at the point of collection and transport for ultimate disposal. OSHA has a number of regulations⁷⁶ related to the safe handling of biohazardous waste to limit the risk of spreading bloodborne pathogens (BBP) in the workplace. However, regulations regarding hazardous waste are set at the state level.

Hazardous waste, composed of infectious waste, pathological waste, sharps, pharmaceutical waste, genotoxic waste, chemical waste, and radioactive waste, is traditionally only 15 percent of all waste within the health sector. While contaminated face masks, gloves, and materials for diagnosing, detecting, and treating COVID-19 can create environmental problems, they do not appear to pose a risk for infection shortly after use.⁷⁷

"According to the Centers for Disease Control and Prevention, management of medical facility laundry, food service utensils and medical waste should be performed in accordance with routine procedures. There is no evidence to suggest that medical waste associated with COVID-19 needs any additional disinfection." ^{78,79}

Of special concern is the waste created through the use of sharps such as needles, scalpels, blades, and pipettes that have come in contact with blood, body fluids, or microorganisms that should be disposed of in a designated disposable sharps container. Other forms of waste generated from procedures, including any items saturated with human blood or other potentially infectious materials (OPIM), such as bandages, gauze, or PPE, are considered RMW or red bag waste. Like any biohazardous waste, COVID-19-related medical waste can cause injury and infection when handled incorrectly. Overall, providers of medical waste services were not overly stressed during COVID-19; however, during the mass vaccination campaigns, there was a shortage of FDA-cleared sharps disposable containers.⁸⁰

C. DISRUPTION IMPACTS FACED BY PROVIDERS AND SUPPLIERS

Through our interviews, surveys, and literature review, we identified 12 distinct vulnerability situations that could lead to a healthcare supply disruption. The cause or trigger of such situations could emanate from a number of circumstances: environmental, epidemiological, political, or manmade. While these disruptions can occur anywhere in the world, they can impact the delivery of healthcare across the U.S. and, in particular, in Arizona.

While some disruption triggers happen with regular frequency (e.g., hurricanes), predicting the timing of many triggers is mostly beyond our capabilities (e.g., pandemics or cyberattacks). And from a supply chain management perspective, what causes the trigger is less important than the situation it creates. Having the capability to mitigate the situation is more important.

To help understand the range and type of supply disruption-driven vulnerabilities, we have categorized the 12 vulnerability situations into four types:

Product Availability Vulnerabilities

⁷⁶ Stericycle. Why is OSHA so Important? URL: https://www.stericycle.com/en-us/resource-center/blog/osha-and-your-safe-workplace?referrer=/knowledge-center/newsletter/osha-and-your-safe-workplace.

⁷⁷State of Oregon Department of Environmental Quality. How to Dispose of Medical Waste Exposed to COVID-19.

⁷⁸ State of Oregon Department of Environmental Quality. How to Dispose of Medical Waste Exposed to COVID-19.

⁷⁹ State of Oregon Department of Environmental Quality, Managing COVID-19 Waste. URL: https://www.oregon.gov/deg/FilterDocs/SW-covid19.pdf

⁸⁰ Medically Necessary: Demand Surge, Supply Shortages Complicate COVID-19 Waste Management, March 2021.

- Product Quality Vulnerabilities
- Product Cost Vulnerabilities
- Supply Chain Management Vulnerabilities

Exhibit 18 below displays these 12 vulnerabilities by type. Each of these vulnerabilities can cause a healthcare supply disruption and, consequently, a failure in the supply chain.

Exhibit 18 – The 12 Disruption Vulnerabilities in the Supply Chain

PRODUCT	PRODUCT	PRODUCT COST	SUPPLY CHAIN
AVAILABILITY	QUALITY		MANAGEMENT
 Increased demand Decreased supply Uncertainty of demand and supply Delivery delays 	Substandard productsCounterfeit products	Increased costCost of qualifying new productsIncreased training	 Lack of information Lack of coordination and trust Lack of best practices

These vulnerabilities have a direct impact on the delivery of healthcare in Arizona. The source of the disruptions that cause them could be global.

We also examined the likelihood of these vulnerabilities having an impact on healthcare providers for the seven product categories we examined. Exhibit 19 below identifies the key disruptions to studied product categories as they relate to availability, quality, cost, and supply chain management practices. The rating indicates the susceptibility to disruption. We found that two of the product categories (disposables and pharma/nutritional products) are more susceptible than others to supply chain disruptions. More attention to these products is warranted.

Exhibit 19 - Susceptibility to Disruptions by Product Category

SUSCEPTIBILITY TO PRODUCT CATEGO		TIONS BY	SUPPLY CHAIN DISRUPTIONS										
PRC			RODUCT AVAILABILITY		PRODUCT QUALITY		PRODUCT COST		SUPPLY CHAIN MANAGEMENT				
CATEGORY			Track Control of the	Ok Outer State of the State of	S. John House I.	or in the last of	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	THE PERSON NO.	and the state of t	Support of the state of the sta	160 00 00 00 00 00 00 00 00 00 00 00 00 0	Say Down The County of the Cou	
Blood						0			•	0	0	0	
Disposables													
Fuel		•		•	0	0	1	•	•	0	0	0	
Hazmat		0		•	0	0	1	•	•	0	0	0	
Leasing		•		•	•	0			•	•			
Medical Gas					0	0	•	0	0	0	0	0	
Pharma/Nutritional													
		KEY	•	High Likeli	hood	(Medium Li	kelihood	0	Low Likelih	nood		

In the sections below, we describe each category and provide findings from our analysis to support them.

1) PRODUCT AVAILABILITY VULNERABILITIES

Likely the first and most apparent supply chain vulnerability resulting from an external disruption is a situation where particular products are not available – either not at all or not in the quantity requested. The cause of the availability shortfall is often complex, as is the supply chain that supports it. Demand for products can increase exponentially, creating a situation where the inventory safety stock provision is exceeded. This was the case often experienced during the COVID-19 pandemic. In other cases, production levels at manufacturing sites could be diminished due to a number of operational problems, including regulatory ones. Such reduction ripples down the supply chain to the organization supplying the healthcare provider, and sufficient product is simply not available. There are other reasons as well for availability shortfalls which will be discussed below.

When product is not available, for whatever reason, orders are filled according to an allocation formula. These allocation formulae are often problematic. We have found that there is no standard process for determining allocation and, in fact, the goals of the allocation methodology vary among suppliers. Some are based simply on historical purchases, while others introduce a criterion reflecting the suppliers' view of the customer's need. Typically, no one gets the quantity of product they desire, with some customers who are short-shipped having a very real need for life-saving situations. Manufacturers who work only through distributors leave allocation in the hands of distributor allocation principles.

We found four specific situations that result from product availability disruptions. Each is discussed in detail below.

i) Increased Demand for Healthcare Products

Typically, manufacturers and distributors hold inventory in the supply chain to accommodate fluctuations in product demand. The expected fluctuations are based on historical demand. Most often, this historical demand does not include unusual 'one-time' black swan (or even 'gray swan') events such as a pandemic. Hence, when such black swan events occur, the safety stock of inventory is insufficient to meet the skyrocketing demand. During the recent COVID-19 pandemic, hospitals did not maintain sufficient stockpiles for high-demand items such as personal protective equipment (PPE). That, along with the increased demand, created severe product availability issues in a number of critical product categories.

Suppliers told us they had faced unprecedented global and national demand, leading to an imbalance in supply versus demand. According to a supply chain leader at a major healthcare system, while the supply chain did not fail them, the demand increase was so great that it could not keep up with the additional demand. Of all of the products facing increased demand, our survey of Arizona providers told us that PPE presented the greatest concern during the COVID-19 pandemic.⁸¹

According to an Arizona state government official, while the Strategic National Stockpile (SNS) managed by the federal government was available with many of the required

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⁸¹ ASU Survey of AzCHER members, 2022.

products, their solution was neither appropriate, useful, nor available. Perhaps this was an unreasonable expectation, since the SNS was intended for medical counter-terrorism measures, not pandemics⁸² and considered to be a "back-up," rather than as a primary source.⁸³ As a result, neither the products nor the authority to release them was right for the situation. This was compounded by the fact that many of the products were old and past their expiration date resulting in substandard quality.

Beyond PPE, shortages were faced by the medical gas industry. As additional bed capacity was quickly brought on stream, many of the new beds were not equipped with oxygen portals at the bedside. Portable cylinders were needed. We were told by a major medical gas company that the "whole world was looking for more cylinders" for oxygen, and other vital medical gases to support the increased demand. National drug shortages also worsened during COVID-19. Antiviral and antibiotic medications have been in short supply and many other intravenous drugs are being used for post-COVID-19 pneumonia and for inpatient care. The FDA published list of shortages is an important resource.

The increased demand for products during a major supply chain disruption can be staggering. The recent COVID-19 pandemic clearly demonstrated that. The lesson it taught us is that we need to be prepared such situations and importantly, know how to mitigate them.

ii) Decreased Supply of Healthcare Products

During some supply chain disruptions where demand increases, a parallel decrease in the supply of products sometimes occurs. During the COVID-19 pandemic, regular product supply lines were being re-routed globally in response to political and medical needs in other parts of the world. This rerouting, combined with workforce reductions due to either COVID-19 quarantines or simply the fear of virus spread, reduced manufacturing capacity worldwide and accessibility to supply. Accordingly, decreased supply of healthcare products is a key determinant of product availability to healthcare providers.

Medical product suppliers reported that their global supply chains were significantly disrupted. A major supplier reported experiencing unprecedented supply chain challenges resulting in limited availability of and access to raw materials, shipping and transportation delays, labor shortages, and backorder situations. ⁸⁶ Given that a single supplier supplies close to 90% of the blood collection tubes, a slowdown here impacts almost all providers in the U.S. healthcare industry. On a broader view, Handfield reported export bans and manufacturing shutdowns globally contributed to ongoing shortfalls. ⁸⁷

Domestically supply constraints hit the blood banks. Due to past industry consolidations many of the smaller centers could no longer compete. When the pandemic hit, safety

⁸² Interview with Arizona Department of Health Services.

⁸³ Handfield, R., Finkenstadt, D. J., Schneller, E. S., Godfrey, A. B., & Guinto, P. (2020). A Commons for a Supply Chain in the Post-COVID-19 Era: The Case for a Reformed Strategic National Stockpile. *The Milbank Quarterly*, *98*(4), 1058–1090.

⁸⁴ Interview with medical gas manufacturer.

⁸⁵ FDA (2022). Medical Device Shortages During the COVID-19 Public Health Emergency, March 17, 2022. URL: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency.

⁸⁶ Correspondence with project team, May 17, 2022.

⁸⁷ Why the U.S. Still Has a Severe Shortage of Medical Supplies, Daniel Joseph Finkenstadt, Robert Handfield, Peter Guinto

concerns led to operational restrictions where blood collection centers went from an efficient operation where they could collect 200 units of blood at one drive in five hours to collecting only 30 units of blood.

Experience has shown that global supply reductions, no matter where in the world they occur, can have a direct impact on product availability for providers in Arizona. They may be caused by manufacturers reducing production levels due to plant operational issues, by exporting countries imposing export restrictions, or by raw materials shortages. Whatever the cause, if the manufacturers and suppliers don't have the products, it just can't be ordered or delivered.

iii) <u>Delivery Delays</u>

Even when demand levels are stable and supply is steady, product availability shortfalls can occur due to disruptions to the transportation network. This causes delayed deliveries. When delivery delays are combined with demand increases and with supply limitations, a perfect storm arises, as it did with the COVID-19 pandemic.

Suppliers reported delivery delays from supply chain disruptions that directly affected product availability. These delays occurred with shipments from manufacturing sites (often offshore) to U.S. distribution centers.⁸⁸ Some of this delay for ocean-bound shipments was due to congestion at the west coast ports. Delivering product to providers has also been an issue due to driver shortages, particularly with specialized products such as fuel and medical gases.

Disruption caused by an earthquake or other natural disaster that disrupts the major petroleum pipelines from Texas and California, the sources for the entire state of Arizona, poses a threat. Further, if a disruption occurred at the Palo Verde nuclear plant west of Phoenix and close to the major rail line from California, as significant portion of the state's fuel supply is in jeopardy.

Just as the increased demand for product during a health emergency places pressure on suppliers, it also places great pressures on transportation networks. Suppliers told us that the demand for increased delivery frequency during the pandemic created need for additional drivers and warehouse staff.⁸⁹. These resources were not available resulting in further delays for product delivery.

iv) Uncertainty of Demand and Supply

Another significant contributor to product availability is uncertainty. Noteworthy are uncertainties inherent in demand projections, uncertainty of suppliers to provide product, and uncertainty of how long and deep the disruption will be. These uncertainties directly impact the providers' management of their product supply chains. Difficult to predict is how much they order, how much should they inventory, and will a substitute product be acceptable from a clinical perspective? Many questions arise that cannot be answered definitively and the ability to change direction, quickly, is necessary. Of constant concern is the impact of product shortage and the operational limitations directly affecting the delivery of healthcare services.

⁸⁸ Interview with representatives from a major GPO.

⁸⁹ Interviews with representatives from a major GPO.

Most providers depend upon distributors. In times of supply chain disruption, the lack of clear visibility of distributor fulfillment capability leads to uncertainty on when and how much product will be delivered. Continued uncertainty leaves providers with dwindling confidence in the normal supply chain and proliferates more maverick and forward buying, as well as hoarding.

During the COVID-19 pandemic, as the mass vaccination programs were rolled out, many providers faced increased uncertainty of the simple availability of needles.⁹⁰ This led one leader from a distributor organization to state that going forward supply chain disruptions are and will be perennial.

In Arizona, our survey indicated that the AzCHER providers were dependent on relatively few suppliers for some product categories (e.g., gas, PPE, and pharma). While this dependency is expected in some categories (e.g., medical gas) where the industry is concentrated, other categories, to assure redundancy, were more concentrated than expected.

Uncertainty of supply leads to operational uncertainty. While most organizations can manage a certain level of uncertainty, when combined with significant increased demand and decreased supply, uncertainty simply exacerbates the operational chaos that ensues.

2) PRODUCT QUALITY VULNERABILITIES

Availability issues deal with quantity. But in addition to access to quantity, the quality of the products can emerge in the course of a supply chain disruption. As sourcing specialists scour the market for new sources of supply, they find that discovered product requires careful consideration. Some may not meet acceptable standards. Others may not be what they claim to be – with counterfeit products, frequently claiming to be brand name products, come into the market. We discuss these below.

i) Substandard products in the market

As demand for product skyrockets providers who are unable to access sufficient supply will typically seek product from new, often untried sources. Usually, this product varies from the standard products sourced. Product variance can be acceptable if it meets minimum standards. However, often during a chaotic period, the demand is so acute that corners are cut, exactitude is short-changed, and below acceptable standard products are acquired.

This situation occurred during the COVID-19 pandemic, particularly for PPE products. As supply for masks and gloves became almost non-existent, many providers, particularly the smaller ones, sought products from suppliers that they had never used previously and for product with dubious providence. In certain situations where infection control needed rigorous attention, the new products created risks for the users.

Distinct from this, many providers (and governments) had expected that in an emergency they could rely, as discussed earlier, on the federal government's Strategic National Stockpile (SNS) for access to PPE. It turned out that despite it being a good idea, when COVID-19 hit, the inventories in the SNS had not been properly maintained and that many of the products had expired or not fit for use. In our survey of AzCHER members, 25% had

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⁹⁰ Interview with a major supplier.

indicated that the SNS products that they had received were either of poor or fair quality. In the healthcare industry that is an unacceptable quality level.⁹¹

ii) Counterfeit products

Healthcare workers rely on certainty of the performance of the products that they use. By standardizing on pre-approved products, this certainty is assured. But if the product inside the box is different than what is labelled on the outside, then this certainty of performance is jeopardized. Increasingly, counterfeit products which attest to be a particular branded item are not. This is misleading. This is fraud. This is deceptive commerce, and it occurred prior to and was of even greater frequency during COVID. 92, 93 But it's happening on a regular basis. The FDA and major manufacturers have taken a strong interest in eliminating counterfeit products, but it is a big industry and many counterfeit items get through.

During the COVID-19 pandemic when providers were prepared to accept whatever PPE product that they were able to get, there were many instances of misrepresented product. 3M, the country's largest supplier of masks, has a department dedicated to dealing with counterfeit products. During the COVID-19 pandemic they received over 18,000 reports of counterfeit products representing over 56 million improperly represented respirators.⁹⁴

3) PRODUCT COST VULNERABILITIES

Supply chain disruption impact behaves according to the laws of economics. When products become scarce either due to increased demand or decreased supply, prices increase. While it would certainly be preferable to avoid price increases, fundamental economics does not operate that way. To a healthcare provider these disruptions affect their costs in three ways:

- Increased product acquisition cost
- Increased training cost
- Increase product selection and qualification cost

During the COVID-19 pandemic these cost impacts were apparent. During other triggered events affecting the supply chain, similar cost vulnerabilities will occur.

i) <u>Increased cost for healthcare pro</u>ducts

The most obvious impact of a supply disruption is that the acquisition price of a product rises. As demand increases beyond supply, prices almost always follow upward. This occurred as suppliers sought to pass on their cost increases due to product shortages or higher costs for manufacturing beyond their planned capacity.

Another driver of price increases is reduced supply due to hoarding. In the early days of the COVID-19 pandemic, the White House was concerned about hoarding medical

⁹¹ Survey of AzCHER members, February 2022.

⁹² U.S. Food & Drug Administration (2017). *Drug Supply Chain Integrity* (June 13, 2017). URL: https://www.fda.gov/drugs/drug-safety-and-availability/drug-supply-chain-integrity.

⁹³ U.S. Food & Drug Administration (2021). *Counterfeit Medicine* (December 12, 2021). URL: https://www.fda.gov/drugs/buying-using-medicine-safely/counterfeit-medicine.

⁹⁴ Interview with 3M representative, May 2022.

supplies and issued a presidential executive order to prevent it. Further, a 2021 White House executive order addressing healthcare supply chain issues recognized the presence of recurrent price gouging in pharmaceuticals and sought a plan to combat it.⁹⁵

ii) Cost of qualifying new products

When new products are proposed for introduction to a healthcare delivery system, the review process is rigorous. Does the product do what it says it does? Is it reliable? How is it used? What steps are needed to apply it? What special training is needed? Are clinicians comfortable using it? Does it achieve the clinical outcomes promised?

During a supply chain disruption, new products, serving as a substitute for those not available, are typically introduced into service. This is an unintended consequence of efforts to replace inventory. Each one requires a qualification process that involves resources and takes time to complete. The process is disruptive and costly. This is an area where there has been great demand and response by the FDA. ⁹⁶ Unfortunately, there are no easy ways to avoid scrutiny and qualification. The challenge to sourcing teams is to ensure access for information and management of the entire product catalog.

iii) Increased cost for training staff in the use of replacement products

When alternative products are introduced, as was the case with new suppliers of PPE and other medical products, clinical staff need new training programs to learn how to use them. While this might sound trivial for relatively simple disposable products, it is not. A switch from an N95 mask to a KN95 mask requires awareness of the mask features and fit. An ill-fitting mask is often as good as no mask at all.⁹⁷

4) SUPPLY CHAIN MANAGEMENT VULNERABILITIES

The previous three categories of vulnerabilities were specific to products. This fourth category addresses vulnerabilities due to a provider organization's inability to manage the supply chain in a resilient manner. When providers (and suppliers as well) are unable to manage their supply chain affairs to avoid disruption, the provider's business competency is a vulnerability itself. We identified three forms of supply chain vulnerability from the management perspective.

i) Lack of information about the system condition

Foremost among the drivers of supply chain disruptions is the lack of information about the state of the supply chain. How much inventory is in place? Where is the inventory located? What products are available? What products are in transit? When will they arrive? And many other questions to be answered. Each stakeholder within the chain usually has suitable and sufficient information about their own affairs, but during times of a supply chain disruption, individual status data is not useful without comparable

⁹⁵ Executive Order on Promoting Competition in the US Economy, July 2021.

⁹⁶ U.S. Food & Drug Administration. (2021). *Coronavirus (COVID-19) Update: FDA Outlines Inspection and Assessment Activities During Pandemic, Roadmap for Future State of Operations* (May 5, 2021). URL: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-outlines-inspection-and-assessment-activities-during-pandemic.

⁹⁷ D'Alessandro, M. & Cichowicz, J. K. (2020). Proper N95 Respirator Use for Respiratory Protection Preparedness. *Centers for Disease Control and Prevention* (March 16, 2020). URL: https://blogs.cdc.gov/niosh-science-blog/2020/03/16/n95-preparedness/.

information from other stakeholders in the supply chain. This requires supply chain transparency. In a competitive market transparency is not offered. In a competitive market during an emergency disruption, it is greatly needed.

When the COVID-19 pandemic began, the supply chain leaders in the major acute care hospitals in Maricopa realized that their inventories for certain products, particularly PPE, were insufficient to support the increased demand. On an informal basis they established a "commons" program with weekly telephone calls to share supply and demand data. While they did not share access to their ERP systems, the source for detailed information, they verbally compared inventories and offered their assistance to others when appropriate and sought extra product as needed. The supply chain leaders acknowledged that during the emergency, information transparency was acceptable and necessary. But this program was temporary and limited to these large IDNs.

Separately the Phoenix Fire Department and 26 neighboring fire departments in central Arizona, regularly share information with each other regarding difficult to source products through their Regional Operations Consistency Committee (ROCC). During the COVID-19 pandemic, this sharing program included many forms of PPE. This program extends beyond supply chain matters to include engineering standards, vehicle specs, and training. These fire departments recognized that fires are not bounded by political boundaries and that cooperation throughout the region is paramount for the large departments as well as the smaller ones. This program, in fact, forms a 'commons' among fire departments and has worked successfully for many years. It may offer some valuable lessons for an emergency healthcare supply chain commons in Arizona.

One of the GPO respondents opined on the problem with a supplier not sharing the extent of back orders for a major medical product. As a result, no one in the industry knew how bad the problem was until it was too late. Earlier cooperation and information sharing would have enabled providers and their support teams to locate alternative suppliers before inventories were depleted.

Supply chain information transparency is critical for all stakeholders to make optimal sourcing decisions. During emergencies when supply chains are disrupted, such information transparency will avoid vulnerability leading to healthcare delivery failures.

ii) Lack of coordination and trust among healthcare product stakeholders

One of the greatest drivers of supply chain vulnerability is the lack of communication and coordination among stakeholders. Timely, informed decisions need to be made regarding product availability. They cannot be made without full knowledge of the quantity and condition of product inventory throughout the supply chain. Typically, such information is guarded and not shared beyond the walls of each organization in the supply chain. This lack of sharing is due to a lack of trust among both partners and competitors within the supply chain. Stakeholders fear that if they release information about inventory levels, competitors will use it against them. This also extends to collaboration among supply chain members to develop optimal product allocation and routing solutions. During stable times, the supply chain operates through a relatively successful fragmented set of organizations who each control their operation and their data. When a crisis occurs due

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⁹⁸ Interview with GPO representative.

to a supply chain disruption, these chain members are neither accustomed or comfortable operating in an open and collaborative manner.

Supply chains typically operate in an equilibrium situation. Some call it synchronicity. Demand is forecasted and manufacturers produce to that forecast. Transportation providers ship the product along regularly scheduled arrangements. In an emergency when demand increases and/or supply decreases, the supply chain goes out of equilibrium and orders for products are not met. In a fully vertically integrated industry, supply chain control tower technology could provide a full view of the situation and take the necessary actions to restore equilibrium. But such technology is not yet in place and the healthcare system is far from vertically integrated with numerous tiers and independent organizations disjointedly operating without knowledge of the other organizations.

In the case study, A Perfect Storm,⁹⁹ the authors describe the lack of communication and coordination among stakeholders as contributing to supply chain disruption. Further, when export bans are imposed, as they were during the early stages of the COVID-19 pandemic, together with lack of information sharing, it leads to the inability to make incisive decisions. Further, even within large provider organizations there is sometimes a disconnect between SCM and EM departments within hospital.¹⁰⁰ Among suppliers when one is not forthcoming with information about product supply issues, the ramifications extend down the chain, as it was with one critical medical supply manufacturer.¹⁰¹ This is further compromised when the objectives of the various parties are misaligned as they often are between manufacturers, distributors, and GPOs.¹⁰²

In addition to communication between suppliers and providers, the communication between suppliers and governments was as bad or worse. Governments that were trying to make decisions on support and recovery had little access to information about the supply chain combined with their general lack of knowledge of how the medical supply chain functioned.

iii) <u>Lack of supply chain management best practices throughout the system including business continuity plans, supply chain mapping, and governance.</u>

Modern supply chains are large, broad, and complex. Managing them requires specialized expertise. While large organizations with established supply chain departments usually have this competency, many medium and small sized providers do not. During normal times, these medium and small providers can get by with standard support from their distributors. However, when a significant disruption emerges, such as the PPE shortage during the COVID-19 pandemic, these smaller providers need access to capabilities that they do not possess. As was seen during the COVID-19 pandemic, their traditional sources of supply and expertise failed them. In today's market, all provider organizations need

⁹⁹ Kraft, Tim; Shah, Jimit; Alagesan, Suriyaprakash; Handfield, RobertDarden, A Perfect Storm Perfect Storm: Examining the Supply Chain for N95 Masks during COVID-19. Case OM-1708 / Published November 30, 2020. http://store.darden.virginia.edu/a-perfect-storm-examining-the-supply-chain-for-n95-masks-during-covid-19.

¹⁰⁰ Interview with a major IDN.

¹⁰¹ Interview with GPO representative.

¹⁰² Interview with GPO representative.

supply chain management expertise to deal with the increasing complexity of modern supply chains.

In medical supply manufacturing, and especially in pharmaceutical manufacturing, the standard for quality and efficiency is GMP, Good Manufacturing Practices. It addresses issues including record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. GMP is, in fact, embedded in FDA regulations. For supply chain management, suppliers as well as providers need a similar code to follow. It should be Good Supply Chain Management Practices (GSCMP). Without them, stakeholders are vulnerable to disruptions as well as other failures.

Our interviews and survey confirmed the lack of best practices leading to supply chain failures. These shortcomings were not limited to providers. Many suppliers struggled with product allocation solutions, typically basing their allocation models on historical demand and not considering clinical need or needs of providers that had never required certain products before (e.g., PPE). Other important stakeholders with a need for better supply chain management expertise were government regulators and emergency operators. There was a concern that when they introduce solutions regulators don't understand SCM sufficiently. As well, the teams managing the SNS lacked the expertise to manage inventories. 104

¹⁰³ Interview with major manufacturer/supplier management team.

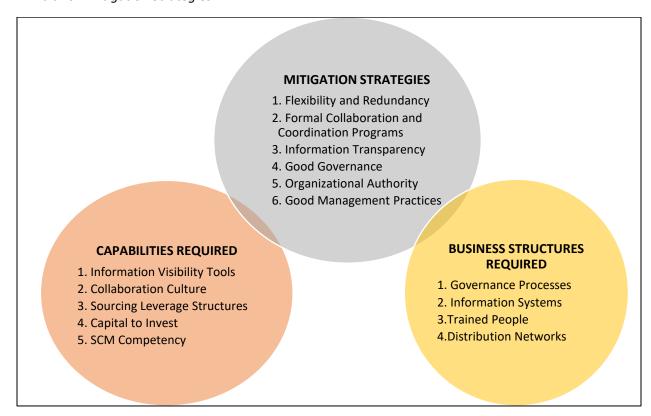
¹⁰⁴ Op., cit. Kraft et. al.

III. MITIGATION STRATEGIES AND CAPABILITIES NEEDED TO BUILD RESILIENCY

The supply chain vulnerabilities presented in the previous chapter can impede the provision of healthcare delivery leading to poor quality and unsatisfactory outcomes. These vulnerabilities can affect all types of providers. They do not discriminate. To avoid these impacts, providers need to inoculate themselves through the application of a set of mitigation strategies. In this chapter we present recommended mitigation strategies that are applicable and relevant for all types of healthcare providers.

We recognize that the application of these strategies cannot occur without the presence of fundamental supply chain capabilities in these organizations. We outline in this chapter the capabilities required. However, organizations cannot develop these capabilities without having supply chain management structures to enable these capabilities. Hence, we lay out a set of six organizational structures that providers will need to achieve these mitigation goals. Exhibit 20 displays these mitigation strategies, the capabilities required, and the enabling supply chain management structures.

Exhibit 20 - Mitigation Strategies



A. MITIGATION STRATEGIES

Our survey, interviews, and literature review revealed six mitigation strategies that organizations in the healthcare supply chain ecosystem have been adopting to improve their resilience to supply chain disruptions. These strategies are flexibility and redundancy, formal collaboration and coordination, information transparency, good governance, organizational authority, and good supply chain management practices. Exhibit 21 provides an overview of these strategies and examples from our analyses.

Exhibit 21 - Mitigation Strategies: Definitions and Examples

Mitigation Strategy	Definition	Examples from Our Analyses
Flexibility and Redundancy	Organizations have some slack in their supply chain operations in terms of spare inventory or capacity that is used as a buffer during supply chain disruptions. Flexibility is the ability to quickly change inputs or outputs as well as the modes of receiving or distributing them.	 Inventory Extra capacity in equipment, beds, rooms Multi-sourcing Multiple manufacturing locations Diversification in the locations of production
Formal Collaboration and Coordination Programs	Supply chain participants (including typically competing providers) work together towards a common set of objectives	 Ad hoc coordination of PPE inventories among Maricopa acute care facilities
Information Transparency	Members of the supply chain share information with each other about the condition of inventories, shipments, and production plans	 Investment in technological tools that provide visibility into inventories in the supply chain network, potential triggers of supply chain disruptions, utilization rates at hospitals, etc.
Good Governance	Decision-making processes are established whereby organizational leaders or groups make decisions and produce results that meet the needs of the organization's stakeholders and make the most efficient use of available resources	 Senior leadership responsible for improving supply chain resilience Senior leadership creates risk awareness and a risk-focused culture
Organizational Authority	Schedules of authority are established clearly delineating the role and power of each member of the community	 Senior leadership creates governance structure/rules that cut across competing and collaborating entities
Good Supply Chain Management Practices	Broad category of mitigation strategies that relate to best practices of supply chain management	 Supply selection includes other metrics, including supply continuity

1) FLEXIBILITY AND REDUNDANCY

Resilience requires supply chains to be flexible to adapt to changing situations. Flexibility is the ability to quickly change the inputs or outputs of a system as well as the modes of receiving inputs

and delivering outputs.¹⁰⁵ Flexibility can relate to *sourcing*, *production*, or *logistics* flexibility. Our analysis of the healthcare supply chain ecosystem revealed that different stakeholders have started investing in improving different aspects of flexibility.

When it comes to *sourcing flexibility*, our analyses have shown that various participants in the supply chain ecosystem, including providers and manufacturers have largely sourced from a single supplier even for critical supplies. The COVID-19 pandemic, however, was a wake up that single-sourcing is a high-risk souring strategy. As a result, different stakeholders have been considering or started implementing at least a dual-sourcing strategy, especially for high-risk materials or components.¹⁰⁶

For example, sourcing from a major supplier is advised but also giving the opportunity to smaller suppliers to participate in RFPs and win contracts since smaller suppliers are more agile, nimble, ¹⁰⁷ and more willing to go out of their way to help a customer in need. Similarly, GPOs have also been advising providers to diversify their supply base and source from multiple suppliers from different locations to mitigate location-specific risks. For example, some GPOs have been recommending a 1/3-1/3 sourcing strategy, such that a third of the procurement spend is with a domestic supplier, a third with a near-shored supplier, and a third with a far-shored supplier. ¹⁰⁸ Finally, other suppliers have found other ways to be flexible. For instance, smaller blood centers quickly shifted from large to small blood drives and run those out of small vehicles during the COVID-19 pandemic in an effort to motivate the public to come out and donate blood. ¹⁰⁹ Although this nimble strategy was not as efficient, it was effective.

When it comes to *production flexibility*, we observed similar mitigation strategies. A medical gas supplier, for example, described their ability to shift production from industrial gas to medical gas, as demand for medical gas had skyrocketed during the COVI-19 pandemic. This supplier was able to do so after their production teams worked with each other to discuss and implement this production change. Besides this ability, distributors and manufacturers have been adjusting their manufacturing footprint to diversify the location risk and include more near-shore locations, while still sourcing from far-shore (e.g., Asian) suppliers. 111

Finally, when it comes to *logistics flexibility*, logistics networks must adapt to changes in global shipping patterns. Some suppliers mentioned they partner with their global transportation providers and local port authorities to move products through alternate routes to address shipping and transportation delays.¹¹²

Frequently, flexibility is enabled by redundancy, which is having spare inventory or capacity that serves as a buffer during supply chain disruptions. For example, manufacturers of PPE and other supplies have started expanding their production capacity so they can be more flexible when demand surges. Distributors and other have been moving towards holding 105 days of global

¹⁰⁵ Pettit, T. J., Fiksel, J., & Croxton, K. L. (2010). Ensuring Supply Chain Resilience: Development of a Conceptual Framework. *Journal of Business Logistics*, 31(1), 1–22.

¹⁰⁶ Written correspondence with manufacturer/supplier.

¹⁰⁷ Interview transcript with major GPO.

¹⁰⁸ Interview transcript with major GPO.

¹⁰⁹ Interview transcript with major GPO.

¹¹⁰ Interview transcript with manufacturer/supplier.

¹¹¹ Written correspondence with distributor.

¹¹² Written correspondence with manufacturer/supplier.

¹¹³ Written correspondence with manufacturer/ supplier.

supply stocked in the U.S.¹¹⁴ Nevertheless, it is unclear what these numbers exactly mean as they depend largely on the context, for example a pandemic versus a regular day. Redundancy is among the easiest yet most expensive mitigation strategies;¹¹⁵ thus, it should not be the only solution in an organization's strategy portfolio.

2) FORMAL COLLABORATION AND COORDINATION PROGRAMS

Collaboration strategies encourage multiple supply chain participants (including typically competing providers) to work together towards a common set of objectives. To enable such collaboration, the parties agree on the timing and direction of specific actions so that the supply chain decisions are made cooperatively and in alignment with each other ensuring optimal access to critical products for all. In our analyses, we observed various ways in which collaboration and coordination manifested in the healthcare supply chain.

For example, before COVID-19, PPE supplies were largely treated as "C" items by organizations. ¹¹⁶ During the pandemic, however, these items became critical. Hence, as a supplier stated during our interviews, they had to engage more closely and at a strategic level with their suppliers to ensure they had sufficient supply. As such, executive leaders from the customer and its suppliers were communicating to receive commitments and make decisions quickly. As the supply chain executive at a blood supplier stated:

"[...] things like PPE supplies, [which are] typically a "C item" [for which] we don't heavily manage... but, in light of the circumstances, they became more of a critical supply. So, when we engage those suppliers, we engage to a better, more strategic level ... I know, most of the executive team at those suppliers ... at the chief operating officer level. So that's the level we were dealing with we had to get to that level people that can make decisions quickly, not only on our side, but commitments from the supplier". 117

In another example from the medical gas industry, presidents of competitors were talking to each other to coordinate a collective effort to provide medical gas to providers. A supply chain executive at a medical gas supplier we interviewed mentioned:

"We all more or less know each other. We respect the competitive lines, when we are trying to win business, but when it comes to making sure that our communities are supported ... we will collaborate as needed. It is a small industry, and we all know each other." 118

To facilitate collaboration across competitors, medical gas suppliers contracted with their competitors. The same supply chain executive mentioned:

"There are contracts in place with our competition.... My competitors in Southern California have more drivers, we had more molecules. They came and picked them up, and because there are already contracts in place, they just came up to our plant, filled their trucks, and go and deliver. So that's where we see a lot of that resilience..."

¹¹⁴ Written correspondence with distributor.

¹¹⁵ Sheffi, Y., & Rice Jr, J. B. (2005). A Supply Chain View of the Resilient Enterprise. *MIT Sloan management review*, 47(1), 41. ¹¹⁶ "C" refers to the "Class C" items in ABC analysis. ABC analysis is an inventory management technique that classifies stock keeping units (SKUs) based on their importance to the organization. The most important stock keeping units (SKUs) in terms of sales volume or profitability are "Class A" items, the next most-important ones are "Class B" items, and the least important as "Class C" items.

¹¹⁷ Interview transcript with manufacturer/ supplier.

¹¹⁸ Interview transcript with manufacturer/ supplier.

¹¹⁹ Interview transcript with manufacturer/ supplier.

Another way to collaborate is to share knowledge around the development and implementation of business continuity plans (BCPs) and use that knowledge to align objectives and operations during supply chain disruptions. For example, a blood supplier mentioned that they try to:

"[...] bring risk awareness to the forefront of every conversation we have with our strategic suppliers." 120

At the same time, some distributors try to go beyond this to integrate their processes and business continuity plans with those of their customers, namely the providers, to ensure that all parties are aligned during a disruption.¹²¹

Finally, leaders from leading providers, GPOs, and suppliers are members of HIRC, as discussed in Chapter I. Members work together to develop plans that help to increase awareness of supply chain risks and appreciation for building resilience in healthcare supply chains. A blood supplier described to us that HIRC members meet every quarter to discuss how to increase engagement for resilience initiatives both within their organizations and across the supply chain. Members agreed to share information and best practices. Others, for example a GPO, had recommended the development of a public-private advisory council that includes representatives from manufacturers, distributors, GPOs, physicians, pharmacists, and laboratorians. Members would share information and knowledge about available suppliers, usage of supplies by providers, and develop plans to ensure supply continuity. 123

Importantly, collaboration can help supply chain participants achieve other capabilities that improve resilience. For example, one executive from a medical gas supplier we interviewed argued that there is a need to eliminate multiple stockpiles in the supply chain and not have each supply chain participant own their warehouse at a very high cost. Additionally, if we take the states or individual cities as examples, the executive mentioned:

"Washington DC has its own stockpile, New York City has its own, LA County has its own, Chicago I think has their own so there's more than just state level. Also, some cities are handled separately." 124

This redundancy across geographies, the executive argued, only adds cost. Therefore, a coordinated effort, perhaps through a public-private partnership, needs to address how stockpiles may be kept in the future to create resilience but not at a detrimental cost.

Nonetheless, collaboration has its challenges. For example, collaboration among large systems is conceptually logical but very complex. Aside from competitive priorities, the lack of product standardization and workforce training and workload issues may hinder collaboration. Additionally, some provider systems do not view collaboration as value-adding. And while recent academic papers demonstrating the case for collaboration, especially in times of disruption, and especially around the idea of pooled resources, have been put forth, little attention to such collaboration is evidenced in the health sector supply chain. 125,126

¹²⁰ Interview transcript with manufacturer/ supplier.

¹²¹ Written correspondence with distributor.

¹²² Interview transcript with manufacturer/ supplier.

¹²³ Interview transcript with major GPO.

¹²⁴ Interview with manufacturer/ supplier.

¹²⁵ Azadegan, A., & Dooley, K. (2021). A typology of supply network resilience strategies: Complex collaborations in a complex world. *Journal of Supply Chain Management*, *57*(1), 17-26.

¹²⁶ Chopra, S., Sodhi, M., & Lücker, F. (2021). Achieving Supply Chain Efficiency and Resilience by Using Multi-Level Commons. *Decision Sciences*, *52*(4), 817-832.

3) INFORMATION TRANSPARENCY

During COVID-19 it was apparent that the interests of the health of the community was paramount. Great effort was made to support the healthcare needs at the community level. In order to make the best supply chain management decisions at a community level, complete information is needed about the condition of the supply chain function within the community (e.g., inventories, shipments, production plans, etc.). This information should be real-time, accessible widely to those in need of it, and comprehensive. Our analyses of the various stakeholders in the healthcare supply chain ecosystem showed that they try to gather and share information for various reasons with multiple techniques, including collaborative planning, forecasting and replenishment (CPFR) programs, subscribing to network mapping tools that help not only map the supply chain but also provide alerts about ongoing events worldwide that might disrupt the supply chain, data analytics techniques for improved forecasting, and advanced shipping technologies that provide data about the status of shipments. We discuss these examples below:

- Collaborative planning, forecasting, and replenishment (CPFR): In a CPFR program, trading partners jointly plan and manage supply chain activities, business planning, sales forecasting, and all other operations required to replenish raw materials and finished goods.¹²⁷ One of the distributors we talk to mentioned they now utilize artificial intelligence (AI) and machine learning so they can know about disruptions sooner and act faster.¹²⁸ Moreover, others have been using predictive analytics to develop better forecasting models to align supply and demand.
- Supply chain mapping and network visibility tools: Supply chain mapping is the process of developing a visual representation of the supply chain. Supply chain maps help with identifying risks and opportunities inherent in the structure of the supply chain, determining which relationships with suppliers or customers need to be managed closely, as well as evaluating opportunities to right-size the supply base and distribution/ marketing channels. Many organizations, including manufacturers and GPOs, have been partnering with technology providers, such as Resilinc, Risk Methods, or Supply Risk Solutions, who are leading providers in mapping and supply risk monitoring solutions. These solutions provide an organization with the ability to know where product is coming from, from which sites, potential vulnerabilities around that site, triggers occurring worldwide that might influence the continuity of supply from that site and real-time alerts.
- Data analytics on product utilization at providers: GPOs have been investing in technologies
 to create robust, timely and transparent data to predict supply levels, product burn rates
 at hospitals. Meanwhile they are also working in sharing this information across the supply
 chain.¹³⁴
- Advanced shipping technology: Distributors have partnered with technology providers that provide real-time visibility of shipments in transit. Specifically, one distributor mentioned:

¹²⁷ Sherman, R. J. (2007). Why has CPFR Failed to Scale? *Supply Chain Quarterly* (July 1, 2007). URL: https://www.supplychainquarterly.com/articles/57-why-has-cpfr-failed-to-scale.

 $^{^{\}rm 128}$ Written correspondence with distributor.

¹²⁹ Gardner, J. T., & Cooper, M. C. (2003). Strategic Supply Chain Mapping Approaches. *Journal of Business Logistics*, 24(2), 37-64.

¹³⁰ Lambert, D. M. (2008). *Supply Chain Management: Processes, Partnerships, Performance*. Supply Chain Management Institute, Sarasota, FL.

¹³¹ Resilinc. URL: https://www.resilinc.com.

¹³² Risk Methods. URL: https://www.riskmethods.net/.

¹³³ Supply Risk Solutions. URL: https://resource.supplyrisk.com/webinar/SRS-HIRC-Risk-Prevention.pdf.

¹³⁴ Interview transcript with major GPO.

"Our planning and sourcing teams will have full visibility to PO level shipment information from the time a supplier places a booking request through final delivery, allowing for better planning, sourcing modeling and the ability to drive supplier behavior through enhanced scorecards." 135

Information transparency is essential for improved resilience in the supply chain. ¹³⁶ Sharing relevant and timely information about the status of assets, such as facilities, equipment, inventories, and personnel can help trading partners make better decisions. Sharing information about upstream and downstream supply chain members can provide insight into extreme concentration and high dependencies in the supply chain. Identifying those critical nodes (e.g., a supplier) or arcs (e.g., a port of entry) can guide decision-making to reduce exposure to those. Additionally, information transparency can enhance forecasting upstream so that upstream suppliers can better plan their sourcing, manufacturing, and logistics operations to meet demand.

However, caution is needed to ensure that information is not shared that directly impacts the competitiveness of a party or leads to incorrect supply chain management decisions. For example, in one of our interviews, a manufacturer emphasized that sharing information about shrinking inventories could lead to irrational behavior such as hoarding product, when in fact, forecast product shipments are pending or production plans indicate replenishment inventory will meet the needs. Information transparency must be intelligent reflecting the possibility that the information could be interpreted incorrectly.

Lastly, it is critical that information flows not only from upstream the supply chain to downstream, for example from suppliers or distributors to providers (e.g., for inventory status, shipping times), but also from downstream the supply chain to upstream. In one interview with a supplier, a senior supply chain risk leader stated that suppliers need information about how they use products, how they prioritize patient care during emergencies, and more qualitative information including their weak spots and their business continuity plans.¹³⁷

4) **GOOD GOVERNANCE**

Governance is a key foundation for building any type of capability to improve resilience. Without appropriate governance, resilience initiatives may start but will never become institutionalized practices and will not "stick" for the long game. Governance refers to the system and the processes by which an organization or multiple organizations are controlled and operate and the mechanisms by which people make decisions, create outputs, and are held accountable for those decisions. Notably, governance can be internal (within an organization) and external (an organization with other supply chain members). In the many cases for successful common action, especially around critical resources, specificity of collaborators to access resources, replenishment and managing bad faith are key aspects of governance. 139

¹³⁵ Written correspondence with distributor.

¹³⁶ Pettit, T. J., Fiksel, J., & Croxton, K. L. (2010). Ensuring Supply Chain Resilience: Development of a Conceptual Framework. *Journal of Business Logistics*, 31(1), 1-21.

¹³⁷ Interview with manufacturer/ supplier.

¹³⁸Graham, J., Plumptre, T. W., & Amos, B. (2003). Principles for Good Governance in the 21st Century. Policy brief no. 15. Ottawa, Canada: Institute on Governance. URL: http://www.iog.ca/publications/policybriefs.

¹³⁹ Gardner, R., Ostrom, E., & Walker, J. M. (1990). The Nature of Common-Pool Resource Problems. *Rationality and society*, *2*(3), 335-358.

Our analyses provided insights regarding internal governance mechanisms that organizations have put in place to (a) develop resilience initiatives and (b) ensure those initiatives are sustained for the long-term. We review some of these mechanisms below:

- Executive leaders that focus on supply chain risk and resilience. The majority of suppliers we interviewed have senior executives in place whose responsibility is to analyze the organization's risk position, develop mitigation techniques, and improve resilience. These leaders oftentimes work with leaders handling the data analytics portion of resilience. These new positions reflect a big step forward for supply chain resilience given that executives focusing on supply chain (e.g., Chief Operating Officers or Chief Supply Chain Officers) are a relatively new development. Important is their focus on supplier risk policy
- Supplier risk council. Some supply chain participants have also implemented supplier risk
 councils. Such a council is essentially an executive committee comprising business unit
 leaders from various functions, responsible for reviewing the risk profiles of suppliers and
 approving the contingency plans that were developed should one of these suppliers be the
 source of a supply disruptions. This committee meets regularly at a specified interval,
 ensuring that the monitoring and continuous management of risky suppliers remains top of
 mind. Specifically, as a supply chain executive from a blood supplier stated:

"[Risky suppliers get reviewed] by an executive committee made up of the executives from those lines of businesses or corporate partners, [including] finance and legal. Every major internal partner is sitting on that board... We have that meeting [on a specified day monthly]. So that's another governance mode that helps us assess risk and keep the business informed that we'll make decisions based on facts." 140

Disruption playbooks and continuous review committees. A playbook is a guide for identifying and assessing risky suppliers and developing plans to monitor potential and recover from supply disruptions caused by those suppliers. Playbooks are imperative for outlining the specific steps to develop and execute a resilience strategy, suggest tools and frameworks by which decisions will be made, providing templates, and ensuring that tribal knowledge is codified.¹⁴¹ Specifically, a supply chain risk executive at a blood supplier stated:

"As we would take these actions, we were memorializing what was working well, where we learned some things. We were creating a playbook as we went along and then, a year later, we actually published that playbook. We're going to keep that as a live document to continue to use and update as needed. [For example] things like 'Oh – we're having trouble getting products through customs, who do we contact in the federal government that can help us that kind of information. This playbook is here so we don't have to remember [who knows who]. So, it's right there in writing, and even if that person has moved on, it gets us that step closer to those contacts."¹⁴²

Importantly, playbooks should be reviewed with other supply chain members, such as suppliers, to ensure the contingency plans have no gaps.

¹⁴⁰ Interview transcript with manufacturer/ supplier.

¹⁴¹ Polyviou, M., & Oke, A. (2020). A Playbook for Category Management. CAPS Research. URL: www.capsresearch.org.

¹⁴² Interview transcript with manufacturer/ supplier.

- Emergency preparedness task forces. These are cross-functional groups who are responsible for implementing the plan once a major supply chain disruption or emergency hits. Most GPOs, distributors, and suppliers participating in our study had created such task forces.
- Finally, supply chain risk is a part of enterprise risk management. One blood supplier
 mentioned that two supply chain risk metrics are part of the enterprise risk management
 scorecard. These metrics are the number of high-risk suppliers, who have a contingency
 plan and the average risk score for the high-risk suppliers.¹⁴³ Including supply chain risk
 metrics at the enterprise level helps to elevate the importance of supply chain risk.

As mentioned, good governance mechanisms, of which a few examples are mentioned above, are essential for the development and employment of other mitigation strategies, including collaboration and coordination, information sharing, and the implementation of good supply chain management practices.

5) ORGANIZATIONAL AUTHORITY

Organization theory teaches us that responsibility and authority must be aligned if an organization is to achieve its goals. Managing the supply chain is a significant responsibility for provider organizations. The mitigation strategies outlined above create significant responsibilities for provider organizations. With those responsibilities there must be sufficient authority to execute these tasks. The authority must provide the decision rights for providers and their staff to make decisions regarding product selection, sourcing, inventory allocation, and distribution. Without this authority, timely action is not taken, opportunities are lost, and product is wasted.

To effectively apply and control authority, organizations need protocols and guidelines. These are typically embedded in a schedule of authorities which directs who and to what extent individuals have the right to decide on financial and operating matters. Schedules of authority clearly delineate the role and power of each member of the organization or in the case of a group of healthcare stakeholders, the community for which it serves.

During the COVID-19 pandemic, the lines of authority became muddled. It was not clear within the federal, state, and local governments, who had authority for certain decisions such as PPE sourcing and distribution. This led to delays and missteps. Clear organizational authority could have prevented that.

During a supply chain disruption, crisis management teams often take over. For effective mitigation of these disruptions, a clear hierarchy of authority is needed. The supply chain needs to be tasked to operate in the best interest of the organization or a community. The leadership hierarchy should be appropriately empowered to act on behalf of the organization or community, whether it be national, state, regional, or local.

6) GOOD SUPPLY CHAIN MANAGEMENT PRACTICES

A crucial key to the successful mitigation of supply chain disruptions is good supply chain management practice. This is a broad category of mitigation practices all derived from the best practices of supply chain management. These practices fall into four key categories of business practice:

¹⁴³ Interview transcript with manufacturer/ supplier.

- <u>People</u>: Access to the highly trained supply chain management professionals with the
 analytical, strategic, tactical, and operational capability to manage a complex supply chain.
 Particular experience in sourcing, distribution, inventory management, finance, and
 information systems is needed. While smaller suppliers and providers may not have the
 resources to assemble a world class team in all of these dimensions, a minimal level of
 competency in as many areas as possible is warranted.
- <u>Processes</u>: Supply chain management business processes direct how work is done and how
 decisions are made. As the field of supply chain management has evolved over the years,
 the design of world class processes has standardized. Today, through the application of
 world class ERP systems, direct access to these processes is realized. These processes
 include:
 - Sourcing: Some GPOs argued for the importance of making supply continuity a relevant metric, perhaps the most relevant metric (versus cost and quality) when selecting suppliers.¹⁴⁴ Furthermore, supplier evaluations for new contracts include not only an assessment of cost and product quality but also risk, including risk reports by third parties such as Dun and Bradstreet (DNB).
 - Contracting and Supplier Management: Contracts have been adjusted to include penalties for non-delivery. Moreover, other contractual provisions have emerged, such as the "take or pay" provision, where the seller is guaranteed a minimum portion of the agreed-on payment if the buyer does not actually buy the full agreed amount of goods. Another contractual provision mentioned in our interviews is to ask suppliers to subscribe to a risk monitoring and supply chain mapping tool. Organizations have also incorporated supplier risk assessments when contracting with a new supplier and when re-evaluating a contract with an incumbent supplier.
 - Product Standardization: Product standardization was a prevalent issue in most of our interviews across supply chain members. Most suppliers and distributors raised the issue of improving cross-references of products and developing lists with product alternatives. Here, the help of and communication from providers is needed to help suppliers learn about the substitutability of products.
 - Inventory Management and Product Allocation: Most organizations participating in our study proceeded with allocation based on prior order volumes (historical demand). Therefore, the lack of appropriate allocation models may have resulted in too much product being sent to those providers who did not necessarily need it, leaving other, usually smaller providers in rural areas without sufficient product.
 - Risk Management: Most organizations have now established a supply chain risk
 management process whereby they bring a cross-functional team together to
 identify and assess suppliers to identify high-risk suppliers.
 - Performance Management: Best practice organizations have recognized and adopted formal processes for measuring and managing performance. With the increased attention to risk management and resilience, organizations need to develop and apply performance management measurements and tools for resilience, disruption vulnerability, and risk mitigation. Noticeably, to date this has not received the attention it deserves.

By adhering to these processes, appropriate and responsive decision-making can greatly help organizations to mitigate most supply chain disruptions.

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¹⁴⁴ Interview transcript with major GPO.

- <u>Systems</u>: To support decision-making, organizations need access to well-designed information systems that provide real time information on the state of the supply chain. Such systems automate the core supply chain business processes named above. They also assist to optimize the decisions made.
- <u>Distribution Networks</u>: essential to a well-functioning supply chain is access to distribution networks to support the movement of products throughout the supply chain. These networks include warehouses to store and package the products along with transportation providers to move the products on its path from manufacturers to point of use.

B. CAPABILITIES REQUIRED

The mitigation strategies above provide a path for provider organizations to reduce the impact of supply chain disruptions and develop a resilient organization. In order to implement these mitigation strategies, organizations need a set of business capabilities to support the supply chain processes and preparedness mission including: (1) information visibility for monitoring risks, product availability, and setting allocation goals, (2) the presence and commitment to a collaborative culture, (3) leveraged sourcing to competitively procure necessary products, (4) capital to finance the implementation and operation of these capabilities, and (5) competencies in the practice of supply chain management. We expand on each of these below.

1) INFORMATION VISIBILITY

A supply chain is only as good as the information that it receives and that it shares. Without accurate and timely information, the operators of a supply chain cannot manage it resulting in customers whose needs are not met. But with good information, managers can monitor, configure, and adjust a supply chain's configuration to deliver the goods efficiently and effectively.

Failing to provide visibility to a supply chain's operations creates uncertainty and suboptimal decision-making. For example, simply not knowing when a shipment of N95 masks will arrive could cause a healthcare system to:

- Utilize masks with a lower protective specification
- Source additional masks from an alternative supplier while waiting for the primary order to arrive
- Postpone elective procedures knowing that clinical staff might not be available to operate safely

In managing supply chains, three factors drive the value of the information received:

- Type of information (e.g., product quantity, product type, product location)
- Accuracy of the information
- Timeliness of that information

Without any one of these factors fully developed, the value of the information is limited.

The above describes the nature of the information. Equally important is the sharing of that information among all stakeholders in the supply chain. Too often, that information is not shared broadly and, in fact, when sought the response is that the information is not available or proprietary and thus not shared. With the use of modern cloud technology in place, the excuse of lack of availability is no longer valid. Dealing with the protective holders of the information addresses the issue of collaboration which is discussed in the following section.

While opening the floodgates of supply chain information may appear appealing, too much information (data) or information received out of context can be misleading. Hence, we support the view that while information should not only be accessible, but it should also be intelligently shared. This means that the design of the information portals and databases should consider sharing only information that contributes to good supply chain decision-making by the stakeholders and avoiding information that could lead to inappropriate decisions.

2) COLLABORATIVE CULTURE

The ecosystem for the healthcare supply chain is characterized by a multitude of highly fragmented organizations including manufacturers, distributors, group purchasing organizations, and providers of care who are influenced by organizations that both fund and regulate activities (Exhibit 3). Many of these organizations compete against each other which leads to a protective veil over information sharing and collaborative decision-making.

Key products for preparedness are manufactured and sold within a commercial environment and held as inventory by both distributors and providers themselves. Under normal conditions, sufficient inventory is available to fulfill all orders placed. However, during times of disruption visibility into inventories is critical as are the decision rights to determine the right allocation of needed products. For many organizations, piercing this protective veil is uncomfortable. Nonetheless, other competitive industries have demonstrated that collaboration across the supply chain can improve service quality without compromising competitiveness. The grocery industry is one industry where this has worked well. Through collaborative planning and forecasting systems, industry partners have shared information and made important production planning decisions collaboratively. Consequently, we have identified (in Exhibit 20) the capability for a collaborative culture to support formal collaboration and coordination as a principal mitigation strategy.

In the early days of COVID-19, we witnessed impressive collaboration within and across communities (e.g., New York City and Seattle collaborating to share ventilators). At the national level, ASPR has established collaborative relations with private industry partners engaged for medical supply chain and delivery, transportation suppliers, shippers to support transportation efforts and enhanced its relationship with commercial distributors and group purchasing organizations. Collaboration in the healthcare space is possible. Industry players need to plan and design the appropriate solutions.

3) LEVERAGED SOURCING AND PROCUREMENT

Healthcare organizations need effective and efficient supply chains to provide competitive services to patients. A key component of this is access to competitively priced supplies. Typically, providers rely on group purchasing organizations (GPOs) to consolidate their spend with others to gain purchasing leverage. Large providers with multiple locations can establish their own economic scale and for some products, bypass GPOs.

But many small and medium sized providers either do not have the awareness of these vehicles or have the infrastructure to participate. Simply relying on the market prices offered by distributors is not sufficient to secure competitive pricing. Further, when a supply chain disruption occurs and alternative sourcing is urgently needed, smaller providers are left at the mercy of the spot market for pricing and availability. Access to leveraging capabilities is important and sometimes a key to economic survival. Collaboration among providers is a solution. Some GPOs and distributors have created solutions for small and medium sized providers.

When sourcing, providers need to conduct risk assessments of the suppliers, their finished goods, and raw materials, many of which are produced and sourced globally. This usually requires partnerships with risk management services firms. When supply chain disruptions occur, sourcing requires a careful consideration of the risk and mitigation strategies identified earlier in this report (Exhibit 21). For sourcing, a major distributor has identified as important capabilities, consistent with the capability requirements detailed earlier to support to:

- Assess opportunities to insource products,
- Evaluate additional suppliers to expand and diversify options,
- Expedite validation and qualification processes
- Collaboration with government entities and industry knowledge to share knowledge and remove barriers and align efforts.

Succinctly, sourcing requires three of the business processes we had identified in Exhibit 13 including governance processes to avoid redundancy and efficiency, information systems to locate goods and their quality, and individuals trained to carry out these processes.

4) CAPITAL

Establishing new capabilities within a supply chain require funding to invest in the tools and people required. While these investments will require a viable business case to proceed, they also require a source of financing of the investment and working capital to operate the business. Since every investment carries some risk, the programs for mitigating supply chain risk will require a source of funding that is willing to underwrite the risk. This may come from a partnership of stakeholders such as providers, suppliers, and distributors. Alternatively, it may come from a federal or state government agency.

Supply chain management investments are principally for technology or facility programs. Due to the commercial nature of most supply chain programs, such investments typically have a positive, measurable, and tangible return on investment. In the case of programs to mitigate risk, many organizations have not formally built risk mitigation into their business plans, yet the experience with the cost of the recent pandemic has raised the awareness to many organizations to the cost of those risks. A business case for capital commitments to risk mitigation will likely be more forthcoming in the post pandemic environment.

5) <u>COMPETENCIES IN THE PRACTICE OF SUPPLY CHAIN MANAGEMENT</u>

Within both provider and supplier organizations the successful practice of supply chain management is critical to organization mission. Required is:

- The ability to anticipate material requirements
- Sourcing, procuring, and obtaining materials
- Assessing supplier risk
- Introducing materials into an organization
- The monitoring of the status of materials as assets and their utilization

While these competencies are necessary during normal operating times, they take on an even greater importance during periods of disruption. Managers were challenged by:

Uncertainty in the early days of COVID-19 made it difficult to anticipate demand, as periods
of surge occurred and what products would be used was subject to change.

- Diverse and frequently inaccurate projections for the disease made it difficult to anticipate volumes of products needed, especially patient protection equipment and materials needed for intensive care.
- A jeopardized global environment for products including the closing of factories, imposition
 of tariffs and shipping channels reduced, the avenues for sourcing and obtaining materials
 were also reduced.
- Risks multiplied by entry of new suppliers, of uncertain quality, into the marketplace
- The hoarding of goods across the supply chain, and, without actionable data, difficult to truly understand and anticipate requirements.
- When conditions deteriorated due to supply chain disruptions, products were typically allocated by manufacturers and distributors based on historical demand. However, many provider organizations without historical use of products needed to combat COVID-19 found that they received little or no product.

Needed during periods of disruption are skills related to managing in times of uncertainty and agility to manage in a new marketplace of risk. It is noteworthy that managing for long term disruption has not been a focal competency for most suppliers or providers. While many larger provider organizations had some specialists trained in supply chain management, most medium and small provider organizations had no staff with the necessary training.

Of note is a series of supply chain competencies required by those who manage preparedness organizations, such as the Strategic National Stockpile or company or regional pools. Supply chain management for these organizations requires a strong understanding of the goods and management processes needed under a variety of disruption triggers (an "all hazards perspective"), securing stocks and assuring/managing their status (as assets), and financing and plans for replenishment over long periods of time.

C. STRUCTURES TO MANAGE THE CAPABILITIES

The capabilities described above will enable an organization to successfully apply the mitigation strategies. However, to establish and manage these capabilities, basic supply chain management structures are needed in the organization (or available to the organization through an alternative means). This section outlines four basic business structures to support the capabilities.

1) **INFORMATION SYSTEMS**

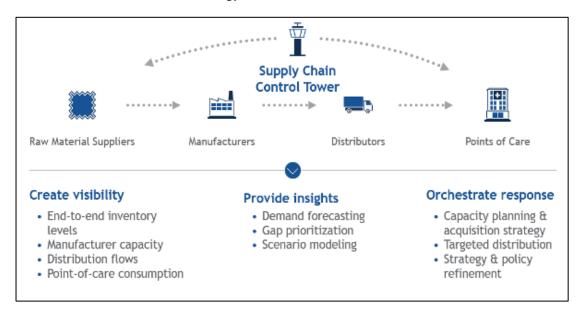
Information systems and related visibility tools are vital to support supply chain decision-making in the end-to-end supply chain. Handfield and his colleagues¹⁴⁵ have pointed out that such tools, for both providers and suppliers can provide visibility and insight into global disruptions. During the past twenty years significant technological developments have occurred to make powerful information technology tools available for most businesses. Many of these tools rely on cloud technology to distribute access to data and applications to any part of the world. In this section we reference two of the more useful information system tools to enable visibility throughout the supply chain.

¹⁴⁵ Finkenstadt, D. J., & Handfield, R. (2021). Blurry Vision: Supply Chain Visibility for Personal Protective Equipment During COVID-19. *Journal of Purchasing and Supply Management*, *27*(3), 100689.

i) Control Tower Technology

Control Tower is a technology that provides end-to-end visibility from the purchase of raw materials through to the production of finished goods and delivery into customer's hands. See Exhibit 22.¹⁴⁶ It accesses enterprise resource planning systems (ERP) to bridge the gaps of the supply chain from the source of raw materials to the customer. Numerous vendors provide applications to support this technology. In addition, control tower technology is being developed to support the Strategic National Stockpile.¹⁴⁷

Exhibit 22 - Control Tower Technology



ii) Block Chain Technology

Block chain is another information technology tool that can support the supply chain capabilities and help mitigate disruptions. It is particularly useful to support the ability to track and trace needed supplies and makes data accessible to parties with limited infrastructures (e.g., pharmacies or hospitals) to determine authenticity of a drug. It is a distributed ledger technology that operates without a central authority provided through a peer-to-peer network connecting business partners across a supply chain. It allows for a traceable, immutable, reliable, and shared transaction ledger.

2) GOVERNANCE PROCESSES

A supply chain is a large, complex, and often disjointed set of links connecting a supplier to a customer (provider). Under normal conditions the relationships between the many links of the chain are governed by commercial terms previously established. However, during a disruption when products are in limited supply and buyer/seller relationships may not yet exist, the normal governance processes are suspended.

¹⁴⁶ Office of the Assistant Secretary for Preparedness and Response (HHS). (2020). *Request for Information (RFI) – Strategic National Stockpile* (May 14, 2020). URL: https://govtribe.com/file/government-file/20200512-sns-rfi-vfinal-dot-pdf.

¹⁴⁷ ASPR. (2021). Expanding and Enhancing SNS Capabilities: Building a More Resilient Strategic National Stockpile. (August 12, 2021). URL: https://www.phe.gov/about/sns/COVID/Pages/expanding-sns-capabilities.aspx.

While products flow in the supply chain during a disruption, they flow slowly, and orders take much longer to fulfill. This creates vulnerabilities in the healthcare delivery systems. To manage this, governments often step in with programs such as the SNS or FEMA. However, governments are not the best organizations to operate supply chains.

A better alternative is for healthcare providers to establish their own governance systems to support their common needs. For example, healthcare organizations in a geographic region could collaborate and self-govern to jointly manage the sourcing and distribution of critical healthcare products. By restricting these joint commons efforts to a limited set of the most critical supplies, the autonomy of the individual providers is not jeopardized nor is it likely that inappropriate trade practices would be alleged. In a regional setting during emergency conditions, all providers face greater challenges when some providers in the region must delay or cancel services due to supply shortages. Working together provides a greater likelihood of success.

3) TRAINED WORKFORCE

A well-managed, resilient supply chain requires competent, experienced management. There are many parts to supply chain management ranging from sourcing to contracting to inventory management to warehousing and transportation. While larger healthcare providers have the organization depth to invest in these competencies, many small and medium sized providers do not. Yet, during a supply chain disruption, it is exactly these competencies that differentiate providers who mitigate the disruptions from those that do not and then suffer the consequences.

Healthcare providers who rely on purchased supplies need to ensure that they have staff with at least minimum qualifications in supply chain management. Today, supply chain management courses are available at most colleges and universities as well as through online programs. Education makes a difference.

4) **DISTRIBUTION NETWORKS**

The final structure required for successful mitigation of supply chain disruptions is a network to distribute products. This includes transportation and warehousing solutions for healthcare products.

Most providers are the receivers of the products and hence do not own or control the distribution network. Typically, they rely on distributors such as Cardinal, McKesson, and Medline to ship their products to them. However, during a disruption, normal channels may not be available or capable.

As an example, during the COVID-19 pandemic many providers sought alternative sources and channels for PPE products. Their standard distribution networks were not available for this. They were often on their own to get the products shipped to their facilities. They needed a distribution network. Providers need to establish access to such distribution networks.

D. SUMMARY

This report has documented the supply chain disruptions experienced by Arizona healthcare providers for medical devices and pharmaceuticals as well as disruptions experienced by the suppliers, distributors, and group purchasing organizations upon which they are dependent. For COVID, an airborne virus, impacting the respiratory system, personal protective equipment and pharmaceuticals were especially impacted. Some supply categories were not very impacted (e.g., fuel and hazardous waste), and others adjusted to meet surges in demand (e.g., medical grade oxygen).

For the seven categories of supplies scrutinized, multiple factors impacted their ability to respond to the experienced surges in demand. Deficiencies in supply, for certain categories, were impacted for various reasons. For others, reliance on the global supply chain significantly impacted the availability of PPE such as masks and gowns. Impacting the supply of blood was the reluctance of donors to come to blood bank locations, due to the fear of travel and being in public places, impacted the supply of blood. Succinctly, the supply chain while apparently simple during times of stability, becomes complex and confounding during disruptive times.

Most providers of care and suppliers recognized the major factors driving disruptions and put forth the many mitigation strategies described above. Strategies, of course, must be matched by the five capabilities detailed in this chapter and accompanied by the structures to effectively manage these capabilities. This requires a broad understanding the issues and a commitment to act on solutions.

In seeking solutions, our scrutiny of the intent for HCCs mandate, discussed in Appendix A to this document, reveals the important roles fulfilled by HCCs and provides insight into their potential role as an important supply chain facilitator. Our scrutiny of a number of HCCs that have extended their scope beyond one of convenor and advisor, to a more coordinative, facilitative and operational role. Observed was the powerful impact that HCCs, working with their provider members, their member's intermediaries, and government can have in assuring a resilient and prepared supply chain. As organizations across the healthcare ecosystem are considering their strategies for mitigation, resilience, and preparedness, and advocating collaboration for supply chain excellence, this is the time for AzCHER and its HCC counterparts to consider their future.

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¹⁴⁸ Office of the Assistant Secretary for Preparedness and Response, 2017-2022, November 2016, Healthcare Preparedness and Response Capabilities Capability 1. Foundation for Healthcare Medical Readiness

APPENDICES

A. THE ROLE FOR A HEALTHCARE COALITION AND ITS MEMBERS

1) THE ROLE FOR A HEALTHCARE COALITION

This report detailed the nature of supply chain challenges during times of disruption for both HCC members and their suppliers. In Chapter 3 we identified vulnerabilities and effective mitigation strategies utilized across the ecosystem. These observations were substantiated in our survey of AzCHER members, extensive interviews with suppliers and intermediaries, learnings from the literature on supply chain risk management, and a review of ASPR's guidelines for a Healthcare Coalition's (HCC) role in healthcare preparedness and response. Our efforts were designed to guide a strategy to better utilize the HCC program to improve healthcare providers' resilience to supply chain disruptions. The HCC roles as defined by ASPR are to:

- Assess hazard vulnerabilities and risks
- Assess regional healthcare resources, including the role of stockpiles and private sector assets¹⁴⁹
- Prioritize resource gaps and mitigation strategies¹⁵⁰

The HCC-funded organizations in Arizona¹⁵¹ have followed these guidelines in undertaking their roles. To date these roles have focused on convening sessions to educate and train providers and to advise on risk mitigation. In the past the HCCs did not offer a significant focus on supply chain risk management, although the recent experience with the COVID-19 pandemic has changed that view.

Many provider organizations participate in these HCC sponsored programs on a routine basis. For many medium and smaller sized provider organizations, applying this approach to risk reduction and participating in a regional approach to address critical infrastructure, including supply chain, while critical to their missing capabilities, has not been a funded priority. 152

In Arizona, healthcare providers' exposure to supply chain disruptions is grounded in a dependency upon a wide range of manufacturers/suppliers, group purchasing organizations, distributors, and 3PL entities to secure needed supplies. Noteworthy is that many AzCHER members, especially those that are relatively small, are not members of a purchasing coalition/GPO to assist with sourcing. They procure supplies on their own without having a formal supply chain department or function. This severely limits their capabilities in dealing with complications arising from supply chain disruptions. Larger providers, many part of large and centralized organizations, have very sophisticated supply chain capabilities and can better manage these complications.

All HCC members need to be aware of and vigilant regarding the many organizations with which they contract and receive supplies. Having awareness of vulnerabilities, a plan for disruption management, and formal relationships with suppliers is good business practice. Members need to learn from their peer organizations, from suppliers, from states that have mandated inventory level requirements, and from the relationships that large entities establish with distributors and other suppliers.

¹⁴⁹ Office of the Assistant Secretary for Preparedness and Response, 2017-2022, November 2016, Healthcare Preparedness and Response Capabilities Capability 1. Foundation for Healthcare Medical Readiness, pp 13-14.

¹⁵⁰ Ibid., p. 14.

¹⁵¹ Primarily AzCHER and the Coyote Crisis Coalition.

¹⁵² Op. cit. Office of the Secretary for Preparedness and Response, p. 33.

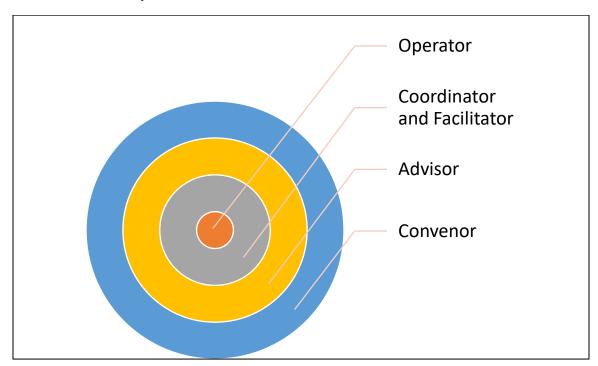
An important and articulated role for an HCC is to examine its supply chain and, as part of its HCC role to develop and coordinate¹⁵³ a Healthcare Coalition Response Plan, be aware of each individual member's resources and responsibilities.¹⁵⁴ Indeed, it is envisioned that an HCC have the ability to collaborate with stakeholders to develop a joint understanding and strategy. This would include:

- Mitigating strategies associated with vendor-and/or distributor-managed inventory stockpiles
- Establishing secondary vendors
- Developing "push" or pre-event disaster supply procedures and triggers for activation¹⁵⁵

Organizations such as HCCs can play one or more of four roles ranging from convenors of participants to directly managing mitigation initiatives. In the context of supply chain management this could involve sourcing and distributing critically needed products. Exhibit 23 displays the increasing depth of involvement for these four roles.

It is within this context that HCCs consider, not only expanding its convenor, advisor, and facilitator role, but to consider the need for an HCC-led operations effort.

Exhibit 23 - The Roles for an HCC



It is important that each individual HCC member examine its supply chain vulnerabilities by collaborating with manufacturers and distributors to determine access to critical supplies that will likely be in demand during an emergency. As well, they need to develop strategies to address

¹⁵³ Ibid., p. 25

¹⁵⁴ Ibid., p. 27

¹⁵⁵ Ibid., p.34

potential shortfalls.¹⁵⁶ Such collaboration, without deep supply chain management capabilities, is difficult to achieve and can lead to great redundancy of effort.

AzCHER recognized this need and, as COVID-19 evolved, provided an important communication and coordination role, a key HCC defined capability.¹⁵⁷ This was especially important during the evolution of COVID-19, as AzCHER gathered information on needed products and sought to aid members in securing such products. HCC members are also expected to collectively determine the prioritization of limited resources provided by distributors, reflecting needs at the time of the emergency. Accordingly, AzCHER's facilitator role is also dependent upon its ability to work with distributors to understand and communicate which healthcare organizations and facilities should receive prioritized deliveries of supplies and equipment (e.g., personal protective equipment) depending on their role in the emergency.

2) RECOMMENDATIONS FOR AN EXPANDED ROLE FOR HCCS

The findings and conclusions in our study recognized that there are clear and significant vulnerabilities to healthcare providers in Arizona from future supply chain disruptions. And these vulnerabilities, as revealed by our survey, can have a significant impact on the care of patients. Based on these vulnerabilities, we identified mitigation strategies that providers can follow to diminish the impact posed by these vulnerabilities. While most large providers have the resources to adopt many of these strategies, most medium and small sized providers do not have the resources or capabilities to comply. A healthcare coalition can provide the missing capabilities as a service to their members. To guide HCCs in this process, we are proposing the development of four programs.

For supply chain issues, these programs would typically be limited in their scope. Healthcare providers utilize thousands of products. Not all of them are subject to supply chain disruptions nor are all of them critical for patient safety. The focus of these recommendations is on a distinct and limited set of healthcare products that are <u>critical</u> to providers and that are <u>vulnerable</u> to a supply chain disruption.

i) Information Competencies and Capabilities

Needed, going forward, as an effective convenor, advisor, and collaborator/facilitator, is the enhancement of supply chain information tools and governance agreements. The focus should pertain to information on agreed-upon products that are vulnerable to disruption during emergencies and pose a threat to patients and populations. Also needed is the ability "to easily access/collect timely, relevant, and actionable information about their own organizations and within the HCC, other members, and additional stakeholders according to established procedures and predefined triggers and in accordance with applicable laws and regulations." Such visibility tools and the emanating information will enhance HCC's communication, coordination, and facilitator roles. Needed, however, is agreement by members who recognize the value of information and its ability to protect against a variety of risks.

¹⁵⁶ Ibid., p. 35

¹⁵⁷ Ibid., p. 25

¹⁵⁸ Ibid., p. 28

An effective HCC should have visibility into member resource needs for equipment and supplies.¹⁵⁹ With this information they can log, track, and vet resource requests across the coalition in coordination with the Emergency Support Function-8 (ESF-8) lead agency. Access to such visibility will require a high level of executive commitment by both providers and suppliers to collaborate for community benefit. It will require agreements across competing organizations. All of this is to meet the goal that healthcare organizations, with support from the HCC and the ESF-8 lead agency, provide uninterrupted, optimal medical care to all populations in the face of damaged or disabled healthcare infrastructure.¹⁶⁰

ii) Enhanced Partnerships

It is anticipated that an HCC will consider a wide range of risk reduction strategies to facilitate each individual member's approach to risk reduction to promote a regional approach to addressing critical infrastructure, including supply chain. To do so HCC should create partnerships with manufacturers and distributors, not only to coordinate efficiency, but to assure the maintenance and rotation of inventories. This could be accomplished by accessing vendor and/or distributor-managed inventory or by establishing secondary vendors to apply "push" or pre-event disaster supply procedures and triggers for activation. The goal here being to utilize bulk purchasing to benefit from advantages in pricing and availability across HCC members.

iii) Training for Preparedness

The researchers, both academic and practitioner, were impressed by the ability of provider organizations to innovate to meet their organizational demands during the evolving months of the COVID-19 pandemic. Yet we were surprised by the lack of supply chain acumen among many of the medium and smaller HCC members. HCC can fulfill an important function by adding supply chain management and preparedness to its important work of providing education for emergencies.

iv) Development of a Common Pool Resource Organization

Moving beyond the convenor, advisor, and facilitator roles is the opportunity to advance HCC, alone, or in collaboration with intermediaries (distributors/GPOs or highly capable IDN members), to enhance, for all HCC members, redundancy and flexibility. This role would focus on a defined set of goods to buffer against supply shortages during a major emergency. Any such HCC effort, into the operating arena, should be around a very limited number of medical and pharmaceutical products — as defined to be critical and most vulnerable to disruption.

A Common Pool Resource Organization (CPRO), focused on a limited number of agreedupon and critical products, could provide stewardship for supplies for the good of the community and a platform for cooperation. A CPRO, facilitated by HCC, could lead to

¹⁵⁹ Ibid., pp. 29-30

¹⁶⁰ Ibid., p. 32

¹⁶¹Ibid., p. 33

¹⁶² Ibid., p. 35

¹⁶³ Ibid., p. 36

solutions to common problems, especially where misaligned incentives and myopic decision-making leads to a failure to meet the needs of all participants in need. ¹⁶⁴ This is not a novel approach to such problems as empirical research on common pool resource management, especially in instances where the behaviors of individuals and the organizations designed to sustain a resource, that, if not available or depleted, poses a threat to individuals, groups, or communities. While the contours of commons as a theory are highly scrutinized and debated, ^{165,166} there is growing recognition that this kind of solution is appropriate, if not necessary, to meet the demands of long-term large disruptions in events such as pandemics. It is a natural extension of the call for financing "global public goods," for pandemic preparedness within the context of a Pandemic Emergency Financing Facility (PEF).

A CPRO would recognize the differences between regular demand and disruption demand, with the latter being relevant for pandemic preparedness. This approach is also amenable to the existence and limitations of physical pools of inventory and the management of preparedness in collaboration with other pools – and thus has the advantage of managing virtual inventory as well as with pooling achieved by CPRO managed inventory. Finally, the approach, while recognizing that individual organizations require pooling and managing inventory within their own boundaries for a wide range of products, the CPRO would be designed for breaking down barriers and sharing inventory that is critical to all – and where the absence of stock can impact the entire ecosystem of providers. A CPRO would be sensitive to the fact that members typically compete for patients or market dominance in normal times. It would parry the urge to pre-emptively procure materials to gain an advantage, which simply makes shortages worse. 168

An HCC Common Pool Resource Organization would require the competencies and capabilities to meet the needs of participants, for a limited number of critical items, in times of extraordinary and long-term disruption. In this sense the HCC/CPRO would serve as an insurance/risk mechanism for preparedness. It would serve the interests of both providers and suppliers by providing a coordination and inventory mechanism. The idea is in-sync with pandemic assurances for system security as part of the move toward "global public goods". Perhaps of greatest importance, it would be a platform for "stickiness."

In the health sector, there are examples of collaborative purchasing through GPOs, catering, principally to hospitals and integrated delivery systems. Some of these are large organizations catering to several thousand hospitals and others more regional. Some require committed purchasing and others are more lenient. In addition, consolidated service centers and shared service organizations have evolved to meet the needs of a

¹⁶⁴ Saunders, F. (2014). The promise of common pool resource theory and the reality of commons projects. *International Journal of the Commons*, 8(2).

¹⁶⁵ Velicu, I., & García-López, G. (2018). Thinking the commons through Ostrom and Butler: Boundedness and vulnerability. *Theory, Culture & Society, 35*(6), 55-73.

¹⁶⁶ Singleton, B. E. (2017). What's missing from Ostrom? Combining design principles with the theory of sociocultural viability. *Environmental Politics*, *26*(6), 994-1014.

¹⁶⁷ Liu, F., Song, J. S., & Tong, J. D. (2016). Building Supply Chain Resilience through Virtual Stockpile Pooling. *Production and Operations Management*, 25(10), 1745-1762.

¹⁶⁸ Bohmer, R., Pisano, G., Sadun, R., & Tsai, T. (2020). How hospitals can manage supply shortages as demand surges. *Harvard Business Review*, 3.

single system or several collaborating systems. These self-governing organizations frequently carry out the key supply chain functions of sourcing, purchasing, inventory management, and distribution utilizing their own staff — while others avail themselves of the services of commercial partners. We put forth this recommendation without bias to any one approach — only to reiterate the need for an approach to meet the challenges for preparedness for disruptions characterized by uncertainties regarding occurrence, depth, breadth and recovery time. Thus, the design of an HCC/CSRO would require consideration of multiple options and openness alignment with stakeholders across government and commercial efforts.

To supplement the CPRO, HCC agreements to share supplies may provide an additional critical resource during emergencies. As suggested by ASPR, these agreements should be developed and documented prior to an emergency. This, of course, requires close collaboration with DHHS, the SNS, and other relevant agencies. It also requires an understanding of supplier, distributor, and GPO plans for redundancy, including risks associated with all unknowingly relying upon the same sources.¹⁶⁹

(a) Rationale for a CPRO in Arizona

The SNS continues to be seen as a back-up for provider organizations in Arizona. HCC intermediaries are also developing strategies to buffer themselves and their customers against disruptions. And HCC member organizations continue, through their relationships with distributors, GPOs, and the systems to which they belong, to have knowledge of and access to preparedness efforts. How long these efforts will be sustained and how likely they are to be successful, remains unknown. HCCs relationship with DHHS is strong and can be enhanced, as DHHS is not a supply chain operating organization. A reliable, designed-for-purpose, primary resource is needed to support the Arizona provider community.

(b) CPRO Characteristics.

CPRO should be designed to be compatible with how members now meet immediate and ongoing demand. An important foundation is the meeting the six mitigation strategies we identified in Chapter III with initial attention to good governance. See Exhibit 24.

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¹⁶⁹ Ibid., p. 36

Exhibit 24 - Mitigation Roles for AzCHER/CPRO

Flexibility and Redundancy	Inventory buffers, multi-sourcing, flexible distribution networks
Formal Collaboration and Coordination	 Supply chain participants (including competing providers) work together towards a common set of objectives
Information Transparency	 Information about the condition of the supply chain (e.g., inventories, shipments, production plans) is shared across supply chain participants.
Good Governance	 Process of making decisions. What decisions need to be made? Who has the right to make a particular decision? How often are the decisions re-evaluated?
Organizational Authority	 Schedules of authority should be established and clearly delineate the role and power of each member of the community
Good Supply Chain Management Practices	Broad category of mitigation practices all derived from the best practices of supply chain management

Governance and agreed-upon mission, scope, fidelity to transparency, and accountability is a critical first step. Leadership competencies and capabilities are critical as is the ability to employ best supply chain operational practices.

Important would be a consideration of macro-organizational characteristics such as its independence (perhaps an independent not-for-profit), existence as a public partnership, interface with other community supply chain resources (e.g., consolidated service centers) and government efforts. At the very least, the mission of the CPRO would be around preparedness and long-term security with a focus on:

- Assuring population health
- Avoiding system failure and assure provider organization sustainability
- Support competition with collaboration
- Support supply chain integrity by reducing hoarding/self-interest
- Taking advantage of public/private partnership opportunities

Not considered here, but key to the design, development, and the importance of organizational "stickiness," is the important question of financing a CPRO. Preparedness is not without cost and it requires a commitment to long term involvement. The cost of collaboration for preparedness, if appropriately interfacing with the plethora of efforts being undertaken by government, suppliers, distributors, and GPOs, can, with good supply chain management practice, be greatly reduced. Discipline around the selection of a limited set of products for preparedness can support standardization challenges frequently associated with high costs and allocation processes that are designed to meet clinically defined goals. Reducing conflicting and unnecessary redundancy efforts can remove some of the costs for preparedness.

¹⁷⁰Botta-Genoulaz, V and Pellegrin, Information-sharing Practices and their Impacts on Supply Chain Performance, Chapter 2 in Botta-Genoulaz, V., Campagne, J. P., Llerena, D., & Pellegrin, C. (Eds.). (2013). *Supply chain performance: Collaboration, alignment and coordination.* John Wiley & Sons.

3) NEXT STEPS

This report provides insight into the vulnerabilities in the healthcare supply chain for emergency preparedness in Arizona, ongoing mitigation efforts by manufacturers, distributors, and GPOs, and government efforts. HCC's concern for supply chain integrity is firmly established in the scope of an HCC as issued by ASPR. Unspecified, however, is how an HCC can best support supply chain preparedness for supply chain disruptions and resilience.

To supplement the ASPR guidelines, we have proffered strategies for enhancing HCC roles in the supply chain for emergency preparedness efforts beyond its current role as a convenor and advisor. We propose that HCC take on a more coordinative, facilitative, and operational role. Ongoing, led by the Healthcare Transformation Institute, with the leadership of Arizona's major acute care organizations, are discussions regarding the acute care organizations' efforts, by themselves and with their collaborators, regarding preparedness. It is noteworthy that many of these organizations belong to larger systems and have alliances with their GPOs and distributors. No such discussion in Arizona has assessed the efforts by and the needs of the much wider range of provider organizations in Arizona.

Our survey of AzCHER members confirms the dominance of PPE availability and replenishment as the principal supply chain challenge over the last two years. A September 2021 survey by SMI of their health provider members, principally large systems, revealed that increased stockpiles and stockpile capacity were not top-of-mind for large IDNs, while ranked higher by suppliers. Storage capacity for providers does not ensure that materials critical for the next disruption will be available; there is a need to encourage a stockpile build to encourage excess production for products of a high level of certainty. The Government, manufacturers, distributors, and GPOs are all subject to internal and external pressures that question how they will operationalize their own plans and collaborate to provide supply visibility and availability. An important role is HCC's vigilance, assessment, and when appropriate, actions to fill gaps.

Moving forward requires HCC to vet this report with representatives of the full HCC membership and other stakeholders to endorse HCC's role in the supply chain for preparedness to monitor to help mitigate supply chain disruptions. Going forward HCC should:

- Enhance their advisory role by:
 - Carrying out a regular, in-depth inventory and analysis of member-initiated resilience/preparedness efforts, both alone and with their suppliers and key intermediaries. This requires careful attention to gaps within and across stakeholder resiliency and preparedness efforts.
 - Developing a set of relevant metrics to annually assess member preparedness, supporting all members in using an annual preparedness report card based on these metrics, and assigning a preparedness maturity score to each organization.
 - Facilitating the learning of best practices within its membership to assist less mature organizations to become more resilient by learning from more mature ones.
 - Carrying out an analysis of other HCC efforts to coordinate, facilitate and provide supplies. This analysis would include assessing how other HCCs are organized to carry out strategic functions, including sourcing, warehousing, and working with strategic partners.

¹⁷¹SMI. (2022). *Planning for a Resilient Supply Chain for Healthcare in a Post-Covid World* (May 2022). URL: https://smi.memberclicks.net/assets/docs/tools/rmm_playbook-2022.pdf.

- Creating an HCC supply chain council to drive and sustain the supply chain priorities of providers.
- Sustain and extend their facilitator and advisory role by:
 - Enhancing technologies to monitor targeted prepared related supplies across Arizona
 - Developing ongoing relationships with appropriate manufacturers, distributors and GPOs to assess and monitor stakeholders' efforts to build inventory pools and improve supply visibility/transparency. In doing so it is important that many are focused on HCC large (and principally acute) members. HCC should encourage the development of an "all provider" emphasis with a focus on preparedness related supplies.
- Extending their role as a provider of supply chain services by:
 - Developing, based on the aforementioned identified gaps, the business case for an HCC-sponsored and or managed CPRO for a limited number of disruption related preparedness products to fill identified gaps by both government and private sector. Careful consideration should be given to:
 - The role of suppliers, distributors, and GPOs
 - Inclusion criteria
 - Governance
 - Funding
 - Stickiness

4) HEALTHCARE COALITIONS AT THE FOREFRONT OF PREPAREDNESS

This report was completed at a time when there was a great deal of discussion, strategizing, and in some cases putting into operation disruption mitigation initiatives. The success of these efforts and their sustainability, or what we have described as "stickiness," remains to be seen. We already hear rumblings of pandemic focused fatigue and wanting to return to, if not the pre-pandemic environment, an environment where disruption concern is not front and center.

We note that outside of the military, little attention has been given to the preparedness for supply chain disruption. This is especially the case for the diversity of providers that characterize the AzCHER members — a diversity found across all U.S. states. Helping providers to mitigate supply chain disruptions requires a comprehensive, inclusive, and clinically supportive supply chain strategy.

HCCs can serve the important strategic role, currently absent in healthcare provider organizations, of assuring that supply chain preparedness is at the forefront. If "stickiness" of supply chain disruption strategies is to be sustained, we believe preparedness strategy and its management must also be at the forefront of a strengthened healthcare system. We hope that this report, commissioned by AzCHER, will be reviewed by HCCs across the country to stimulate discussions around the role of HCCs for preparedness and result in a healthcare system poised to meet the possibilities for supply chain disruption in an uncertain world.

¹⁷² Ramos, G., & Schneller, E. S. (2021). Smoothing It Out: Military Healthcare Supply Chain in Transition. *Hospital Topics*, 1-7.

B. PROJECT COLLABORATORS

1) ARIZONA STATE UNIVERSITY FACULTY/STAFF/INVESTIGATORS

Barr, Phillip, MPA ASU Center for HealthCare Delivery/Policy, Healthcare

Transformation Institute

Cortese, Denis, M.D. Professor, ASU, Former Mayo Clinic Director, President of Healthcare

Transformation Institute

Eckler, Jim, MS Co-Principal Investigator & Adjunct Professor of Supply Chain

Management

Fowler, John, Ph.D. Motorola Professor of Supply Chain Management

Gopalakrishnan, Mohan, Professor of Supply Chain Management, & Senior Associate Dean,

Ph.D. W.P. Carey School of Business

Koeller, Amanda, MBA Project Coordinator

Kull, Thomas, Ph.D. Professor of Supply Chain Management

Polyviou, Mikaella, Ph.D. Co-Principal Investigator & Professor of Supply Chain Management ON Semiconductor Professor of Business, Supply Chain Management

Department

Schneller, Eugene, Ph.D. Co-Principal Investigator & Professor of Supply Chain Management

Wilson, Natalia, M.D., Consultant, Healthcare Transformation Institute, ASU/University of

MPH Arizona

2) ARIZONA STATE UNIVERSITY STUDENTS

Bhavisha, Avlani Supply Chain Management Student

Breedlove, Keely, MBA MBA Student of Supply Chain Management

Daigle, Marie MBA Student, Supply Chain Management, ASU & Mayo Clinic College

of Medicine & Science

Gupta, Saumya, MBA MBA Student of Supply Chain Management

Harrington, Maya, MBA MD/MBA Student at Mayo Clinic Alix School of Medicine & ASU

Hernandez, Yecica Lara

Supply Chain Management Student
Supply Chain Management Student
Supply Chain Management Student
Supply Chain Management Student

Ma, Ning
Doctoral Supply Chain Management Student
Rainbow, Dan
MBA Student of Supply Chain Management
Spink, Casey, MBA
MBA Student of Supply Chain Management

Wegner, Samuel Supply Chain Management Student