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REPORT

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Understanding the Impact and Costs Associated with Medical Device Shortages During the COVID-19 Pandemic on Providers, Health Systems, Patients, and Manufacturers

Linda Thai, Trinidad Beleche, Oluwarantimi Adetunji

This landscape analysis of medical device shortages in the U.S. during the COVID-19 pandemic revealed the types of devices affected, the strategies and resources used to manage shortages, and their associated consequences.

KEY POINTS

- We conducted a landscape analysis to understand the characteristics, impacts, and costs associated with medical device shortages during the COVID-19 pandemic in the U.S.
- Among health systems, nursing homes and rural hospitals were the most impacted by medical device shortages due to high demand and supply transportation issues.
- In this analysis, we found 14 different strategies used by providers, health systems, patients, and manufacturers to manage device shortages, including delaying procedures, substituting for other products, or using unvetted or non-traditional suppliers, which incurred added labor and training costs.
- Patients most vulnerable to device shortages included those under 18 years, those living in rural areas, and those relying on medical services in their home, those using ventilators and state-issued devices, or those living with a chronic disease. These patients also experienced delayed procedures, higher purchase costs, had to re-use devices, or received alternative treatments. Patients also had limited visibility in knowing which devices were on shortage.
- Pre-existing challenges like dependence on foreign sources, natural disasters, transportation issues, and limited supply chain visibility, combined with surge in demand, made medical device supply chains more vulnerable to shortages during the COVID-19 pandemic.

BACKGROUND

Medical devices play an important role in the healthcare system from infection control to treatment. In 2019, the U.S. spent $199.1 billion on medical devices and in-vitro diagnostics, equivalent to 5.2 percent of the national health expenditures. [1, 2] The U.S. accounts for 40 percent of the global medical device market, which relies on the import of raw materials and products. [2-4] The global medical device market

was valued at $518.5 billion in 2023 and is projected to grow from $542.2 billion in 2024 to $886.6 billion by 2032.[5] Natural disasters, the COVID-19 pandemic, shipping port delays, and transportation costs, among others, have strained this supply chain leading to shortages of critical devices such as hemodialysis equipment, intravenous (IV) bags, personal protective equipment (PPE), and ventilators.[6-9] Shortages of medical devices can have severe consequences such as poorer health outcomes for patients and increased costs for manufacturers, providers, and the healthcare system.[10]

Prior to the COVID-19 pandemic, there was minimal literature on medical device shortages despite their role in the healthcare system. This may be due to limited reporting of device shortages prior to 2020.[11] During the pandemic there was an observed increase of annual shortages, from an annual average of five from 2010 to 2019, to over 20 in the first half of 2020.[11] The COVID-19 pandemic put medical device shortages into the forefront and highlighted the complexity and interdependencies of its supply chain. Reasons for shortages not directly related to the pandemic include foreign sourcing, natural disasters, recalls, single sourcing of suppliers (no alternate suppliers), and transportation issues.[4, 6, 12] During the COVID-19 pandemic unprecedented increase in demand for certain medical devices such as ventilators, shortage of labor or components, limited visibility into the distribution channels, and transportation delays (e.g., ports of Los Angeles and Long Beach) further strained the medical device supply chains.[12-15]

In response, Congress granted the U.S. Food and Drug Administration (FDA) expanded authority through the Coronavirus Aid, Relief, and Economic Security Act (CARES Act 2020) to require device manufactures to notify FDA when there will be a "permanent discontinuance or interruption in manufacturing likely to lead to a meaning full disruption in the domestic supply of certain devices during or in advance of, a public health emergency".[16, 17] Since this act, FDA has published a list of all reported device shortages on its website.[16, 18] When the COVID-19 public health emergency expired in May of 2023 manufacturers were no longer required to submit these notifications to FDA, and subsequent notifications have been submitted on a voluntary basis only.[16] As part of a National Strategy for a Resilient Public Health Supply Chain, FDA led a task force to develop a Critical Medical Device List (CMDL) to help government, business and healthcare leaders focus supply chain resiliency resources on those devices where disruptions can lead to serious injury or death to patients or providers. The first CMDL list was published in September 2023.[19]

The purpose of this landscape analysis is to understand the impact of medical device shortages on providers, health systems, patients, and manufacturers during the COVID-19 pandemic. We chose to study this impact during the COVID-19 pandemic due to the widespread effect of shortages. We conducted both a literature review and informant interviews to address these research questions:

- **Providers and Health Systems**
    1. What are the characteristics of providers and health systems (e.g., facility type, geographic location, specialties) affected by device shortages?
    2. How do providers and health systems manage device shortages?
    3. What resources (e.g., costs to buy alternative devices, personnel time resolving shortage, or identifying alternate treatment options) are used when a device goes into shortage?
- **Patients**

1. What are the characteristics (e.g., age, race/ethnicity, health conditions, sociodemographic characteristics) of patients affected by device shortages? Are there disparities in access to devices related to device shortages?
2. How are patients affected by device shortages (e.g., canceled or delayed procedures, differences in cost of substitute devices)? Does impact vary by the type of device in shortage?
3. What is the cost of device shortages to patients?

- **Manufacturers**
  1. How are manufacturers affected by device shortages?
  2. What are the key considerations for manufacturers in managing device shortages?

METHODS

We conducted the landscape analysis in three parts: a targeted literature search, informant interviews, and a data synthesis.

Targeted Literature Search

The targeted literature search, performed by NORC at the University of Chicago, evaluated peer-reviewed and grey literature published on medical device shortages. The search included gray literature to capture current regulations, shortages, and trends. NORC included only English sources and those studying the U.S. population in the search. Appendix A lists the search terms and databases used for the articles extracted. We also limited the time to the start of the COVID-19 pandemic up to 2022.

Key Stakeholder Interviews

The second part, conducted by NORC, involved semi-structured interviews with six key informants. NORC and the authors chose these subject matter experts based on their expertise in medical devices and diverse perspectives. The informants represented health systems (n=1), manufacturers (n=2), providers (n=2), and patient advocates (n=1). As part of the interview protocol, NORC took notes during the interview, and if consent given, also recorded the interviews to facilitate review.

Data Synthesis

The final part, conducted by the authors, was an article and data review that synthesized information from the literature search and the informant interviews. Of the articles found during the literature search, we deemed 28 articles relevant to the research questions and the COVID-19 pandemic. We found additional supplemental articles using a "snowball" approach based on the initial targeted literature search. We also reviewed the informant interview notes and extracted information relevant to the research questions. If articles or interviewees mentioned specific medical devices, these products were categorized using the CMDL.[1] The CMDL classifies devices into clinical subfunctions, category, and type. [19]

[1] Location of the CMDL: Critical Medical Device List: Summary and Recommendations (hhs.gov)

RESULTS

Medical Devices Involved in Shortages

Table 1 summarizes the medical devices found in this landscape analysis. A wide range of devices have been in shortage including: airway and respiratory support, general supportive care, liver and kidney support, PPE, and tests and test systems. [12, 13, 20-22]

Table 1. Medical Device Shortages During the COVID-19 Pandemic in this Landscape Analysis

CDML		
Subfunction	**Device Category**	**Medical Device**
Airway and Respiratory Support	Tracheostomy Tubes	**Tracheostomy Tubes**
Airway and Respiratory Support	Mechanical Ventilators	**Ventilators**
Airway and Respiratory Support	Filters	**Ventilator filter**
Airway and Respiratory Support	Suction Tubes and Catheters	**Suction Canisters**
General Supportive Care	Intravenous (IV) Containers	**IV bags**
General Supportive Care	Beds, Stretchers, and Gurneys	**Hospital beds**
Liver and Kidney Support	Hemodialysis Circuit Accessories, Hemodialysis Dialysate	**Continuous Venovenous Hemofiltration Cartridges, Components, Fluids**
PPE	Non-Sterile PPE	**Face shields**
PPE	Public Use Respirators	**N95**
PPE	Non-Sterile PPE	**Masks**
Tests and Test Systems	N/A	**COVID-19 Test Kits**

Characteristic of manufacturers, providers, health systems, and patients affected by shortages

The supply chain for medical devices consists of manufacturers, suppliers, distributors, group purchasing organizations (GPOs), and consumers, which include health systems, providers, and patients. [14] Manufacturers are responsible for obtaining approvals or clearances with FDA before they can market their product in the United States. [14] They also produce the finished product and sell to distributors, GPOs, or consumers. [14] Suppliers provide components to manufacturers and each supplier has their own set of suppliers. [14] Distributors sell to GPOs or consumers. GPOs are member-based organizations typically consisting of hospitals or physician practices to increase collective buying power for better pricing. [14]

Before the COVID-19 pandemic, heavy dependence on foreign sourced critical components and natural disasters resulted in disruption of raw material supplies leading to shortages of medical devices. [4, 6] A 2011 U.S. Department of Commerce study found that 63.7 percent of medical device manufacturers relied on at least one foreign sourced critical component, partly due to lack of domestic suppliers. [4] In 2017, a natural disaster, Hurricane Maria, wiped out a main supplier of saline solution in Puerto Rico leading to shortages of IV bags. [6]

The COVID-19 pandemic amplified the existing reasons manufacturers faced raw material shortages due to increased demand and inadequate manufacturing capacity. [14] For example, a 2021 winter storm in Texas caused a shortage of specialty plastic resins. [3, 23] This is a raw material used in medical devices such as COVID-19 test kits leading to health systems searching for new suppliers due to its high demand. [24]

PPE (e.g., masks, face shields, N95) is another medical device example that had a significant increase in demand. [8] Shortages of PPE were found across all types of providers and health systems, and according to one informant, even manufacturers. [8, 22, 25] Manufacturers were competing with health systems for PPE needed to build sterile devices. This led to a reduction in build capacity with some companies waiting six to nine months to get them due to their reliance on foreign-sourced masks.

From a health system perspective, the literature search spotlighted PPE shortages in two types of facilities: nursing homes and rural hospitals. McGarry et al. examined the impact of COVID-19 on PPE shortages from May 2020 to July 2020 for Medicare and Medicaid-certified homes to understand which facilities were more likely to report shortages. [22] Their studies showed 98 percent of nursing homes had PPE shortages of which 19.1 percent to 20.7 percent reported severe shortages (defined as having less than one week of PPE supply). [22] For-profit nursing homes and facilities that reported having COVID-19 amongst residents and staff were also more likely to have PPE shortages. [22, 26]

Rural hospitals historically face financial challenges and as a result, had additional issues securing PPE that other larger systems may not have seen. [25, 27] These challenges included being at the end of the supply chain, having limited buying power, and transportation issues (e.g., remote facilities). [25] These types of facilities also have a lack of storage leading to buying in limited quantities (e.g., 15-day or 30-day supply instead of 90-plus-days of PPE). [25] Informants representing manufacturers and a hospital association also mentioned rural hospitals have less ability to share or move devices compared to large, multi-state systems. They also mentioned limited or lack of transportation methods in these areas can cause medical device shortages, affecting only certain geographic regions. Rural hospitals already have fewer services making it difficult to use alternative devices or procedures during a shortage. [27]

Ventilators were also in shortage during the pandemic, leading to rationing and patient prioritization. [28] As there is no national guideline for allocation, states and professional societies created guidelines for this process. [28-31] Anderson et al.'s 2023 review of three states' guidelines showed they prioritized a patient's odds of survival during the acute phase of the disease or health condition. [28]

Medical device shortages during the pandemic also affected chronically ill patients receiving medical services at home. For example, the supply chain of airway and respiratory support devices (e.g., tracheostomy tube, ventilator filters) was disrupted due to increased demand leading to individuals competing against hospitals. [7, 9] As demand increased, the price of tracheostomy tubes also increased, creating a disadvantage for those relying on state-issued devices or are unable to afford the increased cost. [9] Suppliers rationed stock during the pandemic, and some considered not selling product to Medicaid patients. [12] The literature reported that the reimbursement rates Medicaid paid to these suppliers during the pandemic did not keep up with the cost needed to stay profitable. [9]

Another device on shortage for the chronically ill were general support devices (e.g., IV bag). For one family, they were given shipments of significantly smaller IV bags for their son than in previous deliveries, which increased the risk of infection due to more frequent bag changes. [7] The supply chain of these devices was disrupted due to continued increases in demand and transportation delays at the ports of Los Angeles and Long Beach, highlighting the reliance on foreign sources. [7, 9]

The previous examples provided for medical services received at home were for patients under 18. [9, 12] A physician interviewee highlighted that patients under 18 were especially affected during a device shortage due to less alternative options available. Therefore, shortages have a greater impact on patients under 18 due to limited supply alternatives for this population.

Shortages have a greater impact on patients under 18 due to limited supply alternatives for this population.

How providers, health systems, patients, and manufacturers manage shortages

Table 2 summarizes the 14 methods and strategies found through this landscape analysis, along with examples of how providers, patients, health systems, and manufacturers managed device shortages during the pandemic. Providers and health systems used all strategies, while patients used two, and manufacturers used one. These approaches range from asking the community for donations to using unvetted or non-traditional sources.

Table **2**. Methods or Strategies Used by Providers, Health Systems, Patients, and Manufacturers to Manage Medical Device Shortages During the COVID-19 Pandemic

Method or Strategy	Example(s)	Entities			
		Providers	Health Systems	Patients	Manufact-urers
Rationing and prioritizing use or distribution of devices	Re-using or re-sterilizing PPE, and prioritization of ventilators or tracheostomy tubing are examples of rationing devices. [12, 20, 31, 32] Provider decisions to manage ventilator shortages grew during the COVID-19 surges due to increase in demand, with manufacturers also rationing their product by turning away new customers and focusing on existing clients. [9, 28]	X	X	X	X
Using unvetted, non-traditional sources, alternate suppliers	A National Pulse Survey of hospital experiences during the COVID-19 pandemic highlighted hospitals turning towards unvetted and non-traditional sources for PPE such as auto body shops. [20] Rural hospitals also partnered with a local business to produce PPE. [25] When patients experienced shortages in their medical devices used at home, they sought product through resources like Facebook groups. [7, 9, 12]	X	X	X	
Using alternative devices, components, procedures, or treatments	When physicians faced shortages of standard medical devices used for kidney replacement therapy during the COVID-19 pandemic, they turned to other, less-used methods such as peritoneal dialysis. [21, 33] Physicians also repurposed anesthesia equipment, emergency transport ventilators, and continuous positive airway pressure machines in lieu of full-feature ventilators to treat patients. [20, 34]	X	X		
Changing hospital processes/ protocol to reduce waste	The World Gastroenterology Organization released guidance during the COVID-19 pandemic to reduce the number of staff needed during an endoscopic procedure to limit PPE usage. [35]	X	X		

Method or Strategy	Example(s)	Entities			
		Providers	Health Systems	Patients	Manufact-urers
and patient contact					
Asking for community donation	Health systems in places like New York, Ohio, and San Francisco asked the community for PPE donations. [36, 37]	X	X		
Asking for help from manufacturing executives	Physicians contacted executives at a major manufacturer of dialysis fluid and equipment as a plea to send supplies to their hospital for treating patients with kidney disease affected by COVID-19. [13]	X	X		
Centralizing distribution centers	Some rural hospitals joined together to create a centralized distribution center to reduce the impact of transportation delays and improve distribution of COVID-19 related supplies. [25]	X	X		
Deferring elective procedures	The Centers for Medicare and Medicaid Services (CMS) and the American College of Surgeons (ACS) recommended delaying elective procedures to combat shortages of PPE and hospital beds during the COVID-19 pandemic. [8, 32, 38] This led to a 91 percent reduction in elective procedures at Veterans Affairs Hospitals at the beginning of the pandemic. [39]	X	X		
Deploying telehealth and tele-monitoring services	Health systems implemented telehealth services and telemonitoring to limit COVID-19 exposure and PPE needs. [40, 41] A significant increase in telehealth visits for Medicare patients, from 1 percent to 43.5 percent, was observed at the start of the pandemic. [42]	X	X		
Exchanging or sharing unused PPE supplies	Some hospital systems such as those located in a rural region created partnerships for sharing and exchanging of unused PPE supplies. [25]	X	X		
Partnering with hospitals to bulk buy	Rural hospitals joined together to increase their collective buying power of COVID-19 related supplies. [25] An increase in collective buying power can aggregate quantities and meet minimum buys to help move up in prioritization with manufacturers. [25]	X	X		
Re-using and/or re-sterilizing PPE	A National Pulse Survey of hospital experiences during the COVID-19 pandemic showed hospitals had to re-use and re-sterilize PPE. [20] The CDC listed several methods for decontamination of PPE during a crisis and at least one equipment involving the use a hydrogen peroxide system received emergency use authorization from the FDA. [40, 43]	X	X		
Using alternative PPE designs	Staff at a children's hospital in Washington D.C. partnered with academic centers to develop their own PPE when shortages arose due to COVID-19. [44] This included portable plexiglass glass shields, face shields, breath shields, and safety googles. [44]	X	X		
Using the national or a state stockpile	States asked for PPE from the strategic national stockpile (SNS) and some states such as California also maintained their own PPE stockpile during the COVID-19 pandemic. [36, 45]	X	X		

How resources, costs, and patient health outcomes are affected by device shortages

Most approaches to manage device shortages, as outlined in Table 2, require hospital personnel and time. For example, staff involvement such as IT coordination is needed for telehealth and telemonitoring services. [41] Staff are used to assess technology options, determine capability with existing systems, implement the technology, train users, respond to feedback, and develop improvements as needed. [41] One hospital system installed 1,800 inpatient telehealth devices in seven hospitals, underscoring the significant effort used to implement a solution for PPE shortages. [41] In another hospital where PPE shortages were not as dire, there was low adoption of inpatient telehealth leading to no reduction in PPE

usage. [46]

Similarly, the use of alternative devices or procedures required sourcing and training time. As noted by two informant interviewees, healthcare providers are accustomed to using a specific device and the use of alternatives can lead to a change in standard protocol or reduction in quality of care. For example, a shortage in ventilators during the pandemic led to re-purposing of anesthesia machines and single-use emergency ventilators. [20] When there was a shortage of liver and kidney support devices (intermittent hemodialysis and continuous venovenous hemofiltration), healthcare providers were trained on an alternate procedure, peritoneal dialysis. [21, 33]

Hospital staff also spend a significant amount of time finding alternate suppliers when a device shortage occurs. This primarily requires staff engagement with manufacturers or distributors to find solutions. [13, 47] When a major manufacture of dialysis equipment restricted purchases this led to physicians lobbing with distributors and manufacturers to get more units and finding alternatives. [13] The National Pulse Survey for Hospital Experiences also revealed that when hospitals used un-vetted sources their orders were sometimes late, unfulfilled, or different than what was requested. [20] This puts further strain on the staff as multiple strategies are needed to manage shortages.

In addition to impacts on hospital personnel and time, device shortages impact costs. During the COVID-19 pandemic the price of masks was reported to have increased by 12 times ($0.50 to $6.00) and that of a mechanical ventilator by 2 times ($25,000 to $50,000). [20, 48] There can also be costs associated with sourcing from different suppliers or sourcing alternative devices. [20, 25] During the shipping delays at the ports of Los Angeles and Long Beach in 2021, which included a range of medical devices, [12] larger hospitals, like Cedars-Sinai in California, were able to tap into their reserves and used alternate sources to limit impact on their patients. [12] We learned from the informant interviews that larger hospitals engaged in panic buying leaving smaller hospitals that already have less purchasing power with no devices. For example, a community hospital in California worked day and night to find alternate sources for PPE and suction canisters. [12] If deciding to build their own device, as done by one children's hospital, there are costs related to acquiring materials and paying manufacturers. [44]

As device costs increase due to a shortage, there can also be a loss of revenue when procedures are canceled to conserve or prioritize usage. [20] This was highlighted in the findings of National Pulse Survey of Hospital Experiences conducted during the COVID-19 pandemic. [20] As elective procedures were delayed or canceled, hospitals lost a major source of their revenue, putting them at financial risk. [20] Rural or independent hospitals were even more vulnerable as they were less likely to have enough financial reserves to absorb cost increases. [20] The deferring of elective procedures also impacted manufacturers, where one informant revealed sales of medical devices reduced by 10-50 percent, which impacts their ability to improve supply chain resiliency.

Patients are also affected by increasing costs of medical devices during a shortage. [9, 12, 49] Patients may see an increase in both their insurance premiums and out of pocket payments. [9, 12] The increased cost in premiums may occur when insurance companies are unable to pay for higher healthcare costs. [12] This was seen when CMS raised its Medicare Part B premiums, partially due to an increase in costs from the COVID-19 pandemic. [12, 50]

The impact of device shortages on clinical outcomes varied by purpose of the device such as lifesaving, life sustaining, or PPE, and whether alternative products were readily available. The shortage of ventilators, considered lifesaving devices, led to rationing, meaning some patients did not receive ventilator support. [20, 31] When new tracheostomy tubes, a life sustaining device, were scarce, patients re-used and re-sterilized their existing tubes, increasing the chance of infection. [9, 12] The widespread lack of PPE during the COVID-19 pandemic led to deferral of elective procedures. [8, 32] From the informant interviews we learned the deferral of elective procedure led to some cancer patients not receiving their screenings. The impact of delayed cancer screenings during this period is unknown, but there is a potential for missed early intervention opportunities.

The impact of device shortages on clinical outcomes varied by purpose of the device and number of alternative devices available.

A physician informant mentioned the impact of shortages also varies depending on number of alternative devices available and how similar their performance and safety profile are. Usage of alternative devices that are equivalent to the device on shortage will have minimal impact to the patient, such as a different diabetes tool for measuring glucose levels or different b of PPE. However, physicians using a different procedure or medical product would have a larger impact as they may need training to prevent reduction in quality of care. Other interviewees explained device shortages can also cause physicians to deviate from medical guidelines (e.g., limit referral of CT scans), also impacting the quality of patient care. [10]

If no alternative is available, patients may have delayed care. Depending on the severity of the health condition, informants discussed the impact of delayed care leading to a later stage diagnosis and increased costs for the patient and healthcare system. An example provided by one informant was patients with cardiovascular disease needing an implantable device not visiting the hospital or getting treatment during the COVID-19 pandemic due to deferral of elective procedures.

DISCUSSION

Though medical devices make up only 5.2 percent of the national health expenditures, they are an important part of the healthcare system. [1] There are a wide range of devices with approximately 1,700 medical device classifications. [51] The medical device industry includes products designed to diagnose, treat, and prevent chronic and acute conditions such as diagnostic tests, glucose monitors, masks, pacemakers, and ventilators. [52, 53] This landscape analysis revealed several key findings to understand the impact and costs associated with medical device shortages on providers, health systems, patients, and manufacturers during the COVID-19 pandemic.

Key Finding 1. Providers, health systems, patients, and manufacturers used many methods and strategies to manage device shortages during the COVID-19 pandemic.

This landscape analysis revealed 14 different methods and strategies used by providers, health systems, patients, and manufacturers to manage device shortages, with some entities using more than one strategy or method. While providers and health systems used all approaches identified, the literature revealed only two strategies used by patients and only one by manufacturers. This could be due to hospitals having more resources or using a wider variety of medical devices. Alternatively, it may reflect the lack of research on how medical device shortages affect patients and manufacturers, highlighting the need for future research to address this gap.

All these strategies are also resource intensive due to the additional time needed to find and contact suppliers, re-configure clinic layouts, secure equipment, and train on alternative devices or procedures. [20, 21, 54] Though the literature and informant interviews did not provide an associated cost, we can assume there are significant direct and indirect costs needed to deploy these methods. In recent years, there has been significant interest in improving supply chain resilience with involvement from multiple government sectors. [55, 56] Future research could evaluate the effectiveness of these methods and strategies, accounting for both costs and benefits, to increase the resilience of medical device supply chains and optimize healthcare resources.

Though we found these approaches during our research on the COVID-19 pandemic, their methods are not unique to the pandemic. Providers, health systems, patients, and manufactures can use these methods and strategies during any device shortage. Future research can also evaluate how these approaches have changed post the COVID-19 pandemic especially with the heightened interest on medical product shortages from the government.

Key Finding 2. Shortages during the COVID-19 pandemic had severe patient consequences.

A white paper published by ASPE using the U.S. Census Bureau's Pulse Survey revealed that 18 percent of the U.S. adult population in 2023 was impacted by a drug or medical device shortage with reported impacts ranging from delaying care to using alternatives. [52] Though our analysis evaluates an earlier time frame and does not estimate the number of adults impacted by device shortages, our findings align with this work and further expands upon the consequences on patient health. The severity of the patient outcome depends on the type of device on shortage, the strategy used to manage the shortage, the number of alternative devices available, and how alike the alternative devices are. For example, a patient using medical services at home and boiling a tracheostomy tube to re-sterilize an existing product faces a potential infection that could lead to hospitalization. [7, 9, 12] A physician using an alternative device or method where they have less practice can lead to unanticipated procedural complications. However, a hospital using a different type of bed will have minimal patient impact if the bed has the same performance as the original.

As discussed above, when there are shortages, health systems and manufacturers may have to implement allocation measures which limit the supply of medical devices that their patients or customers receive. This can result in conservation strategies that require prioritizing certain populations over others. In Anderson et al.'s 2023 review of three states' guidelines that prioritized certain patients, two of the states used a method that assessed kidney function based on creatinine levels, which is typically higher for Blacks and may have led to exclusion of Blacks from ventilator allocation. [28, 30] This example highlights ethical considerations as well as potential disparities in accessing devices during shortages.

While the earlier ASPE work evaluated the sociodemographic characteristic of adults affected by shortages, our analysis found the patients most vulnerable to device shortages during the COVID-19 pandemic were those under 18, those living in rural areas, and those relying on medical services at home, ventilators, and state-issued devices, or living with a chronic disease. [7, 9, 12, 28, 30, 31] These patients experienced delayed procedures, higher purchase costs, or had to re-use devices, or received alternative treatments. [7, 9, 12, 20, 31] Medical device shortages are not limited to the COVID-19 pandemic and therefore, future research is warranted to further understand the direct and indirect costs of shortages on patients, including among the most vulnerable populations.

Key Finding 3: Pre-existing challenges like dependence on foreign sources, natural disasters, transportation issues, and limited supply chain visibility, combined with surge in demand, made medical device supply chains vulnerable to shortages during the COVID-19 pandemic.

Our analysis also found the COVID-19 pandemic amplified existing supply chain disruption risks for manufacturers such as foreign sourcing, natural disasters, and transportation delays due to significant surge in demand. [4, 12, 57] These findings are in alignment with previous studies including two ASPE reports that described challenges manufacturers faced during the pandemic and another that showed a significant number of U.S. manufacturing sites are located in areas at high risk of natural disasters. [14, 58]

Prior to the CARES Act authority requiring manufacturers to notify FDA of potential device shortages during or in advance of public health emergencies, FDA had limited visibility into the medical device supply chain. The CARES Act was enacted in 2020 and in 2021, a Texas winter storm caused a significant disruption in specialty plastics. [3, 24] Due to the notification requirements from the CARES Act, FDA was able to work with some manufacturers to lessen the impact of this disruption on COVID-19 test kit availability. [3]

Since the expiration of the COVID-19 public health emergency, device manufactures are not required to notify FDA of potential shortages. As a result, FDA is seeking to "remove the temporal limitation on FDA's medical device shortages authorities and require manufacturers to maintain and share risk management plans" as part of their fiscal year 2025 legislative proposals. [59] By removing this limitation, manufacturers would be required to notify the agency of significant supply disruptions at any time to enable FDA to help mitigate impacts to patients and healthcare workers. [3]

From the informant interviews, we learned physicians and patients were unaware of FDA's expanded authority for notifications of supply disruptions. Physicians rely on their inventory manager and suppliers for notification of shortages. An informant also revealed patients learn of shortages through the news and receive no notification from providers or the FDA. Future research could evaluate the communication methods for shortage notification to providers and patients.

We also learned from the manufacturer informant that many device companies have outsourced all or parts of their manufacturing process to contract manufacturers. This makes contract manufacturers a crucial part of the supply chain process. The informant stated these types of companies can help diversify the location of manufacturing and build redundancy in the process to offset surges in demand. The interviewee also mentioned device manufacturers can meet demand if contracts are set up ahead of time, allowing them time to plan and qualify additional suppliers as needed. In a public health emergency or unanticipated crisis, this may not be possible. Future research could examine the role of contract manufacturers and their influence on supply chain challenges.

Though literature exists on causes of supply chain disruptions for medical devices, there is limited research on understanding the characteristics, impacts, and costs associated with device shortages on providers, health systems, patients, and manufacturers. We chose to study this impact during the COVID-19 pandemic due to the widespread reach of medical device shortages. This landscape analysis provides the groundwork for future research on estimating the direct and indirect costs related to device shortages and understanding of the medical device supply chains.

LIMITATIONS

This landscape analysis has several limitations. Though the search terms were broad, the results may not have captured all relevant articles. Further, there were only six stakeholder interviews, which limits the

generalizability of the findings. The interviewees represented health systems, manufacturers, providers, and patient advocates, but did not include patients specifically affected by device shortages. Additionally, estimates on costs, and the perspective of other entities of the medical supply chain such as those of group purchasing organizations and contract manufacturer organizations are not captured in the landscape analysis. Lastly, we limited this landscape analysis to the COVID-19 pandemic and as such limit the interpretation and generalizability of the findings.

CONCLUSION

This report aims to improve the understanding and impact of medical device shortages during the COVID-19 pandemic. The findings suggest medical device shortages have wide-ranging impacts not just on patients but providers, health systems, and manufacturers. While this report provides a glimpse of the impact of devices shortages, more research is needed to understand and quantify the impacts. This understanding can also inform strategies to improve supply chain resilience and prevent or mitigate the impact of future medical device shortages.

APPENDIX A DATABASES AND SEARCH TERMS

The databases used to find peer-reviewed literature were ABI-INFORM, Google Scholar, EBSCO Cumulative Index of Nursing and Allied Health Literature (CINAHL), PubMed, Congressional Record, ScienceDirect, Dow Jones Factiva, and WorldCat. The grey literature sources used were Google, Gartner, Analyst Reports, Fitch, American Medical Association, American Heart Association, Food & Drug Administration, AdvaMed – Advanced Medical Technology Association, World Economic Forum, Milken Institute, D-Rev, CalMatters.org, Medical Devices & Surgical Technology Week, and Fortune Business Insights. Table A-1 below lists the terms used in the literature search. We also limited the scope of the search to the COVID-19 pandemic.

Table A-3. Search Terms

Topic Area	Search Query
All	Medical device market size, (medical device marketplace or medical device industry)
All	design, medical devices; durable medical equipment; appliance design and (shortage* OR problem* OR difficult* OR issue* OR supply chain* OR distribution or innovate* OR trend* OR outlook or forecast* OR future or demand or market size)
Providers and Health Systems	Health care provider* OR hospital* OR clinic* OR primary care provider* OR health system* OR community health provider* AND design, medical devices; durable medical equipment; appliance design
All	medical device shortages medical device industry (title/abs) and issue* OR problem* OR shortage* OR supply chain* OR trend*, medical device industry (title/abs) and issue* OR problem* OR shortage* OR supply chain* OR trend*, (hospital*[Title/Abstract] OR clinic*[Title/Abstract] OR practice*[Title/Abstract] OR network*[Title/Abstract] OR kaiser [Title/Abstract] OR provider*[Title/Abstract])
Providers and Health Systems	medical device AND equipment industry AND (shortage* OR demand* OR supply OR (raw material)) AND (alleviat* OR mitigat* OR relie* OR challeng* OR success*) AND (nonprofit* OR (low income*) OR Kaiser* OR provid* OR metro* OR rural OR urban OR clinic* OR hospital* OR network* OR poor*)) AND ab(shortage*) AND ab((medical (devic* OR equipment))) AND ab((nonprofit* OR (low income*) OR Kaiser* OR provid* OR metro* OR rural OR urban OR clinic* OR hospital* OR network* OR poor*))
Patient	(“medical device*” OR “medical equipment” AND (social determin* of health) AND (poc or color or minorit? or rac* AND underserv* OR “low income”) AND (“health system*” OR provider* or disparit*)
Patient	(((health or medical) (devices or equipment))) AND AB (rural or communit* OR urban or metro* OR private or underserved or racis* OR low-income or middle-income or poor* OR disadvantage* OR inequit*) AND AB (hospital* or network* or facilit* or provide*) AND AB (lack* OR shortage* OR shortfall* OR insufficien* OR suppl* or demand* OR scm)
Patient	hlp=medical devices and (low-income or underserved or inequity or inequities or inequitable or disparity or disparities or racism or racist)
Providers and Health Systems	hlp=medical devices and (rural or metropolitan or states or cities) and (trend or trends or outlook or forecast or forecasted or forecasting or future or strategy or strategies)

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ABOUT THE AUTHORS
Linda Thai, MPH, is an ORISE fellow in the Office of Science and Data Policy in ASPE.
Trinidad Beleche, PhD, is a Senior Economist in the Office of Science and Data Policy in ASPE.
Oluwarantimi Adetunji, PhD, is an Economist and the NIH and ARPA-H portfolio lead in the Office of Science and Data Policy in ASPE.

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