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Understanding the Challenges of Providing Personal Protective Equipment in the United States During COVID-19

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Understanding the Challenges of Providing Personal Protective Equipment in the United States During COVID-19

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Abstract

On March 11, 2020, the World Health Organization designated "coronavirus disease 2019" (COVID-19) a global pandemic. The COVID-19 pandemic caused massive shortages in the Personal Protective Equipment (PPE) supplies needed to treat the virus as the disease spread rapidly throughout the world during 2020. Global supply chains suddenly became a new problem in public attention.

In the United States, there were no reliable databases about what was needed in different hospitals, states, or healthcare systems. Also, there was no accurate database of the production capabilities of U.S. suppliers of PPE.

The aim of our research was to investigate the best approaches to determine the needs for PPE during the pandemic and to improve the methods used to predict the PPE needs for hospitals and other healthcare facilities. The second part of our research was to develop an understanding of the capabilities of the U.S.-based companies to produce large quantities of specific PPE for both the current pandemic and future needs. We feel that this work has implications for anyone in the healthcare supply chain space (Department of Defense [DoD] task forces, Defense Logistics Agency [DLA], Defense Health Agency [DHA], Federal Emergency Management Agency [FEMA], Department of Health and Human Services [DHHS], Department of Homeland Security [DHS], state, local, and healthcare systems).

Keywords: COVID-19, Shortage, Supply Chain Challenges, Personal Protective Equipment

Introduction

In November 2019, Coronavirus Disease 2019 (COVID-19) first appeared in China (Scher, 2020). Soon after, Thailand and Japan became the first and second countries outside China confirming COVID-19 cases in mid-January 2020 (Joseph, 2020; Schnirring, 2020). In quick response, screening travelers was started at three U.S. international airports: Los Angeles (LAX), San Francisco (SFO), and New York (JFK) on January 17, 2020 (Centers for Disease Control and Prevention [CDC], 2020). The first COVID-19 case in the United States was detected in Washington State on January 20, 2020 (Holshue et al., 2020). Then the virus started spreading across the country. COVID-19 has hit the United States harder than any other country in the world (WorldOMeter, n.d.). The number of deaths rose quickly, and just in 4 months, late May 2020, the number of deaths reached 100,000 (Winsor et al., 2020). At the end of March 2021, the total number of cases globally was approximately 129 million, resulting in 2.82 million deaths. About 20% (0.552 million) of these were in the United States (Johns Hopkins University & Medicine, n.d.).

One of the impacts of the COVID-19 pandemic was a major disruption to the PPE supply chains in the United States and large PPE shortages across the country. Before the pandemic, more than 70% of the critical respiratory-related PPE used in the United States was sourced from overseas companies, primarily in China. When high global demand drastically reduced available supplies from China during early 2020, major distributors were unable to fill orders. We quickly saw two major problems. In the United States, there was a lack of information about what was needed in different hospitals, states, or healthcare systems. Models were developed using available estimates of infections, hospitalizations, intensive care unit (ICU) usage, and other factors, but most of these models were seriously flawed. Even worse, the data needed in these

models were not accurate, timely, or complete (Davenport et al., 2020). Without accurate and timely data, it is difficult to construct objective-based responses that provide lifeline services for communities in emergencies.

The second major problem was the lack of an accurate database of the production capabilities of U.S. suppliers of PPE. Many who produced end-product PPE soon discovered the materials they needed were no longer available. Others discovered that they were missing several critical items in the supply chain or that these items were in short supply. Others found they had the capability to ramp up production quickly, but they wanted guarantees of purchases before committing to major investments. Without a national understanding of demand, companies were hesitant to make large investments.

This research investigates the best approaches to determine the needs for PPE during the pandemic, suggests improvements of the methods used to predict the PPE needs for hospitals and other healthcare facilities, and develops a better understanding of the supply chain capabilities for PPE. Future materials acquisition programs for similar situations need better models as well as new data collection, data management, and data quality strategies. This study also provides a better understanding of the capabilities of U.S.-based companies to produce large quantities of specific PPE for both the current pandemic and future needs.

Supply Chain Challenges in Healthcare

Supply chain management in healthcare is a dynamic process that includes manufacturing facilities, purchasers, and distribution services for commodities and services to health providers and patients (Iyengar et al., 2020). Implementation of modern supply chain management strategies in the healthcare area has been extremely slow. The top three challenges in healthcare supply chain management are costs, including invisible costs, lack of supply chain health information technologies, and lack of quality. Many extra costs within the healthcare supply chain are a result of inefficient and unnecessary processes involved in the transportation and delivery of supplies from suppliers to healthcare providers.

The lack of a modern information technology system for demand and supply chain transparency is another challenge. Exchanging health data is often difficult, and there are many problems with digital sharing. The number of competing health systems and different platforms creates addition complications. These inefficiencies often lead to delays, poor-quality care, and additional costs. Healthcare organizations are often highly dependent on group purchasing organizations and usually do not have access to details about the critical supply chains.

During the pandemic, the demands for PPE were far higher than supplies, leading to rapid increases in prices for available PPE and serious shortages. Many new organizations took this opportunity to start producing needed PPE, often with little regard for standards and adequate quality. Many of these organizations, both manufacturers and distributors, had no experience in producing and/or distributing these products. Promises were made with no certainty the supplies could be produced or sourced, extreme delays in delivery—or sometimes any delivery—were common. It is also clear, even in non-pandemic situations, that supply chain management is more complex in healthcare than in other industries because of the impact on people's health, requiring adequate and accurate medical supply according to the patient's needs (Beier, 1995).

Supply Chain of Personal Protective Equipment

According to the Occupational Safety and Health Administration (OSHA), Personal Protective Equipment (PPE) is defined as equipment that is worn with the objective of minimizing the exposure to hazardous substances. The most common items are gloves, foot

and eye protection, protective hearing devices, hard hats, respirators, and full body suits (OSHA, 2004).

PPE plays a critical, major role in healthcare environments and many other industries. PPE is used by professionals, especially healthcare workers, who are exposed to viruses, infections, and disease during their daily activities. The use of PPE is essential to protect healthcare workers from disease spread (CDC, 2004). These protective items like gloves, gowns, masks, respirators, googles, and face shields became especially critical products during the COVID-19 pandemic in healthcare systems.

One of the main characteristics of the supply chain of PPE in the United States is that it is similar to many other goods based on demand. Products are manufactured only in sufficient quantities to cover the anticipated normal demand, leaving little ability to increase production if needed (Patel, 2017). As a result, it becomes extremely difficult to accommodate abrupt increases in the demand, as would happen with a public health crisis similar to the current pandemic, where demand increased rapidly.

Impact of COVID-19 Pandemic in Healthcare Supply Chain and Personal Protective Equipment Shortages

As the coronavirus pandemic spread across the world rapidly, healthcare systems quickly faced major shortages in many countries. Production and distribution of PPE to healthcare frontline workers quickly became one of the main public health challenges during COVID-19.

There are a number of factors that contributed to the massive shortages of PPE. The practice of many healthcare organizations and their purchasing organizations of just-in-time delivery was one of these factors (Rondinone et al., 2021). This practice, which works well in normal time, limited excess inventory and unnecessary costs. However, this model did not have the necessary flexibility to meet the current situation with rapid increases in demand. Suppliers who normally produced based on a predictable and regular demand struggled to change their production processes to meet the rapid changes in demand. The inventory management strategies that meet normal demand cycles need a reconsideration to avoid shortages of essential supplies in medical crises (Patrinley et al., 2020).

Another factor that contributed to the current shortages is the global nature of the medical supply industry. Around 50% of masks used in the world are made in one country, China. As the virus hit China first, the lockdowns there stopped production quickly, causing significant shortages of masks throughout the world (Wang et al., 2020).

U.S. Response to COVID-19 and Personal Protective Equipment Shortages

After the COVID-19 epidemic began, there were no clear ideas for countries to proceed and control the spread of the virus. The spread of the virus is not only through air by coughs and sneezes, but also through contact surfaces as well as community transmission (CDC, 2020; WebMD, n.d.). Different countries responded differently to this situation; preparing PPE for the healthcare frontline workers and general people was a critical and immediate job in every country.

The U.S. government, like other countries, needed proactive responses to ensure the safety of citizens. Travel restriction was one of the first U.S. responses to COVID-19. It was mandatory to confirm that the virus was not carried through travelers from other countries. Screening at the port of entry and mandatory home quarantine was assured for travelers (Department of Homeland Security, 2020).The United States' second action was stay-at-home orders instructing citizens to restrict their commuting outside their homes if not required

(Mervosh et al., 2020). Practicing social distancing and wearing masks in public areas were also recommended by the U.S. government and the CDC (Barthel, 2020; Kopecki, 2020). Many felt that despite these actions, the U.S. government made a delayed response to the COVID-19 crisis (Pew Research Center, 2020).

In addition, the United States faced large PPE shortages during COVID-19. Hospitals and other healthcare providers were faced with extremely high demand for PPE products. The radical increase in demand significantly affected the supply chain network, which caused many shortages of supplies and many disruptions in distribution. Most hospitals had only a few days of PPE on hand when COVID-19 hit their regions, and the national stockpile was exhausted quickly. Most hospitals traditionally relied on third-party organizations for supply chain management, who in turn focused primarily on low-cost supplies primarily manufactured outside of the United States. Many of these offshore suppliers, naturally, had diverted their production to the needs of their own countries. Several U.S. companies that supplied a significant percentage of PPE found that some parts of their supply chains were disrupted (Arangdad et al., 2021).

The United States had not only failed to provide a prompt, transparent response, but it also was not successful in delivering enough PPE to frontline healthcare providers (Zurcher, 2020; Robbins & Garde, 2020). A large number of deaths could had been avoided by timely response (Sebenius & Sebenius, 2020). However, no country was sufficiently prepared for such a pandemic, and the U.S. government is no exception. However, in some ways the U.S. response to COVID-19 has been remarkable. In response to these shortages, many companies, organizations, and universities made great efforts to help with this crisis.

Many apparel companies quickly turned their production lines to making masks and gowns. Nonwoven companies focused the melt blown and spun bond nonwovens facilities and expertise to produce specially designed fabrics that can be delivered to U.S. manufacturers to produce respirators.

Many non-textile manufacturers (e.g., Ford and Honeywell) also responded to contribute to the manufacture of PPE (Ford, 2020; Honeywell, 2021). Many universities also responded to the current critical situation. Even though most universities suspended their normal operations in March, switching to an online format to protect students, professors, staff and some research laboratories remained open to assist with PPE supplies. Institutions around the country have worked hard in the past months to assist with the manufacture of materials required for the construction of PPE, to assemble finished products, or to produce innovative products and technologies as an alternative to the shortages of traditional PPE items.

Management of COVID-19 Data in the United States

The current PPE needs were identified using the data on patients in hospitals, in states, and in regions of the country. In the first few months, PPE needs were further complicated by a lack of testing resources and extremely long turn-around times for test results. This situation created large numbers of “suspected COVID-19 cases” that had to be treated exactly as a known case, creating double or even triple use of PPE. Further complicating the PPE demand estimates was the fact that many PPE were single use, meant to be used once and thrown away. When PPE shortages became critical, many hospitals started reusing these PPE, and many organizations created and published methods for cleaning and reusing what were considered disposable items.

Data helps to evaluate existing situations, predict upcoming crises, and make influential decisions (Lithios, 2020).

The Strategic National Stockpile (SNS) was created in the United States in 2002 through federal funding and other initiatives related to the Public Health Security and Bioterrorism and

Response Act. The expressed purpose was to create a special inventory of items that could provide healthcare workers and other professions with critical supplies during a health crisis. This stockpile included many PPE items such as gloves, masks, and surgical gowns as a result of both real and simulated health emergencies (Yorio et al., 2019). During the recent pandemic, these supplies were quickly exhausted. There was much uncertainty and a lack of unified knowledge in sourcing for specific product components and testing requirements, as well as a lack of connection between product suppliers, healthcare organization needs, and the healthcare systems.

Handfield et al. (2020) have reviewed the current situation of the SNS and made several recommendations for major changes in the SNS. The development of strategic plans was recommended, which can be incorporated in the supply chain. It is essential to use all resources from the federal SNS for PPE manufacturing and exploring the quality of needed products and the required storage space for such products, as well as keeping inventories relevant with the most proper product replacement system (Handfield et al., 2020). The recommendations of Handfield et al. (2020) and others should be a priority for the U.S. Administration and Congress to rethink the SNS.

Prediction Models Based on Personal Protective Equipment Needs

The COVID-19 pandemic has been a fundamental challenge to managing supply and demand on a massive scale. High demand of critical products and shortage in supply had a huge impact on healthcare supply chains. We are just beginning to understand and study what worked and what didn't.

Although the current pandemic has been addressed primarily by the healthcare systems and public health organizations, concepts from operations management shed light on many of the challenges faced by the healthcare industry. It is clear that many of the operational problems during the COVID-19 pandemic stem from the current supply chain management systems that have been primarily designed for cost efficiency. The challenges managing supply chains during a pandemic require flexible systems designed to quickly adapt to a rapidly changing landscape. COVID-19 has taught us that healthcare systems must have more flexible backup systems for supply chains to stymie disease spread and adequately equip providers to care for patients in their time of need (Patrinley et al., 2020).

Three Short Examples

The following three short examples illustrate many of the problems in creating working supply chains for PPE during a pandemic.

One of the first shortages was protective gowns for nurses, patients, and others in healthcare settings. Soon, pictures were appearing in the national press of nurses wearing garbage bags in an effort to be at least partially protected. Although a high percentage of hospital gowns were usually made by a major U.S. company, it was soon discovered that their major supplier of fabric in Central America had been closed, and existing fabric supplies were soon exhausted. Two of the largest cotton yarn manufacturers in the world are located in the United States, and there is actually a large weaving capacity. A number of companies soon created a coalition to respond to the crisis, providing millions of yards of high-quality fabric for the production of gowns. But as soon as low-cost supplies were available from other countries, the gown manufacturers sourced the cheapest fabrics, and the U.S. manufacturers were left holding millions of yards of fabric in unsold inventories.

Face shields were also in extremely short supply during the early days of the pandemic, and some healthcare providers are still reporting difficulties in sourcing the numbers they need. There were many stories of organizations quickly pivoting to make these shields. Many

organizations, especially research labs in universities, have numerous 3D printers. Designs for the face shields were rapidly shared, and soon tens of thousands of face shields were being produced. One university even partnered with a nearby medical school whose students worked in its mechanical engineering labs in shifts, producing shields for all the nearby hospitals. Although there were some problems sourcing the polymers for the shields, the main bottleneck quickly became the elastic for the headbands for the shields. The shield makers, almost all not connected to the apparel and textile manufacturing complex, found themselves competing with the manufacturers of surgical face masks and N95 respirators for short-supply, narrow-width elastic fabrics.

The most critical PPE shortage was the N95 respirators needed in healthcare settings. The N95 respirator is designed to achieve a close facial fit and efficiently filter airborne particles when properly worn. The FDA states that the N95 should be discarded after each patient encounter. They should not be shared or reused. The N95 respirator is evaluated, tested, and approved by the National Institute for Occupational Safety and Health (NIOSH) as per the requirements of 42 C.F.R. Part 84. The CDC did not recommend these for the general public since they are critical supplies that should be reserved for healthcare workers and other medical first responders. The shortages of these critical PPE items were so great that many healthcare workers were asked to wear theirs for several days or even weeks or resorted to wearing the less efficient surgical masks or even homemade cloth masks.

The N95 respirator is typically made of three layers of nonwoven materials, two spun bond and one melt blown, with the spun bond layers providing structural integrity and the melt blown layer providing the filtering capability. Although the United States is still the number one producer of nonwovens in the world, almost all plants were already running at close to full capacity prior to the pandemic, with many making other critical healthcare supplies. It was difficult, but not impossible, for these companies to pivot to add the melt blown fabric capabilities to produce the critical filter layer. But almost all of the high-quality nonwoven machinery is made outside the United States; backlogs for the German equipment that could help companies ramp up to meet the N95 needs were 3 to 6 months, even with expedited deliveries. Other equipment was needed to add automated lines to mold the completed respirators into the critical shapes required, to attach the headbands, and to package the completed product. Although these upgrades to the nonwoven manufacturing plants were available—even after a rather long delay—the potential manufacturers were reluctant to make the multi-million-dollar investments with the uncertain market conditions and the almost certain feeling that the healthcare providers would switch quickly to lower-cost offshore products as soon as they were again available (FDA, 2020).

The previous examples illustrate several major issues. Almost all of the critical PPE could be manufactured in the United States and distributed quickly to the healthcare providers and others with critical needs. No producer of the end items controlled the supply chains end-to-end needed to produce these items. Most producers were concerned that critical elements of the supply chain would revert to the lowest cost producers outside the United States as soon as possible. These concerns were well founded. Most potential producers of PPE were concerned that they would not be able to recoup their investments in new equipment or facilities, as purchasers would revert to sourcing the lowest cost products when they could. Many also feared that critical elements of the supply chain would soon be refocused on higher-end products as retail customers returned or companies returned to normal production.

Other countries countered these concerns in several ways. Taiwan created an adequate supply of face masks quickly by providing loans for new equipment that would be forgiven after a specified number of masks were provided to the government. This strategy worked amazingly well. Not only were the supplies created for use in Taiwan quickly, but these companies soon

became exporters of these masks to other countries still facing shortages (Jao, 2020). The United Kingdom, also facing severe shortages, used a different approach. The government guaranteed purchase of a large number of critical PPE items if manufacturers quickly ramped up production to provide what was needed. This is almost the identical approach the United States used for accelerating the creation and production of the vaccines by Pfizer. Some countries just made direct grants for needed equipment to encourage companies to become capable of producing needed PPE.

Compounding the problems addressed previously was the lack of reliable test facilities for assuring that the products created or rapidly sourced from new suppliers and distributors met the quality standards created by the FDA, CDC, and NIOSH. Examples of products that failed even the basic measures of quality were common. Sometimes over 80–90% of masks were found to be substandard in a large shipment. Some healthcare providers enlisted labs at local universities to provide basic testing on shipments of suspect quality. Other organizations created in-house facilities to do at least rudimentary testing. The largest provider of the critical N95 mask in the United States sued five vendors who targeted officials in three states by offering nonexistent N95 respirators. Federal agents in the United States seized more than 10 million fake 3M brand N95 masks in early 2021 (Long, 2021). In the United Kingdom, 50 million masks bought by the government were not used by the National Health Service (NHS) because of safety concerns (Kemp, 2020).

COVID-19 and the U.S. Textile Supply Chain

The U.S. textile supply chain is actually far stronger than most people realize. In 2019, the U.S. textile supply chain accounted for 585,000 jobs and $29 billion in exports, with the total value of shipments of man-made fibers, yarns, fabrics, apparel, and non-apparel sewn products around $76 billion. New investments in 2018 (the last year data are available) were $2.5 billion. The United States is the world's second largest exporter of textiles (Glas, 2021).

The economic crisis of COVID-19 led to sharp drops in demand from retail customers, forcing many textile and apparel companies to reduce capacity. Clothing sales fell by 49% in March 2020, 87% in April, and 63% in May. Some textile companies were running at 10% of capacity at the height of the crisis (Glas, 2021). The capabilities of the U.S. textile and apparel supply chains and the available capacities during the COVID-19 pandemic makes one wonder whether even the most basic coordination efforts and leadership by the U.S. government could have created surpluses of critical PPE rather than the shortages which still exist in 2021. We feel that any of the approaches used to stimulate production mentioned previously could have made major impacts.

There are currently many proposals in the U.S. Congress for stimulating the production of PPE in the United States and providing a more stable manufacturing base before the next crisis. Information on some of these initiatives is available at the website created by the National Council of Textile Organizations, *MakeAmericaPPE.org.* One worry is that we will create nationalistic policies to restrict exports when questions arise as to how much inventory resides in stockpiles (Finkenstadt & Handfield, 2021). These are desperate measures taken by governments under pressure by citizens concerned about their own healthcare system shortages and ignore the bigger issues facing governments in the face of a crisis: the lack of global stewardship for combating a world crisis (Finkenstadt & Handfield, 2021).

Discussion and Conclusion

When the demand for products changes rapidly and dramatically, the supply chain is stressed. Normally, products are manufactured only in sufficient quantities to cover the

anticipated normal demand, leaving little ability to increase production if needed (Patel et al., 2017)

There was uncertainty and a lack of unified knowledge in sourcing for specific product components, testing requirements, and a lack of connection between product suppliers, needs, and the healthcare systems.

One of the pervasive challenges throughout this pandemic has been the lack of information. Data needed to understand what was needed, when, and where was often totally lacking or of extremely poor quality. Over 6 months into the pandemic, the federal government was still making changes to who was responsible for the data collection and analysis on even such basic information as number of cases, hospitalization, ICU utilization, and deaths (Davenport et al., 2020).

Blindly ordering materials based on flawed best guesses will create many shortages, overstocks, and even wrong supplies similar to what we have experienced with COVID-19.

The second part of our research was to develop an understanding of the capabilities of U.S.-based companies to produce large quantities of specific PPE for both the current pandemic and future needs. Unlike supply chains in the automotive and aerospace industries with well-defined tiers of suppliers with which we were familiar, we found healthcare systems were heavily reliant on group purchasing organizations that are focused almost entirely on the costs of the end items. These organizations have little knowledge of the critical supply chain elements. Future healthcare materials acquisition programs should be based on much deeper understandings of the entire supply chain. Clear specifications not just for end products but also for intermediate materials must be developed. Quality measurement plans must be implemented for each critical phase of the supply chains. There needs to be a strong feedback from end users back through each stage of the supply chain to quickly address problems. We feel that this work has implications for anyone in the healthcare supply chain space (DoD task forces, DLA, DHA, FEMA, DHHS, DHS, state, local, and healthcare systems). Even beyond the healthcare supply chain space, this work should be of use to anyone concerned about better approaches to prepare for contingency sourcing.

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