


Improving Safety by Evaluating the Impact of the Supply Chain and Drug Shortages on Health-Systems

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Abstract

Background: The COVID-19 pandemic has shown how fragile our healthcare supply chain is with product delays, drug shortages, and labor shortages being exacerbated in recent years. **Objective:** This article reviews current threats to the healthcare supply chain that impact patient safety and highlights potential solutions for the future. **Method:** A review of the literature was conducted, and important up-to-date resources associated with drug shortages and supply chain were analyzed to build foundational knowledge. Potential supply chain threats and solutions were then explored through further literature analyses. **Conclusions:** The information provided in this article helps to brief pharmacy leaders on current supply chain issues and solutions that can be integrated throughout the healthcare supply chain in the future.

Keywords

supply chain, drug shortages, labor shortages, patient safety, product delays, optimization

What Is the Healthcare Supply Chain?

Hospitals in the United States spend over \$25 billion in unnecessary supply chain issues every year.¹ To understand root causes, it is important to understand how the healthcare supply chain operates. The healthcare supply chain can be broken down into 3 parts: the manufacturer, the mediator, and the stakeholder.² The manufacturers take the raw materials and create the product. They may work with other suppliers to source the active pharmaceutical ingredients (APIs) and other medicinal products such as syringes and Personal Protective Equipment (PPE) needed to make the product. The mediator can be either a distributor or a group purchasing organization. These entities work with multiple manufacturers to ensure the product gets to the stakeholder and may help negotiate a price. The stakeholder can be traditional hospitals, outpatient facilities, nursing homes, and ultimately the patient. Logistics and transportation are also heavily considered as it will impact all 3 parts together. Although seemingly simple, complex coordination of multiple manufacturers, mediators, and stakeholders requires thorough organization and transparency. A failure in any part of the supply chain can lead to detrimental downstream effects and supply chain issues.

What Are the Main Issues With the Healthcare Supply Chain?

In 2017, Hurricane Maria made landfall in Puerto Rico and destroyed Baxter's manufacturing plant.³ This manufacturing

plant supplied about 50% of small-volume saline bags (250 mL or less) to all United States hospitals.³ With small-volume saline bags already being in shortage and the 2 other manufacturers of the saline bags not able to increase production, a major drug sterile products shortage occurred, ultimately showing how a supply chain disruption can test the resiliency of an already fragile supply chain. Shortage issues similar to this example can lead to various medication errors such as confusion between routes of administration (i.e., administering as an intravenous push rather than a short intravenous infusion), dilution errors, protocol deviations, and microbial contamination.⁴ Understanding causes of healthcare supply chain issues can help hospitals and practitioners build a more resilient supply chain.

Two major healthcare supply chain issues that lead to patient harm include product delays and drug shortages. Product delays can be associated with medical products such as active and inactive pharmaceutical ingredients, and supplementary materials such as syringes, gloves, masks, needles, testing materials, and other PPE. Product delays can lead to product and drug shortages. Drug shortages have been documented through various non-profit organizations and the United States Food and Drug Administration (FDA).

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Per the American Society of Health-System Pharmacists (ASHP) drug shortage list, there are 220 ongoing shortages as of August 12th, 2022.⁵ These shortages lead to stakeholders having to potentially use a medication that may not be the most effective for a patient or no product at all. In order to improve medication safety, a healthcare provider needs to understand how these issues arise, the impact it is currently having on medication safety, and mitigation strategies.

When looking at healthcare associated product sourcing in the United States, many products are being imported. In 2019, 72% of APIs were being imported from outside the United States with a growing presence of sourcing from China and India.⁶ Early in the COVID-19 pandemic, there were many product delays involving PPE due to an increase in demand with COVID regulations. With the increase in demand and shortage of supplies, there were product delays which led to sub-optimal care for patients and healthcare providers. If we retrospectively analyze these product delays, we will find that an increase in demand coupled with sourcing issues, traceability, and labor shortages converged to challenge our fragile healthcare supply chain.⁷ To build a resilient supply chain, we must further analyze some of the major issues associated with product delays and drug shortages.

Issues and Solutions for Healthcare Supply Chain Delays and Shortages

Transparency and Traceability

Although eliminating product delays and drug shortages all together would be ideal, it is unlikely that we can do this for every medical product. With the various entities associated in the healthcare supply chain, it can be difficult to anticipate every challenge that may arise. Sometimes there are many different shipments between different companies before the product gets to the end user and that information may not be shared and leads to loss in transparency. However, if we can anticipate when a supply issue may occur, downstream entities can better prepare for these delays and shortages. Supply chain transparency between the manufacturers, suppliers, wholesalers, hospitals, and other entities in the supply chain must be integrated in order to deliver medications to patients in a safe and effective manner.

Transparency cannot exist without traceability. Examining other distributors (e.g., Amazon, Walmart), you can see how if you order a product online, you can track exactly where in the process it is prior to being delivered. If there are any delays, those will also show up. A similar process should be implemented in the healthcare supply chain where you can use bar-code scanning to give live updates as to where your drug product is in the supply chain. In order to do this requires collaboration between the different entities the drug product goes through such as the API supplier, manufacturer,

distributor, and ultimately the end user (e.g., health-system). In order to coordinate this will require some type of agreement for information sharing with each other and the end user. Doing so, allows for transparency, increased traceability, and ultimately allows each entity to better plan for any issues that may arise in the supply chain.

Shift to Continuous Manufacturing From Batch Manufacturing

In recent years there has been a preference toward continuous manufacturing compared with batch manufacturing to increase product production and decrease product shortages. Continuous manufacturing allows for manufacturing that is without interruption and can be run for longer periods of time or even 24/7. Batch manufacturing includes the drug product being manufactured in stages where the product cannot be moved to the next phase until a batch of products are completed at the stage. This process involves more human involvement and takes longer to complete. See Figure 1 for how each manufacturing style compares to each other.⁸ Overall, continuous manufacturing allows for automation and continuous production of products compared to batch manufacturing which is limited by people and how long it takes for each step in the process.

Although this technology will improve production, it has been slow to be integrated in the healthcare supply chain. One reason why is because it is difficult to move toward automation when a drug is already on shortage since this would mean stopping drug production operations for a set amount of time. Furthermore, FDA qualifies and approves what drugs can be made on specific production lines.⁹ Switching to continuous manufacturing will also require FDA approval of the new production line which can limit drug production during that phase. Therefore, changing from batch to continuous manufacturing lines would require significant planning and money with a high chance that drugs may go on a further shortage during the changeover. In order to mitigate the short-term risk of drug shortages, transparency with the other supply chain entities should be utilized. A streamlined FDA approval process and financial compensation in some form should be explored to incentivize manufacturers to make this change to continuous manufacturing.⁸ Finally, new manufacturing facilities being developed should consider continuous manufacturing to improve long-term, interruption free, production.⁸

Strategic Stockpiling and Risk Management Planning

At state and national levels, a strategic stockpiling strategy should be implemented. In order to be successful, a list of drugs most likely to go on shortage should be created based

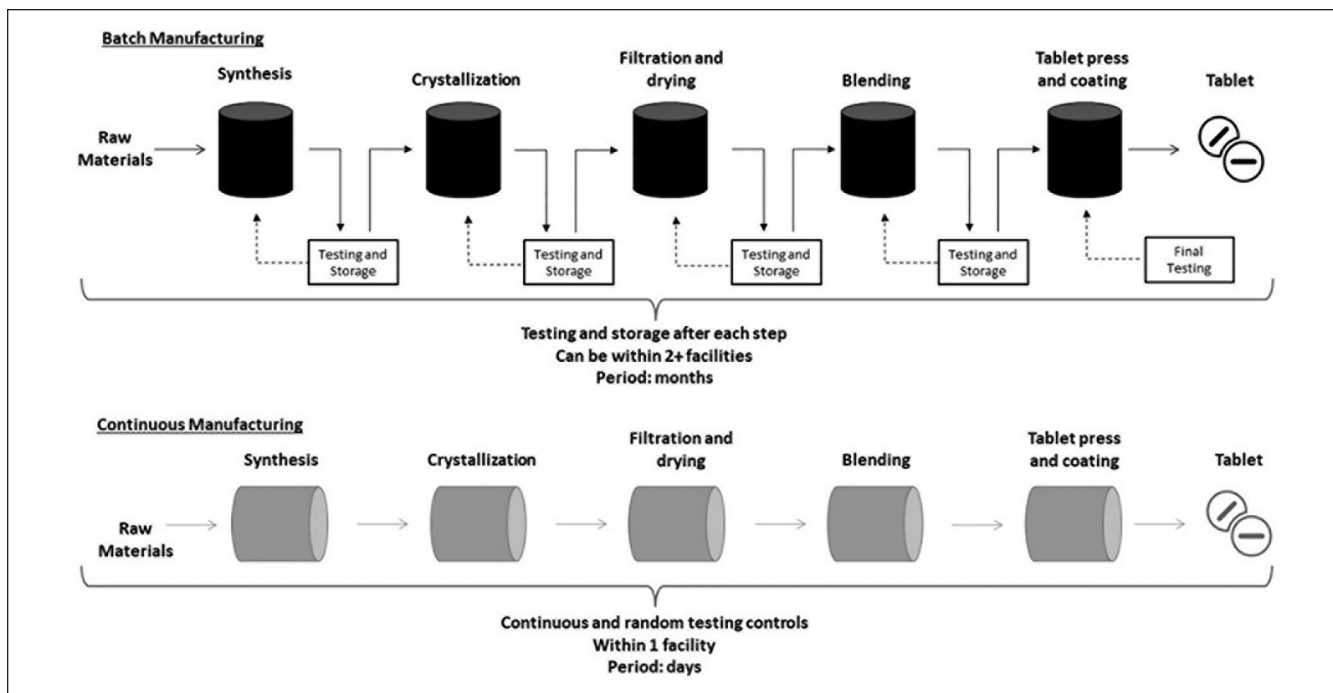


Figure 1. Continuous manufacturing versus batch manufacturing overview.

Source. Adapted from Hock et al.⁸

on therapeutic area and in coordination with the manufacturer. Furthermore, expiry dates should be coordinated so that supplies within the stockpile are not expiring before use. It will require coordination between manufacturer, state and national stockpile coordinator, and the end hospital user. Ultimately this coordination depends on transparency between each entity within the supply chain to know exactly what drugs and products should be coordinated.⁷ The risk management plans associated with strategic stockpiling should be coordinated through manufacturer transparency. This will involve manufacturers and other supply chain entities reporting discontinuations and other interruptions in the supply chain with any materials involved and/or products. Most likely this will have to involve some type of legislation to make sure that the information passed on is regulated in a professional manner. ASHP suggests amending section 704(a)(4) of the FD&C Act to make sure there is a risk management plan in place.⁷

Vertical Integration

Vertical integration simply means to move everything in-house under 1 organization. This would require all the essential tasks (manufacturing and distributing) to be done under 1 entity. Supplies should be made in-house when possible and sourced from reliable consistent suppliers otherwise. An increase in transparency will likely be noted since everything is under the control of 1 company. This should ultimately be

shared with the end user so they can see where their products are in the supply chain. Although this may have a high initial cost, something to investigate for new products being manufactured and distributed.

Staffing Issues and Increase in Demand From Staff

The scarcity of labor is having many effects on businesses worldwide and is causing delays and disruptions in the local, regional, and global supply chains. This poses a significant problem as employees are a company's greatest assets and play a vital role in ensuring that the supply chain runs smoothly. Without proper staffing at any stage of the supply chain, whether it be due to the manufacturer, the mediator, or the stakeholder, there is a risk of creating bottlenecks and increasing supply chain pressures such as hospitals having drug and equipment shortages.

According to an Altarum analysis of U.S. Bureau of Labor Statistics, overall health care employment is 52 400 jobs (3.2%) below the February 2020 pre-pandemic peak and since 2020, hospital employment has declined by nearly 93 000 jobs and is expected to increase only slightly in the next few years, making this a long-term problem that needs to be promptly addressed.¹⁰ The increase in the demand from healthcare staff has posed to be a safety concern for both the employee and patients. One of the main reasons many healthcare professionals quit their jobs in recent years

is due to being overworked and being expected to take on more roles and responsibilities to compensate for the understaffing taking place in their workplaces.¹¹ Nurses, pharmacists, and physicians, for example, have been working more hours and longer shifts with less workforce support. They have been required to take on care for more patients than ever before. These factors create unsafe work environments as these workers become physically, mentally, and emotionally exhausted and that, unintentionally, can impact the care patients receive.¹² Without having enough hospital staff present, there will be gaps in keeping sufficient supplies or staying ahead of current drug shortages and, in turn, providing the best and safest patient care might be compromised. Increasing the workload for individual workers leads to burn out which prompts individuals to quit their jobs.

The COVID-19 pandemic exacerbated staffing shortages and has created a “new normal” regarding staff wages. As the demand for workers has exceeded supply, the cost of labor has increased. Employers have been forced to provide more compensation through wage increases to attract workers. The rapid increase in wages then sparks a “wage war” or signing bonus competition. Since the identification of COVID-19, average hourly earnings increased 12% according to the U.S. Bureau of Labor Statistics, with transport and warehousing being one of the most affected in terms of cost.¹¹ As hospital systems see staff wages increase, supply and service costs increase as well. Not all hospitals can afford to continue to increase spending in all these departments. Those businesses that cannot afford to partake in these “wage wars” are at a higher risk of not having enough hospital staff. Consistency and stability in wages across similar jobs would positively impact staffing issues in healthcare and other industries but money is not everything.¹³ It is important to remember that employees also want good bosses, staff, and safe working conditions. Prioritizing creating a healthy and safe workplace starts with providing enough

help and resources to do the job as well as finding individuals that are passionate about what they do and have a goal of helping their patients to the best of their ability. Without these factors, good bosses, staff, and safe work conditions, in any industry, employees will continue to be scarce and supply chain issues will continue to be present.¹⁴

Change in Demand of Services (i.e., Lower Outpatient Services Offered and Utilized Due to Pandemic)

The staffing issues mentioned above have been further exacerbated as the COVID-19 pandemic provoked unprecedented shifts in the demands of services. During the start of the pandemic, hospitals and physicians temporarily halted non-emergent procedures and a reduced patient volume was seen in preventative care, emergency rooms, and chronic condition management and other outpatient services.¹⁵ Still seen 2 years after the start of COVID-19, there has been an increase in the use of Intensive Care Units (ICUs) and commonly used ICU medications, equipment, and medical devices.¹⁵ This demand drove the supply of these life-saving medications and devices down tremendously. This demand also increased the need for ICU physicians, nurses, pharmacists, respiratory therapists, and other healthcare professionals. Not having enough professionals certified to work in ICUs to occupy staff positions and not being able to receive in-demand medications and medical equipment was and continues to be a detrimental supply-chain-related issue that negatively impacts both patient safety and employee safety as well.

Main Takeaways

Outlined in Table 1 are the top 10 takeaways from this article to help healthcare professionals lead a safe healthcare supply chain today, and plan for the challenges of tomorrow.

Table 1. Top 10 Takeaways for Healthcare Professionals Involved in the Healthcare Supply Chain.

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| 1. Transparency between different entities in the supply chain is crucial to improving patient safety. | 6. Vertical integration can help improve traceability and transparency within an organization as everything is housed under 1 entity. |
| 2. Using new technology to improve traceability of medical products is necessary to improve transparency. | 7. A resilient healthcare supply chain requires having proper staffing at all stages of the supply chain. |
| 3. A shift toward continuous manufacturing will take time and patience due to costs and other constraints. | 8. Increased demand for workers exceeding supply resulting in an increase in the cost of labor and further resulting in a “wage war” must be broken to avoid further supply chain issues. |
| 4. Risk management plan legislation needs to be advocated for manufacturers and other entities in the supply chain to improve transparency with the end user. | 9. Unexpected shifts in the demand for services occur, making having proper staffing in every department in every industry vital to ensure supply chains are uninterrupted. |
| 5. Creating a list of drugs and supplies most likely to go on shortage in coordination with your manufacturer and supplier and creating a strategic stockpile is necessary to combat unexpected drug and supply shortages. | 10. Develop a resiliency plan to anticipate and mitigate possible supply chain disruptions. Review this multi-disciplinary plan at least yearly to ensure the information is updated and reflects an ever-changing healthcare environment. |

Conclusion

The healthcare supply chain is complicated and with many moving parts that can impact patient safety. Understanding why supply chain issues such as product delays, drug shortages, and labor shortages occur is the first step in combating this complex issue. Ultimately, healthcare providers and all entities within the supply chain must work together to improve transparency for the sake of patient safety around the world.

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