




Pharmacists leadership in a medication shortage response: Illustrative examples from a health system response to the COVID-19 crisis

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Abstract

As medication experts, clinical pharmacists play an active and dynamic role in a medication shortage response. Supplementing existing guidelines with an actionable framework of discrete activities to support effective medication shortage responses can expand the scope of pharmacy practice and improve patient care. Dissemination of best practices and illustrative, networked examples from health systems can support the adoption of innovative solutions. In this descriptive report, we document the translation of published shortage mitigation guidelines into system success through broad pharmacist engagement and the adaptation and implementation of targeted strategies. The profound, wide-reaching medication shortages that accompanied the coronavirus disease 2019 (COVID-19) pandemic are used to highlight coordinated but distinct practices and how they have been combined to expand the influence of the pharmacy enterprise.

KEYWORDS

hospital, learning health system, pharmacists, pharmacy service, quality improvement

1 | INTRODUCTION

Medication shortages pose an ever-present challenge to optimal patient care within the United States. Market, regulatory, and supply chain forces play varied and intertwined roles in the availability of medications. In 2019, the Food and Drug Administration identified 166 new medication shortages, 39% of which involved parenteral products.¹ Each shortage forces providers to rely on second-line or nonstandard therapies, disrupting usual practices and potentially

resulting in untoward effects.² A retrospective analysis of the 2011 norepinephrine shortage demonstrated significant clinical impact and increased in-hospital septic shock mortality in hospitals unable to source this essential medication.³

The development of strategies to optimize inventory and acquisition, conserve scarce products, and ensure appropriate utilization are essential safeguards against the ever-present threat of short supply. Health systems must weigh the anticipated duration of the disruption and co-occurring market factors when designing and implementing therapeutic alternatives and process changes to respond to medication shortages effectively. Although shortage mitigation strategies

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support patient care continuity, they can significantly increase the direct costs of health systems as they acquire alternative therapeutics, compound alternatives, resource the development of revised policies and procedures, and re-educate staff.

The coronavirus disease 2019 (COVID-19) pandemic has led to an unprecedented number of medication shortages through record demand for essential medications and widespread supply chain disruption. Entire medication classes became scarce during the initial wave of infections and continue to be in short supply, including neuromuscular blockers, sedatives, analgesics, and vasopressors.⁴ These products, particularly in injectable form, are foundational to the care provided to all critically ill, mechanically ventilated, and perioperative patients. These profound shortages have not only affected the care of patients infected with COVID-19, they have also impacted the overall health system capacity and, in some cases, delayed the resumption of routine care activities.

As medication experts, pharmacists possess comprehensive knowledge of applied therapeutics, insight into medication workflows, and understanding of a shortage's impact. Their leadership can mitigate the untoward effect of medication shortages. Dissemination of pharmacist-driven strategies in a shortage response can promote improved patient care and advancement of the profession.

2 | EFFECTIVELY NAVIGATING MEDICATION SHORTAGES

Health systems seeking to mitigate the deleterious effects of medication shortages have access to many foundational published resources. The American Society of Health-System Pharmacists (ASHP) Guideline on managing drug product shortages presents a widely cited response model that describes discrete elements of effective response: identification, parallel operational and clinical assessments, impact analysis, and finalization of a shortage response plan followed by parallel efforts to implement and communicate process changes across the organization.⁵ In this model, pharmacists lead the logistical elements of medication shortage response as part of a multidisciplinary team from which clinical strategy emerges.⁵

There is little published guidance detailing discrete strategies to position pharmacists to accelerate an effective shortage response. Literature reporting the impact of pharmacist leadership within shortage response efforts has primarily focused on operational optimization, drug use policy creation, and educational efforts.⁵⁻¹¹ Site-specific reports have described mechanisms by which pharmacy technicians and students can serve as team extenders to mitigate the effects of medication shortages in alignment with well-described practice advancement initiatives.¹² Dissemination of successful implementations can catalyze change and accelerate pharmacists' advancement.

2.1 | Setting

Yale New Haven Health (YNHH) is a multi-hospital academic health system located along the Connecticut shoreline comprised of four

delivery networks spanning from the New York border into Rhode Island with 2475 total beds.

In 2012, YNHH began to consolidate and systematize its response to medication shortages across all inpatient sites. Broad approval of an aligned, dynamic approach to shortage mitigation was garnered in 2017 and allowed for coordinated management of limited resources to minimize patient harm. This oversight system has continued to expand through iterative improvements over the past 3 years.

YNHH has adapted the American Society of Health-System Pharmacists (ASHP) medication shortage response guidance to meet system needs, reframing and adjusting the workflow described in the broad guidance into a framework consisting of five distinct phases that temporally overlap and create an iterative cycle to meet system needs (Figure 1). The described system has emerged through an iterative process, guided by Lean methodology and established implementation frameworks.¹³⁻¹⁶ The first phase, identification, integrates operational assessment and impact analysis to support a robust understanding of the pending medication shortage and the projected disruption within our health system. The second phase evaluates therapeutic alternatives from a clinical perspective, incorporating operational insights into proposed solutions. Once a potential alternative is identified, key clinical stakeholders are engaged to develop buy-in and obtain endorsement and official ratification when needed. Implementation of accepted strategies involves developing messaging and decision support tools in the electronic medical record (EMR), education efforts to ensure clinical team awareness, and integrating active clinical workflows. Once a shortage has been managed, effort shifts to ensuring system sustainability by monitoring real-time use, refining management strategies, and building system capacity by incorporating any learnings or efficiencies gained into standard operating procedures.¹⁷ Throughout each of these five phases, clinical specialists and unit-based pharmacists engage in discrete actions that support the clinical, administrative, and operational success of shortage mitigation (Figure 2). Ongoing collaboration between the procurement team coordinating the identification of shortages and care-focused pharmacists ensures that mitigation strategies are firmly rooted in robust practice-based insight. This collaboration allows for increased capacity and accelerated response time.

To detect real-time supply chain disruption, dedicated procurement staff continually review the supply of medications, flagging products as they become backordered or are placed on supply allocation. Follow-up with both the product manufacturer and wholesaler provides insight into the disruption's origin and project duration. This information, in conjunction with supply on-hand, is used to place the agent into one of three defined severity classifications: stable supply, limited supply, and critical supply. Inventory management strategies flow from these groupings. Communication of new, worsening, or resolved medication shortages occurs throughout the system and follows a standardized template combining core elements of interest to clinical stakeholders. Additionally, a medication shortage overview occurs as part of monthly formulary meetings.

Our geographical location placed us within the early epicenter for the coronavirus pandemic. From mid-March to mid-June 2020,



FIGURE 1 Yale New Haven Health (YNHH) framework for medication shortage resolution

YNHH cared for over 40% of the state of Connecticut's admitted COVID-19 population. Pharmacists garnered system approval for a record number of mitigation measures to support patient care and therapeutic continuation throughout severe, multidimensional shortages during these 90 days. We have previously reported the adaptation of established YNHH medication shortage processes to anticipate medication needs during the COVID-19 pandemic.¹⁷ Clinical pharmacist insight was instrumental in providing a

strategic shortage response in real-time at the onset of the COVID-19 pandemic by identifying potential gaps in supply and guiding the implementation of possible medication alternatives. Nonformulary options were procured to meet patient needs, guidelines were created to direct use of alternatives in line with evidence-based care, and step restrictions ensured short supplies were channeled to areas of greatest patient need. Weekly updates to the COVID-19 treatment algorithm ensured the appropriate,

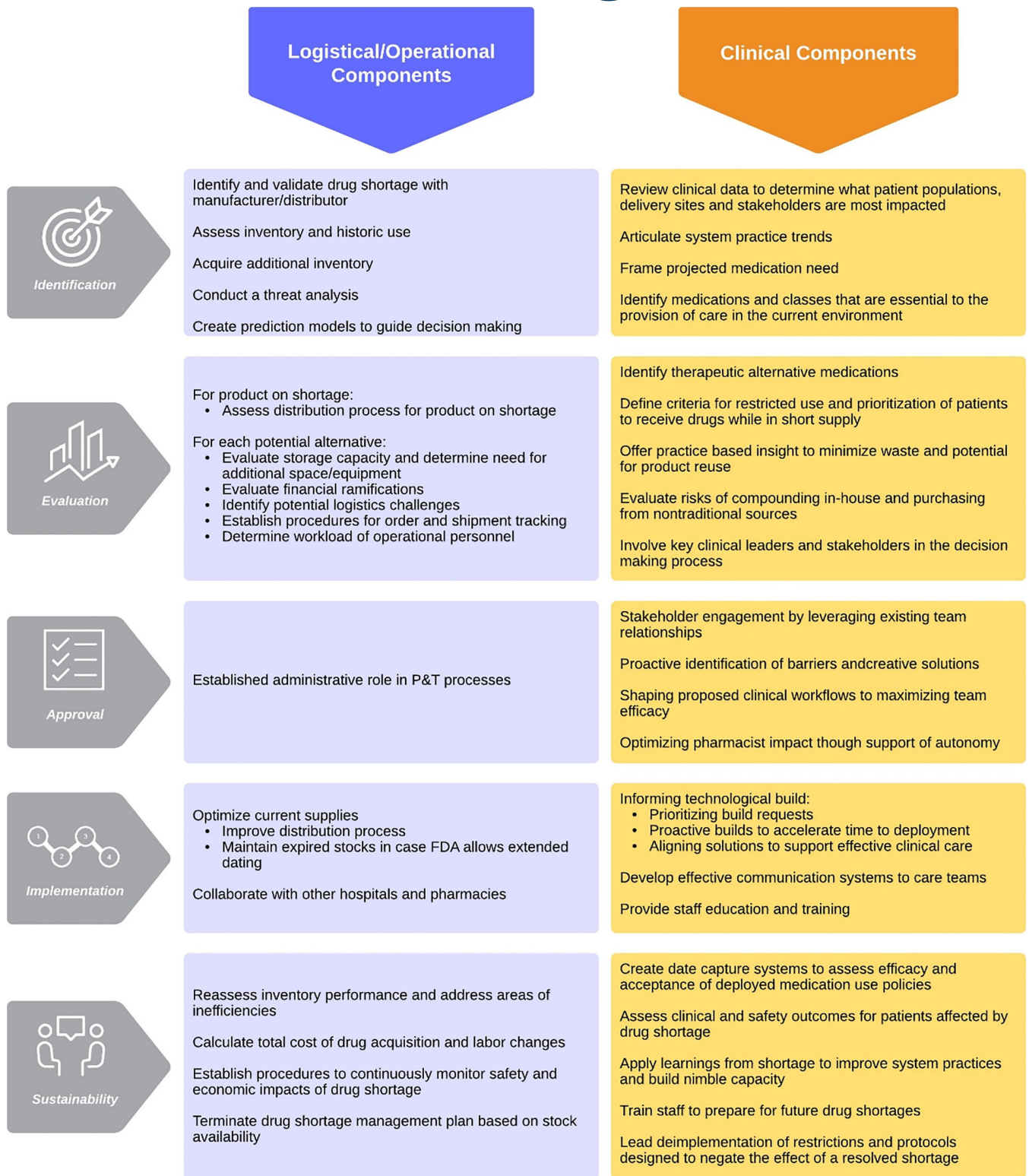


FIGURE 2 Operational and clinical activities across each phase of a medication shortage response. Throughout each phase of a medication shortage response, pharmacists are positioned to impact clinical, administrative, logistical, and operational success of a health system. P&T, Pharmacy and Therapeutics committee

coordinated use of medications in short supply, disseminated coordinated restrictions, and introduced new guidance based on emerging evidence.

In this report, we seek to document and disseminate many of the discrete steps taken by clinical pharmacists within YNHH that support our system's ability to rapidly and successfully navigate medication

shortages to support the broader adaptation of actionable strategies and promote practice advancement.

3 | PHASE ONE—IDENTIFICATION: UNDERSTAND SCOPE AND PREDICT IMPACT

3.1 | Define medication demand

At shortage identification, clinical pharmacists rapidly articulate the current use of affected products and quantify medication needs. Profound shortages across many injectable opioid products threatened our system's ability to address patient pain adequately. Quantification of average daily and weekly intravenous opioid use throughout the system allowed for the expression of therapeutic need in morphine equivalents. Use of a normalized measure of analgesic burn rate allowed for rapid evaluation of all available alternatives. Remifentanyl, an agent previously reserved for use by anesthesiology providers, was identified as a viable therapeutic alternative that could ensure effective pain control in critically ill patients.^{18,19}

Engaging pharmacists across multiple practice settings ensured a comprehensive understanding of therapeutic indications for products on the shortage, particularly expected emergent use not directly tied to the care of COVID-19 patients. From the outset of the COVID-19 surge, supply management for ketamine and benzodiazepine products focused solely on the sedation of critically ill patients undergoing mechanical ventilation who failed to achieve adequate sedation with propofol or dexmedetomidine. Emergency medicine pharmacists quickly identified the need to support the use of bolus ketamine for conscious sedation during emergent procedures, and psychiatric pharmacists identified the need to maintain supplies of ketamine for use in electroconvulsive therapy. Furthermore, clinical pharmacists within our neurocritical care units identified the emergent role of benzodiazepines in status epilepticus. These insights prompted the creation of strategic reserves for both ketamine and lorazepam for these indications during a period of possible increased utilization.

3.2 | Define critical medications

In preparation of the anticipated surge, clinical pharmacy specialists from infectious diseases, critical care, internal medicine, and cardiology were tasked to define pharmacotherapies that could improve the care of patients presenting with COVID-19. The initial list of COVID-19 essential medications contained antibiotics, potential antivirals, analgesics, immunologic therapies, respiratory treatment, and medications used in critical care such as sedatives and vasopressors. As our COVID-19 census increased, pharmacists quickly identified additional medications such as acetaminophen, neuromuscular blockers, sedatives, eye lubricants, and agents that control secretions. The recognition of an increased incidence of thrombotic complications within patients infected with COVID-19 prompted the addition of anticoagulant agents. As clinical experience revealed that antibiotics, specific

antivirals, and inhaled medications (outside of albuterol) did not play a critical role in treating COVID-19, these products were removed.

Knowledge of dosing and medication use practices allowed pharmacists to articulate medication use in a manner that ensured anticipatory ordering or alternative planning. Critical care pharmacists leveraged their experience caring for previous patients with acute respiratory distress syndrome to estimate the daily neuromuscular blocker and sedative requirements for patients requiring prolonged mechanical ventilation secondary to severe COVID-19. Articulated in a per average patient per day manner allowed for scaled projections of drug class needs ahead of an anticipated sharp rise in COVID-19 patients.

4 | PHASE TWO—EVALUATION: IDENTIFY ALTERNATIVE OPTIONS

4.1 | Medication class and literature review

A thorough drug class review and literature review can provide a health system with evidence-based alternatives with which to navigate inadequate supply. In evaluating potential alternatives, one must identify when an alternative may be safely substituted and any risk associated with the alternative such as side effects, sound-alike or look-alike errors, and lack of institutional experience.²⁰ For example, recognizing a profound shortage in neuromuscular blockers prompted a class review in parallel with the patient characteristic assessment reported above. This effort uncovered four intermediate-acting agents, atracurium, cisatracurium, rocuronium, and vecuronium, and a single long-acting agent pancuronium. Based on this review and market availability, rocuronium was proposed as the first-line agent, restricting vecuronium for use in pediatrics and cisatracurium to patients with hepatic or renal insufficiency.^{21,22} At the same time, guidelines were developed for the use of atracurium in case the supply of cisatracurium was insufficient despite restrictions.²³

A single agent shortage may extend to additional medications within the same class as hospitals turn to alternatives. Due to a combination of manufacturing delays and a substantial increase in usage, widespread sedative shortages occurred with propofol, and later, lorazepam and midazolam, necessitating the use of all available alternatives.⁴ Clinical pharmacists first identified that dexmedetomidine could be used preferentially in patients for light sedation and not in those that required deep sedation. This allowed continuous infusion benzodiazepines to be reserved for patients who required deep sedation or those who experienced hypertriglyceridemia while on propofol.²⁴ When it became apparent that benzodiazepines, particularly lorazepam, were in short supply, pharmacists performed a literature review to identify alternative agents that could be used in place of benzodiazepines for conditions other than ICU sedation. This review identified phenobarbital as a safe and effective option for the treatment of alcohol withdrawal in lieu of benzodiazepines.²⁵ The review also identified alternative anti-epileptic medications that could be utilized to manage alcohol withdrawal as an adjunct to decrease benzodiazepine usage.²⁶

4.2 | Alternative routes of administration

Engaging pharmacists to promote the use of enteral and transdermal alternatives to parenteral therapy has been well reported as an impactful medication intervention and proved an effective means of conserving critical medication supply during shortages of parenteral potassium products.²⁷ To conserve injectable opioid supply during the COVID-19 surge, pharmacists identified and promoted three previously reported strategies to replace continuous opioid infusions with enteral oxycodone, enteral methadone, and transdermal fentanyl in patients tolerating an oral diet.²⁸⁻³¹

4.3 | Develop criteria-based restrictions and limit waste

Restricting medications to patients meeting specific criteria is a standard conservation strategy. During the COVID-19 pandemic, the use of benzodiazepines was restricted to patients who failed to achieve adequate sedation after receiving a high dose of propofol (65 mcg/kg/min) or not tolerating propofol due to elevated triglyceride levels (>1000 mg/dL).³² Benzodiazepine continuous infusion was restricted to the treatment of status epilepticus and severe alcohol withdrawal syndrome to conserve supply. Potential COVID-19 therapies were restricted to use only in patients with confirmed COVID-19 infection and met health system established criteria for use.

Prior to the COVID-19 pandemic, most patients receiving mechanical ventilation or extracorporeal membrane oxygenation (ECMO) within our institutions were paralyzed using cisatracurium, as dosing is not affected by liver or kidney function.³³ The shortage of neuromuscular blockers during the COVID-19 surge prompted a historical evaluation of patients' liver and kidney function and showed that the majority of patients could safely receive an alternative neuromuscular blocker. This clinical insight allowed for rapid deployment of restriction criteria for cisatracurium to limit use within patients with evidence of liver and/or kidney dysfunction. Following a medication class review, existing guidelines were adapted to promote the first line use of rocuronium in all other patients on mechanical ventilation or ECMO.³³

During medication shortages, the clinical pharmacist can also evaluate the existing infusion bag sizes, concentrations, and medication utilization to identify the most efficient concentration and volume to dispense. In our institution, we dispense multiple concentrations of the same medication based on the patient's requirements and utilize existing smart pump libraries with preset limits to prevent medication-related errors with any changes. For example, the concentrated fentanyl and morphine vials used to compound continuous infusions were in shortage during the COVID-19 surge. An evaluation of the current hydromorphone infusion bag size and utilization revealed a change from hydromorphone 10 mg/50 mL (0.2 mg/mL) to 40 mg/100 mL (0.4 mg/mL) would reduce the workload of the intravenous (IV) room without resulting in excessive drug waste. This change had the additional benefit of reducing the frequency that nurses needed to replace

the infusion bag, thereby potentially decreasing room entries and the amount of personal protective equipment (PPE) used.

5 | PHASE THREE—APPROVAL: LEVERAGE SUPPORT

As trusted team members, clinical pharmacists are positioned to engage key stakeholders, identify potential barriers, and propose clinically and operationally sound solutions to ensure the medication shortage's successful navigation.

5.1 | Engage key stakeholders

Through their established relationships, pharmacists can identify key physicians, advance care providers, nurses, respiratory therapists, and clinical leadership to aid in the development and review of effective medication-shortage mitigation strategies.

During the COVID-19 surge, pharmacists were embedded within the Incident Command Management groups to coordinate the institutional response to pandemic challenges.¹⁷ In addition, our pharmacy-driven Antimicrobial Stewardship Team (AST) became vital members of the team founded to actively identify COVID-19 treatment algorithms. These sanctioning bodies enabled accelerated review and approval of medication use guidelines and protocols to mitigate medication shortage during COVID-19. Due to the COVID-19 surge's acuity, proposals approved by these groups were implemented in an expedited manner to meet urgent needs, often within a single day. After implementation, the existing system Pharmacy and Therapeutics (P&T) committee structures completed post-hoc review of these recommendations.

5.2 | Identify barriers and develop creative solutions

Given their understanding of the clinical, operational, and regulatory challenges that can hinder a timely response to a medication shortage, pharmacists are positioned to assess system needs and coordinate creative solutions.

Meter dose inhalers (MDI) quickly became the delivery mechanism of choice for inhaled products for presumptive or confirmed, nonintubated COVID-19 patients due to the risk of aerosol generation with traditional nebulization. The spike in demand for albuterol MDIs with the emergence of COVID-19 led to a severe shortage. A recycling process and common canister policy was implemented to manage the increased demand for albuterol MDIs. A previously proposed pharmacy-backed MDI conservation initiative had failed to gain clinical support for over 5 years. The extreme shortage that arose during the pandemic fostered consensus amongst infection control, respiratory therapy, nursing leadership, pharmacy operations, and regulatory to support patient care and resulted in adopting a canister recycling policy for MDIs within 3 weeks.

5.3 | Ensure medication safety and maximize team efficacy

Pharmacists are positioned to hardwire safety practices into clinical workflows by reducing intra-patient variation and ensuring compliance. Pharmacists can assume comprehensive ownership of medication prescribing and monitoring through guidelines, protocols, standing orders, or system policies. In addition to ensuring safe practices, these arrangements elevate pharmacists' roles, maximize team efficacy, and support the dissemination of vital tasks across workgroups. The development and approval of a comprehensive, system-wide initiative titled, "The Pharmacist COVID-19 Drug Monitoring Standing Order" allowed for increased pharmacist autonomy during COVID-19. The first facet of this proposal empowered clinical pharmacists to independently initiate orders for a pre-specified set of drug monitoring labs to ensure patient safety, such as tying continuous propofol infusions to triglyceride monitoring. Other actions supported by this standing order included pharmacist optimization of infusion volumes and concentrations based upon clear, predefined logic maximizing the safe and appropriate use of nonstandard agents within our existing smart-pump library. Decentralized pharmacists reviewed this proposal at multiple points during its development for accuracy and logistical feasibility to ensure team support.

6 | PHASE FOUR—IMPLEMENTATION: ACCELERATE RESPONSE

6.1 | Build technology and smart systems

The EMR plays an essential role in disseminating information to the right person at the right time in the workflow.³⁴ A close-working relationship between clinical pharmacists and Information Technology Service (ITS) analysts ensures that approved restrictions and shortage recommendations are promptly implemented into the EMR and clinical workflow, accelerating impact through prioritization and creation of tools to support patient care. During the COVID-19 surge, clinical pharmacists met with ITS analysts three times weekly to discuss optimization requests, build progress, and tentative go-live dates. During a surge, all COVID-19 ITS requests received priority assignment.

The EMR provides a mechanism by which the use of alternative agents can be improved by creating ordering screens and alerts that provide decision support to providers, administration instructions for nursing, and admixture instructions. Anticipatory inclusion of alternative products in an environment of scarcity ensures rapid operational flexibility. The EMR can also be engineered to capture and collate medication shortage mitigation strategies and frontline pharmacists' insights.

Clinical pharmacist involvement in implementing EMR changes allows for direct recommendations to providers about alternative medications at the time of order entry. It can provide guidance and restriction criteria for medications on shortage. For example, during the fentanyl shortage in the COVID-19 surge, providers received an

alert notifying them of the shortage when a fentanyl infusion was ordered. Also, the alert provided the recommendation to utilize the alternative agent, hydromorphone. This alternative order contained all applicable parameters for monitoring and titration. Finally, providers were instructed to contact their unit pharmacist to order remifentanyl for patients who could not use hydromorphone. An EMR tool was created to alert the pharmacist to potential adverse reactions (ie, triglycerides >500 mg/dL on propofol therapy and liver function test abnormalities for patients on remdesivir) and prioritized interventions for those patients in real-time to ensure safe utilization of alternative or restricted agents. Additional builds to support medication shortages throughout the COVID-19 surge included alternative profiles for phenobarbital and cisatracurium, modified alcohol withdrawal order sets curtailing the use of benzodiazepines, and a COVID-19 specific pharmacist alert for internal pharmacist documentation.

As widespread shortages were expected throughout the COVID-19 surge, anticipatory builds of medication profiles were initiated for nonformulary products, and internal identifiers were added for nonstandard products. This deviation from the standard practice of completing these builds in real-time decreased the time needed to switch to alternatives as supplies dwindled.

Through the creation of the COVID-19 descriptor within the internal pharmacist documentation system, real-time insight from frontline pharmacists was leveraged to improve a system medication shortage response. Suggestions relating to standard bag sizes, workflows, and challenges were transformed into mitigation strategies. This innovative application of the EMR not only accelerated change, but it also provided an effective mechanism of collecting responses from across the pharmacy team.

6.2 | Communicate changes

Once a recommendation to manage a medication shortage has been approved through the aforementioned health system channels, and EMR updates have been deployed, effective communication to front line staff, including pharmacists, nurses, and providers, ensures implementation success. Providing brief and specific messaging across various communication formats ensures clear communication of medication shortage strategies across the entire health system, which complements information provided within the EMR. As integrated clinical care teams, clinical pharmacists can ensure successful communication of medication use changes due to shortages by providing consistent messaging and collating rapidly changing information in real-time. Although email communication provides a convenient way of disseminating communication about shortages and process changes, utilizing a brief and specific format, such as the Situation, Background, Assessment, and Plan (SBAR) technique, allows the reader to determine the important points at a glance.³⁵ Internal pharmacy enterprise communication was optimized by collating all medication shortage recommendations into a single electronic communication that was distributed by the pharmacy incident command center daily. Additionally, all shortage-related recommendations

were also distributed through the hospital's incident command to all team members.

6.3 | Educate and train pharmacy staff

A weekly live educational meeting for pharmacy enterprise staff provided medication shortage updates and reinforced the information included in the EMR and written announcements.³⁵ These virtual meetings allowed all pharmacy staff members to ask clarifying questions when appropriate and to provide feedback on implementation measures. Recordings were saved on the pharmacy enterprise intranet page for staff members unable to attend in real time.

Partnering with a third-party mobile messaging platform provided a nontraditional means of disseminating information. The pharmacy incident command center sent a mass text message to all pharmacy team members with a secure web link to real-time clinical and medication shortage updates on a weekly basis during the COVID-19 surge. The messaging platform allowed leadership to collaborate staff questions and concerns and allowed frontline staff to attain the information without accessing their emails or the pharmacy enterprise intranet. Additionally, this method provided real-time insight into staff engagement, quantifying the proportion of staff members who interacted with the provided information but required an accurate roster of staff mobile phone numbers to be effective.

7 | PHASE FIVE—SUSTAINABILITY: ENSURING QUALITY PATIENT CARE

7.1 | Monitor and improve mitigation strategies

Pharmacists are uniquely positioned to assess the efficacy of implemented mitigation strategies through real-time data collection and medication use monitoring given their familiarity with standard clinical workflow and shortage mitigation recommendations. Progress can be assessed by tracking the number of patients receiving restricted medications vs alternatives or being evaluated through chart review to gauge the implemented changes' effectiveness. With real-time surveillance of medication use, recommendations, which failed to improve a medication shortage, could be identified and re-evaluated through plan-do-study-act (medication shortage) cycles. An example of this was the monitoring of ketamine use for continuous sedation and analgesia in the intensive care unit (ICU). Pharmacists identified that most patients required less than 2500 mg of ketamine per day. As a result, ketamine infusion was changed from 5000 mg/500 mL to 2500 mg/250 mL, effectively reducing waste. As noted previously, cisatracurium was restricted to use in those with liver or renal insufficiency and transitioned to pharmacist order entry. Alternative neuromuscular blockers became first-line. By tracking the number of patients receiving each neuromuscular blocker over time, clinical pharmacists demonstrated the effectiveness of the implemented medication use policy and provided an additional layer

of surveillance to ensure restrictions were followed. One week following policy implementation, the proportion of patients on cisatracurium vs alternative agents had decreased markedly. This data supported the successful implementation of the restriction criteria to conserve our existing cisatracurium supply.

7.2 | Build system capacity

Many lessons learned throughout the COVID-19 response have been integrated into standard health system practice by the pharmacy enterprise. As with many shortages, introducing alternatives and optimizing existing formulary drugs can drive changes to increase efficient medication use. Critical care pharmacists played a vital role in establishing criteria for appropriate use, along with guidance built into our computerized physician order entry system on dosing and administration. This key guidance will remain in place following the resolution of sedative shortages and COVID-19.

Historical approval of alternatives to medications in short supply at our health system involved building a consensus among prescriber stakeholders. When implementing alternatives, or restrictions were not deemed urgent, formulary and drug use policy changes were comprehensively reviewed and approved by the P&T committee at each hospital in the health system and the Formulary Integration Committee. However, COVID-19 required expedited review and approval of alternatives via incident command groups. The success of this expedited process has led to a re-evaluation of the role of P&T review. This re-evaluation may result in a sustained expedited review and approval process even after the COVID-19 surge has abated.

8 | DISCUSSION

The COVID-19 pandemic has provided a real-time stress test of the shortage response strategies that have evolved within our system over the past 5 years. This descriptive report details the complement of tactics our pharmacists employ to minimize the impact of medication shortages. Well-laid foundational processes have enhanced our ability to navigate the continually changing supply landscape. Three key organizational factors have facilitated our success:

1. *An established framework for accelerated medication use policy approval*
Having a predefined mechanism to rapidly approve policy changes in light of medication shortages ahead of the COVID-19 surge has allowed our team to focus on executing a response instead of scrambling to implement policy.
2. *A collaborative, team-based approach to pharmacy enterprise initiatives including shortage mitigation, medication policy development, cost containment, and research*
Having project expectations as an inherent component of all pharmacist role descriptions across the health system has created reserve capacity that could be leveraged during crisis response.

3. Enhanced pharmacist autonomy over medication processes through institutional policy measures

A track record of success has established broad based trust in our pharmacists' clinical judgment and has allowed for expanded opportunities to improve medication use and increase workflow efficiency through standing orders.

Our accelerated approval framework provides an example of pharmacy's evolving role within health system governance and medication policy development. Pharmacists are relied upon as the embedded medication expert within this framework and thus are empowered to guide medication use and are positioned to optimize medications following a diagnostic workup. While many pharmacists have assumed the role of facilitators within P&T committees, our experience throughout COVID-19 foreshadows a future wherein pharmacists direct medication use. Establishing a track record of successful development and execution of innovative medication policies will highlight the essential value of pharmacist-provided cognitive services and promote pharmacists as clinical leaders who specialize in medication management.

The medication shortages throughout the COVID-19 pandemic have underscored the importance of engaging all pharmacists in medication shortage response and mitigation, and the need to codify this responsibility into pharmacy practice. Medication shortages are an ever-present threat to clinical practice, and supply disruption increases costs and negatively impacts the quality of care provided to patients. Opportunities for pharmacists to accelerate and improve medication shortage responses lay far beyond historically defined logistical support and policy development roles. Documenting and disseminating discrete examples of success throughout COVID-19 can demonstrate our profession's value and support practice advancement. The value added by pharmacists throughout this crisis provides an opportunity to expand the scope of our practice.

The pressures introduced by the COVID-19 pandemic provided an opportunity for pharmacists to play an expanded role within the health care team. Institutional standing orders, such as the Pharmacist COVID-19 Drug Monitoring Standing Order, provided system pharmacists oversight of therapeutic agents with low care team familiarity, optimizing care and increasing workflow efficiency. These processes' success foreshadows the potential impact of expanded pharmacist practice autonomy.

9 | CONCLUSION

The unprecedented medication demand and widespread supply chain disruption throughout the COVID-19 pandemic have underscored the importance of dynamic and agile approaches to medication shortage mitigation. Dissemination of successful strategies from this period can support practice advancement and innovation.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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