



Exploring Strategies for Identifying and Managing Medication Shortages in CMS Region VIII

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3	Executive Summary
4	Introduction
6	Region VIII Drug Shortage Demonstration Project
7	Findings
14	Recommendations at a Glance
15	Recommendations
17	Demonstration Project Challenges and Limitations
18	Conclusion
18	Endnotes

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Executive Summary

Drug shortages have reached an all-time high. In the first quarter of 2024, there were 323 active drug shortages, marking a new record.¹ Hospital pharmacy staff need more systemic support to manage these shortages.

This report describes a demonstration project examining the current state of medication shortage management in Centers for Medicare and Medicaid Services (CMS) Region VIII and offers recommendations for building a coordinated regional approach to drug shortages.

The Mountain Plains Regional Disaster Health Response System (MPRDHRS) works to improve medical surge and clinical specialty capabilities during regional emergencies and public health crises. It is a collaborative effort across the six states in CMS Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming) and is housed at Denver Health and Hospital Authority. Beginning in late 2023, MPRDHRS conducted a demonstration project to understand the state of inpatient drug shortage management. The effort included nine interviews with pharmacy staff at various hospitals and hospital systems in four Region VIII states.

Results from the interviews underscore the variety of approaches that hospitals take to

track and manage drug shortages. Pharmacy staff work adaptively from shortage to shortage, often changing strategies depending on the nature of the shortage and their patients' needs. Sharing drugs among hospital systems is uncommon, and the feasibility of sharing drugs across state lines remains unclear.

A regional approach has the potential to address some of these pain points, yet the extent of its impact remains uncertain. In order to better understand how a regional approach to addressing drug shortages could be established, MPRDHRS recommends that regional and national entities:

- Explore regional and national strategies to create a standardized approach to identifying emerging drug shortages.
- Study strategies to facilitate a regional approach to managing drug shortages in health care.
- Explore practical and regulatory issues related to sharing hospital resources and drugs across state lines.










Introduction

Medication shortages have plagued the health care system for years, but recently the problem has grown to critical levels. In some cases, rationing of certain medications has been necessary. In the first quarter of 2024, there were 323 active medication shortages, according to the American Society of Health-System Pharmacists (ASHP).¹ The medications on shortage spanned therapeutic categories, including antibiotics, sedatives, vasoactive medications for critically ill patients, and chemotherapeutic agents.

These shortages exacerbate existing inequities between larger and smaller health systems, as larger hospitals often have more purchasing power and direct relationships with manufacturers and wholesalers. Climate change-related disasters pose an additional threat to the drug supply chain. In 2023 a tornado damaged a Pfizer manufacturing plant in North Carolina, leading to panic buying and stockpiling of medications among hospitals.² This incident underscores how such disasters can lead to uncoordinated, inequitable responses to drug management that favor hospital systems with existing purchasing power.

The U.S. Food and Drug Administration (FDA) has set goals to address drug shortages, including improving mitigation responses to imminent or existing shortages and implementing strategies for the long-term prevention of shortages by focusing on their root causes.³ However, it is unclear whether and how individual hospitals and hospital systems, both large and small, are creating plans to address the shortages. The extent to which hospitals share information about shortages and the drugs themselves is also poorly understood.

Figure 1: Common causes of drug shortages⁴

	Supply Problems	Suppliers are unable to provide some ingredients or containers needed.
	Business Decisions	Manufacturer discontinuations or reductions in drug production quantity due to a business strategy.
	Quality Issues	Drug production reduction or delay due to quality issues.
	Mergers	The merging of companies that make the same drug may lead to less of a drug being available afterward.
	Natural Disasters	Natural disasters destroying manufacturing infrastructure or disrupting drug transport.
	Pandemics	Pandemics overwhelm the health system and trigger intense demand for treatment drugs as well as the need to ration or allocate drugs.
	Other Drug Shortages	The effects of one drug shortage can compound and cause a shortage for another drug that is used as a therapeutic alternative.

About MPRDHRS

The [MPRDHRS](#) is a collaborative effort, housed at Denver Health and Hospital Authority, in partnership with the six states in CMS Region VIII. It is funded by the Administration of Strategic Preparedness and Response (ASPR) to improve medical surge and clinical specialty capabilities during regional emergencies and public health crises. The MPRDHRS is designed to provide logistical and operational support to any state agency or organization that requests assistance during a public health crisis.

The primary objectives of the MPRDHRS are to:

- Improve bidirectional communication and situational awareness of the medical needs and issues of the response between health care organizations and local, state, regional, and federal partners.
- Leverage, build, or augment the highly specialized clinical capabilities critical to unusual hazards or catastrophic events.
- Augment the horizontal (whole of community) integration of key stakeholders that comprise health care coalitions with readily accessible clinical capabilities that are largely missing from the current configuration of such coalitions.

The Medical Advisory Panel (MAP) is a subgroup of MPRDHRS leadership and was created to provide medical expertise in addressing public health crises. The MAP enhances MPRDHRS's work by providing fast, actionable guidance to inform health system and hospital responses to these catastrophic events.

The MAP consists of medical providers, including physicians, nurses, pharmacists, and public health experts, and is supported by administrative staff for programmatic and grant management. The MAP has overseen the activities of this exercise, and a pharmacist working with the MAP conducted the interviews with pharmacy staff at identified hospitals.

About CHI

The [Colorado Health Institute](#) (CHI) is a nonprofit, mission-driven research and convening organization advancing equity and well-being. CHI supported the demonstration project design and recruitment of interviewees; analyzed and synthesized the transcripts of the interviews, extracting key themes and takeaways; and led the writing of this report, with guidance from the MAP and other MPRDHRS members.

Region VIII Drug Shortage Demonstration Project

Background

The MAP engaged with CHI to conduct a demonstration project to contact pharmacy staff across Region VIII to understand their strategies for addressing an emerging crisis with medication shortages. The goal of this demonstration project was to test the feasibility of contacting pharmacy staff across different hospital systems and analyze the MAP's ability to address regional needs. Based on the findings, MPRDHRS formed recommendations for stakeholders to consider to support hospitals in managing medication shortages.

Methods

Interviews

A pharmacist from MPRDHRS conducted the interviews for this demonstration project. The interviewer gathered information through conversations with hospital pharmacy staff who manage drug shortages in hospital settings. Hospitals were asked to identify the pharmacy staff more directly responsible for managing shortages. Selected interviewees included pharmacy directors, clinical managers, and informatics specialists. The years of experience of pharmacy staff varied, ranging from recent graduates to professionals who have been in their roles for 30 years.

At the outset, the interviewer asked pharmacy staff how they handled shortages of four drugs: midazolam, dobutamine, heparin, and valganciclovir. These four drugs had recently been in a shortage and are used in a variety of settings. However, most staff were unable to recall the specifics of the shortages of these four drugs and defaulted to speaking about the most recent drugs on shortage. As a result, after four interviews, the interview guide was changed to focus on the most recent drug shortages.

Hospital Locations

MPRDHRS conducted nine interviews of pharmacy staff across hospitals and hospital systems with locations in four states in Region VIII from January

through August 2024. In order to get in contact with pharmacy staff, the MAP requested its executive committee members provide referrals. Additionally, CHI developed a contact matrix, with a sampling of hospitals of all sizes from all six states. Hospitals were contacted using a convenience sampling approach with the goal of interviewing a variety of hospitals with differing characteristics, including size, specialty, and urban status. MPRDHRS used this sampling matrix to make cold calls to health system pharmacies.

Most hospitals declined the interview request or did not respond; 29 hospitals were contacted in total, 23 provided contact information to receive an interview request, and nine accepted and participated in interviews. Of the six states in Region VIII, interviews were conducted with hospital systems in four: Colorado, Montana, Utah, and Wyoming. No hospitals in North Dakota or South Dakota responded. Table 1 lists the hospital and hospital systems interviewed and their number of inpatient beds.

Hospital interviewees spoke about how they manage drug shortages at that specific hospital location, which typically involved coordination with other hospitals in the same system. Six hospitals are in urban areas, and one is in a rural area. Accordingly, the size of the hospitals varied, from 25 to 721 beds. Most hospitals serve broad patient populations and support a variety of services, from emergency medicine to oncology. One of the hospitals primarily serves pediatric patients.

Health system interviewees spoke about how they manage drug shortages at the systems level. Both Intermountain Health and Banner Health have locations in rural and urban areas and serve a broad patient population.

Analysis Approach

Transcripts were generated for all interviews and then qualitatively coded to identify themes. For the first three interviews, the transcripts were double-coded to ensure theme calibration. During the analysis, coded segments were pulled and summarized.

Table 1. Hospitals and health systems interviewed for demonstration project

Hospitals					
State	City	Hospital Name	Inpatient Bed Count	Part of Hospital System	Rural or Urban
Colorado	Aurora	University of Colorado Hospital	721 ⁵	Yes	Urban
	Colorado Springs	UCHealth Memorial Hospital	413 ⁶	Yes	Urban
	Fort Collins	UCHealth Poudre Valley Hospital	300 ⁷	Yes	Urban
	Denver	Denver Health	525 ⁸	Yes	Urban
Montana	Helena	Shodair Children’s Hospital	82 ⁹	No	Urban
Wyoming	Cheyenne	Cheyenne Regional Medical Center	222 ¹⁰	Yes	Urban
	Saratoga	North Platte Valley Medical	25 ¹¹	No	Rural

Hospital Systems	
Region	Health System Name
Colorado and Utah	Intermountain Health
Arizona, California, Colorado, Nebraska, Nevada, and Wyoming	Banner Health

Findings

Themes from interviews with pharmacy staff fell into three categories: identifying shortages, classifying the severity of shortages, and addressing shortages.

Identifying Shortages

Specific challenges and opportunities related to identifying drug shortages can be better understood by examining the channels of information used to alert pharmacy staff to shortages and the relationships that support this flow of information.

Information Channels

Takeaway: Pharmacy staff learn of shortages through various channels, which differ from hospital to hospital. Some have direct relationships to buyers, drug suppliers, and representatives from hospital software companies that help them track shortages, while others check availability through wholesaler ordering software or ASHP bulletins.

Pharmacy staff play a critical role in identifying and tracking drug shortages, yet their approach is not standard. Sources of information used to track and monitor shortages include wholesaler ordering software, invoices, and notifications; third-party software; ASHP bulletins; email chains; and conversations with buyers and wholesalers.

Among the hospitals interviewed, there was variation in which pharmacy team member was responsible for tracking drug shortages. In hospitals with buyers or buyer teams, these positions typically handled the tracking. However, in other hospitals, a pharmacy director or a technician sometimes filled this role. Generally, there was no single staff member dedicated to tracking shortages, and the responsibilities were usually shared among staff, especially those on the drug shortage management team.

Figure 2: How pharmacy staff learn of drug shortages

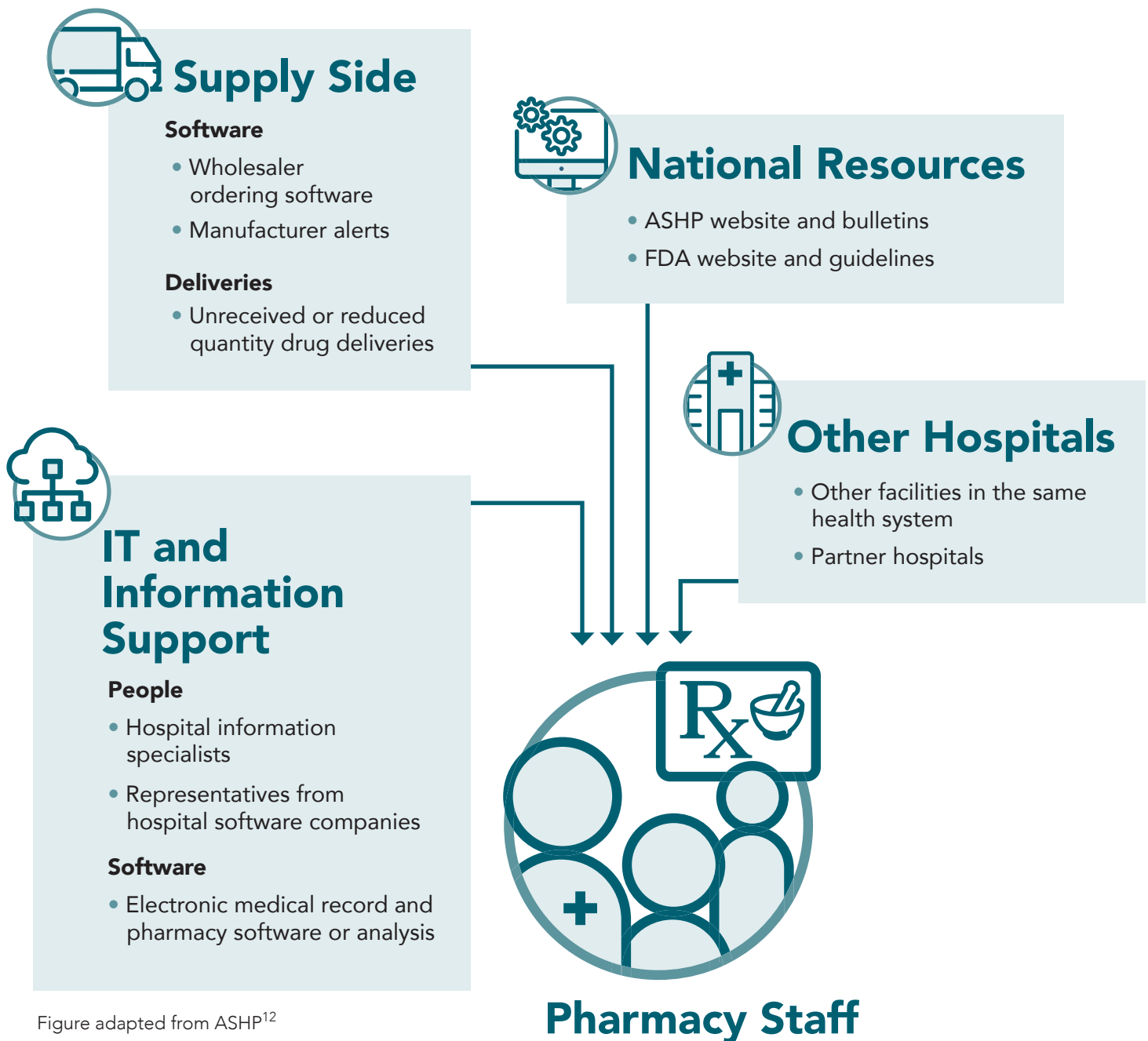


Figure adapted from ASHP¹²

Pharmacy Staff

A pharmacy team may consist of...

- Pharmacy Directors, Managers, or Supervisors
- Pharmacy Specialists
- Pharmacists
- Buyers
- Technicians
- Informatics Specialists

Supply Side: Wholesaler Ordering Software and Notifications

Many pharmacy staff, especially buyers, first learn about shortages when they order drugs from a drug wholesaler or manufacturer such as Cardinal, AmerisourceBergen, or McKesson. Often when a drug is on shortage, deliveries will fail to arrive or arrive with reduced quantity. These unreceived or reduced quantity orders are a common way for pharmacy staff first learn of a drug shortage.

Wholesalers and manufacturers often indicate when a drug is on shortage through their ordering software. Estimated delivery dates and quantities are often not provided when a drug is in short supply. If the wholesaler does provide an estimated date, this is usually the date the local distributor will receive some stock but does not specify the quantity. Wholesalers and manufacturers may also send out notifications to pharmacy staff about specific drugs going on shortage. Often pharmacy staff will call in to get more information about the shortage specifics and availability of therapeutic alternatives.

Once pharmacy staff receive estimates on when the shortage might be resolved, they use this information, along with estimates of their drug burn rate and current supply, to estimate how many days of supply they have left. This flow of information between wholesalers and manufacturers to pharmacy staff is crucial to be able to estimate the severity of the shortage for their hospital.

National Resources: ASHP and FDA

ASHP

Most of the pharmacy staff interviewed were familiar with the ASHP website and regularly used the resources on the site to learn of drug shortages. Only one person interviewed was not familiar with ASHP's drug shortage information. When available, pharmacy staff would compare the ASHP's estimated resupply dates to those given by the wholesalers and manufacturers to get multiple measures of a potential resolution date.

*"I use the ASHP drug shortage list a lot. That's my source of truth. If I'm finding issues, I want to see what's going on with that. They're a great resource. They stay very up to date."
– Pharmacy Staff Member*

FDA

The FDA website was not mentioned by any of the pharmacy staff interviewed as a resource for day-to-day tracking and drug management. However, pharmacy staff mentioned keeping updated on FDA guidance and regulations for the management of long-term and highly critical shortages.

IT and Informatics Support

Larger hospitals have larger pharmacy teams and more internal staff capacity to run analysis on their drug inventory and usage rates than smaller hospitals. For example, some of the larger hospitals have specific analysts or informatics specialists who support their pharmacy teams. At these larger facilities, informatics specialists are more integrated into routine drug-shortage meetings, which speeds their ability to implement electronic medical record (EMR) changes. Larger hospitals also had connections to representatives from their EMR software or other types of hospital or pharmacy software who support tracking drug utilization and demand within the software. These representatives also commonly attended regular drug shortage committee meetings.

Other Hospitals

Infrequently, hospitals with close partnerships to other hospitals communicate directly with one another to verify whether a shortage is happening. This was primarily true for hospitals located in the same area.

Stakeholder Involvement

Takeaway: Pharmacy staff often meet weekly with drug shortage management committees to address current and ongoing shortages. Pharmacy staff will often directly contact medical care providers to seek advice on shortage management, including therapeutic alternatives, early on.

Communication between pharmacy staff, providers, and hospital leadership is key in identifying and quickly communicating shortages. All hospitals have some form of a shortage management committee that meets on

a frequent basis to address shortages. On a daily or near-daily basis, pharmacy staff are also reaching out to providers, especially in the emergency department, to communicate shortages and collaborate on solutions. This stakeholder engagement occurs in the context of committees and via direct contact with providers.

Committees

The two primary committees that support drug shortage tracking and management at the interviewed hospitals were shortage management committees and pharmacy and therapeutics committees.

Shortage Management Committee

Most hospitals have committees that meet at least weekly to talk about drug shortages. These meetings are more frequent than and separate from pharmacy and therapeutics committee meetings. Who attends these shortage management meetings depends on hospital size and pharmacy staff size. Typically, pharmacy managers, pharmacy technicians, buyers, and providers attend these meetings. Although no buyers were interviewed, they were often cited as key players in early identification of drug shortages in these management meetings. Emergency meetings of drug shortage committees are scheduled as needed.

Pharmacy and Therapeutics Committee

Pharmacy and therapeutics committees meet less often than shortage management committees. Pharmacy and therapeutics committees consist primarily of pharmacy and clinical leadership who manage shortages and other senior staff, such as medical directors and administrative leaders. These leaders can give approval for significant changes in drug management, such as drug restrictions or a change in the drug formulary.

Most interviewees said their hospitals have a standing agenda item in the pharmacy and therapeutics committee meetings for updates related to drug shortages. While the role of the pharmacy and therapeutics committee is important for decision-making in critical care scenarios, the drug shortage management committee is often the most available and responsive committee to address drug shortages that do not meet a critical level.

When needed, hospitals will schedule emergency pharmacy and therapeutics committee meetings or reach out to leaders on the committee between standing meeting dates.



Differences Between Committees

The role separation and staff composition of the shortage management committee and pharmacy and therapeutics committee differed at each hospital. Some pharmacy staff are on both committees while others are just on the shortage management committee. What roles were on which committee varied by hospital. While the pharmacy and therapeutics committee is responsible for approving changes to the formulary and other significant shortage management decisions, at most hospitals, the committee did not meet frequently enough to address every emerging shortage. Therefore, pharmacy staff would usually reach out to pharmacy and therapeutics committee members individually to get approval to implement a change, which may be reviewed afterward when the committee next meets. Some pharmacy staff noted that this structure can make it difficult to gather the right stakeholders when needed.

“It depends a bit on the scenario, but usually with drug shortages, you don’t have a ton of time to deliberate. I will say, the vast majority of the time, it’s that drug-shortage committee ... who’s saying, ‘Listen. This is something that we definitely need to escalate.’” – Pharmacy Staff Member

Contact with Providers

Effective communication with providers is vital for successful shortage management. Shortage managers frequently consult emergency department providers or supervisors for their expertise on therapeutic alternatives when a potential shortage is identified. Additionally, clinical managers collaborate with pharmacy staff to communicate patient needs and share information about drug shortages. All pharmacy staff interviewed emphasized the importance of direct and early conversations with providers to identify and implement solutions promptly.

“I do emails to both the staff providers and the ER staff, so not just the providers themselves, but we have a lot of EMTs and nurses working in our ER, so they understand the drug shortages as well. Then when I go in in the morning, I do a face-to-face, and if I’m short on anything or I have anything new, I will talk to the provider face-to-face and let them know.”
– Pharmacy Staff Member

Classifying the Severity of Shortages

Takeaway: The severity of a drug shortage is often loosely defined and varies by hospital. There is no standardized system for classifying the severity of shortages, and none of the hospitals interviewed have implemented a formal, tiered system for restrictions or rationing during shortages.

Pharmacy staff described how they rank the severity of drug shortages and how they consider whether a shortage is critical or not. In most cases, pharmacy staff used their expertise and experience to determine shortage severity levels rather than a defined ranking or severity scale.

Determining Shortage Severity

All pharmacy staff interviewed described some method of prioritization for how they adjust their workflow to address the most urgent drug shortages in a timely manner. For most, the shortage management committee serves this function, where committee members bring up what should be the priority for that week. Others had more formalized trackers, such as spreadsheets where they would mark shortages as low, medium, or high priority.

Most staff had also had an approximate threshold by which they would start to consider a shortage highest priority or critical; typically this threshold was listed as a certain number of days of remaining supply. The number of days’ supply remaining that triggered this threshold ranged from 30 days to one week. However, crossing this threshold did not necessarily lead to specific next steps in the management of each drug, as the management of the shortage depended on the scenario of the shortage. The scenario of the shortage includes factors such as type of drug, ability to substitute a therapeutic alternative, and ability to find another ordering avenue. A theme of the interviews was the lack of a clear definition for a high-priority or critical shortage or what it means to classify a drug shortage as high-priority or critical, given the specific and at times complex nature of each drug shortage scenario.

The judgment for addressing a shortage as high priority or critical often came down to the pharmacy staff relying on their expertise and years of experience. Since most staff interviewed had been in their positions for more than a year, many said they were able to find a recent example of how their hospital handled a recent similar shortage and look back at shortage plans or tactics that worked well and adapt those.

“We [rank shortage severity] based on how critical we think it is. If it’s suddenly, completely unavailable, even if we have a lot on hand, we may consider that critical until we have a plan in place for it. We try to do it off of quantity on hand and usage per week to see what that looks like. In our perfect situation, we would run our meeting off of those things, like what’s the most critical would always go to the top, but we don’t really necessarily have a solution for that yet.” – Pharmacy Staff Member

Using Software to Support Shortage Tracking

A contributing factor to the variation in how hospitals track and classify shortages is the range of tracking tools and software used. While all hospitals interviewed had some capacity to monitor and retrieve current drug supply information, larger hospitals often had access to more advanced software that allowed them to better identify shortages using their internal data. For example, some software, such as Epic SlicerDicer, can combine current supply and patient data to calculate usage rates. Other tools can create reports of current patient needs and the drugs that would be needed for the next seven days. Logicstream, which is used by a few of the interviewed hospitals, goes a step further by aggregating national data to detect undelivered orders.

No software was able to comprehensively combine information about drug supply, patient need, and drug availability. Pharmacy staff using these tools still must supplement this software with manually updated spreadsheets. As a result, pulling all the information needed about a specific drug shortage remained a manual and time-consuming process for all hospitals interviewed.

Addressing Shortages

Takeaway: Each hospital had a different process for addressing and communicating shortages. The process also differs by drug and shortage scenario.

Pharmacy staff employ diverse strategies to manage drug shortages, with approaches varying based on the specific drug and shortage severity. This includes how the pharmacy staff communicate recommendations to others in the hospital and the strategy they ultimately use to address the shortage. Pharmacy and therapeutics committees participate in shortage management by offering essential guidance and oversight in more critical shortage scenarios.

Communication

A key to addressing shortages is communication and relationships between pharmacy staff, the pharmacy and therapeutics committee, clinical leaders, and other staff. The most common way pharmacy staff solicited input on developing recommendations for addressing shortages was by calling or by having direct conversations with stakeholders. For instance, open dialogue with providers is crucial for understanding the clinical impact of shortages and developing appropriate treatment alternatives. Regular shortage management meetings were vital for keeping communication channels open and for making timely recommendations. Interviewees at hospitals with regular shortage and pharmacy and therapeutic meetings expressed satisfaction with how the meetings helped facilitate clear communication.

“We reach out on a personal level [to clinical leaders] ... to ask about what their thoughts are and what our response plan is to see if we need to make any other adjustments. We do lean on them if we’re thinking there’s something that potentially doesn’t have a good alternative, especially. Then we’ll say, ‘Is there a way that you think that we could expand our supplies?’ or ‘Is there a specific patient population you’d like to [prioritize]?’ ... Just getting as creative as we can.” – Pharmacy Staff Member

Once recommendations for how to address a shortage were developed, pharmacy staff would send the information out to clinical leaders or directly to providers, following up with one-on-one conversations as necessary. Emails containing shortage information were a commonly used communication tool, although many staff said their effectiveness varies. Many hospitals use their electronic medical record (EMR) software to create order alerts for drugs that are in shortage. These alerts pop up when drug orders are created and notify the user of alternatives.

EMR order alerts known as legacy medication alternatives “have been probably the most effective tool because not everybody reads their email. When they put in an order and that comes up, they know that there is a shortage, and they know what their alternatives are.” – Pharmacy Staff Member

Strategies to Address Shortages

Pharmacy staff spoke about various strategies to mitigate the impact of drug shortages. A common tactic was sequestration, which involves limiting drug access by consolidating drug supply and restricting orders within the electronic medical record or other software systems. This was often done using Pyxis stations (medication dispensing systems) and alerts in EMR software.

Additionally, hospitals commonly turned to therapeutic alternatives to address shortages. Before deciding on a therapeutic alternative, pharmacy staff would consult the pharmacy and therapeutics committee and clinical managers and providers as early as possible in the drug shortage tracking process. While using therapeutic alternatives is common, it frequently creates logistical challenges related to preparing and administering medications. For example, if the alternative requires a different delivery method, such as switching from an injection to an oral formulation, it may necessitate additional training for staff and adjustments in patient care routines. Differences in dosage can also complicate the transition, requiring careful calculations and

monitoring. Additionally, a therapeutic alternative may require developing new compounding procedures and associated software builds. Depending on the drug, new EMR order builds and the updating of order sets may also be required, all adding to administrative burden for pharmacy staff.

Sharing Drugs Among Hospital Systems

Sharing drugs with other hospital systems is not a common practice among the hospitals interviewed. Hospitals that managed shortages at a system level commonly shifted drugs around their system to meet overall system needs. It was much less common to share with hospitals outside of their system. Pharmacy staff noted that sharing among different hospital systems is usually patient-specific, meaning a small quantity of specific drugs is needed for specific patient care.

No participating hospital reported sharing medications across state lines. Pharmacy staff stated that within the same region, hospitals often experience similar drug shortages, limiting the potential for sharing among hospital systems. Additionally regional drug shortages may further discourage hospitals from sharing because they are all trying to meet their patient demand.

“Once you see a shortage start to develop, everybody just grabs whatever they can. That’s kind of how I tend to see the overall landscape when it comes to drug shortages. I don’t like that. I don’t think that’s good for the average patient, but just with how fractured our health care system is, that’s just what I see over and over again...We just don’t have good tools to sort of address the larger issues.” – Pharmacy Staff Member

Some pharmacy staff said they were unsure how feasible sharing across state lines would be due to the certificates and documentation for drug distribution needed by regulations such as the Drug Supply Chain Act. These requirements can create administrative challenges and deter hospitals from engaging in cross-state drug sharing.



Recommendations at a Glance

Findings from interviews with hospital pharmacy staff from the MPRDHRS demonstration project highlight a variety of strategies used by hospitals to identify, track, and address drug shortages. Pharmacy staff tailor their approaches depending on the specific drug and patient needs. Sharing medications between hospital systems is rare, and the practicality of cross-state drug sharing remains uncertain. To develop a regional strategy for addressing drug shortages, MPRDHRS recommends the following actions for regional and national entities.

RECOMMENDATION 1:

Explore regional and national strategies to create a standardized approach to identifying emerging drug shortages.

Hospitals rely on various information channels to learn about drug shortages, including updates from wholesalers to ASHP bulletins. This results in a lack of standardization in how shortages are identified and tracked. Regional and national strategies could create a unified approach and establish a common understanding of emerging and ongoing shortages.

RECOMMENDATION 2:

Study strategies to facilitate a regional approach to managing drug shortages in health care.

A regional approach to managing drug shortages involving multiple hospitals and hospital systems across states could offer several advantages. This includes more equitable and efficient drug distribution, greater resilience to supply chain disruptions, and reduced impact of shortages on underserved communities and smaller health

care facilities. Further research is needed to explore strategies that could support this regional approach and its benefit to patients. This includes studying strategies such as standardized drug shortage severity classifications and standards of practice for managing shortages.

RECOMMENDATION 3:

Explore practical and regulatory issues around sharing hospital resources and drugs across state lines.

A better understanding of the practical and regulatory considerations for sharing drugs across state lines could help hospitals participate in a regional approach to addressing drug shortages. This includes assessing the feasibility of sharing across state lines in a timely and cost-effective manner while staying in compliance with federal and state laws and regulations. By understanding regulatory barriers and logistical challenges, health care leaders and policymakers can make informed decisions about how to structure a potential regional approach to addressing drug shortages.

Recommendations

RECOMMENDATION 1:

Explore regional and national strategies to create a standardized approach to identifying emerging drug shortages.

Hospitals depend on a variety of information sources to identify drug shortages. Often, proactive planning is difficult because pharmacy staff may only learn of shortages when a drug order fails to be delivered or arrives in reduced quantities. A standardized, proactive regional or national strategy to identify drug shortages could help hospitals plan, coordinate with others, and provide the best patient care possible. An exploration of strategies, including the roles of stakeholders, is needed to assess the feasibility of regional or national coordination. The following factors should be considered for developing a standardized approach to identifying shortages.

Broad Stakeholder Engagement

The MPRDHRS demonstration project focused on how pharmacy staff manage drug shortages within hospitals. However, drug shortage management involves many other components beyond the hospital setting. On the supply side, drug manufacturers, wholesalers, and distributors also implement strategies to manage shortages, though it remains unclear how well these strategies align with those used by hospitals, if at all. To fully grasp the complexities of drug shortage causes and management, broader engagement with stakeholders on both the supply and purchasing sides is essential. This includes collaboration with drug manufacturers, wholesalers, distributors, prime vendors, group purchasing organizations, and health care institutions. Regional, state, or national organizations or governments could play a key role in bringing these stakeholders together to facilitate coordinated efforts.

Standard Use of National Resources

ASHP and the FDA both maintain lists and databases of drug shortages, including present and past shortages. These lists differ in key ways,

including which drugs are listed as on shortage. ASHP is not a government entity, so its list is primarily an informative resource and hospitals interviewed for the demonstration project used it for day-to-day management of drug shortages. The FDA's drug shortage list and guidance, on the other hand, carry regulatory and policy implications, including emergency use authorizations that allow for increased production of drugs outside of typical regulatory constraints.

There is no consistency in the way hospital pharmacy staff reference and use these national resources. A unified way of receiving and interpreting national resources would be beneficial for building shared understanding of shortages. This could look like the consolidation of information into a single list of drug shortages. In order to allow the most time possible for disaster planning, national resources would ideally provide the earliest possible information that indicates a potential shortage. This would necessitate exploring how to incorporate information that manufacturers see about potential shortages, such as ingredient or material shortages. However, study is needed to ensure this information is shared responsibly and there is accompanying guidance to interpret the information.

RECOMMENDATION 2:

Study strategies to facilitate a regional approach to managing drug shortages in health care.

Coordination among different hospitals or hospital systems in managing drug shortages is uncommon. Smaller health care facilities and facilities in underserved communities often have less purchasing power and are more vulnerable to the impacts of drug shortages. A regional approach to managing active drug shortages could facilitate an equitable distribution of medications. However, significant groundwork is needed to establish the basis for such an approach, including the considerations about identifying shortages in Recommendation 1. In addition to identifying shortages, the following factors should be considered when coordinating a regional response to an active shortage.

Regional Communication

A regional approach to drug shortages would involve enhanced communication regarding potential shortages across states and hospitals. State governments, hospital associations, regional organizations, and other stakeholders can all play a part in this enhanced communication. In order to establish clearly defined roles, partnerships and collaboration for a potential regional response should be explored between these entities. This exploration should include best practices in sharing information. Additionally, many of the interviewees in the demonstration project expressed a strong desire to learn from other hospitals and understand how they are handling drug shortages. Enhanced regional communication could allow hospitals to learn from each other and easily share insights and informational resources.

Role of Standardization

Some degree of standardization in drug shortage management may be necessary as a basis for a regional response to an active shortage. However, hospitals all have different relationships with specific manufacturers or suppliers and existing shortage management strategies, so more study of the role and utility of standardization is needed.

A key element in drug shortage management is determining how critical a shortage is. Developing a standardized framework to classify the severity of drug shortages could be beneficial in the prioritization of shortages and in understanding what parts of a region are most in need. However, research is necessary to determine how such a framework could be effectively implemented and adapted to various drug types, shortage scenarios, and hospital settings. In a regional response, how levels of severity classification would activate regional resources or processes would also need to be explored.

There are no standard operating procedures for managing active drug shortages among hospitals. However, it is unclear if this is a benefit or a challenge, as variability in approaches to shortages may allow staff to respond with the nimbleness needed to match differing shortage scenarios. Findings from the interviews showed that each

medication required a different response to address the shortage. Providing space for staff to be flexible in these situations may be the appropriate strategy.

A potential solution is a hybrid model of standardization that has a detailed framework for classifying shortage severity while allowing for flexibility in how the shortage is addressed. More research is needed to understand how a model would operate. MPRDHRS and other groups could support adaptability by providing data on what other hospitals are doing, a list of leaders to contact during crises, or training on best practices.

Technology Solutions

Increased regional coordination would likely raise the need for integrated technology solutions capable of facilitating communication across the different software that hospital systems use. Depending on the hospital, they may use different types of software for ordering drugs, accessing the EMR, managing inventory, and keeping track of shortages. Interoperable solutions such as health information exchanges (HIEs) that allow information sharing between various software platforms can play an important role in unified communication and measurement of shortages.

RECOMMENDATION 3: Explore practical and regulatory issues around sharing hospital resources and drugs across state lines.

To consider participating in a regional response and facilitate drug sharing across state lines during shortages, hospitals require more explicit regulatory guidance. State and federal governments are crucial stakeholders in clarifying regulatory requirements and considerations. Additionally regional and national organizations can help share practical guidance and best practices around sharing drugs across state lines.

Government

The federal government, through the FDA, already monitors and responds to drug shortages. Because regional responses to drug shortages are not common, further federal guidance may be needed to understand the feasibility of a regional response. ASPR is a key federal agency that could provide guidance on considerations for regional responses to critical drug shortages. This is especially important given the complexity of different regulatory landscapes based on considerations such as federal or state emergency declarations, full FDA approval of drugs versus emergency use authorization, and other legal factors.

State governments also play an important role in a potential regional response as state health departments are uniquely positioned to provide essential information regarding waivers, regulations, and best practices for hospitals to address regional drug shortages. By clarifying the regulatory landscape and offering actionable steps, state health departments can encourage hospitals to participate in collaborative regional solutions. State government can also work with hospital associations to ensure the most effective communication to hospital pharmacists. Beyond communication about regulations, the role of state governments in the coordination of a regional response to drug shortages should be further explored.

Regional and National Organizations

MPRDHRS and other regional and national organizations, such as ASHP, can also help share useful regulatory information relevant to a regional response. Additionally, these organizations can foster communication and coordinate efforts among hospitals and hospital associations to explore the practical challenges of establishing a regional response. This could include sharing best practices for managing shortages, developing standard operating procedures, providing education and training, and advocating for needed policy change.

Demonstration Project Challenges and Limitations

This demonstration project covered many themes and revealed key insights into how hospitals manage drug shortages. However, the project encountered several challenges and has limitations that must be factored into next steps or future demonstration projects. This section describes these challenges and limitations and suggests solutions for future work.

Contacting Pharmacy Staff for Interviews

Getting in touch with the appropriate pharmacy staff who manage shortages proved challenging. MPH D HRS does not have a centralized list or directory of pharmacy staff, so getting contact information was a slow process. CHI created a contact matrix with a sampling of hospitals of all sizes from all six states. This matrix only had the generic pharmacy contact number, so most calls were cold calls. During the cold calls, many pharmacy staff were unfamiliar with MPRD HRS or skeptical of a call coming from someone they did not know, so they declined an interview.

Many other staff may also have not wanted to participate in the hour-long interview process. In a true disaster scenario, it may be easier to contact with pharmacy staff because addressing drug shortages regionally may be a higher priority. However, the alternative may also be true, as pharmacists' capacity to support knowledge transfer during a crisis may be limited.

In order to prepare for a disaster scenario, a better avenue to contacting pharmacy staff should be established. This communication could be coordinated through hospital associations or the state government. A directory of pharmacy staff who manage drug shortages by hospital or hospital system housed by a regional or state entity could also be useful in a rapid response to a disaster. Leaders then may be able to contact each other directly, and organizations such as MPRD HRS could more effectively and efficiently gather data in rapid response situations.

Rapid Response

An original goal of the demonstration project was to understand how efficiently MPRDHRS staff could rapidly contact pharmacy staff, review drug shortage management practices, and share the results across the region. Due to the difficulty of contacting the appropriate staff members, the demonstration project was unsuccessful in this goal. The project also gathered a relatively small number of interviews with pharmacy staff. A limitation to the rapid response could also be the approach of contacting individual hospitals. It may be more efficient in the future to contact statewide or regional groups of hospitals and assess drug management practices at that level. Additionally, an alternate methodology to interviews could improve the speed of the collection of data. A survey, open-response email, or call line could allow pharmacy staff to submit information more quickly.

Conclusion

Drug shortages are common, and pharmacy staff face a variety of complicated drug shortage scenarios each year. Each hospital system is handling the management of these shortages in a different way, but all rely heavily on the experience and adaptiveness of pharmacy staff. A regionally coordinated response to drug shortages could help improve sharing of drugs and funnel resources to where they are most needed. However, given the variety of ways hospital systems deal with shortages, research is needed to understand what is needed for a regionally coordinated response, including potential standardization of shortage severity and management.

Endnotes

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