End Drug Shortages Alliance

A Summary of the End Drug Shortages Alliance Committees

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Table of Contents

Pharmaceutical supply chain disruptions jeopardize providers' abilities to deliver lifesaving care to patients. The End Drug Shortages Alliance aims to minimize and ultimately prevent such disruptions to categorically end drug shortages.

Summary

Shortages of essential, life-saving drugs are common, chronic and not acceptable. The End Drug Shortages Alliance (EDSA) was created in November 2021 to improve quality and resiliency of pharmaceutical supply chains and guide the industry's transition from reactive minimization to proactive prevention of drug shortages. The EDSA aims to increase visibility, access and advocacy regarding drug shortages. The vision of the EDSA is to end drug shortages by ensuring access to essential medications and improving quality of life for patients who rely on these medications. The EDSA and its four committees – Transparency and Redundancy, Quality, Supply Readiness and Pediatric and Special Populations – each provide and promote a multi-stakeholder forum for communication and collaboration that leads to action. Each committee has specific goals and practical plans for how to achieve those goals. As of September 2023, the EDSA includes more than 180 member organizations and paid membership is open to all.

Introduction

Shortages of essential, life-saving drugs are not acceptable, yet over the last 20 years, hundreds of such shortages have occurred, continue to occur and even re-occur. Making matters worse pharmaceutical supply chains and the markets they serve were severely challenged by a wide range of worldwide health, economic, logistic, and geopolitical factors in recent years. These challenges have not entirely subsided and continue to place extreme pressure on the entire global supply of drugs, thereby resulting in critical shortages of many drugs. Even today, the United States continues to experience critical shortages of essential and life-saving drugs such as albuterol, amoxicillin, cisplatin, carboplatin, and epinephrine injection.[1, 2]

Transparency limitations often hide the specific reasons for these shortages. The resulting lack of information erodes trust in the supply chain, contributes to a scarcity mindset among consumers and suppliers and makes all providers' responses to drug shortages challenging, time-consuming and inefficient. This simultaneously triggers behaviors by consumers and suppliers, such as hoarding and over ordering, that further exacerbate and prolong drug shortages.

The United States Food and Drug Administration (FDA) considers drug shortages a top priority, defining shortages as "a period when the demand, or projected demand, for a medically necessary drug in the United States exceeds its supply."[3] An FDA report to Congress for calendar year 2021 indicated the need for better understanding and insight into the supply chain, as well as increased resilience in the supply chain to address redundancy.[4] As a result of the ongoing challenges in the marketplace, connection and collaboration among stakeholders can bring further clarity and resolution to ongoing difficulties. This is why the End Drug Shortages Alliance (EDSA) was created: to provide and promote a forum for communication and collaboration that leads to action, thereby improving the quality and resiliency of the pharmaceutical supply chain.

The EDSA attempts to remediate drug shortages by providing a multi-stakeholder forum across the entire pharmaceutical supply chain, from patient to manufacturer. The forum is intended to facilitate connections and foster dialog that leads to informed, data-based decisions and rational actions by stakeholders. This includes health system, supply chain and industry stakeholders.

The EDSA functions in two ways. First, all EDSA members interact regularly to address concerns that impact all stakeholders. Soon after the EDSA's formation, the need for smaller, functional groups that focus on critical issues became clear. Four EDSA committees were created:

- Transparency and Redundancy
- Quality
- Supply Readiness
- Pediatric and Special Populations

Each committee has grown steadily in structure, membership and strategic direction. Collaboration within each committee's respective domain can—and will—lead to clarity, transparency and the ability to identify gaps across the pharmaceutical supply chain. This white paper presents the purpose, intended audience, current state, areas of focus and goals of each EDSA committee as well as gaps, barriers and expected actions.

Overview of the EDSA Committees

Transparency and Redundancy Committee: As a key initiative in the efforts to unify individual stakeholders across the medication supply chain, the Transparency and Redundancy Committee examines sources of drug shortages and prioritizes communication throughout drug production, distribution and administration pathways to mitigate and prevent shortages. The committee's objective is facilitating collaboration among pharmaceutical supply stakeholders to generate effective and standardized communication throughout the industry as well as best practices for inventory management.

Quality Committee: The Quality Committee connects industry stakeholders and health system leaders to promote fundamental product quality, service quality and quality of patient care. The focus is supporting drug procurement and other processes that promote quality standards for drug manufacturing and distribution. The committee's ultimate goal is ending quality issues that cause drug shortages. It does this in two ways. First, the committee works to detail how quality gaps negatively impact patient outcomes and product availability. The committee also produces a comprehensive resource guide to assist stakeholders in determining product quality and reliability.

Supply Readiness Committee: The Supply Readiness Committee aims to prevent, minimize and quickly recover from drug shortages. Committee members analyze barriers and risks to supply distribution/production and identify metrics and best practices to support a robust supply of medications in the marketplace. A robust supply may include re-distribution of existing supply and/or production of additional supply.

Pediatric and Special Populations Committee: The Pediatric and Special Populations Committee serves to advance the unique needs of pediatric patients and other special populations as well as support, create and implement EDSA efforts that positively affect vulnerable patient populations. The committee works to define vulnerability and tracks metrics in the pediatric and special population drug supply chain while encouraging inclusion, education and advocacy for this patient population.

EDSA Committees: Areas of Focus and Goals

Transparency and Redundancy Committee

Purpose

Foster collaboration, communication, data collection, data use and transparency throughout the pharmaceutical supply chain to proactively engage stakeholders in information sharing and then build redundant practices needed to recover from disruption.

Audience

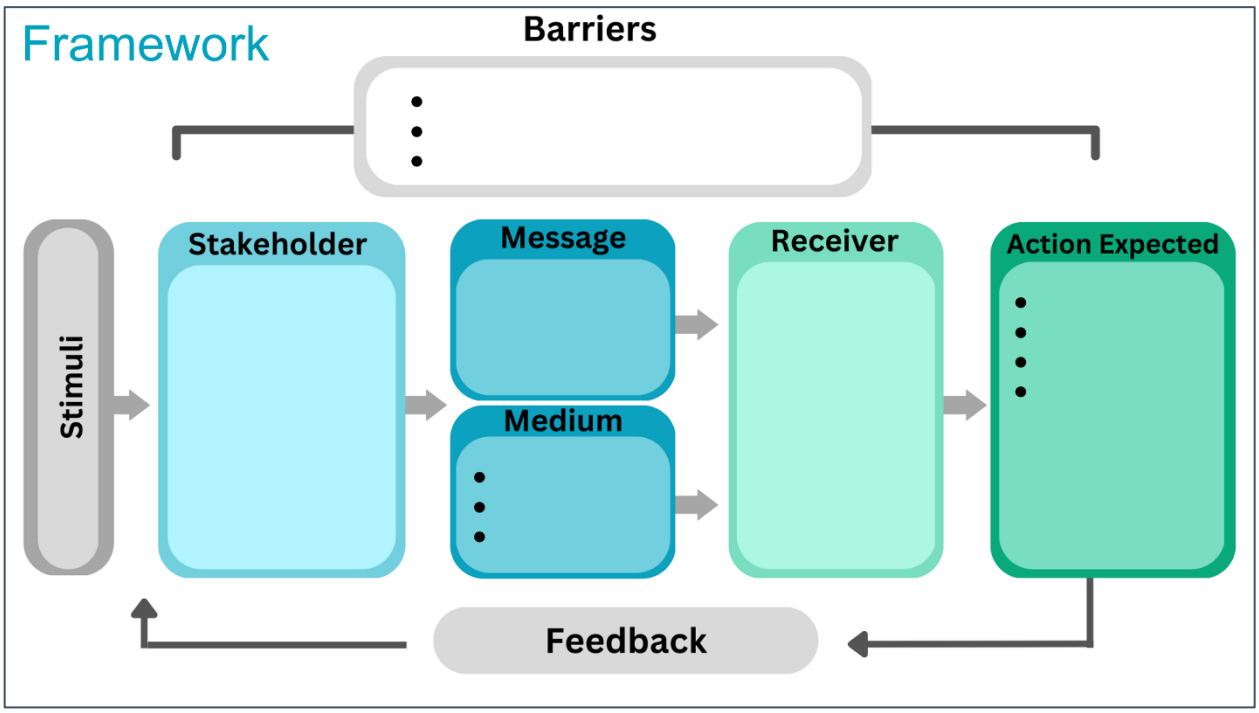
All stakeholders, especially manufacturers, group purchasing organizations, distributors, health system contracting and purchasing decision makers, patient advocacy organizations, as well as government agencies and policymakers.

Current State

The Transparency and Redundancy Committee conducted a gap analysis of the current communication and drug shortage information pathways in early 2023. Using input from all stakeholders, the committee created a current state map, highlighted opportunities for more effective communication and identified barriers that need further research. Prior to the one-day, in-person workshop, each stakeholder mapped their response and actions related to notice of a drug shortage. At the workshop, the committee leveraged input to develop a current state map and prioritize future projects and opportunities including:

1. Develop or leverage a technology platform that allows stakeholders to collaborate on active and future shortages,
2. Partner with the Pediatric and Special Populations Committee to conduct a pilot project to create greater transparency across the system related to a drug shortage, and
3. Create a set of standards or certification to align stakeholders in preventing future shortages through open and transparent communication.

During the workshop, the stakeholders broke into three groups and combined input into a common set of findings using this framework:



Following the workshop, the committee used the framework as a guide to further refine the input and identify priority projects and findings.

Stakeholders

The EDSA and the committee sought to include as many stakeholder perspectives as possible at the workshop. Those unable to travel to the workshop had the opportunity to provide input and react to the committee's findings for inclusion in this white paper.

- Stakeholders represented at the workshop and within the current state map included:
  - Manufacturers.
  - Wholesalers and distributors.
  - Health systems, clinics, specialty and hospital-owned retail pharmacies.
  - Group Purchasing Organizations (GPOs).
  - Center for Drug and Evaluation Research (CDER) and Food and Drug Administration (FDA) Office of Drug Shortage.
  - Professional associations.
  - United States Pharmacopeia (USP), and
  - Compounders.

- Other stakeholders considered in the current state map that were unable to participate include:
  - American Society of Health-System Pharmacists (ASHP),
  - Patients,
  - API/raw materials/packaging partners,
  - Payors and Pharmacy Benefit Managers (PBMs), and
  - Retail pharmacy (CVS, Walgreens, independent retailers, etc.).

Barriers

The committee identified common barriers when dealing with a drug shortage and learned a great deal about the different vantage points of those working to mitigate and end a drug shortage based on their role within the pharmacy supply chain. The barriers follow four main themes:

1. Independent/disconnected systems: There are no common technology platforms, systems or methods of communicating the status and availability of a drug between all stakeholders. Instead, everyone uses their own platforms and methods to manage inventory. There is no connectivity or centralized reporting platform to view available inventory and demand across all stakeholders at any given time. Current drug shortage reporting systems, like ASHP and FDA, require a level of confirmation for the shortage, which means the shortage level is often already dire by the time it makes the lists. Furthermore, each stakeholder is trained to think of their own needs and prepare for the worst due to the lack of a trustworthy and well-functioning shared approach to managing drugs in short supply.

2. Competitive market and competing incentives: Anti-competition concerns, competitive price pressure and contract award status hinder transparency and redundant manufacturing. Challenges related to understanding market position, sources for API, availability of finished products, manufacturing locations, available capacity and variables of the commercial market affect a shortage event or change in the market offering. All supplier parties seek to meet demand, ensuring supply for their customers and patients, but getting a clear picture of inventory across all sources is challenging. Without a clear picture, supply chain recovery may be delayed as stakeholders react to incomplete data.

   Additionally, the lack of aligned incentives throughout the marketplace, demand predictability and the cost of manufacturing interests are often at odds. Stakeholders are incentivized to protective purchase, which disincentivizes transparent communication before, during and after a shortage event. Purchasing decisions made during a shortage can artificially inflate demand, which drops off dramatically after the event, creating further instability. The difficulty of predicting demand beyond the shortage event disincentivizes new entrants to market.

3. Regulatory, legal and legislative barriers: All stakeholders within the pharmacy supply chain are subject to numerous regulations to ensure the safety and efficacy of products manufactured, distributed and administered in the system. All stakeholders must honor various legal considerations related to patents and contracts with partners throughout the supply chain. This need for confidentiality and adherence to regulation contributes to the timing of sharing information about a potential or ongoing shortage.

   Lack of trust: The barriers above combine to create a lack of trust between stakeholders regarding drug shortages. All stakeholders have been conditioned over time to look out for themselves and potentially even work against one another in times of scarcity. An active exchange of information, both real and unverified, can accelerate shortages as stakeholders question the reliability of the supply based on interpersonal communications, rumors and hearsay.

Stimuli

The workshop focused on stimuli within the drug supply chain, primarily focusing on the acute care market while acknowledging ties to other partners and parts of the industry. Committee members quickly observed that each stakeholder learns about drug shortages in different ways, and the stimuli communications are often incomplete and unsubstantiated.

Due to the lack of common systems, notifications of changes in demand, disruption in supply, inability to supply and time to recovery of the shortage negate the ability for all stakeholders to easily coordinate a rational and measured response. The actions of each stakeholder based on the information they receive about a shortage often serves as stimuli to other stakeholders, thereby exacerbating the issues. These reactions feed an active and often unproductive rumor mill, both within the professional community and the media, adding to the challenge of managing the shortage.

Messages and Mediums

The committee identified the inclusion, or desired inclusion, of key information when conveying messages about an emerging or existing drug shortage. Acknowledging the likelihood of information gaps during any future drug shortages, committee members recommended stakeholders collaborate to create common definitions and ways to share essential information.

- The common elements of a drug shortage notification should include, but are not limited to:
  - Drug and format impacted,
  - Known cause,
  - Anticipated duration of shortage,
  - Volume or scope of impact (e.g., all drug, small portion, etc.),

    - Mitigation strategy recommended. (e.g., therapeutic interchange, allocation, alternative products, etc.), and
    - Anticipated effects (e.g., change in therapy/dosing, need for extended storage, change in patient scheduling costs).
- Including these elements would enable a quick, effective response to drug shortages through all mediums of communication including:
    - Alerts (e.g., emails, letters, electronic health records at time of ordering, verbal),
    - Website listings (e.g., ASHP drug shortage site), and
    - Planning/response meetings.

Action Expected

The committee's review of the framework found most stakeholders take similar actions to respond and react to a shortage. In many cases, this improves communication and cooperation across all stakeholders when shortages occur.

- Identify and implement mitigation strategies, noting escalating negative impact.
    - Practice good drug shortage stewardship.
    - Implement allocation strategies based on historic demand and/or prioritized need.
    - Responsibly secure additional supply for customers and patients.
    - Find alternatives to sustain care for patients.
    - Cancel cases or care.
- Create or identify additional supply.
- Ramp up manufacturing, understanding this is a complicated solution.
    - Identify, warehouse, appropriately distribute to rotate stock and eventually replenish stockpiles.
    - Import supply.
    - Seek alternative manufacturing solutions (e.g., 503B compounding).
- Continuously communicate until shortage is resolved.
    - Provide regular updates on status and resolution of the cause of the shortage.
    - Share information and best practices on effectiveness of mitigation strategies.
- Proactively identify and begin working through issues that arise from shortage.
    - Create awareness of "domino" effect of shortage (e.g., leads to shortage of other formats or alternative drugs in use).
    - Impact of delayed or cancelled care.
    - Increase in time for workforce managing shortage (e.g., overtime, new work, etc.).

Feedback

As part of the framework, each stakeholder provided feedback to inform the process. These lessons highlight the challenges and begin to form the basis for opportunities to collaborate and improve across all stakeholders.

Despite the desire to have information sooner, almost every stakeholder recognized proactive communication requires a delicate balancing act during a shortage. Oftentimes, stakeholders are under pressure to act once they are aware of a real or potential shortage. This challenge can lead to surges in demand that accelerate, or even create, a shortage. To combat this, the committee recommends validating a minimum set of details and sending vetted information to stakeholders from a trusted source. Each stakeholder should also have plans and communication vehicles in place to quickly reach downstream stakeholders.

Stakeholders noted that they currently receive drug shortage information from numerous sources, but the information is not always consistent. While sources such as manufacturers, wholesalers, hospitals, ASHP, GPO, consultants and the FDA are typically trusted sources, inconsistencies, variations in timing and detail and level of accuracy creates confusion and a lack of trust. By implementing a standard set of elements with shared definitions for all drug shortage communications, the committee believes the industry can tackle this challenge.

Lastly, the committee noted the lack of a common communication system or platform creates a broken feedback loop. While various stakeholders within the drug supply chain may have communicated the necessary information, there is no way to confirm the information was received and appropriately acted upon by all parties. Further, since all communications are not sent to all stakeholders, rumors become time consuming to quell at best and disruptive at worst.

Quality Committee

Purpose

The Quality Committee connects industry stakeholders and health-system leaders to promote fundamental product quality, service quality and quality of patient care. The committee works to support drug procurement and other processes that promote quality standards for drug manufacturing and distribution. The Quality Committee's objectives include:

- Aligning on a shared definition of quality,
- Detailing how gaps in quality can negatively impact patient outcomes and product availability,
- Providing a comprehensive resource guide of quality measures, including supply chain reliability measures, and
- Eliminating quality issues that lead to drug shortages.

Audience

All EDSA members, with a focus on group purchasing organizations (GPO), health system contracting and purchasing decision makers.

Current State

With hundreds of lifesaving and life-sustaining drugs medications listed in shortage by the FDA and ASHP, patients are suffering the consequences.[5, 6] Drug shortages negatively impact patient care by increasing the risk of medication safety events, delaying, and disrupting critical procedures and increasing the cost of care when more expensive alternatives are used.

The 2019 FDA Drug Shortages Task Force report identified manufacturing quality issues as the primary driver of drug shortages and quality concerns remain a large contributor of shortages.[7] As a result, the Quality Committee brought the collective expertise of dozens of EDSA member organizations together to create a Quality Measures Resource Guide and Best Practices resource. This resource is a tool to support executive decision-making within health system pharmacy purchasing or GPO pharmacy contracting teams, with a wide range of applicability across multiple sectors.

While it's impossible to include every available resource, this resource serves as a comprehensive listing of known quality-related resources or resources committee members would like to be made available in the near future. Incorporating every listed resource in contracting and purchasing decisions is not feasible, so the committee recommends prioritizing high-impact resources and utilizing consolidated tools that aggregate inputs from many of the listed resources into simple, user-friendly formats.

Goals

Goal 1: *Communicate a shared definition of Pharmaceutical Quality with the three pillars identified by the committee.*

- Fundamental Product Quality: Does the physical product meet consumers' expectations?
  - Is the product safe and effective?
  - Was the product produced using current Good Manufacturing Practices (cGMP) and distributed under appropriate conditions?
  - Is the product within specifications?
  - Is the product free of defects?

- Service Quality: Does the service of the product manufacturer meet consumers' expectations?
  - Is the product available in adequate quantities?
  - Is the product available when and where it is needed?
  - Are ordering and access mechanisms clear and easy to use?
  - Is information transparent and readily available from the manufacturer or distributor?
  - Does the manufacturer or distributor have effective risk management plans and a resilient supply chain in place to appropriately respond to disruptions?
  - Can consumers provide feedback on supplier service quality?

- Quality of Patient Care: What impact do shortages have on the quality of patient care?
  - What medication safety hazards and risks are introduced?
  - How do shortages contribute to adverse patient outcomes?
  - Do gaps prevent providers from administering necessary medications?
  - Are resources available to manage mitigation of shortages?
  - What impacts do drug shortages have on providers?

Goal 2: *Identify quality measures, including measures that are currently available and measures that are not yet available, but should be.*

For each pillar of quality, the guide outlines resources that are currently available, the source of each resource, how to access them, whether they are publicly available and if there is a cost or additional steps to access them. See an example below:

Quality Measure	Description of Measure	Source Organization	Source Link	Access	Availability
FDA Warning Letters	FDA notifications to manufacturers of significant violations of FDA regulations.	FDA Redica	*FDA Warning Letters (5-year archives)* *Redica*	FDA – Free; Public access Redica – Subscription required	

The complete *Quality Measures and Best Practice Guide for Contracting and Purchasing Decisions* includes more than 35 quality measures and is available for EDSA members to download on the EDSA members-resources webpage.

This resource guide also includes emerging resources that may currently have a limited scope and others that do not yet exist. The Quality Committee strongly believes that additional quality resources must be supported, from development to implementation to scale-up, to best achieve our goal of ending drug shortages.

Goal 3: *Embed best practices for quality measures into contracting and purchasing decisions.*

Health systems that purchase drugs for millions of patients in the U.S. have been increasingly using specific, fundamental product quality metrics—such as levels of harmful impurities—as part of contract requirements. For example, health systems require independent certification of each batch of certain generic drug products where the certification entails independent chemical testing for multiple objective measures of fundamental product quality. Pilot programs have shown these activities do not significantly add cost to pharmacy procurement nor do they result in operational delays or detriments. Recent studies of previous drug recalls due to carcinogenic impurities have shown no significant impact to price or access of affected medications, further underscoring the need for actionable transparency to differentiate, and preferentially purchase or contract, for quality medications. [8]

Health systems and GPOs have also embedded pharmaceutical service quality measures into pharmaceutical contracting and purchasing decisions. For example, Vizient requires additional information on raw ingredient supply and additional safety stock inventory to be held through its Novaplus Enhanced Supply program. RISCS and Vizient entered into a pilot in 2022 to further understand how additional visibility into various supply chain aspects such as redundancy in raw material supply, available production capacity and production flexibility, inventory practices, location differentiation and geopolitical risks could potentially lead to more resiliency within the drug supply chain.[9] US Pharmacopeia's Medicine Supply Map, a new early warning system for possible drug shortages and supply chain mapping tool, is also being considered. TraceLink's Product Availability Intelligence tool utilizes drug serialization data to provide actionable insights that prevent critical medicine shortages up to 90 days in advance of current sources.

Embedding quality measures into contracting and purchasing decisions will increase access to essential medicines for patients and providers and incentivize manufacturers to invest in robust quality systems and resilient supply chains. A commonality between these nascent resources is that their uptake has been slow. We look forward to working together as an alliance to ensure accurate, useful quality measures are developed and appropriately included in pharmaceutical contracting and purchasing evaluations.

Supply Readiness Committee

Purpose

Ensure supply meets demand whenever and wherever possible for all drugs, especially for essential and life-saving drugs.

Audience

All drug supply chain stakeholders from point-of-need (the patient) to manufacturers of the active pharmaceutical ingredient (API) and API precursors of any particular drug, including all stakeholders in between, such as purchasers and distributors.

Current State

The Supply Readiness Committee seeks answers to the fundamental questions surrounding Supply Readiness. These questions are simple and intuitive: *What is "supply chain readiness?" What constitutes "good" supply readiness? What constitutes "bad" supply readiness? What are the barriers to supply readiness, and what are the best practices of supply readiness? When a drug shortage occurs, what should be done, when, and by whom?* The answers to these simple and intuitive questions are, however, not simple or intuitive. Furthermore, committee members suspect the answers to each of these questions differs for different drugs and their supply chains. This is why the EDSA Supply Readiness Committee is pursuing answers to these questions on a drug-by-drug, one-by-one basis. The committee will first analyze the supply chain for albuterol. As more drug supply chains are analyzed, the Supply Readiness Committee will look for trends and common denominators.

Goals

1. Prevent and end drug shortages by ensuring that supply can and does meet demand whenever and wherever possible. This includes local, regional and worldwide shortages.

2. Minimize and quickly recover from drug shortages by being prepared for them in the form of having and continuously maintaining drug-specific lists of pre-vetted actions and best practices that can be immediately utilized to minimize the impact of a specific drug shortage and to expedite recovery from that specific shortage.

Barriers

Drug supply and demand landscapes are broad, drug-specific and always changing. These challenges can be addressed by continuously monitoring the landscapes for changes in the supply chain and by making adaptations in response to those changes. Other challenges, however, will be much more difficult to address. These other challenges include:

- Availability, accuracy and completeness of both supply and demand data for specific drugs,
- Practical limitations of and the long times required for increasing drug production (response timelines),
- Regulatory constraints, and
- Trust or distrust of buyers, sellers, distributors, prescribers, pharmacists, administrators and patients.

An additional complicating factor is that many of the stakeholders in the supply chain can have fundamentally different goals concerning the provision and the business of health care. For example, how do you reconcile the goal of restoring the health of a patient with the goal of a for-profit business making a profit by selling health-restoring products and services? Both goals are necessary, and neither goal is bad, but these goals can be diametrically opposed, and therein lies the complication.

Addressing the challenge of availability, accuracy and completeness of both supply and demand data for specific drugs is intuitively simple but quite difficult to execute. Who has this data or at least parts of it? Does anyone, anywhere have a complete set of supply and demand data for a specific drug? Even if someone has a complete set of supply and demand data for a specific drug, can they legally provide that data during a drug shortage without compromising intellectual property restrictions or violating laws that ban anti-competitive practices? Answering these questions involves formidable challenges.

Unfortunately, acquiring good supply and demand data is just the first step in the process of adjusting and re-distributing the supply of a specific drug to meet demand. That process can take months under non-shortage conditions; the urgency of an acute shortage only exacerbates the problems of making such adjustments. Assuming enough data of sufficiently good quality can be acquired quickly enough to allow drug suppliers and distributors to make rational adjustments to drug supply, the response timeline for such adjustments

could still take months to achieve. The EDSA Supply Chain Readiness Committee looks closely at how these response timelines can be improved.

Shortening response timelines in drug supply and distribution is one of the more daunting challenges that the Supply Readiness Committee faces. To understand this challenge, it's important to understand that drug manufacturing is not like most other types of consumer product goods (CPG) manufacturing. Whereas most CPG production can be adjusted within days or weeks to meet changing demand, drug manufacturing can require months to increase production. Typically, pharmaceutical drug manufacturing requires balancing supply and demand over a nine-to-24-month time frame. This is due to the combination and dynamic interaction of data, regulatory constraints, trust/distrust and differing goals of various entities along the entire healthcare supply chain. Gaining knowledge and understanding of the interaction between these pieces is a key part of what the Supply Readiness Committee must do in order to make rational recommendations about actions to take when a drug shortage occurs.

The combination and dynamic interaction of this vast array of factors can, and does, lead to uncertain and untimely decisions and outcomes. Uncertainty about the data alone, combined with long timelines, makes it difficult to balance upstream factors. These factors include the length of time required to ramp up manufacturing, related product testing and regulatory requirements as well as downstream factors like the shelf life of manufactured products and changes in prescribed therapies.

Human-based uncertainties exacerbate these problems. The lack of trust and confidence among all of the decision-makers in these supply chains play significant roles in the supply/demand dynamics for pharmaceutical drugs. Hospitals and pharmacists may lack confidence that a manufacturer can or will deliver a product in sufficient quantities at a cost-effective price with sufficient quality and within their required timeframes. Decision-makers at drug manufacturers may be leery to commit time, money and resources to manufacture additional supplies that won't be needed or wanted. There is also the possibility that the manufacturer will not be allowed to sell the product due to unforeseen regulatory issues. The fee-for-service wholesaler system that stocks drug products based on the demand of certain manufacturers may not widely stock other manufacturers' products. Further, due to new regulatory requirements surrounding drug serialization, it is becoming more challenging to rebalance distribution center inventories during shortages.

Action Expected

The Supply Readiness Committee has created strategic and tactical plans to achieve its goals.

1. Identify how to acquire and then obtain high quality supply and demand data for a specific drug.

2. Identify and rank all the factors that control or influence the supply and demand data for this specific drug.

3. Identify the risks associated with all these factors, including what is known, what is not known, what can be known and what cannot be known about the supply and demand data.

4. Identify specific risk mitigation strategies and tactics that will help prevent this drug from going into shortage, understanding that no single variable will ever tell us everything we need to know or fix any given situation.

5. Identify what can be done, when and by whom if this drug goes into shortage and specify the anticipated outcomes of these actions.

6. Identify what should be done, when and by whom if this drug goes into shortage and specify the anticipated outcomes of these actions.

7. Connect the supply chain to get the right things to the right people in the right places at the right times.

8. Continuously monitor the supply and demand landscapes for this drug, note changes and adapt the recommendations as needed.

9. Repeat this evaluation process for multiple drugs and look for patterns in the findings across all drugs evaluated. Then recommend courses of action that affect the Supply Readiness Committee's long-term goal of better understanding supply and demand.

10. Evaluate patterns observed in recommendations aimed at preventing, minimizing and expediting recovery from shortages, to determine if quantitative mathematical modeling and analysis can be used to assess, characterize and perhaps even proactively identify potential drug shortages.

The strategic plan outlined above has been developed into a tactical plan that the Supply Readiness Committee will use to perform its work. However, the details of the tactical plan are beyond the scope of this white paper. Executing these plans will involve practical steps such as identifying key groups with access to the supply and demand data for the specific drug and then establishing timely, accurate and reliable communication channels among those key groups. The most difficult and time-consuming aspects of performing this work will involve the detailed, wide-ranging analyses and evaluations of the many factors that contribute to and influence supply and demand. Some of these factors will be simple, such as time, money, quality and medical-necessity, and some factors will be much more subtle categories like dosage form, required drug storage conditions, unintended regulatory constraints, geographic distribution issues and even geopolitical factors. In all cases, the Supply Readiness Committee will work to identify and rank all such factors and then identify actions that are possible and legal to do now, and actions that should be recommended as policy or legal changes that allow for future implementation.

Pediatric and Special Populations Committee

Purpose

The Pediatric and Special Populations Committee works to call attention to groups with unique needs to assure that EDSA efforts create a positive impact for these populations rather than a negative one.

Audience

All EDSA members, especially group purchasing organizations, distributors, health system contracting and purchasing decision makers, as well as government agencies and policy makers.

Current State

Drugs and supplies intended for children and special populations are unique. Many pediatric drugs come in formulations to support safer dosing, such as an altered concentration or format. To best serve our most vulnerable populations, pediatric-specific supplies are created with sensitive skin, growing bodies and smaller sizes in mind. These pediatric products are not used as often as standard products and are frequently the first affected by shortages.

When drugs or supplies are in, or nearing, shortage, important patient procedures may be delayed or even canceled. Sometimes the location of care must abruptly change, meaning care intended to be administered in a setting close to a child's home may have to be moved to a main hospital. Shortages can also affect care protocols when drugs or supplies must be changed to alternatives. Any of these situations can put unnecessary burden on patients and families by causing patients to miss school and activities. The caregiver might also miss work or be unable to care for other children in the family. Children's hospitals have long dealt with shortages of drugs and supplies that patients rely on for care, treatment and recovery.

The Pediatric and Special Populations Committee is currently focused on the current gaps and next steps for pediatric patients and will eventually expand to other special populations, and they will apply their learnings to all disproportionately affected populations.

Next Steps

The committee uses data from suppliers and hospitals to determine the effect of drug shortages and pediatric-specific needs. After that, we determine how pediatrics are disproportionately affected, as compared to adults, and why the shortage has occurred. Currently, there are gaps in defining which medications disproportionately affect pediatric and special populations. For example, the FDA shortage list does not recognize special populations or specific dosage forms needed by special populations, when alternative dosage forms remain available, such as bulk albuterol and oral sildenafil solution. Additionally, adjusting the FDA drug shortages list to account for pediatric and special population drug formulations remains a policy priority for the EDSA. There are also gaps in supporting special populations and pediatrics in the 503B market, which is only able to respond to shortages when a drug is listed on the FDA drug shortage list.

Work is underway to define the disproportionate impact and create the first pediatric score card for essential medications for pediatric and special populations. Additional projects include collaboration with other EDSA committees such as:

- Supply Readiness: Reduce the risk of pediatric drug and supply shortages by encouraging readiness to supply and competition in production of pediatric products that are often sole-sourced or under-resourced.
- Transparency and Redundancy: Ensuring additional transparency within the supply chain, including the location of production, to heighten awareness and garner support for the needs of pediatric and special populations.

Action Expected

Finally, the group will organize and share best practices and educational resources for health-system level drug use and inventory management for specific, disproportionate pediatric medications and unique patient populations.

Report Conclusion

Drug shortages are unacceptable, especially critical shortages of essential, life-saving drugs. The End Drug Shortages Alliance (EDSA) was created in November 2021 to minimize and ultimately prevent pharmaceutical supply chain disruptions to categorically end drug shortages. The EDSA provides a multi-stakeholder forum across the entire pharmaceutical supply chain from patient to manufacturer to facilitate connections and foster dialogue that can subsequently lead to informed, data-based decisions and rational actions by stakeholders. The ultimate results of the EDSA's activities will lead to improved quality and resiliency of pharmaceutical supply chains and a transition from reactive minimization to proactive prevention of drug shortages.

We must all work together to categorically end drug shortages. If you are a member of the EDSA, thank you. Please continue your efforts to end drug shortages. If you are not a member of the EDSA, this is your call to action and your invitation to join. Please join the EDSA by emailing info@enddrugshortages.com or by visiting www.enddrugshortages.com.

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End Drug Shortages Alliance

Formed in December 2021, the End Drug Shortages Alliance brings together health systems, manufacturers, and other industry stakeholders across the supply chain who are dedicated to solving pharmaceutical supply challenges by collaborating to increase visibility, access, and advocacy. Collectively we will end drug shortages through focus on transparency, communication, quality, redundancy, and supply readiness to achieve measurable and sustainable results.

To learn more, please visit enddrugshortages.com, or contact us at info@enddrugshortages.com.