

In July 2023, the ASHP Drug Shortages Resource Center was updated with the latest quarterly drug shortage statistics from the University of Utah Drug Information Service.¹ At the end of the second quarter of 2023, there were 309 active, ongoing drug shortages — the highest number in nearly a decade and close to the all-time high of 320 shortages. ASHP surveyed a sample of its members to learn the severity and impact of ongoing shortages of select categories of drugs. The survey also collected information about the management of drug shortages, the estimated impact to pharmacy budgets, and interest in manufacturer and product quality.

The survey results include responses from 1,123 participants who answered at least part of the online questionnaire. The survey was conducted from June 23 through July 14.

KEY FINDINGS

- Over 99% of respondents reported they are experiencing drug shortages.
- Most respondents categorized the current state of drug shortages as either critically impactful (32%) or moderately impactful (63%). Critically impactful was defined as rationing, delaying, or canceling treatments or procedures.
- More than half of respondents (57%) said shortages of antineoplastic (chemotherapy) drugs were critically impactful.
- Most respondents who are involved in their department's annual budgeting process estimated that drug shortages add between 5% and 20% to the budgets.
 - » 73% of respondents estimated between a 6% to 20% increase in their drug budget.
 - » 71% of respondents estimated between a 0% to 15% increase in their labor budget.
- 87% of respondents who are involved with purchasing decisions rated manufacturer and product quality as very important.
 - » 59% would preferably buy products from manufacturers that meet a predefined quality standard — potentially addressing one of the major root causes of drug shortages.
 - » 85% would be willing to spend 5% or more above their annual generic injectable drug budget to buy from manufacturers that achieve quality recognition.

SURVEY PARTICIPANTS

The survey was deployed to a sample of ASHP members on June 23 and generated 1,123 useable responses after excluding participants whose roles were not applicable to the questions. Three email reminders were sent to the survey sample. The survey was closed on July 14.

Demographics

- Participant category (n = 1,123)
 - » Pharmacists (93%)
 - » Pharmacy technicians (5%)
 - » Pharmacy residents (1%)
 - » Other (1%)
- Work setting (n=1,123)
 - » Hospital or health system (88%)
 - » Ambulatory clinic or similar setting (6%)
 - » Other settings, such as long-term care, home infusion, and home care (4%)
 - » Outpatient or specialty pharmacies (2%)

- Hospital size (based on patient beds) among applicable participants (n = 915)
 - » < 200 beds (24%)
 - » 200–499 beds (36%)
 - » ≥ 500 beds (41%)
- Prescription volume among applicable participants (n = 426)
 - » < 200 per day (27%)
 - » 200–300 per day (14%)
 - » 301–400 per day (19%)
 - » > 400 per day (48%)

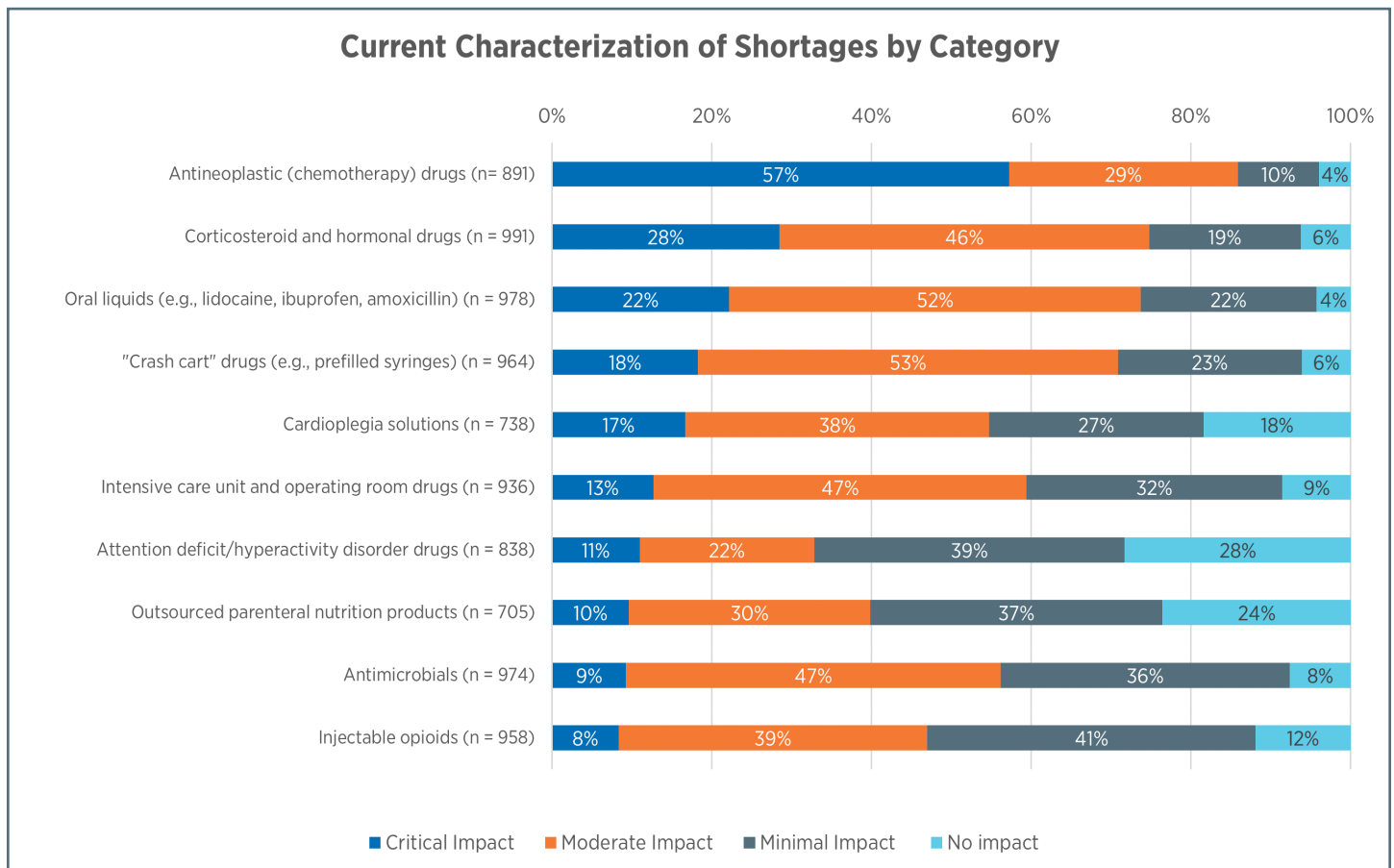
SURVEY RESULTS

Severity of Shortages

Participants were asked to rank the current state of drug shortages using a scale of not experiencing a shortage, minimal impact (managing shortages through operational changes with no effect on patient care), moderate impact (managing through operational strategies but also affecting patient care), or critical impact (rationing, canceling, or delaying treatment or procedures).

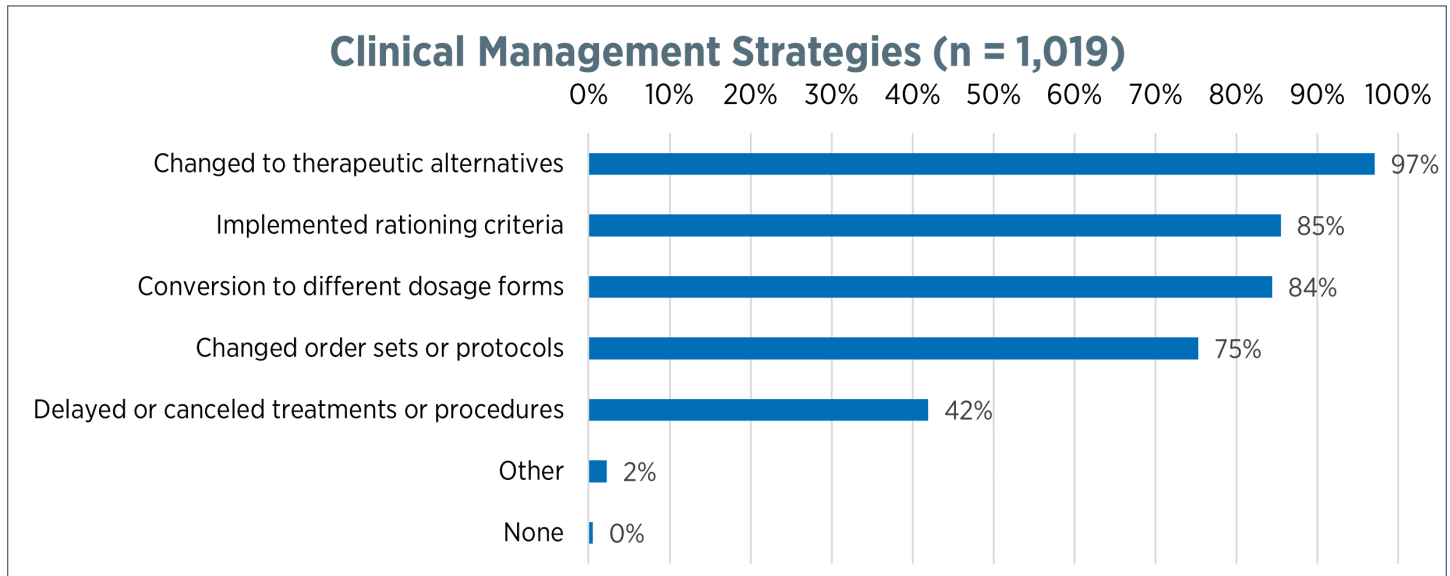
About one-third (32%) of respondents characterized the current state of drug shortages as critical, and 63% characterized them as moderate. Four percent characterized shortages as having minimal impact. Only three respondents indicated their organization was not experiencing any shortages.

Respondents were asked to further characterize the severity of shortages by specific categories of drugs. Not all of these drug categories are used in all care settings, so calculations are based on the number of responses for each category and exclude “not applicable” responses.

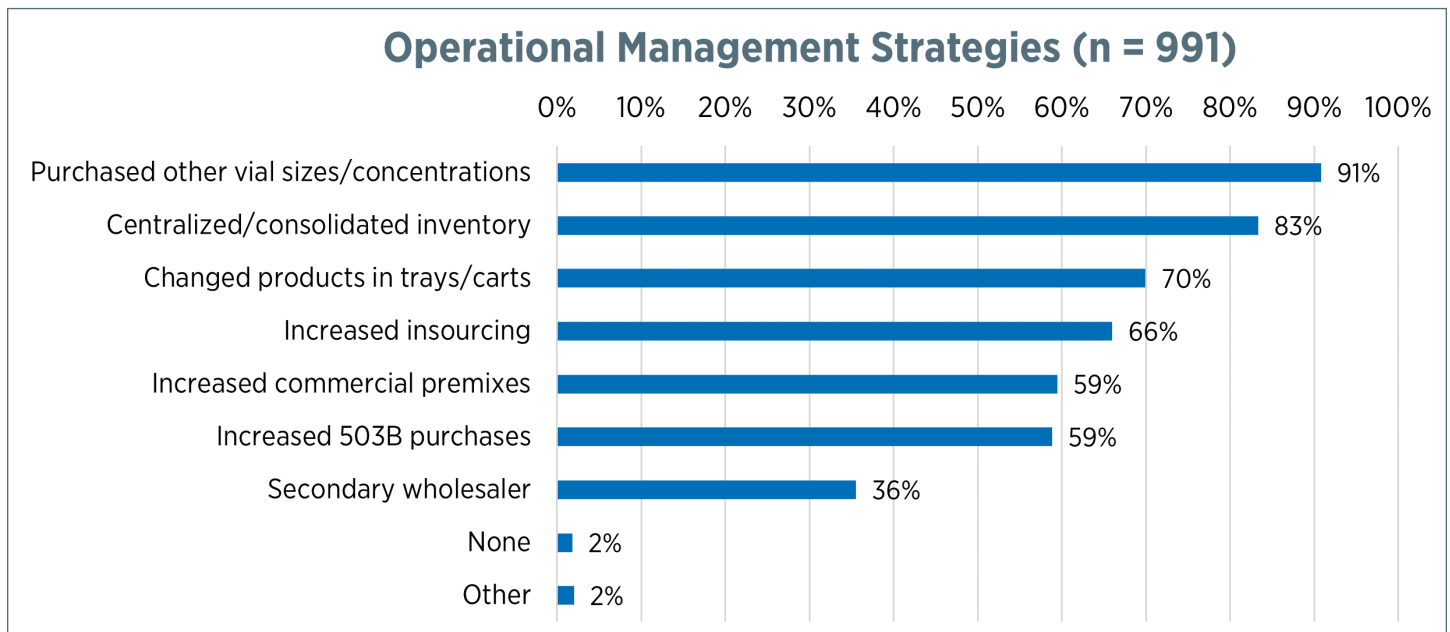


Managing Shortages

Survey participants were asked about clinical and operational management of current drug shortages. Clinical management often affects how a patient receives treatment, such as switching to a therapeutic alternative or a different route of administration (e.g., an oral tablet instead of an intravenous injection).



Operational management refers to strategies generally used within the pharmacy and affect how a drug is purchased, prepared, or stored. Examples include purchasing packages and dosage forms not typically stocked and shifting inventory to closely monitor quantities on hand.



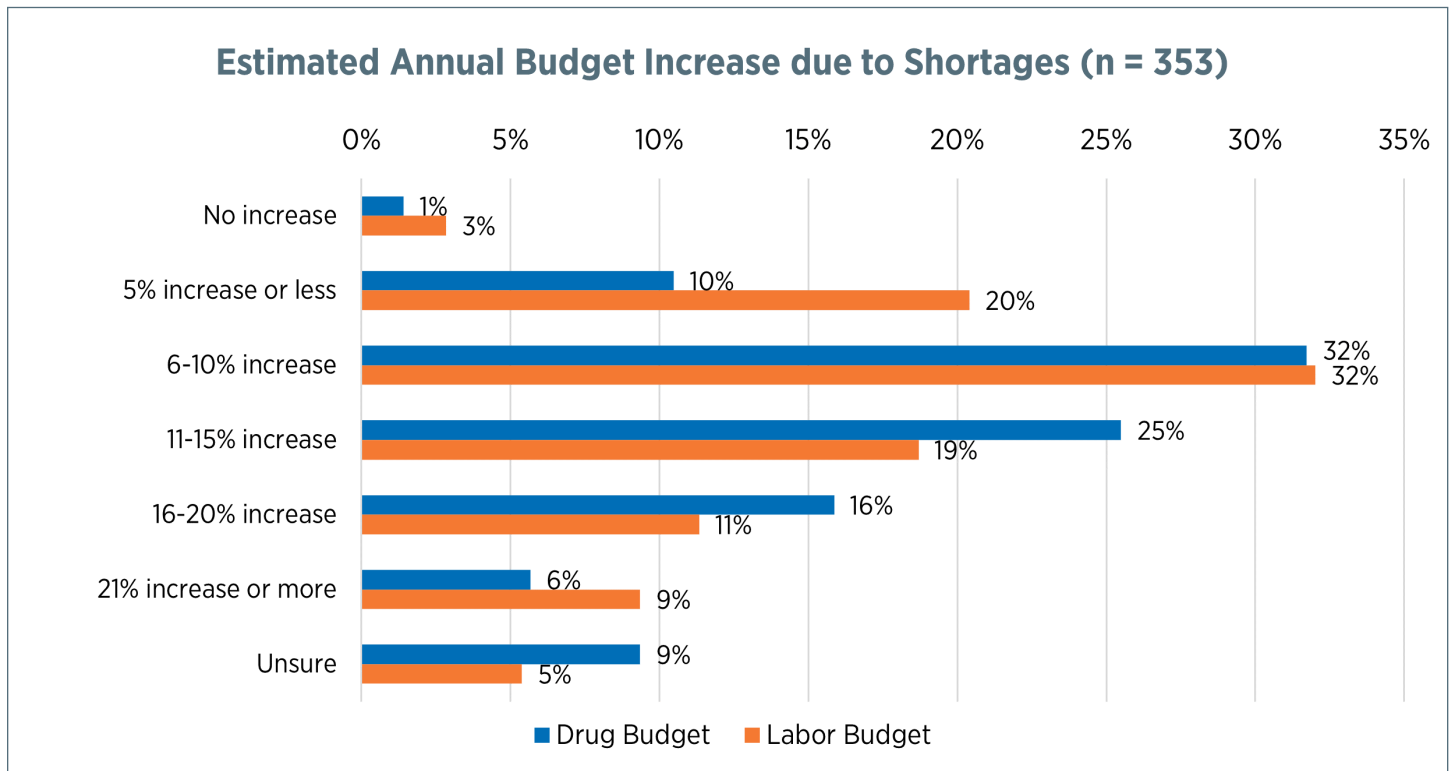
The Cost of Shortages

Managing drug shortages is a labor-intensive process. Operational and clinical drug shortage management strategies can divert time and resources away from clinical care. An analysis published in 2019 estimated that the annual labor cost of drug shortages to U.S. hospitals is \$359 million.² Purchasing alternative package sizes or concentrations, sourcing from alternative suppliers, and purchasing products from 503B outsourcing facilities can also increase spending on drug products.

Survey participants were asked if they are involved in their department’s annual budget process. The 354 respondents who reported budget involvement were asked to estimate the increase over baseline that drug shortage management adds to their labor and drug budgets.

Respondents estimated a larger impact on their annual drug budget compared to annual labor expenses.

- In both categories, the majority of responses were between a 5% and 15% increase over baseline.
- The two most common ranges for drug budgets were a 6–10% increase (32%) and 11–15% increase (25%).
- The two most common ranges for labor budgets were a 6–10% increase (32%) and a 5% increase or less (20%).



Manufacturing and Drug Quality

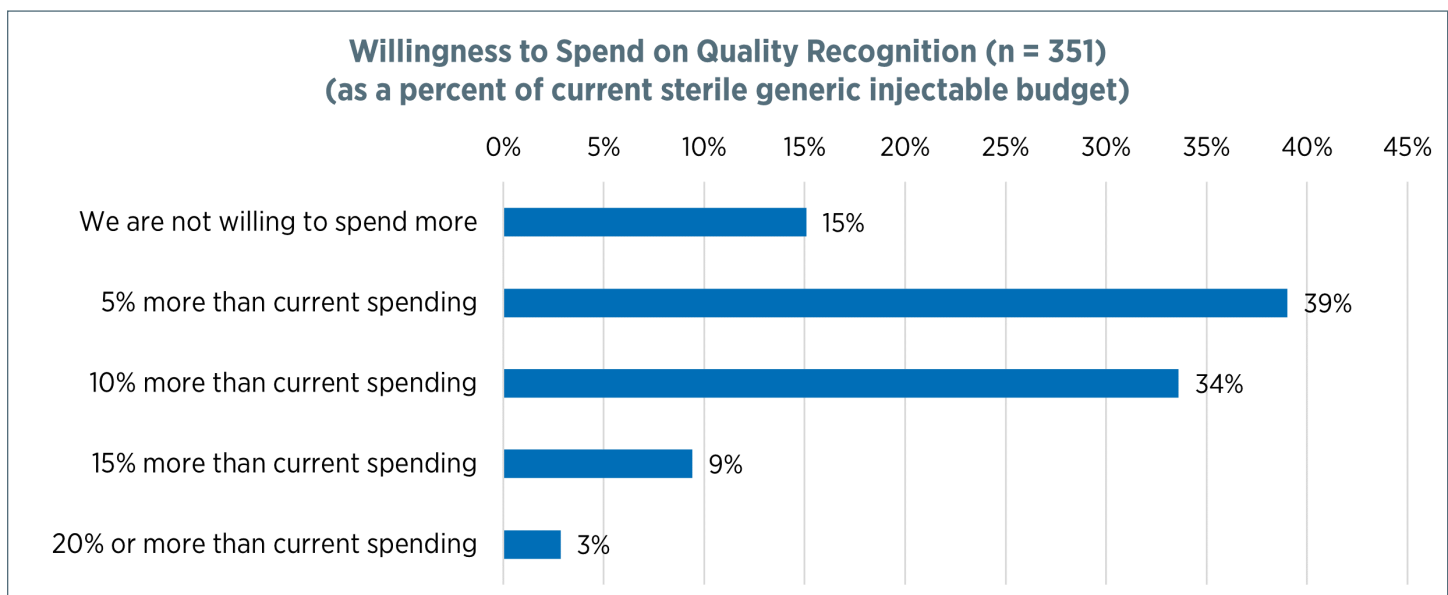
A 2019 report issued by the U.S. Food and Drug Administration (FDA) identified the lack of market recognition of mature quality systems as a root cause of drug shortages.³ Survey participants were asked if they had input into purchasing and formulary decisions. The 617 respondents who indicated involvement with purchasing decisions were asked about the role of drug and manufacturer quality in deciding which products to buy.

- 87% reported that manufacturer and product quality were very important.
- 54% routinely considered quality when making purchasing decisions, and another 36% consider quality some of the time depending on the specific drug.

Importantly, 59% said they would preferably purchase drugs from a manufacturer that achieves a predetermined quality standard, potentially addressing the root cause identified by the FDA report and providing market recognition of mature quality systems. And 40% would consider purchasing products that are preferred on their group purchasing organization (GPO) contracts, highlighting the important role GPOs can have in recognizing mature quality systems as part of their contracting process.

Quality Recognition Programs

The 354 survey respondents who said they participate in drug budgeting were also asked if they are willing to spend more on drug products from manufacturers that achieve quality recognition. In all, 85% were willing to spend more on such products. Most respondents were willing to spend 5% more (39%) or 10% more (34%).



The concept of a quality recognition program for drug manufacturers is not new. A 2013 article written by FDA staff and published in *Clinical Pharmacology & Therapeutics* concluded that the agency could support purchasing decisions by providing manufacturer quality metrics.⁴ While there are potential unintended consequences of quality metrics or a rating system for drug manufacturers,⁵ the drug shortage crisis is not improving under the status quo.

Despite speculation that purchasers may not pay more for products from manufacturers that achieve quality recognition, the survey data emphasize that quality is important to purchasers — and many are willing to spend more for the assurance of manufacturer quality.

REFERENCES

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