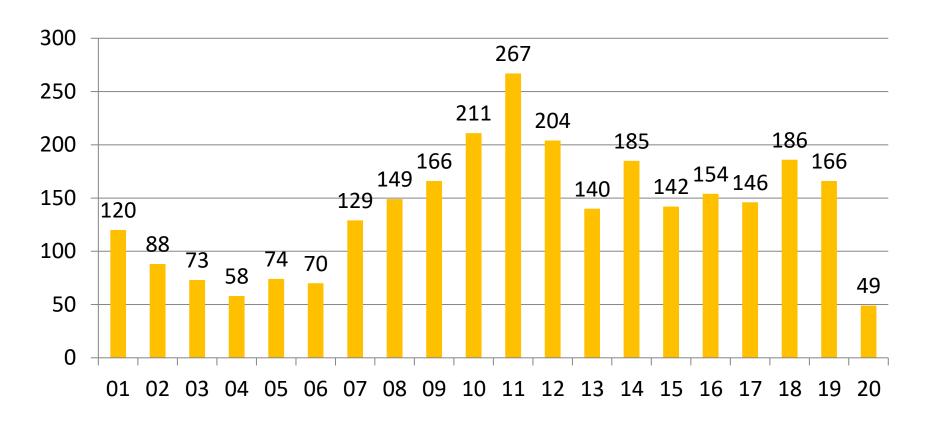
Drug Shortages and Supply Chain Quality

Erin R. Fox, PharmD, BCPS
University of Utah Health

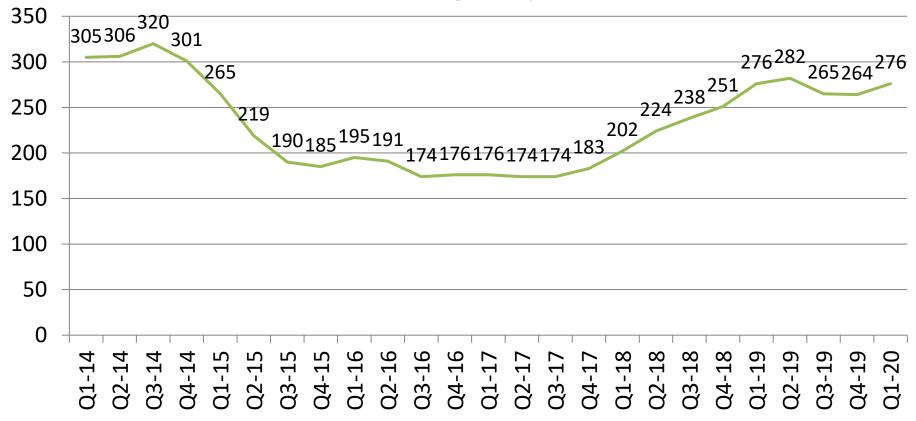
National Drug Shortages - New Shortages by Year January 2001 to March 31, 2020



Note: Each column represents the number of new shortages identified during that year. University of Utah Drug Information Service

Erin.Fox@hsc.utah.edu, @foxerinr

National Drug Shortages Active Shortages by Quarter



Note: Each point represents the number of active shortages at the end of each quarter. University of Utah Drug Information Service

Erin.Fox@hsc.utah.edu, @foxerinr

What do these numbers mean?

- Hospitals were already experiencing shortages of key injectable drugs prior to COVID-19
- Unprecedented demand due to surge of critically ill patients with COVID-19 is worsening shortages, especially analgesics, sedatives, and paralytics
- Most shortages due to manufacturing problems / poor quality
- Patients have been harmed by poor quality products

"... supply chain challenges stem from a global manufacturing system that needs a much greater emphasis on quality."

Ideas to Improve Quality

"to truly eradicate...drug shortages, manufacturers must not only comply with GMP, but must also must invest in modernizing and/or improving manufacturing quality systems."

- No requirement to disclose which company or factory makes a product.
- FDA sees quality differences between companies and products but does not disclose – simply pass/fail
- Provide public quality ratings to allow payers and patients to reward companies with higher quality products

European journal of clinical pharmacology. 2014;70(12):1405-1412. Clinical pharmacology and therapeutics. 2013;93(2):170-176. https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions.