

COVID-19 casts new light on an old problem: Drug shortages

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Hospitals have been experiencing drug shortages for decades, but the influx of critically ill patients with COVID-19 and the scramble to try off-label treatments for the disease have driven up the number of medications in short supply. An AMA webinar provided an update on national drug-shortage trend data and summarized efforts underway to head off shortages both during the pandemic and long term.

The webinar, “National Drug Shortages: Reacting to Current Shortages and Proactively Anticipating the Future,” was hosted by the AMA Organized Medical Staff Section. Led by Amy B. Cadwallader, PhD, director of science and drug policy at the AMA, the webinar also provided links to useful resources for tracking and reporting shortages in your region.

The AMA and the Centers for Disease Control and Prevention are closely monitoring the COVID-19 pandemic. Learn more at the AMA COVID-19 resource center and the AMA’s physician guide to COVID-19.

No let up in 2020

While drug shortages had been going down nationally in 2017 and 2018, they began to tick up again in 2019, when there were 166 new shortages for the year and more than 260 active shortages in any quarter. In the first quarter of this year, there were 49 new shortages and over 270 active shortages.

“One of the things that is noteworthy that we’re hearing from officials is that shortages really do vary by drug and by location,” Cadwallader said, noting that the five classes of drugs most in shortage are central nervous system medications, antimicrobials, cardiovascular medications, ophthalmic and chemotherapy agents. “So where you are might impact the shortages that you’re seeing.”

The COVID-19 pandemic has worsened some shortages and created others. Roughly half of all drugs in shortage are injectables, including analgesics, sedatives and paralytics used for intubating critically

ill patients. Meanwhile, off-label prescribing of rumored COVID-19 treatments—hydroxychloroquine is the most obvious example—has created drug shortages for patients with chronic illnesses, such as lupus and rheumatoid arthritis.

Read about responsible prescribing in a pandemic, as well as a joint statement of the AMA, American Pharmacists Association and American Society of Health-System Pharmacists on ordering, prescribing or dispensing COVID-19 medications.

More transparency needed

Though demand for drugs is fairly well understood, supply of drugs is not. A whopping 82% of shortages in 2019 were for unknown reasons, Cadwallader noted, according to the American Society of Health-System Pharmacists and the University of Utah Drug Information Service.

“Many manufacturers at this point are reluctant to release some of that information on the grounds that it is confidential or proprietary or patented,” Cadwallader said, noting that the Food and Drug Administration (FDA) may be aware of some of the details but cannot report them to the public.

Still, the FDA’s own Drug Shortage Task Force issued a report in 2019 stating that more than 60% of shortages from 2013 to 2017 were due to manufacturers’ quality issues. It also cites the lack of incentives for manufacturers to produce low-margin drugs and the failure to incentivize manufacturers to invest in quality management programs as root causes.

The AMA has policy on national drug shortages, which supports recommendations that have been developed by stakeholders to improve manufacturing quality systems and advocates for numerous other activities to address this urgent public health crisis.

Report the shortages you see

The AMA has been working with numerous stakeholders—including the FDA, the Drug Enforcement Administration (DEA) and the American Society of Health-System Pharmacists—to increase supplies of drugs in shortage and ease regulations during the COVID-19 pandemic.

This has already resulted in the DEA’s increasing quotas of injectable Schedule II controlled substances and making exceptions to regulations for DEA-registered hospitals and clinics, as well as the FDA’s issuing a new policy allowing repackaging of propofol into new volumes and quantities.

“This is going to be my ask for you: to let us know, over the next several weeks, months, on an ongoing basis, if you or members of your medical society or members of your staff encounter issues related to controlled substances,” Cadwallader said, asking physicians to email the AMA’s Science, Medicine and Public Health staff at SMPH@ama-assn.org.

She also stressed the importance of reporting shortages to the FDA by email or phone or via the agency’s smartphone app, which also provides updates on drug shortages and notifications.

“Because remember, if the people who can help don't know that they need to help, then they have a hard time doing that,” Cadwallader said.