



ACMT

American College
of Medical Toxicology

ACMT Position Statement: Medication Shortages During Coronavirus Disease Pandemic

Prescription drug shortages are a major public health problem, and the coronavirus disease 2019 (COVID-19) pandemic has the potential to further precipitate critical shortages of essential medications. These shortages may compromise quality of care and pose a threat to patient safety at a time when the healthcare system is overwhelmed by critically ill patients. ACMT calls upon stakeholders to implement measures to ensure patient safety and access to medications in the setting of this unprecedented global pandemic.

Background

In recent years, shortages of drugs and basic medical supplies- including saline solutions and sterile water- have affected all medical specialties.¹⁻⁵ Historically, prescription drug shortages primarily impact generic injectable products and are commonly caused by quality problems at production sites.^{1,2-6}

COVID-19 Drug Shortages

The COVID-19 pandemic first recognized in 2019 in Wuhan, China will result in critical drug shortages for a variety of reasons. First, nearly two-thirds of active ingredients for generic drugs are made in China, where illness and mandatory business shutdowns have interrupted the production and export of drugs.⁷ Medications manufactured in India are also affected by illness and quarantine. That nation has, for the moment, banned exportation of several medications, including hydroxychloroquine.

In addition to supply factors, domestic demand is anticipated to drive shortages of key medications. Because many COVID-19 patients require mechanical ventilation, we anticipate high demand for sedatives, analgesics, and paralytics. Sedatives and analgesics are commonly affected by drug shortages, even prior to the current pandemic. Demand has risen for sedatives by 51% and for analgesics by 67% in the

month of March. Both have had fill rates of less than 100%, setting up concerns for impending shortages.⁹ Insufficient sedation may result in patient discomfort and unplanned self-extubation of mechanically ventilated patients, which is harmful to patients and places staff at risk of disease transmission. Multifocal pneumonia and sepsis will require treatment with antibiotics and vasopressors, which have also already been affected by drug shortages.^{2,3} Although chloroquine and hydroxychloroquine recently received emergency use authorization from the Strategic National Stockpile by the Food and Drug Administration for COVID-19 treatment, there are already reported shortages of these medications. This shortage is caused by a combination of importation restriction and increased demand, caused in part by hoarding of medications, clinical trials for the treatment of COVID-19, and off-label use. Although wholesalers have responded to hoarding by allocating products based on past purchase history, hospitals surging to accommodate 2-5 times the number of patients will still need a proportional increase in medications.⁹ As a result, patients who are on hydroxychloroquine for autoimmune diseases have reported difficulty obtaining their chronic medications.¹⁰ Because nebulizer treatments can aerosolize and promote coronavirus transmission, increased demand for metered dose inhalers has impacted availability of these items as well. Additionally, patients with underlying lung disease may have worsening of their disease in the setting of COVID-19, which may further increase demand.¹¹

Effects of Drug Shortages

Drug shortages have the potential to impact patient care.¹²⁻¹⁴ When a first-line medication is not available, therapeutic alternatives may be less effective or more toxic. Substitution of a less familiar product can result in errors in several ways. A dosing error may occur when the usual concentration is unavailable and a different concentration is substituted or when pharmacies must compound products previously available in a pre-mixed form.¹³⁻¹⁵ Although some product can be conserved by using vials multiple times to minimize waste, this practice can compromise sterility.¹⁶ Information technology resources are required to safeguard against medication errors by making changes in the electronic health records or barcode scanners; however, these resources may be in short supply in the setting of a pandemic.

Given the impact drug shortages can have on patient care and safety, and the healthcare system as a whole, ACMT calls upon stakeholders to implement measures to mitigate the impact of drug shortages during the COVID-19 pandemic.

Methodology

The authors performed a literature search when drafting this position statement. Only articles written in English were reviewed. All relevant articles were reviewed as well as any applicable references in the bibliography.

This document was reviewed and approved by the ACMT Board of Directors.

Recommendations

Government

- Require disclosure of the actual manufacturer of a drug and manufacturing capabilities to increase transparency.
- Lengthen expiration dates on medications that are in critical supply when this can be done safely.
- Require risk management plans on the part of manufacturers to identify vulnerabilities in the supply chain.
- Provide incentives to manufacturers who are able to divert resources to produce pharmacy products in critical shortage
- Allow for a temporary increase in importation of drugs when safe and feasible. However, the ability to do this may be limited as other countries may also be experiencing shortages and have limitations on exportation of drugs.
- The Department of Health and Human Services and the Department of Homeland Security should review drug supply, including the number of suppliers and location of production as a part of national security measures.

Manufacturers/Distributors

- Communicate with the FDA as soon as a drug shortage is anticipated and also when demand for product increases.
- Manufacturers should establish business continuity plans and redundancy in manufacturing for critical and life-saving products.
- Suppliers can also provide more transparency around which manufacturers are actually producing products as well as the location, which will help to identify problems in the supply chain.

Hospitals and Healthcare Systems

- Purchase high quality products from suppliers with reputation for availability and quality.
- Invest in information technology support and pharmacy experts to integrate alternative products into EHR ordering platforms.

- Use devices and practices that conserve metered dose inhalers (MDI), including MDI canister disinfection and BiPAP masks operated in a closed circuit. Expand institutional drug formularies to include alternative medications that may not be as commonly used to mitigate shortages.
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Health Care Providers

- Healthcare providers should establish interprofessional committees to manage drug shortages.
- Providers should establish protocols for use of therapeutic alternatives during shortages to ensure patient safety, being prepared to include even third and fourth line therapies.
- Establish protocols to minimize waste and optimize use of limited supplies.
- Consider alternate routes of administration whenever possible.
- Providers should use an ethical framework for rationing limited supplies.
- Only prescribe treatments for coronavirus for evidence-based indications.
- Discourage hoarding of medications.

Disclaimer

While individual practitioners may differ, these are the positions of the American College of Medical Toxicology (ACMT) at the time of writing, after a review of the issue and pertinent literature.

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