

## Rising antibiotic shortages raise concerns about patient care

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Shortages of key antibiotics, including gold-standard therapies and drugs used to treat highly resistant infections, are on the rise, according to a new study of shortages from 2001 to 2013 published in *Clinical Infectious Diseases* and available online. The trends raise serious concerns about the effects on patient care, particularly for infections without effective alternative treatment options.

"We found a tremendous number of drugs that are used to treat life threatening infections that just were not available," said study author Larissa May, MD, of George Washington University. "There are implications that patients may not do as well clinically or potentially even die because these agents are not available."

Analyzing data from the University of Utah Drug Information Service database, a national database of <u>drug shortages</u>, the researchers found that 148 antibiotics experienced shortages during the study period, with an upward trend starting in 2007. Almost half—46 percent—of the shortages involved antibiotics used to treat high-risk pathogens, including C. difficile, carbapenem-resistant Enterobacteriaceae (CRE), methicillin-resistant Staphylococcus aureus (MRSA), and Pseudomonas aeruginosa, among others.

Shortages, as defined by the Food and Drug Administration (FDA), are situations in which the total supply of all clinically interchangeable versions of an FDA-regulated drug product is inadequate to meet the projected demand. A shortage can occur for several reasons, including



manufacturer mergers, facility consolidation, manufacturing quality issues, and narrow profit margins for generic drugs.

In the study, a high proportion of recent antibiotic shortages affected broad-spectrum antibiotics, injectable drugs, medications with no alternative sources, or those used to treat infections with limited alternative treatment options or pediatric patients. Many involved gold-standard therapies, such as aztreonam, which treats serious infections in patients allergic to penicillin, and trimethoprim/sulfamethoxazole for the treatment of pneumocystis pneumonia.

Thirty-two antibiotics (22 percent) experienced multiple shortages, with a median duration of more than six months. At the end of the study period in December 2013, 26 <u>antibiotics</u> were still in short supply or not available.

Several measures could help limit the impact of antibiotic shortages on patient care, the study authors noted. Mandatory earlier reporting of shortages by manufacturers would make this information more available, allowing more time to make contingency plans. Similarly, improved communication between pharmacists and clinicians so physicians are aware of shortages earlier—before they attempt to prescribe a drug that's not available—would also help.

Institutions could also prospectively track potential shortages and make recommendations for safe and appropriate alternatives. Antibiotic stewardship efforts, guideline development, and clinician education on alternative treatment options could play important roles as well.

"This is a big problem, one that we don't really yet have a strategy to deal with," Dr. May said. "There are some significant implications for <u>patient</u> <u>care</u> that are very disturbing and are likely to become more significant unless we take steps to mitigate them."



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