Infectious outbreak in critically ill children leads to recall of contaminated medication

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Infection prevention and control experts at Texas Children's Hospital halted a 24-patient outbreak of Burkholderia cepacia in critically ill children after identifying docusate, a liquid stool softener, as the underlying source of the bacteria. Details of the six-month investigation, published online in *Infection Control & Hospital Epidemiology*, the journal for the Society for Healthcare Epidemiology of America, led to a national recall of all liquid products manufactured by PharmTech.

"Using a multidisciplinary approach and by sharing information with other institutions, our detailed investigation stopped short a national outbreak of *B. cepacia*" said Lucila Marquez, MD, MPH, lead author of the study. "This work also provided our team an opportunity to improve our infection prevention practices for the care of all patients."

After identifying a cluster of critically ill-infected patients, the infection control and prevention team launched a detailed investigation to identify risk factors for infection. The team also sought to audit infection control practices by assessing hand hygiene and other care practices of the health care team and performing environment of care rounds with members of the clinical care and environmental services teams.

Testing of patient samples identified the bacteria and showed that the samples were the same strain of *B. cepacia*, a bacterium found in water and previously linked with contaminated products. The team cultured various water sources, products, medications, and formulas. This testing identified unopened syringes of liquid docusate revealing the same

bacteria strain as found in the patients. The team determined that a median of 13.5 doses (range 2-78) of the docusate were given to each patient before positive culture with a median time of 16.5 days (range 1-81) from the first dose.

The team submitted the strain to the Research Laboratory and Repository at the University of Michigan. The laboratory confirmed the strain and that it had never before been identified in the 20-year-old repository of bacteria, but shortly thereafter was identified in samples submitted by another pediatric healthcare institution.

As a result of the investigation, the FDA announced a voluntary nationwide recall of the product, and the Centers for Disease Control and Prevention recommended that liquid docusate generally not be used in any patients.

More information: Lucila Marquez et al, An Outbreak of Burkholderia cepacia Complex Infections Associated with Contaminated Liquid Docusate, *Infection Control & Hospital Epidemiology* (2017). DOI: 10.1017/ice.2017.11

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