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Clostridium sordellii Toxic Shock Syndrome After Medical Abortion with Mifepristone and Intravaginal Misoprostol — United States and Canada, 2001–2005

On July 19, 2005, the Food and Drug Administration (FDA) issued a public health advisory regarding the deaths of four women in the United States after medical abortions with Mifeprex® (mifepristone, formerly RU-486; Danco Laboratories, New York, New York) and intravaginal misoprostol (1). Two of these deaths occurred in 2003, one in 2004, and one in 2005. Two of these U.S. cases had clinical illness consistent with toxic shock and had evidence of endometrial infection with Clostridium sordellii, a gram-positive, toxin-forming anaerobic bacteria. In addition, a fatal case of C. sordellii toxic shock syndrome after medical abortion with mifepristone and misoprostol was reported in 2001, in Canada (2). All three cases of C. sordellii infection were notable for lack of fever, and all had refractory hypotension, multiple effusions, hemoconcentration, and a profound leukocytosis. C. sordellii previously has been described as a cause of pregnancy-associated toxic shock syndrome (3).

Investigation by FDA, CDC, and state and local health departments into the two most recently identified U.S. deaths after medical abortion is ongoing. Empiric therapy for

patients suspected of having postpartum or postabortion toxic shock syndrome should include antimicrobials with anaerobic activity against *Clostridium* species. Health-care providers are encouraged to report any cases of postpartum or postabortion toxic shock syndrome to their state or local health department and to CDC at telephone 800-893-0485. Cases potentially associated with use of mifepristone or misoprostol should also be reported through the FDA MedWatch system available at http://www.fda.gov/medwatch/index.html or telephone 800-FDA-1088.

References

- 1. Food and Drug Administration. FDA Public Health Advisory: sepsis and medical abortion. Rockville, Maryland: Food and Drug Administration, Center for Drug Evaluation and Research; 2005. Available at http://www.fda.gov/cder/drug/advisory/mifeprex.htm.
- 2. Sinave C, Le Templier G, Blouin D, Leveille F, Deland E. Toxic shock syndrome due to *Clostridium sordellii*: a dramatic postpartum and postabortion disease. Clin Infect Dis 2002;35:1441–3.
- 3. McGregor JA, Soper DE, Lovell G, Todd JK. Maternal deaths associated with *Clostridium sordellii* infection. Am J Obstet Gynecol 1989;161:987–95.