

Evaluation of new anti-infective drugs for the treatment of intraabdominal infections. Infectious Diseases Society of America and the Food and Drug Administration.

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These guidelines deal with the evaluation of anti-infective drugs for the treatment of intraabdominal infections. The clinical entities consist of infections arising from any part of the gastrointestinal tract, from the distal esophagus to the colon. These include surgical infections of the bowel, biliary tree, liver, spleen, and pancreas. Virtually all intraabdominal infections are due to multiple microorganisms resident in the gastrointestinal tract; these include aerobes and facultative and obligate anaerobes. Infections are classified as complicated (requiring an operative procedure), uncomplicated (managed medically), and postoperative wound (the operative procedure should be curative, but anti-infective drugs are used to prevent further infection at the site). Clinical criteria are paramount for entry into a study and for evaluation of efficacy. For complicated infections an adequate operation is an important determinant of outcome and needs assessment. Cultures of purulent intraabdominal fluid or abscess material are the only valid microbiologic indicators of infection. The acute physiology and chronic health evaluation score is useful in defining the severity of acute illness. The control regimen should consist of effective, established drugs and surgical procedures for the condition. Duration of therapy for complicated infections is usually 5-14 days; for uncomplicated infections, 3-7 days; and for postoperative wound infection, 2-5 days. Periodic assessment of safety and efficacy must be conducted during therapy. The outcome at final assessment is cure, failure, or indeterminate.