

Evaluation of new anti-infective drugs for the treatment of acute infectious diarrhea. Infectious Diseases Society of America and the Food and Drug Administration.

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This guideline includes diarrhea causing infantile mortality in which a bacterial pathogen is recovered and for which oral rehydration therapy is an important component of care as well as traveler's diarrhea (with or without recovery of a pathogen). Diarrhea is defined as the passage of three or more unformed stools per day plus--in all patients except infants--one or more signs or symptoms of enteric infection. The preferred study design is prospective and randomized, with an active concurrent control and (when possible) blinding. Placebo-controlled trials may be performed if the severity of disease is judged by the investigator to be mild or moderate. It is desirable that both clinical and microbiological outcome be determined. Microbiological eradication is paramount.