

Evaluation of new anti-infective drugs for surgical prophylaxis. Infectious Diseases Society of America and the Food and Drug Administration.

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It has been established by substantial research that antimicrobial prophylaxis for various surgical procedures can reduce the risk of postoperative morbidity and mortality. When the incidence of infectious complications is high, the reduction with prophylaxis is most dramatic. However, even for many "clean" procedures (vascular procedures, total joint replacement), the small reduction in potentially calamitous complications justifies the use of prophylaxis. Many issues of detail remain unanswered: timing and duration of administration of antimicrobial drug; type of drug; use of topical anti-infective agents as ancillary measures; and choices for high-risk individuals and others ordinarily excluded from clinical trials. An approach to the conduct of clinical trials of anti-infective drugs for surgical prophylaxis is provided. Both general guidelines and specific recommendations for total hip replacement, colorectal operations, appendectomy, and transurethral resection of the prostate are included.