

Evaluation of new antifungal drugs for the treatment of systemic fungal infections. Infectious Diseases Society of America and the Food and Drug Administration.

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These guidelines are applicable to all fungal pathogens that produce systemic infections in humans. Specific examples are provided whenever they might clarify special issues. Systemic fungal infections usually are divided into two broad categories: endemic systemic fungal diseases, which occur classically in healthy hosts, and opportunistic fungal diseases, which occur almost exclusively in patients with impaired host defenses. Both the increasing frequency of disseminated histoplasmosis and coccidioidomycosis in patients with AIDS and the occurrence of candidemia due to vascular-line infections have begun to blur this distinction. The fungi included in these guidelines are *Histoplasma capsulatum*, *Coccidioides immitis*, *Blastomyces dermatitidis*, *Candida* species, *Cryptococcus neoformans*, *Aspergillus* species, and *Sporothrix schenckii*. Diagnosis of infections caused by these fungi should be based on culture of infected body fluids or tissues whenever possible. Cryptococcal and coccidioidal meningitis are exceptions. Amphotericin B remains the standard comparative agent for most new agents. Further studies of the efficacy of new oral agents used alone or after a hospital course of amphotericin B are needed. The agents currently available are usually inadequate for eradication of fungal infections in patients with AIDS, who may need prolonged treatment. Final assessment for these patients may need to be classified as clinical cure with presumed microbiologic persistence.