

Medical News

EDITED BY GINA PUGLIESE, RN, MS; MARTIN S. FAVERO, PHD

CMS and CDC Launch National Surgical Infection Prevention Project

The Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) are collaborating on a national initiative, the CMS/CDC Surgical Infection Prevention (SIP) Project. The project's goal is to improve the selection and timing of administration of prophylactic antibiotics, both factors proven to reduce the risk of surgical infections. State Quality Improvement Organizations (QIOs), formerly known as Peer Review Organizations (PROs), will oversee the project, which will be phased in during 3 years. Twenty states will begin the project on August 1, 2002; 16 states plus the District of Columbia on November 1, 2002; and the remaining 14 states plus Puerto Rico and the Virgin Islands on February 1, 2003.

This project builds on the experience of the CDC's National Nosocomial Infections Surveillance system and previous CMS projects administered through its Health Care Quality Improvement Program. Surgical procedures to be studied for this project include coronary artery bypass graft (CABG), cardiac, colon, hip and knee arthroplasty, abdominal and vaginal hysterectomy, and selected vascular procedures. Quality indicators will include the proportion of patients (1) who receive antibiotics within 1 hour before surgical incision; (2) who receive prophylactic antibiotics consistent with current recommendations; and (3) whose prophylactic antibiotics were discontinued within 24 hours after surgery.

For more information, visit the project's web site at www.surgicalinfectionprevention.org.

Acquired Rifamycin Resistance in Persons With Advanced HIV

Rifamycin drugs (ie, rifampin, rifabutin, and rifapentine) are essential for short-course chemotherapy in persons with active tuberculosis (TB). However, adverse drug-drug interactions complicate the concurrent use of rifamycins and protease inhibitor drugs in persons with active TB who also are infected with human immunodeficiency virus (HIV-TB). The Centers for Disease Control and Prevention (CDC) has recommended the use of rifabutin in place of rifampin in multidrug regimens for the treatment of active TB in HIV-TB because rifabutin can be administered with antiretroviral treatment regimens that include protease inhibitors. These recommendations included twice-weekly intermittent therapy. Because intermittent rifabutin-based regimens had not been evaluated in clinical trials of HIV-TB, the CDC's TB Trials Consortium (TBTC) initiated TBTC Study 23, a single-arm trial of twice-weekly rifabutin-based therapy for the treatment of HIV-TB.

On March 6, the TBTC's Data and Safety Monitoring Board advised the CDC to suspend enrollment in Study 23 because of the occurrence of five cases of acquired rifamycin resistance among patients enrolled in the study. Although the rate of treatment failure or relapse in the study has been low (preliminary life table rate of 4.1% among the 156 patients with some time at risk), all five patients with failure or relapse had acquired rifamycin resistance. All are responding well to treatment with alternative regimens.

In the study, common features in patients with acquired rifamycin resistance were very low CD4 cell count (all < 60/mm³) at diagnosis of TB and receipt of twice-weekly therapy (in four of five) during the intensive phase (ie, the first 2 months of rifamycin-based short-course therapy for TB); all five received twice-weekly therapy in the continuation phase. The low relapse rate suggests that rifabutin has excellent activity in the treatment of HIV-TB. However, a relation appears to exist between the frequency of dosing and the risk for acquired resistance. In an earlier study of treatment of HIV-TB using once-weekly rifapentine plus isoniazid, acquired rifamycin resistance was common. Acquired rifamycin resistance also occurred in a previous study of HIV-TB treated with twice-weekly rifampin plus isoniazid. It is not known whether the risk for acquired rifamycin resistance is greater with rifabutin than with rifampin. In all of these studies, patients with acquired rifamycin resistance had very low CD4 cell counts at the time of diagnosis of TB. The consistency of these findings suggests that once- or twice-weekly therapy including isoniazid and a rifamycin increases the risk for acquired rifamycin resistance among patients with TB who have advanced HIV.

Additional data are needed to clarify these issues. Until data become available, the CDC recommends that persons with HIV-TB and CD4 cell counts below 100/mm³ not be treated with highly intermittent (ie, once- or twice-weekly) regimens. These patients should receive daily therapy during the intensive phase, and daily or three doses a week during the continuation phase. In this group of patients, the CDC recommends directly observed therapy for both daily and three-doses-a-week regimens. The low relapse rate suggests that current recommendations concerning duration are sufficient (ie, 6 months minimum, extended to 9 months in patients with a delayed response to therapy).

The CDC does not advise additional action at this time for patients with advanced HIV who have completed TB therapy with intermittent regimens and are clinically stable. However, clinicians should treat suspected relapse in such patients with regimens active against rifamycin-resistant TB until the results of susceptibility testing are available.

For HIV-TB patients with CD4 cell counts of less than 100/mm³ who are being treated with twice-weekly rifamycin-based therapy, the CDC recommends more frequent thera-