HIV Screening Reimbursement Faces Roadblocks

BY MIRIAM E. TUCKER
Senior Writer

WASHINGTON — Reimbursement for routine, universal HIV screening will prove challenging in both the private and public sectors, Dr. Michael Horberg and Ms. Christine Lubinski said in separate presentations at a meeting on HIV diagnosis and prevention and access to care.

In September 2006, the Centers for Disease Control and Prevention recommended that diagnostic HIV testing and "opt-out" HIV screening be made a part of routine clinical care in all health care settings for patients aged 13-64 years (MMWR 2006;55[RR-14]).

Kaiser Permanente, the country's largest staff-model HMO, is "grappling with this now. We have to look at the implications," said Dr. Horberg, director of HIV/AIDS Policy, Quality Improvement, and Research at Kaiser.

"Yes, we have the capacity to do it, and yes, we have the will to do it. But it is a lot of money," said Dr. Horberg.

As for the public sector, "There are significant roadblocks. … The Centers for Medicare and Medicaid Services and the [Bush] administration have little commitment to expand the federal contribution to the Medicaid program in any way, shape, or form," said Ms. Lubinski, executive director of the HIV Medicine Association. This association is a multidisciplinary arm of the Infectious Diseases Society of America that represents medical professionals involved in HIV care.

'Yes, we have the capacity to do [routine screening], and yes, we have the will to do it. But it is a lot of money.'

DR. HORBERG

However, a few states—most notably New Jersey—have committed their Medicaid funds to cover broad-based HIV testing for low-income beneficiaries, Ms. Lubinski noted.

The Kaiser Permanente/Group Health Cooperative system covers approximately 3% of the U.S. population, including more than 16,000 active HIV-infected patients.

Nearly two-thirds of HIV-infected patients within Kaiser are not diagnosed until they meet AIDS criteria, "which means our case-finding is not very good," Dr. Horberg remarked. Once diagnosed, however, more than 90% enter into care within 120 days of diagnosis. Last year, more than 70% of those patients were on highly active antiretroviral therapy, he said.

Kaiser has been performing about 340,000 HIV antibody tests a year, which account for 15% of its target population aged 13-65 years. The majority are pregnant women, of whom more than 90% are currently tested. If Kaiser were to adopt the CDC guidelines, it would mean about 5 million more tests—and 1,773 newly identified cases—at a cost of at least $26,599,450 annually.

Aside from cost, other barriers to expanded HIV screening include the fact that many managed care organizations follow recommendations from the U.S. Preventive Services Task Force, not the CDC, in determining what type of tests to cover. The USPSTF has not yet issued guidelines on universal HIV screening. While most managed care organizations support targeted screening for pregnant women and for individuals with high-risk behavior, they have not generated broader screening policies. "Most are probably waiting for the USPSTF," Dr. Horberg said.

The CDC's provision that prevention counseling should not be required as part of HIV screening is already posing problems in states that require informed consent for HIV testing, including many of the states Kaiser serves. Kaiser differentiates between "screening," defined as testing without counseling, and "testing," which includes the HIV antibody test, counseling, and patient education. "Testing in [Kaiser Permanente/Group Health Cooperative] is the desired norm. … We are uncomfortable screening without a proper testing process," Dr. Horberg said.

But, he added, despite the potential roadblocks, "We are confident we can handle all new HIV-infected patients identified."

The public sector is another story. It would take an act of Congress before Medicare, which has only recently begun to cover any preventive health services, would cover HIV screening. Since the upper tar-

get age of the CDC recommendation is 64 years, the only people for whom Medicare would cover screening are the 6.8 million current beneficiaries under age 65 who qualify by disability, Ms. Lubinski said.

Thus, the bulk of the reimbursement for HIV screening would fall to Medicaid, which currently provides health coverage to about half of all people with AIDS in the United States and a significant number of those newly diagnosed with HIV. In an analysis done in 25 states, 22% of HIV-infected individuals were already Medicaid eligible at the time of diagnosis.

Federal law allows HIV screening to be covered by states either under fee-for-service or Medicaid managed care, but this service is "optional." A recent study by George Washington University's Center for Health Services Research and Policy found that Medicaid programs in 32 of the 48 states surveyed covered targeted HIV testing and counseling. A few state programs also covered services such as HIV risk assessment and case management.

But as yet, with the exception of New Jersey, most state Medicaid programs have not adopted routine HIV testing. California has employed a special waiver to provide broad family planning services including HIV testing and counseling for men and women of childbearing age up to 200% of the poverty level. However, that type of waiver is unlikely to be granted elsewhere, she noted.

States could opt to cover HIV screening under a "diagnostic, screening, preventive, and rehabilitative" (DSPR) benefit. The state would need to broaden the definition of medical necessity to allow for preventive services such as HIV screening, as Massachusetts has done. There, a service is "medically necessary if it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, or cause suffering or pain."

Such definitions could theoretically make HIV testing and counseling eligible for reimbursement, Ms. Lubinski said.

She said she believes the federal government must contribute more to Medicaid to implement the CDC guidelines, noting: "It is absolutely unreasonable to think that the modest amount of discretionary funding through the CDC, Ryan White [Comprehensive AIDS Resources Emergency Act], or state and local health departments [will] be adequate. … Medicaid, with its significant reach into low-income populations and ethnic/racial minorities, must be part of the financing mix. Federal leadership could and should facilitate coverage of routine screening by state Medicaid programs." ■

Device Safety Monitoring to Get Tune-Up

The Food and Drug Administration has announced that it is taking steps to improve its postmarketing surveillance of medical device safety, including moving ahead on a proposal to require electronic reporting of adverse events.

The agency said it has created an action plan based on a major review that was completed in 2005. That review looked at how the Center for Radiological Devices and Health (CDRH) handles recalls and enforcement actions against manufacturers that are not in compliance with FDA rules.

The report "details a number of action items that we believe will transform the postmarketing safety program," Dr. Daniel Schultz, director of CDRH, said in a briefing with reporters.

The FDA will focus on improvements in four major areas: collaboration among experts within CDRH, data systems, communications with patients and physicians about risks and benefits, and enforcement.

CDRH leaders will encourage more cross-organizational collaboration so premarket, postmarket, and enforcement efforts are better coordinated, he said.

Some of the biggest changes will come in data collection and analysis. The agency hopes to integrate its passive adverse events reporting system (Manufacturer and User Facility Device Experience Database, also known as MAUDE) and its active system, the Medical Product Safety Device Network (MedSun), Dr. Schultz said. Currently, 350 hospitals have been trained to report device problems on MedSun. One goal is to recruit more facilities and upgrade reporting so it is closer to real-time.

The agency also hopes to require manufacturers and others to electronically report adverse events. Currently, FDA receives about 200,000 reports to MAUDE each year, and most are on paper, which delays entry into the system and analysis for safety signals, Dr. Schultz said. The FDA has been piloting an electronic reporting program, and is writing a rule to require electronic reporting, he said.

Once data are being reported and analyzed more quickly, enforcement will be more timely also. This will let the FDA focus enforcement efforts on the highest-risk products, Dr. Schultz said.

—Alicia Ault