Federal update

From the NIH

AIDS drug given at birth reduces mother-to-infant HIV transmission after I year

Follow-up results of a trial supported by the National Institute of Allergy and Infectious Diseases, National Institutes of Health, indicate that the reduced rate of HIV transmission between mother and child when both were given a short regimen of nevirapine at birth was sustained after 1 year, and that the reduced transmission rate was sustained even when infants were breastfed.

Two groups were used for the study, which compared the safety and efficacy of nevirapine with another AIDS drug, AZT (zidovudine). One group of women received nevirapine during labor, their newborns one dose within 72 hours of birth; the second group of women received AZT during labor, their newborns twice-daily doses. Mothers and infants who received nevirapine had a 42% lower risk of HIV transmission compared with those who received AZT, and the difference in risk of HIV transmission continued at 12 months (39%) and 18 months (42%). Further, results of genetic analysis suggest that repeat doses of nevirapine given to the mother will continue to prevent HIV transmission during future pregnancies.

The report was presented at the 13th International AIDS Conference in South Africa.

Interruption of highly active antiretroviral therapy (HAART) may help long-term control of HIV

A new approach of interrupting HAART for variable periods of time as long-term treatment of patients with HIV is based on studies indicating that a reservoir of

latently infected CD4+ T cells is established in lymphoid organs soon after infection. Researchers from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, state that while the reservoir is not relevant during bursts of viremia, it becomes relevant during the aviremic state induced by HAART, and that interrupting therapy is a means of determining whether HIV has been eliminated.

Various approaches to interrupting therapy are used, such as single interruption and structured therapy interruptions, for example, therapy resumption when plasma viremia reaches established levels.

Plasma viremia with parallel levels of HIV-specific CD8+ T cells rebounded in patients in whom HAART treatment was interrupted; however, the delay in rebound of plasma viremia may allow periods without therapy.

The report was presented at the 13th International AIDS Conference.

Compound that interferes with nicotine metabolism reduces urge to smoke

In a study funded by the National Institute on Drug Abuse, National Institutes of Health, researchers found that a compound, methoxsalen, blocks the ability of an enzyme (CYP2A6) to metabolize nicotine, resulting in the improved efficacy of oral nicotine replacement to reduce the urge for nicotine.

Earlier studies indicated that individuals with a genetic deficiency in CYP2A6 metabolism were less likely to begin smoking than those with normal levels of the enzyme. Methoxsalen, used to treat skin disorders, was found to be a potent CYP2A6 inhibitor. In one of two studies, smokers who received methoxsalen maintained higher nicotine levels and reduced desire to smoke than those taking placebo

with oral nicotine replacement. In the second study, smokers allowed to smoke at will following administration of methoxsalen smoked fewer cigarettes with longer intervals between cigarettes than those who received placebo alone or with nicotine.

The report can be found in the July issue of *Clinical Pharmacology and Therapeutics*.

From the AHRQ

Women over 80 years of age less likely to receive radiation therapy for breast cancer

A study by the Agency for Healthcare Research and Quality found that women over 80 years of age with early-stage breast cancer were less likely to be referred to a radiation oncologist. Further, the same population was three times more likely not to receive radiation therapy following breast-conserving therapy, when risk of recurrence is 40% within 10 years when radiation is not given. Radiation following lumpectomy was even less likely for black women than for white women. The study also showed that older women's preferences determined selection of and satisfaction with treatment.

This was one of the first studies of breast cancer treatment for older women that includes a defined stage of the disease and factors affecting treatment patterns.

The report can be found in the August 1 issue of *Cancer*.

Papanicolaou test, while moderately accurate, remains effective

A review of studies that compared conventional and newer Papanicolaou tests with a current reference standard found

conventional Pap tests to be only moderately accurate without achieving high sensitivity and specificity. However, say researchers from the Agency for Healthcare Research and Quality, the Pap test remains effective for cervical cancer screening because the disease is slow-growing, and abnormalities will be detected that were missed in one screening. Data that measure the accuracy of new methods, such as thin-layer cytology, computerized rescreening, and the algorithmic classifier, are insufficient to estimate their accuracy.

Two thirds of false-negative Pap test results are caused by sampling errors such as failure to collect abnormal cells and failure to transfer abnormal cells to slide, or detection errors, for example, samples being missed or misinterpreted.

Cervical cancer rates have declined from 14 per 100,000 women in 1973 to 8 per 100,000 women in 1994; however, cervical cancer remains a leading cause of cancer death in American women.

From the FDA

FDA recalls SangCya oral solution

The Food and Drug Administration has recalled SangCya oral solution, a generic version of the anti-rejection drug, cyclosporine (Neoral oral solution). Results of a study indicate that the generic drug's absorption is reduced compared with Neoral oral solution if it is administered with apple juice. The drug's labeling suggests that it be taken with apple juice or orange juice.

The FDA will allow SangCya oral solution to remain in pharmacies to allow patients to gradually transition to another cyclosporine product.

FDA approves Malarone for malaria

The Food and Drug Administration has approved the combination drug, atovaquone and proguanil HCL (Malarone) for the prevention and treatment of patients with acute malaria caused by *Plasmodium falciparum*. In 1948, proguanil hydrochloride was approved in the Unit-

ed States for treatment of patients with acute malaria caused by *P falciparum*. Atovaquone (Mepron) is currently marketed for treatment of patients with *Pneumocystis carinii* pneumonia.

Malarone underwent evaluation as treatment for malaria in eight trials and was found to have an overall efficacy rate of 98.7%. Malarone was also evaluated for the prophylaxis of malaria in four trials in which 2 of 279 patients who had received Malarone contracted malaria compared with 92 of 297 patients who were given a placebo.

FDA approves Pulmicort Respules for children with asthma

The FDA approved budesonide inhalation suspension (Pulmicort Respules) for children between the ages of 1 and 8 years who have asthma. No other inhaled corticosteroid has been approved for use in children younger than 4 years of age.

Approval for the budesonide inhalation suspension was based on three randomized, 12-week studies involving 1000 children between the ages of 6 months and 8 years who had persistent asthma.

A side effect of reduced growth velocity is associated with inhaled corticosteroids. Side effects observed during trials using Pulmicort Respules included respiratory infection, rhinitis, and coughing.

Maintenance therapy with all inhaled corticosteroids may reduce the inflammation that precipitates an asthma attack or bronchospasm, but they are not indicated for relief of acute bronchospasm or acute episodes of asthma.

From the CDC

Teen pregnancy rates decline

A report published by the Centers for Disease Control and Prevention states that between 1995 and 1997, the national pregnancy rate for adolescents aged 15 to 19 years declined by 7.8%, representing declines in 40 of the 43 reporting areas. Additionally, the abortion rate for adolescents aged 15 to 19 years declined by 7.5% nationally, representing 32 of the

43 areas where data were available. Further, while sexual activity among adolescents increased during the 1980s, the rate leveled off from 1988 to 1995.

The United States has the highest adolescent pregnancy rate among developed countries, with over 800,000 teenagers becoming pregnant each year.

CDC survey for 1996 and 1997 shows differences in health concerns between men and women

The Behavioral Risk Factor Surveillance System, a survey of adults 18 years of age and older conducted by the Centers for Disease Control and Prevention, shows differences between American men and women with regard to health issues in 1996 and 1997.

In the category of risk factors for chronic diseases, approximately 53% of adults were overweight, with men more likely than women to report being overweight (1996: 60.7% and 44.0%, respectively; 1997: 62.2% and 44.5%). The percentage of adults who smoked remained approximately 25% (since 1991), with men slightly more likely to smoke than women (1996: 25.5% and 21.9%; 1997: 25.3% and 21.1%). The difference in smoking rates increased for younger men and women (1996 and 1997 combined: 28.8% and 26.6%; respectively). Data also show that men were seven times more likely than women to be a chronic drinker (1997: 5.4% and 0.8%) and three times more likely to binge drink (1997: 22.3% and

In terms of screening for chronic diseases, data show that women were more likely than men to have their blood cholesterol levels checked (1997: 76.7% and 70.8%), while more men than women reported undergoing sigmoidoscopy or proctoscopy (1997: 45.3% and 37%).◆