Federal update

From the NIH

Shortened cervix in second trimester may predict preterm birth

A shortened cervix in the second trimester of pregnancy in women who previously gave birth prematurely may be a warning sign of impending premature birth, according to a study by the National Institute of Child Health and Human Development, National Institutes of Health. Scientists note that this finding provides a means of predicting preterm birth early in pregnancy.

The study involved 183 pregnant women who had spontaneous preterm births before the 32nd week of pregnancy. Ultrasonography was used for cervix examination between 16 and 18 weeks of pregnancy, and 4 ultrasound evaluations were given before the 23rd week.

Women whose cervixes had shortened to less than 25 mm by the first ultrasound evaluation were 3.3 times more likely to give birth prematurely than other women in the study. Women whose cervixes had not shortened until later ultrasound evaluations were also more likely to give birth prematurely.

Preterm birth complicates 8% to 10% of all births. Most premature infant deaths occur before the 32nd week of pregnancy, while those born before the 37th week have a higher risk of infection, respiratory distress, and necrotizing enterocolitis.

Decreased bone density found in postmenopausal women treated with inhaled corticosteroids

Premenopausal women who use inhaled corticosteroids to treat persistent asthma may have accelerated bone loss in the hip, compared to those who do not use inhaled steroids, according to researchers at the National Heart, Lung, and Blood Institute and the National Center for Research

Resources—both of the National Institutes of Health. Although rates of bone density loss varied, the effects were greater with higher dosages and longer duration of inhaled steroid treatment.

The 3-year study involved 109 women between the ages of 18 and 45 years randomly assigned to groups who received inhaled triamcinolone acetonide at two dosage levels (4 to 8 puffs per day versus more than 8 puffs per day) and those who did not receive inhaled steroids. Women who received inhaled steroids had doserelated decreases in bone density in the hip but not in the spine or femoral neck.

Researchers recommend that all patients with asthma work with their physicians on a plan to have the lowest possible dose of inhaled corticosteroids that provides the best daily control of persistent asthma—as well as develop measures to maintain bone health, such as ensuring adequate calcium and vitamin D uptake. Scientists note that supplementing inhaled steroids with longacting β -agonists may help to reduce steroid dosage while maintaining symptom control; but they warn that treatment with long-acting β -agonists alone may lead to worsened symptoms.

HIV/AIDS studies to increase, add minorities

The two largest studies of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) in women and homosexual or bisexual men is increasing by 60% the size of its study groups and increasing the proportion of ethnic and racial minority participants to reflect the proportion of the "minority" HIV population in the United States, according to researchers at the National Institute of Allergy and Infectious Diseases, National Institutes of Health.

Researchers note that the studies will focus on current questions about the conditions, particularly as the population most

affected currently includes a greater number of minority populations—50% of newly infected men are African American and 20% are Hispanic; 64% of newly infected women are African American and 18% are Hispanic—and highly active antiretroviral therapy (HAART) has changed the outcome of treatment, creating a population of people with HIV who do not have AIDS.

The improved survival rate raises questions regarding the safety and benefits of long-term treatment, HIV's effects in older populations, and immune-system function during chronic infection. Both studies track HIV-infected and uninfected populations so the virus' effects can be separated from other factors.

Brain imaging shows patterns specific to objects being viewed

Patterns of brain activity indicate the type of object (house, face, automobile) a person is viewing, with different response patterns for each object category, according to scientists at the National Institute of Mental Health who measured and identified responses in the ventral temporal lobe of the visual cortex. The discovery may explain how the brain encodes complex visual information.

The NIMH researchers contend that the brain "recognized" complex and varied information by storing it in and retrieving it from several locations organized in a functional, overlapping architecture, which they refer to as "object form topography." Therefore, within discrete object categories, patterns of response can be distinguished for other objects. Further, extensive responses that represent complex attributes of objects and faces are related, leading to an unlimited number of object categories.

Using functional magnetic resonance imaging, researchers measured patterns of response in six people as they viewed images of faces, cats, and man-made objects, such as chairs, shoes, and bottles, with pictures of scrambled nonsense as control. The responses predicted each category with 96% accuracy

From the CDC

Need for increased counseling of women taking isotretinoin

Women who take isotretinoin (Accutane)—a drug prescribed for severe acne and known to cause birth defects—continue to become pregnant despite an aggressive education campaign and use of a warning symbol in drug package text, according to scientists at the Centers for Disease Control and Prevention (CDC). In 1988, the CDC and the Food and Drug Administration (FDA) joined efforts to educate health professionals about the risk of birth defects caused by isotretinoin, which include brain, heart, and facial defects.

Recommendations for women taking isotretinoin include the following:

- Before beginning the medication, women should have two negative pregnancy test results, including one on the second day of the next normal menstrual period.
- Use two forms of effective birth control.
- Have repeat pregnancy tests every month.
- Register with the survey that monitors the experiences of women on this medication.

The drug package text warning symbol features a pregnant woman in a circle with a slash through it. This teratogen warning symbol was misinterpreted by one third of study participants to mean that the product would provide birth control. Many other women were simply unable to determine the symbol's meaning.

As more than 2000 isotretinoin-exposed pregnancies were reported in the United States between 1982 and 2000, the FDA and the manufacturer of Accutane, Hoffman–LaRoche, Inc, will launch an enhanced risk-management program for the drug.

From the AHRO

Report summarizes evidence for diagnosis and management of breast disease

In an evidence report summarizing management of breast abnormalities, the Agency for Healthcare Research and Quality recommends performing an excisional biopsy after a stereotaxic core needle biopsy diagnosis of atypical ductal hyperplasia because a core needle biopsy may fail to include cancerous tissue in sampling. Further, while studies continue to suggest sentinel lymph node biopsy is successful in determining whether breast cancer has spread through the lymph nodes, researchers recommend that outcome data be considered before this procedure becomes the standard of care.

According to scientists, although atypical ductal hyperplasia and lobular carcinoma in situ are noncancerous, both conditions place women at increased risk for breast cancer. Tamoxifen citrate decreases incidence of breast cancer but is associated with increased risk of endometrial cancer, thromoembolic disease, and other complications.

Exercise may ease symptoms of patients with chronic fatigue syndrome

Physical exercise may ease fatigue in patients with chronic fatigue syndrome, with no particular exercise found to be more effective than another, according to an evidence report by the Agency for Healthcare Research and Quality. Further, researchers were unable to draw conclusions about the effectiveness of standard treatments for patients with chronic fatigue syndrome, such as immune therapy, corticosteroids, and antidepressants.

The report, "Defining and Managing Chronic Fatigue Syndrome," is available at http://www.ahrq.gov/clinic/cfssum.htm.

From the FDA

Drug combination for breast cancer approved

The Food and Drug Administration approved the combination of capecitabine (Xeloda) and docetaxel (Taxotere) for women with breast cancer who failed to respond to standard treatment. Increased median survival of the 511 women with advanced breast cancer who participated in the study ranged from 11.5 months for patients who received docetaxel alone to 14.5 months for patients who received the drug combination, according to results of a study funded by Xeloda's manufacturer, the Roche Group.

In the United States, breast cancer is the second leading cause of cancer mortality in women and is diagnosed in more than 192,000 women each year.

Safety Tip-Lok, prefilled syringes approved for pediatric vaccines

The Food and Drug Administration approved Safety Tip-Lok, prefilled syringes packaged with BD SafetyGlide needles, manufactured by GlaxoSmithKline, for pediatric doses of inactivated hepatitis A and recombinant hepatitis B vaccines—the only syringes that feature the Safety Tip-Lok system, and the only vaccines available with an all-in-one delivery system.

The system meets the new Occupational Safety and Health Administration's bloodborne pathogens standard of April 18, 2001, designed to protect healthcare workers from needle-stick injuries. The needle features a shield that covers the tip after activation to protect the person administering the vaccine. More than 800,000 needle-stick injuries and potential exposures to blood-borne pathogens occur each year.

Further information is available at http://gskvaccines.com/vaccines/index_public.jsp.