

UPDATES FROM US HEALTH AGENCIES

Recent activity in government and non-government agencies may affect readers of *Ethnicity & Disease* and other healthcare professionals working with ethnic minority and under-served populations. Below are some current items of interest.

FROM THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

Study Tests Anti-inflammatory Drug for Poorly Controlled Type 2 Diabetes

Researchers in 20 medical centers across the country are enrolling adults with type 2 diabetes who have poorly controlled blood glucose to participate in a clinical study, Targeting Inflammation with Salsalate in Type 2 Diabetes (TINSAL-T2D). The study is investigating whether salsalate, an anti-inflammatory drug used for years to manage arthritis pain, can reduce blood glucose levels in people with type 2 diabetes. If successful, the trial could lead to

an effective, inexpensive way to treat the most common form of diabetes.

The study is based on the promising results of earlier studies that showed that salsalate effectively lowered blood sugars when given for 3 months to adults with type 2 diabetes. Now researchers want to determine whether the drug will be well tolerated and effective over a longer period of time. "This important study is testing whether reducing inflammation

with this drug will be an effective treatment for type 2 diabetes," said principal investigator Steven E. Shoelson, MD, PhD. "Given what we're learning about the role of inflammation in the development of type 2 diabetes, this therapy might be getting at an underlying cause of the disease. We hope that this drug will provide an additional tool for improving glucose control and thus reducing the risk of diabetes complications."

Salsalate, which belongs to a class of drugs called nonsteroidal anti-inflammatory drugs is approved by the Food and Drug

Administration to relieve mild to moderate pain, fever, arthritis, and other musculoskeletal conditions. Chemically similar to aspirin, it has fewer side effects and has been used for more than 40 years to treat pain associated with arthritis. "The outcome of this study has the potential for significant public health benefit," said Myrlene Staten, MD, NIDDK's senior advisor for diabetes translational research. "If salsalate improves the control of type 2 diabetes, we would have a much-needed, inexpensive addition to our arsenal of drug options."

FROM THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK) AND THE OFFICE OF RESEARCH ON WOMEN'S HEALTH (ORWH)

Weight Loss in Overweight and Obese Women Reduces Urinary Incontinence

Reducing urinary incontinence can now be added to the extensive list of health benefits of weight loss, according to a clinical trial. The Program to Reduce Incontinence by Diet and Exercise (PRIDE), conducted in Birmingham, Alabama, and Providence, Rhode Island, recruited 338 obese and over-

weight women who leaked urine at least 10 times per week. The women were randomly assigned to either an intensive 6-month weight loss program of diet, exercise, and behavior modification or to a group that received information about diet and exercise but no training to help them change habits.

The investigators report that women in the intensive weight-loss group lost an average 8% of their body weight (≈ 17 pounds) and reduced weekly urinary incontinence episodes by nearly half (47%). In contrast, women in the information-only group lost an average 1.6% of body weight (≈ 3 pounds) and had 28% fewer episodes. "Clearly, weight loss can have a significant, positive impact on urinary

incontinence, a finding that may help motivate weight loss, which has additional health benefits such as preventing type 2 diabetes," said NIDDK Director Griffin P. Rodgers, MD.

Urinary incontinence affects more than 13 million women in the United States and accounts for an estimated \$20 billion in annual healthcare costs. Obesity is an established and modifiable risk factor for urinary inconti-

nence, but conclusive evidence for a beneficial effect of weight loss on urinary incontinence has been lacking. The PRIDE trial provides evidence that supports weight loss as a treatment for incontinence.

Among women in the weight loss group, 41% achieved a clinically relevant reduction of $\geq 70\%$ of total incontinence episodes per week, whereas 22% of women in the information-only group achieved the

same level of reduction. At 6 months, women in the weight loss group were significantly more satisfied with the change in their incontinence than were women in the information-only group. This was assessed

through self-reported perceived change in frequency of incontinence, volume of urine loss, the degree to which incontinence was a problem, and satisfaction with the change in incontinence.

FROM THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Anti-HIV Gel Shows Promise in Large-scale Study in Women

An investigational vaginal gel intended to prevent HIV infection in women has demonstrated encouraging signs of success in a clinical trial conducted in Africa and the United States. Study investigators found the microbicide gel—known as PRO 2000 (Indevus Pharmaceuticals, Inc, Lexington, Mass)—to be safe and $\approx 30\%$ effective. This is the first human clinical study to suggest that a microbicide may prevent male-to-female sexual transmission of HIV infection.

“Although more data are needed to conclusively determine whether PRO 2000 protects women from HIV infection, the results of this study are encouraging,” says NIAID Director Anthony S. Fauci, MD. “An effective microbicide would be a valuable tool that women could use to protect themselves against

HIV and one that could substantially reduce the number of new HIV infections worldwide.”

Women make up half of all people worldwide living with HIV. In sub-Saharan Africa, women represent nearly 60% of adults living with HIV, and in several southern African countries, young women are ≥ 3 times more likely to be HIV-positive than are young men. In most cases, women become infected with HIV through sexual intercourse with an infected male partner. An effective microbicide could provide women with an HIV prevention method they initiate. This would be particularly helpful in situations where it is difficult or impossible for women to refuse sex or negotiate condom use with their male partners.

The study, known as HPTN 035, began in 2005 and enrolled

3099 women at 6 sites in Africa and 1 in the United States. The clinical trial tested 2 candidate microbicide gels for safety and their ability to prevent HIV infection: PRO 2000 (.5% dose), and BufferGel (ReProtect Inc, Baltimore, Md). PRO 2000 inhibits the entry of HIV into cells; BufferGel boosts the natural acidity of the vagina in the presence of seminal fluid, which can help to inactivate HIV and other pathogens. Participants reported regular use of the investigational gels (81% of sex acts), and nearly all (99%) said they would use the products if approved for HIV prevention. Condom usage was also high throughout the course of the trial (74%).

In the final analysis, 194 women in the study became infected with HIV. Of these infections, 36 occurred in the PRO 2000 group, 54 in the BufferGel group, 51 in the

placebo group, and 53 in those who did not use gel. Based on these data, PRO 2000 was 30% effective, while BufferGel had no detectable preventive effect on HIV infection. Both PRO 2000 and BufferGel were found to be safe.

Study participants are being informed of the findings and counseled on the continued need to follow safe sex practices in order to avoid possible HIV exposure. Women who became infected with HIV during the trial were counseled and referred to appropriate medical care and support, including antiretroviral therapy. These same women were also given the opportunity to participate in a clinical study examining the nature of HIV progression and treatment response in HIV-infected women who were using topical microbicides or oral antiretrovirals as an HIV preventive measure when they acquired HIV infection.