

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 NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

Mothers' High-Normal Blood Sugar Levels Place Infants at Risk for Birth Problems

Pregnant women with blood sugar levels in the higher range of normal—but not high enough to be considered diabetes—are more likely than women with lower blood sugar levels to give birth to babies at risk for many of the same problems seen in babies born to women with diabetes during pregnancy, including greater likelihood for Caesarean delivery and an abnormally large body size at birth. Infants born to women with higher blood sugar levels were

also at risk for shoulder dystocia, a condition that occurs during birth in which an infant's shoulder becomes lodged inside the mother's body, effectively halting the birth process.

Researchers were unable to identify a precise level where an elevation in blood sugar increased the risk for any of the outcomes observed in the study. Rather, the chances for the outcomes were observed to increase gradually, corresponding with increases in the women's

blood sugar levels. This study is the first to document that blood sugar levels that are not high enough to be considered diabetes also convey these increased risks. When the researchers mathematically adjusted for other potential causes of these risks—such as older maternal age, obesity, and high blood pressure—the increased risks due to higher blood sugar levels were still present.

“These important new findings highlight the risks of elevated blood sugar levels during pregnancy,” said Duane Alexander, MD, director of the

NICHD. “NIH-supported studies now in progress will provide guidance on how to manage them. Until the results of those studies are available, all pregnant women should consult a healthcare professional about being screened for diabetes during pregnancy.”

At a consensus conference that took place June 11–13 in Pasadena, California, researchers, clinical experts, members of professional organizations, and others discussed the findings. Information on the conference is available at <http://www.iadpsg.org/>.

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

Kidney Disease Substantially Worsens in a Fourth of African Americans Despite Therapy for Hypertension

The best available treatment for chronic kidney disease from high blood pressure did not keep the disease from substantially worsening in approximately a fourth of African Americans studied, according to long-term results of a National Institutes of Health (NIH) study.

The largest and longest study of chronic kidney disease in

African-Americans—the African American Study of Kidney Disease and Hypertension (AASK)—found that the disease substantially worsened in approximately one-fourth of participants, even with very good blood pressure control and use of kidney protecting medications, currently the best available treatment. This subgroup of

patients either lost half their kidney function or reached end-stage renal disease.

“Despite these sobering results, blood pressure control is still vital in kidney disease and in many other diseases,” said NIH director Elias A. Zerhouni, MD. “But this research clearly signals the importance of preventing kidney disease, better understanding causes and finding better ways to manage it in the 26 million Americans who already have it.”

Good news also emerged from the study. About one-third of participants experienced a slow decline in kidney function, about what is generally observed with aging. “The factors that may be responsible for such a small loss of kidney function need to be studied,” said Lawrence Y. Agodoa, MD, senior author of the study and director of kidney failure research at NIDDK.

The AASK Cohort Study observed ≈750 African Ameri-

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cans on recommended therapy for chronic kidney disease from 2002 to 2007. Study participants were initially recruited in 1995 for the AASK Clinical

Trial, which concluded in 2001 that an angiotensin-converting enzyme (ACE) inhibitor protected the kidneys better than did two other classes of blood pres-

sure drugs. During the Cohort Study, nearly 9 out of 10 participants were taking an ACE inhibitor or an angiotensin-receptor blocker drug, and

average blood pressure was 133/78 mm Hg, which is close to national guidelines for high blood pressure in people with chronic kidney disease.

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

Studies Test New Approaches to Islet Transplantation

Researchers from 11 medical centers in the United States, Canada, Sweden, and Norway have begun testing new approaches to transplanting clusters of insulin-producing islets in adults with difficult-to-control type 1 diabetes. The clinical studies will determine whether changes to current methods of islet transplantation lead to improved, long-lasting control of blood glucose with fewer side effects.

In islet transplantation, clusters of islets are extracted from a donor pancreas and infused into the recipient's liver. In a successful transplant, the islets become embedded in the liver and begin

producing insulin. "A major goal of the National Institutes of Health (NIH) research program in type 1 diabetes is to develop therapies that replace the insulin-producing cells destroyed by the autoimmune process," said NIH director Elias A. Zerhouni, MD. "These studies, which build on advances in immunology and transplantation research, may open the door to more widespread use of islet transplantation for patients with severe type 1 diabetes."

In 2000, a research team led by Dr James Shapiro at the University of Alberta in Edmonton, Canada, reported sustained insulin independence in seven

patients transplanted with islets from two to four donor pancreases and treated with an immunosuppressive regimen that omitted glucocorticoids, thought to be toxic to islets. In the next few years, other researchers replicated the "Edmonton protocol," and most centers adopted this approach to islet transplantation. The protocol greatly benefits some patients with severe type 1 diabetes, but two or more infusions of islets are usually needed, and the islets tend to lose their insulin-producing ability over time. Participating in an islet transplant study is appropriate for people with severe hypoglycemia (dangerously low levels of blood sugar) and for those with type 1 diabetes who have had a

kidney transplant to treat kidney failure, a complication of diabetes.

Since the Edmonton advance, scientists have been working to lengthen the survival of donor islets and reduce the side effects—such as anemia, nerve and kidney damage, and vulnerability to infection—of drugs that prevent the body's destruction of donor islets. In the new studies, the researchers will culture islets before transplantation to enhance their viability. They will also compare specific antirejection drugs for the ability to maximize islet survival while reducing toxicity. As the procedure becomes safer and new sources of beta cells become available, more people are likely to benefit.

FROM THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

Aggressively Lowering Cholesterol and Blood Pressure May Reverse Atherosclerosis in Adults with Diabetes

Aggressively lowering cholesterol and blood pressure levels below current targets in adults with type 2 diabetes may help to prevent—and possibly reverse—atherosclerosis, according to new research supported by the

NHLBI. The three-year study of 499 participants is the first to compare two treatment targets for low-density lipoprotein (LDL) cholesterol and systolic blood pressure levels in people with diabetes.

"This study provides good news for adults with type 2 diabetes," said Elizabeth G. Nabel, MD, NHLBI director. "These patients are two to four times more likely than people without diabetes to die from heart disease. For the first time, we have evidence that aggressively lowering LDL cholesterol and blood pressure can actually re-

verse damage to the arteries in middle-aged adults with diabetes."

In the Stop Atherosclerosis in Native Diabetics Study (SANDS), approximately one-half of the participants (247) were asked to lower to standard levels their LDL cholesterol (to ≤ 100 mg/dL) and blood pressure (systolic blood pressure

≤130 mm Hg), while the other half (252) aimed for more aggressive reductions (LDL cholesterol ≤70 mg/dL and systolic blood pressure ≤115 mm Hg). All participants were American Indians aged ≥40 years who had diabetes, high blood cholesterol, and high blood pressure but no history of heart attack or other evidence of heart disease.

“American Indians have a high rate of diabetes and cardiovascular disease related to diabetes, but there are few clinical trials that address these issues in this population,” said Barbara V. Howard, PhD, of MedStar Research Institute, lead author

of the article. “These study results provide needed evidence to help develop community-based programs to treat and prevent the epidemic of cardiovascular disease among American Indians. At the same time, we are increasing our understanding of the effects of intensively lowering cholesterol and blood pressure in adults with type 2 diabetes, which might also apply to other populations.”

On average, participants in both groups reached and maintained their target goals for cholesterol and blood pressure levels. The numbers of heart

attacks and other cardiovascular events were similar between the two groups and lower than expected. In addition, carotid artery thickness measurements of participants in the aggressive treatment group were significantly lower than those in the standard treatment group. Researchers report that, compared to baseline, carotid artery thickness increased slightly in the standard group and regressed in the aggressive treatment group, indicating a partial reversal of atherosclerosis. Furthermore, although heart size decreased from baseline in both groups, the beneficial change was signifi-

cantly greater among participants in the aggressive treatment group.

“These encouraging findings from SANDS suggest that more aggressive blood pressure and cholesterol targets than those currently recommended in patients with diabetes may reduce their future cardiovascular risk,” said Jerome L. Fleg, MD, NHLBI project officer of the study and a coauthor of the article. “Longer term followup of this population as well as additional studies in other populations are needed to confirm the benefit and cost-effectiveness of these lower targets.”