

# UPDATES FROM US HEALTH AGENCIES

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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.

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

### Clinical Trial Results Find Late Angioplasty after Heart Attack Offers No Advantage Over Standard Drug Therapy

Approximately one third of heart attack patients do not receive treatment to open blocked arteries within the recommended 12-hour timeframe after a heart attack. Treatment such as angioplasty or clot-dissolving drugs may not be given because patients arrive at the hospital too late. For years, conventional wisdom has said that late balloon angioplasty of these patients' arteries, if they are totally blocked, is still beneficial and might prevent future heart failure, another heart attack, or death. However, according to the results of a large international multicenter clinical trial, stable patients who had angioplasty plus stenting 3–28 days after a heart attack did no better than patients on medical therapy (primarily drug treatment) alone.

“These results challenge the long-standing belief that opening

a blocked artery is always good. Instead, the study suggests that late angioplasty is unnecessary in this circumstance. The good news is there have been tremendous advances in drug therapy for heart attack patients. Drug therapy is an important treatment option,” said NHLBI Director Elizabeth G. Nabel, MD

“Our findings indicate that routine late opening of the heart attack-related coronary artery is not appropriate and should be reserved only for certain patients, such as those who are unstable or continue to have chest pain following a heart attack. These results should lead to lower rates of unnecessary coronary interventions in this specific group of stable patients,” said Judith Hochman, MD, study chair.

Hochman expressed concern about a trend in the study

toward more heart attacks in the angioplasty group. Although the trend was not statistically significant, she said, it needs to be studied and the patients followed for a longer time to determine if the trend continues or whether other trends emerge. According to Hochman, whether the increase in heart attacks will lead to an excess risk of heart failure or death or reduced quality of life is not known.

The investigators offer a possible explanation for the trend toward more heart attacks in the angioplasty group. According to Hochman, when someone has a 100% blocked artery, the heart muscle may still be somewhat protected by small vessels that provide blood flow from the other coronary arteries. “These vessels are so small that if an easier blood flow path is reestablished via angioplasty, they close down, either temporarily or permanently. If the artery that had the angioplasty re-closes,

these small vessels would not be rapidly available to supply blood to your heart muscle at the time of your next heart attack,” she said. In addition, Hochman said that some heart muscle damage due to dislodging of clots and plaque at the time of the angioplasty procedure may counteract other potential long-term benefits.

“There’s an important public health lesson to be learned from the OAT trial results: seek care very early after heart attack symptoms begin because that’s when there is a great deal of benefit from angioplasty,” said Alice Mascette, MD, chief of NHLBI’s Heart Failure and Arrhythmias Branch and member of the OAT study steering committee. “And we should not forget that controlling the risk factors for heart disease—such as high cholesterol and high blood pressure—can go a long way toward preventing heart attack in the first place.”

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### FROM THE NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

#### Young African American Adults at High Risk for HIV, Sexually Transmitted Diseases, Even in Absence of High-Risk Behaviors

Results of a new study supported by NIDA suggest that young African American adults—but not young White adults—are at high risk for HIV and other sexually transmitted diseases (STDs) even when their relative level of risky behaviors is low. The findings imply that the marked racial disparities in the prevalence of these diseases are not exclusively affected by individual risk behaviors.

“Improving our understanding of the factors that contribute to the health disparities seen in HIV is one of our top priorities,” says Dr. Elias Zerhouni, director of the National Institutes of Health. “Studies like this help define the problem, but further research may provide us with a greater understanding of why this population is at higher risk and how best to intervene.”

Environmental, institutional, and contextual influences, such as differences in social and dating patterns, are among the many factors identified by the researchers that may play a role in one’s risk for HIV. The authors recognize that research that seeks to address racial disparities in STD and HIV infection must proceed with sensitivity and involve dialogue and consensus among all community groups.

“NIDA has conducted many studies that link drug abuse and other risky behaviors to HIV infection,” says NIDA director Dr. Nora D. Volkow. “This study is particularly interesting because it suggests that given similar patterns of risk behaviors across racial groups, young African American adults are more likely to become infected. As

a result, we need to look beyond strategies that target individual risk behaviors and focus on outreach and education for this population as a group.”

“We found that the most normative category for young African American adults (almost 38% of participants) was one of the lowest-risk categories, characterized by having few sexual partners and low alcohol, tobacco, or drug abuse. Yet these same individuals were more than seven times as likely as young White adults in the same category to harbor an STD/HIV infection,” says lead scientist Dr. Denise Hallfors of the Pacific Institute for Research and Evaluation in Chapel Hill, North Carolina.

The researchers analyzed 2001–2002 population-based data from 6,257 young White adults and 2,449 young African American adults nationwide age 18–26 years. They were participants in The National Longitu-

dinal Study of Adolescent Health and had completed initial surveys when they were in 7th to 12th grades in 1994–1995. In this assessment, participants used computer assisted self-interviewing technology to respond to sensitive questions about sexual and substance abuse history. Following the interview, participants were tested for STDs and HIV.

“These surprising new findings suggest that a more comprehensive research approach is needed to understand the factors that make young African American adults vulnerable to STD and HIV infection beyond the commonly known individual risk behaviors,” says Dr. Volkow. “Most STDs can be cured, the health and lifespan of people infected with HIV can be significantly increased by available therapies, and prompt diagnosis and treatment may reduce the spread of these diseases.”

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### FROM THE NATIONAL INSTITUTES OF HEALTH (NIH)

#### Malaria Vaccine Prompts Victims’ Immune System to Eliminate Parasite From Mosquitoes

Researchers at the NIH have developed an experimental vaccine that could, theoretically, eliminate malaria from entire geographic regions by eradicating the malaria parasite from an area’s mosquitoes.

The vaccine, so far tested only in mice, would prompt the immune system of a person who receives it to eliminate the

parasite from the digestive tract of a malaria-carrying mosquito, after the mosquito has fed upon the blood of the vaccinated individual. The vaccine would not prevent or limit malarial disease in the person who received it.

The vaccine was developed with conjugate technology, which joins or “conjugates”

molecules the immune system has great difficulty recognizing to molecules the immune system can recognize easily. Primed by the conjugate vaccine, the immune system begins making antibodies—immune proteins that target specific molecules. The antibodies then eliminate molecules the immune system would fail to detect.

“With conjugate technology, NIH researchers have developed effective vaccines against such

scourges as *Haemophilus influenzae* type b meningitis and typhoid fever,” said Elias A. Zerhouni, MD, director of the National Institutes of Health. “The experimental malaria vaccine shows great promise for combating a terrible disease that exacts a devastating toll on the world’s children.”

Malaria is caused by a single-celled parasite of the genus *Plasmodium*. In all, four species of *Plasmodium* cause malaria in

humans, and *P. falciparum* causes the most severe form. The malarial parasite spends part of its life cycle in humans and part in mosquitoes. The parasite is injected into a human by the bite of an infected mosquito. Numerous experimental vaccines have been tried against the form of the parasite that resides in humans but have been unsuccessful or produced limited immunity. *Plasmodium* cells escape the human immune system by hiding in liver and blood cells, which makes them difficult to target with a vaccine. During the human phase of the infection, these cells, for the most part, exist in an asexual form.

Some of the *Plasmodium* cells, however, transform into gametocytes—the sexual forms of the

parasite that are equivalent to sperm and eggs. Fertilization takes place in the mosquito gut, after which the parasite embeds itself in the gut lining. There, it passes through discrete stages, before migrating to the insect's salivary glands, where it is passed on to the next host through a mosquito bite.

The protein Pfs25 (*P. falciparum* surface protein 25) is found only on the surface of the ookinete, a stage of the parasite that lives in the mosquito gut, and does not appear on any other stage of the parasite. When injected into human volunteers, Pfs25 fails to generate a sufficient level of antibodies to target the parasite.

In their article, the researchers described several strategies for

using conjugate technology to make an effective vaccine based on Pfs25. These consisted of chemically linking numerous Pfs25 molecules to each other and to other proteins: *Pseudomonas aeruginosa* exotoxin A, a protein from a species of bacteria that infects people with weakened immune systems, and ovalbumin, a protein found in egg whites. All of the conjugates produced high levels of antibodies in mice. Adsorbing the conjugate molecules to the surface of molecules of aluminum hydroxide produced even higher levels of antibodies.

The researchers also discovered that the ability of the mice to produce antibodies to the vaccine increased with time. In fact, the animals produced

higher levels of antibodies when they were tested three and seven months after their initial set of immunizations than they did one week after their immunizations were completed.

Next, the researchers fed serum containing the antibodies to mosquitoes carrying *P. falciparum*. Microscopic examination of the mosquito digestive tracts revealed that the antibodies were capable of completely eliminating the ookinetes. The study authors noted that Psv25H, a molecule similar to Pfs25, is found on the surface of ookinetes of another species of *Plasmodium* that causes malaria, *P. vivax*. They wrote that the conjugate technology could be easily adapted to make a vaccine against Psv25H.