

Current clinical research related to the health of ethnic minority populations is essential to eliminate health disparities. Readers of *Ethnicity & Disease* may be interested in the progress and results of the following clinical trials. These trials describe only some of the research performed in ethnic minority health; other current trials may be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). The information below was accurate at press time; the study researchers should be contacted for more information.

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## NATURAL HISTORY OF HPV INFECTION IN MEN: THE HIM STUDY

Sponsored by: the H. Lee Moffitt Cancer Center and  
Research Institute, National Cancer Institute

Although the natural history of human papillomavirus (HPV) infection in women is under investigation in several large cohort studies, no prospective studies of HPV infection in men who may transmit HPV to women are in progress. To date, only small cross-sectional studies and small prospective studies in northern Europe have been conducted among heterosexual men. To more fully understand HPV disease in both men and women, there is a need for information regarding the natural his-

tory of male HPV infection. Several questions remain to be answered before prevention strategies, such as implementation of an HPV prevention vaccine, can be fully implemented. These questions include types of HPV infecting men, incidence of infections, duration and persistence of infections, type-specific antibody response to HPV infections, and factors associated with incidence, persistence, and HPV antibody response in men. This is a prospective male HPV

cohort study to develop a fuller understanding of HPV infection in men. This study would be the first study of the natural history of penile HPV infection in US, Brazilian, and Mexican men.

Inclusion criteria: age 18–70 years; resident of southern Florida, Sao Paulo, Brazil, or the state of Morelos, Mexico; no prior diagnosis of penile or anal cancer; never been diagnosed with genital and anal warts; no prior diagnosis with AIDS or HIV.

Exclusion criteria: symptoms of any sexually transmitted infection (excluding HPV) during screening.

Study start: June 2005  
Study end: July 2014

This study is currently recruiting participants. Contact Martha Abrahamsen, H. Lee Moffitt Cancer Center and Research Institute, Inc, Tampa, FL 33612; 813-745-6055; [martha.abrahamsen@moffitt.org](mailto:martha.abrahamsen@moffitt.org).

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## HOST FACTORS IN INVASIVE AND RECURRENT STAPHYLOCOCCUS AUREUS INFECTION

Sponsored by: the National Institute of Allergy and  
Infectious Diseases

The incidence of community-acquired staphylococcal infections, especially those caused by methicillin-resistant *Staphylococcus aureus* (MRSA), has increased dramatically in recent years. Although most of these infections are limited to the skin and soft tissue and thus not life threatening, the number of invasive cases in otherwise healthy people is increasing and some are fatal. As a first step toward

understanding pathogenesis, there has been focus on elucidating the key community-acquired MRSA virulence factors, but there has been little focus on host factors associated with these invasive infections. In this protocol, we will recruit 100 otherwise healthy participants with invasive staphylococcal infection, 50 otherwise healthy participants with recurrent staphylococcal infections, and obtain

samples from 150 unidentified healthy controls from the blood bank to investigate host immunologic factors predisposing people to staphylococcal infection. Participants will receive standard of care treatment for acute or recurrent staphylococcal infections. The primary objective of this research is to identify host genetic factors that contribute to susceptibility or severity of community-acquired staphylococcal

diseases. We will use 3 experimental approaches to complete this objective: 1) expression microarray analyses of study participants' (subjects and controls) leukocytes (neutrophils and peripheral blood mononuclear cells) at rest and stimulated with staphylococci, 2) evaluation of toll-like receptor pathways in study participants' cells, and 3) evaluation of Th17 cells. The proposed research will address a

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key area of staphylococcal pathogenesis for which there is a striking lack of information. We fully anticipate that the research also will provide critical new information directly relevant to vaccine, diagnostics, and therapeutics.

Inclusion criteria: age  $\geq 2$  years, current or past *S aureus*

infection, either invasive or soft tissue, willingness to allow storage of blood and tissue samples for future use.

Exclusion criteria: infection with HIV-1 or HIV-2, evidence of intravenous drug abuse in the year before the first (or only) *S aureus* infection, previously known immunodeficiency syn-

drome, evidence of active malignancy, any condition that the investigators judge would compromise the results of the study, diabetes mellitus.

Study start: May 2009

Study end: April 2019

This study is currently recruiting

participants. Contact Patient Recruitment and Public Liaison Office, National Institutes of Health Clinical Center, 9000 Rockville Pike, Bethesda, MD 20892; 800-411-1222; prpl@mail.cc.nih.gov.

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## PROSPECTIVE STUDY OF METHICILLIN-RESISTANT *STAPHYLOCOCCUS AUREUS* (MRSA) AMONG HIV-INFECTED PERSONS

This study will prospectively evaluate the prevalence and incidence (during a 2-year period) of methicillin-resistant *Staphylococcus aureus* (MRSA) colonization and infection among HIV-infected military beneficiaries to determine predictors for the development of MRSA colonization and infection. This study will

also investigate the utility of decolonization procedures for clearance of MRSA carriage and prevention of MRSA infections. Finally, the molecular characteristics and the antimicrobial sensitivities of isolates in this population will be determined.

Inclusion criteria: age  $\geq 18$  years, HIV positive, able to

Sponsored by: the Uniformed Services University of the Health Sciences, Infectious Diseases Clinical Research Program, National Institute of Allergy and Infectious Diseases, US Military HIV Research Program

attend study visits every 6 months.

Exclusion criteria: allergy to mupirocin nasal ointment or hexachlorophene soaps or constituents of these products, pregnant or breastfeeding, healthcare providers with direct patient contact.

Study start: May 2007

Study end: May 2011

This study is currently recruiting participants. Contact Nancy Crum-Cianflone, MD, Naval Medical Center San Diego/Infectious Disease Division, San Diego, CA 92134-1201; 619-532-7475; nancy.crum@med.navy.mil.