

Colombia's Instituto Nacional de Salud (INS) began surveillance for ZIKV in 2015, reporting the first autochthonous transmission in October 2015 in the north of the country. As of October 2016, Colombia has reported over 105,000 suspected ZIKV cases, with over 19,000 of them among pregnant women. With a causal link established between ZIKV infection in pregnancy and microcephaly, there is an urgent need to understand: How ZIKV transmission can be prevented; the full spectrum of adverse maternal, fetal, and infant health outcomes associated with ZIKV infection; and risk factors for occurrence of these outcomes. To answer these questions, INS and the U.S. Centers for Disease Control and Prevention (CDC) will follow 5,000 women enrolled in the first trimester of pregnancy, their male partners, and their infants, in various cities in Colombia where ZIKV transmission is currently ongoing.

The primary study objectives are to: (1) Describe the sociodemographic and clinical characteristics of the study population; (2) Identify risk factors for ZIKV infection in pregnant women and their infants. These include behaviors such as use of mosquito-bite prevention measures or condoms, and factors associated with maternal-to-child transmission; (3) Assess the risk for adverse maternal, fetal, and infant

outcomes associated with ZIKV infection; (4) Assess modifiers of the risk for adverse outcomes among pregnant women and their infants following ZIKV infection. This includes investigating associations with gestational age at infection, presence of ZIKV symptoms, extended viremia, mode of transmission, prior infections or immunizations, and co-infections.

The project aims to enroll approximately 5,000 women, 1,250 male partners, and 4,500 newborns. Pregnant women will be recruited in the first trimester of pregnancy for study enrollment, followed by assessments during pregnancy (every other week until 32 weeks gestation and monthly thereafter), and within 10 days postpartum. At all visits, participants will complete visit-specific questionnaires. In addition to the questionnaires, at all pregnancy and delivery visits, participants will receive Colombian national recommended clinical care and provide samples for laboratory testing.

Male partners will be recruited around the time of the pregnant partners' study enrollment, followed by monthly visits until his pregnant partner reaches the third trimester (approximately 27 weeks gestation). If the male partner contracts ZIKV during this time, visits will occur every other week until the partner has two negative

consecutive tests for ZIKV or the pregnancy ends. At all study visits, male partners will complete visit-specific questionnaires and provide samples for laboratory testing.

All newborns of mothers participating in the study will be followed every other week from birth to 6 months of age. At all visits, infants will receive national recommended clinical care (at birth and clinic visits at 1, 2, and 6 months), provide samples for laboratory testing, and mothers will complete study-specific questionnaires about infant ZIKV symptoms and developmental milestones. During follow-up, infants will also have cranial ultrasounds, their head circumference measured, and hearing and vision tests. For mothers and their infants, relevant information collected as part of clinical care will be abstracted from medical records. Study results will be used to guide recommendations made by both INS and CDC to prevent ZIKV infection; to improve counseling of patients about risks to themselves, their pregnancies, their partners, and their infants; and to help agencies prepare to provide services to affected children and families. Participation in this study is voluntary. The estimated number of annual Burden Hours are 20,548 and there are no costs to participants other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Pregnant women .....	Pregnant women eligibility questionnaire .....	3,125	1	5/60
	Pregnant women enrollment questionnaire ...	2,500	1	35/60
	Adult symptom questionnaire .....	2,500	15	10/60
	Pregnant women follow-up questionnaire .....	2,500	8	15/60
	Infant symptoms questionnaire .....	2,250	14	10/60
	Infant Ages and Stages Questionnaire: 2 Month.	2,250	1	15/60
	Infant Ages and Stages Questionnaire: 6 Month.	2,250	1	15/60
Male partners .....	Male partner eligibility questionnaire .....	2,500	1	5/60
	Male enrollment questionnaire .....	625	1	25/60
	Adult symptom questionnaire .....	625	7	10/60

**Leroy A. Richardson,**  
*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day-17-17BZ]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) has submitted the

following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your

comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Project PrIDE (PrEP Implementation, Data to Care & Evaluation)—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Approximately 50,000 people in the United States are newly infected with HIV each year. Gay, bisexual, and other

men who have sex with men (MSM) remain the US population most heavily affected by HIV infection. Among MSM, those who are black and Hispanic comprise 58% of all new infections. To address the burden of HIV in this population, high impact HIV prevention approaches should be implemented by state, local, and territorial health departments to reduce new HIV infections among MSM of color, and to improve outcomes along the HIV continuum of care for MSM of color living with HIV.

Antiretroviral (ARV) medications for pre-exposure prophylaxis (PrEP) can be used for HIV prevention by MSM at substantial risk for HIV acquisition or by those with a possible HIV exposure in the past 72 hours post-exposure prophylaxis (nPEP). The daily use of co-formulated tenofovir disoproxil fumarate and emtricitabine (marketed as Truvada) for PrEP has been proven to significantly reduce the risk of HIV acquisition among sexually active MSM. In July 2012, the US Food and Drug Administration approved an HIV prevention indication for Truvada, and in May 2014 CDC published clinical practice guidelines for provision of PrEP. Given the high incidence of HIV among MSM of color, those who are sexually active are considered at risk for HIV acquisition and thus could benefit from prevention services such as routine and frequent HIV screening with lab-based 4th generation HIV tests, routine screening for STDs, assessment of PrEP eligibility, provision of PrEP (if at substantial risk for HIV acquisition), provision of nPEP (if a possible HIV exposure occurred in the past 72 hours), and/or other risk reduction interventions.

Among people living with HIV (PLWH), ARV treatment can suppress HIV viral load, which both improves health outcomes of individuals and

reduces the risk of HIV transmission. Two studies, one that demonstrated the effectiveness of ARV treatment in preventing HIV transmission, and one that demonstrated improved health outcomes for individuals whose ARV treatment was initiated immediately, have led to increased public health focus on interventions and strategies designed to initiate ARV treatment, link, retain, and re-engage PLWH in HIV care, and to provide support for adherence to ARV medications.

The purpose of the project is to implement PrEP demonstration projects. Health departments that are funded under this cooperative agreement will be required to prioritize their services to MSM and transgender persons at high risk of HIV infection, particularly persons of color. PrEP services may also be provided to HIV-negative persons at substantial risk for HIV who are not MSM or transgender. Additionally, Data to Care services may be provided to persons diagnosed with HIV infection and out of care, those who are in care but not virally suppressed, or those who have ongoing risk behavior who are not MSM or transgender.

The goals of PrIDE are consistent with the long-term goals of the National HIV/AIDS Strategy (NHAS) including reducing HIV incidence, increasing access to HIV care and optimizing health outcomes, and reducing HIV-related health disparities.

To evaluate the impact of PrIDE in the 12 jurisdictions, data will be collected from both existing CDC data sources and through new data collection activities.

CDC HIV program grantees will collect, enter or upload, and report agency-identifying information, budget data, information on the HIV prevention and care services, and client demographic characteristics. The total annual burden hours are 1,104.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Clients .....	Data Elements .....	2,400	1	25/60
Health Departments .....	Data Management Upload .....	12	2	20/60
Health Departments .....	Performance Progress Report .....	12	1	8

**Leroy A. Richardson,**

Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Centers for Disease Control and  
Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****Healthcare Infection Control Practices Advisory Committee (HICPAC)**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) announces a meeting of the aforementioned committee:

*Times and Dates:*

9:00 a.m.–5:00 p.m., EDT, July 13, 2017  
9:00 a.m.–12:00 p.m., EDT, July 14, 2017

*Place:* Centers for Disease Control and Prevention, Global Communications Center, Building 19, Auditorium B, 1600 Clifton Road NE., Atlanta, Georgia, 30329.

*Status:* Open to the public, limited only by the space available. Time will be available for public comment. The public is welcome to submit written comments in advance of the meeting. Comments should be submitted in writing by email to the contact person listed below. The deadline for receipt is June 30, 2017. All requests must contain the name, address, and organizational affiliation of the speaker, as well as the topic being addressed. Written comments should not exceed one single-spaced typed page in length and delivered in 3 minutes or less. Members of the public who wish to provide public comments should plan to attend the public comment session at the start time listed. Please note that the public comment period may end before the time indicated on the agenda, following the last call for comments. Written comments received in advance of the meeting will be included in the official record of the meeting.

*Purpose:* The Committee is charged with providing advice and guidance to the Director, Division of Healthcare Quality Promotion (DHQP), the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the Director, CDC, the Secretary, Health and Human Services regarding (1) the practice of healthcare infection

prevention and control; (2) strategies for surveillance, prevention, and control of infections, antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of CDC guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

*Matters for Discussion:* The agenda will include updates on CDC's activities for prevention of healthcare associated infections (HAIs), an update on the Division of Healthcare Quality Promotion's (DHQP) modeling activities, updates on the Guideline for Prevention of Infection in Neonatal Intensive Care Unit (NICU) Patients and the Guideline for Prevention of Infection in Healthcare Personnel, and updates from the following HICPAC workgroups: The workgroup on antibiotic stewardship principles for inclusion into clinical practice guidelines, the workgroup on updating the CDC recommendation categorization scheme, the workgroup on developing CDC recommendations for products and practices, and the National Healthcare Safety Network (NHSN) Surveillance Workgroup.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Erin Stone, M.A., HICPAC, Division of Healthcare Quality Promotion, NCEZID, CDC, 1600 Clifton Road NE., Mailstop A-07, Atlanta, Georgia 30329, Telephone (404) 639-4045. Email: [hicpac@cdc.gov](mailto:hicpac@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Secondary Review**

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the secondary review of applications in response to Funding Opportunity Announcements (FOAs), CE17-003, Research Grants for Preventing Violence and Violence Related Injury (R01); and PHS 2016-02 Omnibus Solicitation of the NIH, CDC FDA, and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44]).

*Time and Date:* 8:00 a.m.–5:00 p.m., EDT, July 18, 2017 (Closed).

*Place:* Teleconference.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters for Discussion:* The meeting will include the secondary review, discussion, and evaluation of applications received in response to FOAs "Research Grants for Preventing Violence and Violence Related Injury (R01)", CE17-003; and "PHS 2016-02 Omnibus Solicitation of the NIH, CDC FDA, and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])".

*Contact Person for More Information:* Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE., Mailstop F-63, Atlanta, Georgia 30341, Telephone (770) 488-1430.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and