Major Study of Combination HIV Prevention Gets Underway
HPTN 071 (PopART) Seeks to Reduce HIV Transmission

September 30, 2013—The HIV Prevention Trials Network (HPTN) is pleased to announce the launch of the HPTN 071 study (PopART—Population Effects of Antiretroviral Therapy to Reduce HIV Transmission). This study will be conducted in South Africa and Zambia and will determine the impact of a combined package of several HIV prevention interventions in reducing the number of new HIV infections in communities. The prevention package includes a universal HIV test and treat model (UTT), with annual home-based HIV testing, linkage of those found to be HIV positive to care and the offer of immediate antiretroviral therapy (ART) for all HIV-infected adults, irrespective of CD4 count.

Data from recent clinical trials have demonstrated the efficacy of components of the combination prevention package that will be offered. While most of these prevention approaches are now offered in many high HIV prevalence settings, achieving high enough coverage to reduce the number of new infections has proven challenging. The HPTN 071 (PopART) study will aim to deliver the prevention package to all households within a community to enhance coverage and thereby reduce new HIV infections at the population level. Specially trained community health workers will play a key role in achieving high coverage of the interventions.

“There is a very strong rationale for test-and-treat as a new approach to HIV prevention,” said Richard Hayes, HPTN 071 (PopART) Principal Investigator and Professor of Epidemiology and International Health at the London School of Hygiene and Tropical Medicine. “The study will help determine whether this approach can be delivered on a wide scale in sub-Saharan Africa with high uptake and coverage, and what impact this will have on HIV incidence at the population level.”

HPTN 071 (PopART) builds upon previous research that bolsters the argument for this prevention approach. HPTN 052 was the first randomized trial to demonstrate that treating an HIV-infected individual with ART can significantly reduce the risk of sexual transmission of HIV to an uninfected partner, and the HPTN study Project Accept (HPTN 043) found that adding community mobilization and mobile HIV counseling and testing to facility-based testing can improve rates of testing in rural communities compared to facility-based testing alone. In a recent observational study in KwaZulu-Natal, expansion of HIV treatment (according to prevailing South African guidelines) at advanced stage of HIV disease was also shown to be associated with a reduction in HIV incidence.

“HPTN 071 (PopART) is a natural extension of HPTN’s HIV prevention research portfolio as it relates to integrated strategies for HIV prevention,” said Dr. Wafaa El-Sadr, HPTN Principal Investigator. “The findings from HPTN 071 (PopART) will be critical for policy makers as this study will determine whether such an HIV prevention package will work at population level and whether it is cost effective.”
The study will involve 21 communities in South Africa and Zambia with a total population of 1.2 million. The communities were randomly assigned to one of three groups (arms) in a public randomization ceremony. The full HPTN 071 (PopART) intervention package will be offered to seven communities (Arm A), another seven communities will receive the full package but with ART initiated according to current national guidelines (Arm B) and the remaining seven communities will receive current standard of care for both testing and treatment (Arm C). To measure the impact of the intervention, a population cohort consisting of a representative sample of 2,500 adults will be recruited from the general population of each community (a total of 52,500 across all 21 communities) and will be followed up annually for three years. The occurrence of new HIV infections in these communities will be compared between the three study arms to determine the effect of the PopART interventions.

The full PopART HIV prevention package that will be offered includes:

- House-to-house voluntary HIV testing offered at annual intervals
- Linkage of HIV-infected individuals to HIV care
- Promotion of voluntary medical circumcision for HIV-uninfected men
- Promotion of steps to prevent mother-to-child HIV transmission
- Referral of individuals with symptoms suggestive of TB or sexually transmitted infections for diagnosis and care at the local health center
- Provision of condoms

“This study represents an important research milestone,” said Helen Ayles, HPTN 071 (PopART) Site Principal Investigator in Zambia and ZAMBART Project Coordinator. “It represents another critical step in the global effort to identify combination prevention strategies that can significantly reduce HIV incidence in populations that bear a disproportionate burden of HIV infection.”

The study is in line with the goals of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) which aims to match interventions and investments with epidemiological trends and needs in order to improve impact.

“HPTN 071 (PopART) will make it possible for universities, departments of health, non-governmental organizations and communities to work together to find novel ways of reducing the transmission of HIV,” said Nulda Beyers, HPTN 071 (PopART) Site Principal Investigator in South Africa and the Director of the Desmond Tutu TB Centre (DTTC) at Stellenbosch University. “The end result we hope is better health for populations at risk for HIV infection.”

The study is being conducted by the National Institutes of Health-funded HIV Prevention Trials Network (HPTN). The study is led by investigators at the London School of Hygiene and Tropical Medicine in collaboration with Imperial College London, the Zambia AIDS Related Tuberculosis Project (ZAMBART) and the Desmond Tutu TB Centre at Stellenbosch University, South Africa. The study is sponsored by NIH’s National Institute of Allergy and Infectious Diseases (NIAID), with funding from PEPFAR. Additional funding is provided by the International Initiative for Impact Evaluation with support from the Bill & Melinda Gates Foundation, as well as by NIAID, the National Institute on Drug Abuse and the National Institute of Mental Health, all part of NIH.