

HPTN 058: RAPID POLICY ASSESSMENT FOR CHINA AND THAILAND

HPTN 058 is an NIH-funded Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection among opiate dependent injectors. It is the first randomized trial to compare two approaches to drug treatment as HIV prevention. Participants in this trial are active drug injectors in Chiang Mai, Thailand and Guangxi and Xinjiang Provinces, China. Recognizing the potential for trial participation to disclose the status of the drug using participant and to increase the risk of legal and social harms, the HPTN 058 protocol included the following proviso:

“Given the status of illegal drug use, the associated social stigma and perceptions of drug users held by many members of the communities in which the study will be conducted, social harms could occur purely as a result of participation in a study targeting drug users. These could include discriminatory treatment and violence associated with possible disclosure of participants’ drug or sex-related behaviors or of their HIV serostatus. Prior to site activation, a review of local and national policies and practice affecting injection drug users will be conducted. The purpose of this review will be to verify that law, policies and enforcement strategies do not place participants in the research at significantly elevated risk of arrest, incarceration, physical harm, unwanted disclosure of drug use, or loss of access to health care relative to injection drug users not participating in the research.

“The assessment will consist of two components. The first component will review and analyze the law relevant to injection drug use by examining laws concerning drug control, drug use, access to health care and privacy of medical information in each study country. This review will identify and collate constitutions and any treaties that have the force of law, statutes passed by the national, regional or local legislature, administrative regulations with the force of law and relevant court decisions interpreting these laws or regulations. This review will be conducted with the close involvement of independent legal experts in each study country. The second component will assess how these laws are put into practice and what possible influence they have on the risks and benefits of IDU participation in the study. Qualitative data regarding the effects of law on IDUs will be gathered, along with data on stigma, social risk, and social attitudes as they apply to IDUs. These data will be collected via interviews with key informants in the legal and public health fields as well as current and former injection drug users. Data will be collected via standardized interview forms by independent researchers at each site. The review will provide a narrative summary and analysis of the law and its likely effects on study participants. As these laws, policies and practice strategies can be expected to change over time, this review will be updated on an annual basis for the duration of HPTN 058.” (HPTN 058 Protocol, Version 1.0; Section 6.3; 7 October 2005)

This report summarizes the findings of the social and legal risk analysis. The work was version of Rapid Policy Assessment and Response (RPAR). RPAR combines standard legal research (collecting “law on the books”) with rapid qualitative assessment of how these laws are actually applied by government agencies and the effects law enforcement has on legally

marginalized people at risk of HIV/AIDS (“law on the streets”). (for more information see www.rpar.org).