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Development and implementation of participant safety plans for international research with stigmatised populations

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People who inject drugs with high-risk sharing practices have high rates of HIV transmission and face barriers to HIV care. Interventions to overcome these barriers are needed; however, stigmatisation of drug use and HIV infection leads to safety concerns during the planning and conduct of research on such interventions. In preparing to address concerns about safety and wellbeing of participants in an international research study, HIV Prevention Trials Network 074, we developed participant safety plans (PSPs) at each site to supplement local research ethics committee oversight, community engagement, and usual clinical trial procedures. The PSPs were informed by systematic local legal and policy assessments, and interviews with key stakeholders. After PSP refinement and implementation, we assessed social impacts at each study visit to ensure continued safety. Throughout the study, five participants reported a negative social impact, with three resulting from study participation. Future research with stigmatised populations should consider using and assessing this approach to enhance safety and welfare.

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Introduction

High-risk sharing practices among people who inject drugs (PWID) are associated with high rates of HIV transmission in several parts of the world,[1] where PWID also face barriers to HIV testing and engagement in care. Interventions that overcome these barriers need to be developed and tested;[2] however, stigmatisation of drug use and HIV infection lead to safety concerns during the conduct of such research. Accordingly, in designing and completing a study among injection networks in Indonesia, Ukraine, and Vietnam, we created a formalised, multistage process to ensure participant safety by developing and implementing procedures that minimise risk and respond to social harms that might occur (figure).

HIV Prevention Trials Network (HPTN) 074 (NCT02935296) involved random assignment of injection networks in Indonesia, Ukraine, and Vietnam to an integrated intervention compared with standard of care.[3] The study included single sites in Jakarta, Indonesia and Kiev, Ukraine; in Vietnam, two study sites were used, both within the province of Thai Nguyen. After site selection, we identified the legal and social risks at each site in two phases. First, a local drug and HIV/AIDS legal and policy assessment was done by local experts. Second, site teams did a series of semistructured, qualitative interviews with key stakeholders including PWID, clinicians involved in treating drug use or HIV infection, law enforcement officials, and people with expertise on national drug policies to help place this formal policy review into context and to identify potential risks associated with study participation. Interview topics included: social attitudes towards PWID and access to care, law enforcement practices that might increase PWID participant risk, and awareness of research with PWID. The Health Research Ethics Committee of the Faculty of Medicine at the University of Indonesia, the Ukrainian Institute on Public Health Policy Institutional Review Board 1, and the Hanoi School of Public Health Institutional Review Board approved these stakeholder interviews, which were done after obtaining oral consent.

The local teams prepared summaries of the findings that did not include personal identifiers. The findings from all sites were reviewed by study leadership as well as members of the larger HPTN Ethics Working Group with particular expertise in ethics (JS) and laws regarding research with humans (MB). Additional information was requested from the local experts and study teams when needed. Patient safety plans (PSPs) were then developed at each site on the basis of the aggregate information obtained. If investigators had a difference of opinion regarding a particular risk, the sites erred on the side of caution and incorporated these concerns into the PSPs. None of the sites experienced conflict during PSP development. Draft PSPs from each site were reviewed by study leadership and the Ethics Working Group members, refined, and then implemented. To identify problems associated with research participation, we routinely assessed social impacts at each study visit. Specifically, participants were asked: "Because of your participation in this study, did anything negative or bad happen to you that you have not reported to us already?" If they answered yes, a series of questions was asked regarding the nature of the negative social impacts.

Local site assessments

Various laws relate to drug use at all sites, and some measures, such as mandatory medical examinations, can cause personal and social harms to clients. Although trial enrolment was not expected to be high risk for research participants, the need to have stringent measures to protect confidentiality was a concern. Furthermore, PWID living with HIV can face layered stigma stemming from drug use behaviours and HIV status, which necessitated explicit consideration during study implementation. Additionally, discretion in law enforcement can lead to selective policing, which in turn increases opportunities for possible corruption and

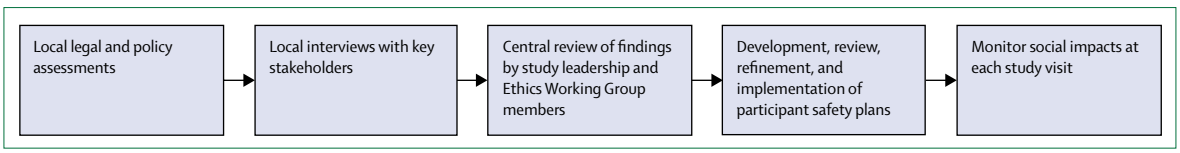

Figure: **Participant safety plan development, implementation, and assessment**

unfairness in law enforcement that have been documented in other settings.[4] We present a brief summary of the findings at each site.

Indonesia

The Government of Indonesia endorses harm reduction programmes such as scaling up of needle and syringe exchange programmes and methadone maintenance treatment (MMT) in provinces with high numbers of PWID.[5] Government policies show a commitment to treating PWID as patients rather than as criminals.[6,7] As long as PWID are not involved in criminal activity, including drug dealing, trafficking, or smuggling, they are referred to drug treatment rather than being incarcerated. The government is also increasing HIV treatment coverage among key populations, including PWID.[6] Because HPTN 074 was aligned with these policies, the study was not anticipated to increase risks or harms to participants. Nonetheless, stigma and discrimination towards PWID in Indonesia still exist. Basic health care and HIV treatment are accessible to PWID, and the attitudes of health workers and counsellors who work in drug and HIV treatment towards PWID are generally positive. Communities do not pay particular attention to PWID as long as they are not committing crimes in their neighbourhoods. Participants showed concern about keeping their HIV status confidential if they became involved in HIV-related research. All PWID interviewees said that involvement in previous research activities did not result in any harmful events. Thus, the social risks for participants in HIV-related studies were expected to be low.

Ukraine

To address challenges in combating illicit drug use, the Government of Ukraine identifies people who illegally use drugs,[8] performs compulsory medical examinations and drug testing of people who use drugs or psychotropic substances,[9] and provides voluntary treatment for people with drug addiction.[10,11] The government can forcefully bring individuals who evade medical examination or testing to a drug rehabilitation facility with an authorised police representative.[9] Additionally, a person is exempt from criminal liability if they voluntarily contacted a health-care facility and started treatment for drug use. Yet, policies such as compulsory medical examinations raise concerns about how the legal system views people who inject drugs. Nevertheless, the HPTN 074 study was not anticipated to increase the risk of police interception because the study site is located at the community centre of a non-governmental organisation that has well established relationships with local stakeholders, including the police. Similarly, as suggested by previous studies in Ukraine, study participation alone does not increase participants' risk of stigma and discrimination. Nevertheless, a breach of confidentiality could substantially affect study participants and result in multiple issues in different social domains (eg, employment, interpersonal relations, medical care, and the law). Additionally, the underfunding of the national HIV and AIDS programme could increase motivation to participate in HIV-related studies, as study participation might be an opportunity to receive additional services.

Vietnam

PWID in Vietnam, including those in prisons or mandatory detoxification centres, have equal rights to access health-care services.[12] Many PWID receive antiretroviral therapy or MMT; according to Vietnamese law, these services must be provided without interference from law enforcement officials.[13] Law enforcement officials cannot look for or arrest PWID at MMT clinics unless individuals directly violate a law at the clinic, such as selling drugs on clinic property.[13] Similarly, personal and identifying information about patients is confidential by law, thus no one may disclose this information to law enforcement unless a patient violates a law or is incarcerated.[12] PWID are subject to arrest if caught selling drugs and police can create a drug record for individuals who test positive for drugs.[14] Any person who has a drug record and is not in MMT can be subject to mandatory drug treatment for up to 2 years through a court decision.[14] Although some social stigma exists, community and law enforcement officials strongly support MMT and research projects that facilitate access to it. Additionally, PWID reported very positive experiences with past research participation.

Participant safety plans

The PSPs across all sites shared common features: protecting confidentiality, reducing stigma and discrimination, providing emergency contacts, implementing staff training and standard operating procedures, and monitoring of social harm (panel). However, each site developed unique approaches on the basis of local policies and social context, and the issues identified in the local site assessments. Although some of the measures implemented as part of the PSPs at the sites are commonplace in well done clinical trials (eg, measures to maintain data security and staff training regarding

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good clinical practices), others are not (eg, training on stigma, having emergency plans for social harms, and routine monitoring of social harms at study visits).

Indonesia

The Indonesian PSP had six key components: specific procedures to minimise risks, routine social harm assessment and reporting, a safety committee to review all harms to participants, training for staff on participant security and safety, designating emergency contacts, and monitoring staff interactions with participants. The procedures to minimise risk included referring to the study as an HIV prevention activity rather than one involving PWID or people living with HIV/AIDs (PLWH), making referrals for treatment without mention of the study, keeping study information separate from personally identifying information, designating all study records as health records to add legal confidentiality protections, and having all staff sign confidentiality agreements. Additionally, par-ticipants could directly contact trial site leadership with concerns and were provided with their private phone numbers.

Ukraine

The Ukrainian PSP had five key components: monitoring harms (at each study visit as well as providing a phone number for reporting); privacy protections; police interference prevention; stigma and discrimination reduction, primarily by employing staff with experience in working with PWID; and communication with stakeholders through attendance at community advisory board (CAB) meetings or by arranging other opportunities for discourse. In addition to the use of standard procedures for ensuring data security, procedures were developed in collaboration with the CAB to minimise concerns about privacy and confidentiality. For example, information obtained and recorded at study visits was restricted to that necessary for study conduct. Because participants' names were not collected at these visits, study information was not legally required to be reported to authorities. Furthermore, issues related to confidentiality were included in the informed consent process for the study. To protect participants from police interference, the site was located at a community-based non-governmental organisation with long-established relationships with local police; no cases of police interference, seizure of clients for medical examination, or abuse of programme clients have been reported in or near the community centre. Additional engagement of the CAB with local police facilitated the implementation of the PSP. Finally, participants were referred to human rights protection seminars to minimise problems with inappropriate police in-terventions.

Vietnam

The Vietnamese PSP had six main components: minimising risks related to confidentiality and stigma, routine social harm assessment and reporting, establishing an emergency plan that included front-line staff training to immediately address concerns that can be escalated as needed, taking practical measures to mitigate risk, providing training for staff on participant security and safety, and designating emergency contacts. To minimise stigma, the study was done at a site where multiple medical services are delivered, thereby not distinguishing study participants. Additionally, routine CAB engagement provided a way for staff to be aware of stigma in the community. Practical measures to mitigate risk included not referring to the study as involving PWID or PLWH, targeted recruitment instead of recruitment in the general population, the use of participant identification numbers rather than names, standard data security measures supplemented with staff signing confidentiality statements, monitoring staff interactions with participants, and providing a way for participants to report inappropriate staff behaviour in confidence to study site leadership.

Panel: **Common features of participant safety plans (PSPs) and selected implementation measures**

Protecting confidentiality

- Identification of the study as aimed at understanding HIV/AIDS, not a study of people who inject drugs or people living with HIV/AIDs
- Study identification numbers instead of names used on all materials
- Participant locator information kept separately from study data in a separate, locked location only accessible by selected staff
- Secure data storage
- Confidentiality agreements

Stigma and discrimination reduction tactics

- Selected study locations
- Meetings with community advisory boards
- Private means to contact study leadership or chair of the institutional review board with complaints about study staff

Emergency plan or contacts

- Pocket-sized cards with contact information given to participants upon enrolment
- Collaboration with local authorities in case problems occurred

Staff training and standard operating procedures

- Training on confidentiality and stigma reduction as well as good clinical practices, good participatory practices, and human research participant protection
- Standard operating procedures related to PSPs

Social harm monitoring

- Routine monitoring for social harms at each study visit along with scheduled trial procedures

Social impacts

During the HPTN 074 trial, five participants reported negative social impacts. Two cases occurred in Indonesia as a result of law enforcement actions unrelated to study participation. Three others resulted from participants sharing HIV information that might not have been known had they not joined the study: one participant in Vietnam reported that his girlfriend left him because of his presumed HIV status and participation in the study, another in Vietnam described being isolated from his family and losing housing after revealing his HIV status, and one in Ukraine indicated he was divorced by his partner after disclosure of his high viral load. Study teams did not intervene in cases of law enforcement actions unrelated to the study; however, they provided counselling and support for study-related negative social impacts at study visits. Although specific provisions for long-term support of negative social impacts were not included in the PSPs, none of the participants required further help. Additionally, no sites needed to use the emergency procedures described in their PSPs during the trial and none of the sites amended their PSP plan after implementation.

Discussion

A systematic approach to the identification of potential social harms and the development and implementation of PSPs on the basis of the potential harms before beginning research with a stigmatised population was associated with minimal reports of social harms and successful enrolment and completion of the trial. The multistage process involved both local reviews of relevant laws and policies as well as in-depth interviews with key stakeholders at sites. The in-depth interviews facilitated an assessment of the risks that participants might face during the trial and this information was used to develop site-specific PSPs that became part of trial operations. Monitoring social impacts was routinely done at all sites to provide additional protection. However, the negative social impacts caused by study participation in HPTN 074 were related to personal disclosures about HIV status to others rather than governmental policies or other forms of stigma from local communities or staff. Accordingly, future work in the development of PSPs should consider incorporating measures to minimise social risks associated with personal disclosures of health information.

Ensuring that we obtained accurate and current information about laws and policies in each country, and whether and how they were enforced, was challenging. We addressed this challenge by carefully selecting legal and policy experts to facilitate initial reviews and the stakeholders we interviewed.

We incorporated previously described elements of approaches used to identify and to manage the social risks associated with research with stigmatised populations. An approach used for this purpose with good results in similar settings is a rapid policy assessment (RPA).[15] The RPA previously commissioned for an international HIV prevention trial with PWID involved substantial time and resources, and was somewhat distinct from other important community engagement activities related to the trial.[16] Other approaches to making similar assessments have been described; for example, the American Bar Association's Rule of Law Initiative published an HIV/AIDS Legal Assessment Tool.[17] The tool is designed "to conduct assessments of the legal rights of PLHIV and key populations, providing a roadmap for addressing HIV-related discrimination and ensuring States' compliance with the applicable international legal standards".[17] Similar to an RPA and the related approach we used, the tool specifically assesses both de jure and de facto policies. The latter necessitates engagement with key stakeholders to understand enforcement practices. However, the assessment is a broad and resource-intensive undertaking that primarily relates to the law. The endeavour is also not necessarily focused on the particular incremental social risks that might be faced in the context of proposed research.

Of additional relevance are best practices designed particularly for research involving men who have sex with men in stigmatised settings (Respect, Protect, Fulfill), which were developed as a joint effort of amfAR, the International AIDS Vaccine Initiative, the Johns Hopkins Center for Public Health and Human Rights, and the UN Development Program.[18] The best practices emphasise the crucial importance of community engagement and provide checklists for key stakeholders (researchers, community organisations, volunteers, and staff and security) that should mitigate social harms in this context. Nevertheless, in relevant settings this approach might need to be supplemented with a formalised legal assessment, such as the one described here. Additionally, other issues of particular relevance to PWID might not be captured in these best practices.

Although we cannot necessarily attribute the occurrence of only minimal negative social impacts to the PSPs, future research with stigmatised populations should consider using, assessing, and revising this approach to enhance participants' safety and welfare, which in turn should increase peoples' willingness to take part in the study. Further reporting of the methods used would also help to establish best practices in the field.

Contributors

JS conceived of the project, reviewed information from sites, analysed the participant safety plans, reviewed data regarding negative social impacts, and drafted and revised the manuscript. MB reviewed information from sites, analysed the participant safety plans, and revised the manuscript. SR coordinated the development of participant safety plans (PSPs) and revised the manuscript. KD developed the PSP in Ukraine and revised the manuscript. RS developed the PSP in Indonesia and revised the manuscript. HTV developed the PSP in Vietnam and revised the manuscript. OZ worked on the policy assessment and the PSP in Ukraine and revised the manuscript. HS helped to develop the PSP in Indonesia and revised the manuscript. VG helped supervise data collection and data

analysis, helped develop the PSP at the Vietnam site, interpreted data, and revised the manuscript. IH and WCM helped supervise the development of the PSP at all sites, interpreted the data, and revised the manuscript.

Declaration of interests

JS serves on the Merck KGaA Bioethics Advisory Panel and Stem Cell Research Oversight Committee, and the IQVIA Ethics Advisory Panel. He receives consulting income for this work and support for travel to meetings of these committees. MB is a partner in an international law firm that represents universities, academic medical centres, and industry entities in matters related to clinical trials. All other authors declare no competing interests.

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