

EDITORIAL

Unlinked anonymous HIV testing in population-based surveys in India

SUNEETA KRISHNAN¹, AMAR JESANI²

¹Women's Global Health Imperative, RTI International, San Francisco; University of California, Berkeley; 114 Sansome Street, Suite 500, San Francisco, CA 94104, USA
email: suneeta.krishnan@gmail.com ²Indian Journal of Medical Ethics, Anusandhan Trust; Sai Ashray, Aaram Society Road, Vakola, Santacruz East, Mumbai 400055
INDIA email: amar.jesani@gmail.com

The most recent National Family Health Survey (NFHS 3, 2005-2006) was the first population-based survey in India to collect HIV prevalence data from a representative sample of women and men (1). As in other population-based surveys aimed at estimating national HIV prevalence, the NFHS conducted voluntary, unlinked anonymous testing (UAT) (2, 3). Eligible individuals were read an informed consent statement including the information that they would not receive test results. Those consenting provided blood spot samples (1). Although HIV status could not be traced back to the individual, the data were linked to non-identifying information from individuals such as educational attainment, household wealth, and behavioural factors to facilitate an examination of the patterns and correlates of HIV infection.

In light of the national commitment to ensuring access to prevention and treatment as evidenced by the policy on free antiretroviral therapy (ART) and the expansion of prevention of parent to child transmission programmes (4), it is critical to examine the ethical dimensions of population-based HIV prevalence surveys in India. Two key questions are: Was the use of UAT in the NFHS 3 ethically justified? Should a national population-based survey using this approach be repeated?

UAT in the context of sentinel and population-based surveys continues to be recommended for estimation of HIV prevalence in resource-constrained settings (5). Population-based surveys provide countries with critical insights on the prevalence and distribution of HIV infection, and help guide and monitor prevention, care and treatment programmes (2). In settings where access to and utilisation of voluntary counselling and testing (VCT) facilities are limited, population-based surveys may be the only way in which credible information on HIV epidemics can be obtained. However, a number of logistical and ethical concerns arise depending on how HIV testing and counselling are implemented in these surveys.

The complexities of offering HIV counselling and testing in population-based surveys

The logistics of implementing HIV testing in population-based surveys can be complex and vary depending on the testing venue (6, 7). For example, testing offered through fixed VCT units (stand-alone units which individuals have to access for services) require greater investment in testing infrastructure than mobile or home-based testing in which services are directly taken to community residents. Further, reporting procedures can differ depending on where (in the field or at a central laboratory) and how (using rapid or other test) specimens are processed. Overall, logistics have been considerably eased with the advent of rapid testing technologies that facilitate home-based testing (8, 9). Blood samples can be obtained through a finger prick, processed, and reported within 15 minutes, negating the need to establish extensive testing infrastructure, and eliminating delays in reporting of test results and the need to re-contact participants.

However, ensuring privacy and confidentiality during HIV testing can pose significant challenges in situations where survey interviewers may attract attention or data collection occurs in people's homes – as is often the case in developing country settings (6, 8-10). Further, the implications of breaches in privacy and confidentiality may be acute where AIDS related stigma and discrimination are widespread such as in India. Inadvertent disclosure of an individual's HIV status to family or community members can have serious social, economic and psychological repercussions. While these risks may be greatest in surveys that implement home-based testing, they remain a concern even when testing is conducted in a clinical setting.

The ethical basis of unlinked anonymous testing UAT

In the case of UAT, there is minimal risk of breaches in participants' privacy and confidentiality since biological samples are not linked to individuals and results are not reported (5, 6). Further, a key strength of UAT is the ability to minimise selection bias due to refusal of testing. Refusal rates tend to be low (or nil when informed consent is not obtained) and information on those who refuse can be used to adjust prevalence estimates when consent is elicited. However, the ethical basis of this testing approach is weak in the face of expanding availability of effective prevention and treatment options.

Indeed, in the United States (US) and other developed countries, population-based surveys involving the collection of biological data are obligated to report results of tests that yield important physiological or clinical information, although exceptions may be made (6).

The Government of India (GOI) voiced a commitment to ensuring access to free antiretroviral therapy as far back as December 2003, and officially launched its treatment programme, albeit in selected states, in April 2004 (11). Notably, in 2005, at around the same time as the launch of the NFHS 3, two Phase 1 AIDS vaccine trials were also launched with trial sponsors agreeing to provide free ART for the first five years and to advocate for continued governmental provision (12).

It is unclear whether provision of test results and linkage to ART services were adequately considered prior to the decision to implement UAT in NFHS 3. These were theoretically possible at the time of the survey (an endeavour of the government ministry of health and family welfare), at least in high prevalence states.

The justification of UAT can also be questioned on the ground that the NFHS 3 was partly financed by agencies in countries that no longer use UAT themselves. In addition to GOI and organisations of the United Nations system, resources were provided by governmental and non-governmental agencies of developed countries such as the US that were no longer using UAT (5, 13). For example, after 1995, the Centers for Disease Control and Prevention (CDC) withdrew support for UAT surveys of HIV in the US in recognition of the availability of care and treatment services (5). However, a similar move was not advocated in developing countries because of a concern regarding insufficient resources to scale up prevention and care services. The extent to which resource constraints are a legitimate reason for India to implement UAT must be debated, considering, for example, the fact that the country is increasingly a destination for medical tourists (14).

Ethical justification for UAT in India

The paucity of reliable and comprehensive information on HIV prevalence in India, including a reliance on antenatal care based sentinel surveillance, which has been shown to overestimate HIV prevalence (2), has made national programming a precarious and controversial exercise (15, 16). NFHS 3 has the potential to make significant contributions to decisions regarding the allocation of prevention and treatment resources, with recent analyses providing insights into the unique challenges of the Indian epidemic (17, 18).

Given the potential contributions of the survey to the national planning process, it may be argued that the benefits of the survey outweigh the risks and burdens to individual participants. The burden of participation was relatively low, having primarily to do with the type of questions posed, time taken to complete the survey, and the provision of a blood spot sample (6).

At the same time, individuals were offered few direct benefits for participation (1). Participants were offered a pamphlet on HIV/AIDS, a voucher for free VCT services for HIV, and a list of the nearest VCT centres where the voucher could be redeemed. Although the training manual detailed referral procedures in the case of anaemia, few details were provided for HIV-related referrals (1). Furthermore, the NFHS organisation has not published any information on the post-survey utilisation of VCT services, including participants' access to those services, leaving open the question of whether any HIV prevention-related benefits were realised.

In an era of expanding access to an array of prevention and care services, including prevention of parent to child transmission (PPTCT) programmes and ART, the obligation to report HIV test results is difficult to ignore. It is worth noting that other national population-based surveys conducted prior to or around the same time as the NFHS 3 made more vigorous attempts to improve participants' knowledge of their HIV status (7). In Malawi and Cambodia, participants of Demographic and Health Surveys (DHS) were reimbursed travel costs to the nearest HIV testing site. Mali, Ethiopia and Uganda improved or established new VCT centres in conjunction with their DHS. Finally, mobile or outreach VCT provision through teams that made post-survey visits were implemented as part of the DHS in Uganda, the Democratic Republic of Congo, and Kenya.

Importantly, recent research in Malawi has revealed extremely high levels of acceptance of home-based HIV testing – with participants highlighting three key reasons: convenience of home-based testing, high quality of VCT services, including maintenance of confidentiality by survey-trained counsellors, and the credibility of the rapid test (8). These findings question the assumption that fear and stigma hinder uptake of VCT and suggest that, if resources are appropriately mobilised, it is possible to collect high quality data without compromising key ethical principles.

In summary, UAT has been viewed as ethically acceptable in settings where HIV prevalence estimates are urgently needed, but resources are severely limited. Moreover, this approach minimises the risk of HIV positive individuals being unwittingly identified. However, even in the context of UAT, provision of basic information on HIV/AIDS and access to VCT services is universally recognised. The NFHS organisation should clarify the implementation, monitoring and outcome of the provision of information on and access to HIV related services in NFHS 3. Furthermore, given the national commitment to ensuring access to an array of HIV prevention, care and treatment services, including PPTCT and ART, future national population-based surveys that propose to conduct UAT will not be ethically justifiable. Researchers will need to fulfil their ethical obligation to report HIV test results and to link individuals to appropriate care and treatment programmes. Given the experience of other developing countries, this is not an unrealistic goal for India.

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