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# Prevalence and incidence of HIV-1 infection in a community-based men who have sex with men (MSM) cohort in Ulaanbaatar, Mongolia

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**Abstract:** The number of HIV-1-infected men who have sex with men (MSM) Mongolian patients started to increase steeply just before 2011. We started collaborative work with community-based organizations that promote safer sex and HIV testing for MSM since mid-2010. Since early 2013, the Mongolian Government has implemented the treat-all strategy for MSM. To determine the efficacy of these countermeasures, we established an MSM cohort in the capital of Mongolia, Ulaanbaatar, in December 2013. HIV antibody was examined at every visit by rapid test. Syphilis was also examined to monitor their sexual behavior. Clients positive for either rapid test were referred to the National Center for Communicable Diseases, Ulaanbaatar, to confirm the results and treatment. Since safer sex promotion is one of the purposes of this cohort, HIV-positive clients were also eligible to participate. A total of 849 MSM were registered and 2,409 HIV/syphilis tests were conducted until December 2017. During this period, 499 (58.8%) clients visited the testing sites repeatedly. Among the 849 clients, HIV-1 infection was confirmed in 83 at registration (prevalence of HIV-1: 9.8%). One HIV-1 seroconverter was identified (from negative to positive), resulting in incidence of HIV-1 of 0.10/100 person-years (PY). Syphilis was positive in 144 cases at registration (syphilis prevalence: 17.0%), and 53 new syphilis infection cases were diagnosed during the same period, with an incidence of 5.66/100 PY. Despite the high prevalence of HIV-1, the incidence was very low. The results suggest that countermeasures for HIV-1 prevention seem effective in this cohort, however, we still need further strategies for syphilis control.

***Keywords*:** prevention, deep finger vein authentication system, syphilis

## Introduction

Mongolia is a very low HIV-1 epidemic country (*1,2*). The Second-Generation HIV/STI Surveillance (SGS) was established in Mongolia in 2002 for a better understanding of the sexual behaviors that drive the epidemic and disease trends, and to use surveillance data to monitor and plan for the national response. Since the fourth round in 2005, the Ministry of Health and the National Center for Communicable Diseases (NCCD) conducted SGS. Based on the national surveillance data, the first HIV-1 case in Mongolia was reported in 1992 (*3*) and 250 HIV-1 cases had been reported by the end of 2017 (*4*). Apart from the first 5 cases, all other HIV-1 cases had been reported since 2005. Among the reported HIV-1 cases, 81% were males, 80% of them were men who had sex with men (MSM) (*3*).

In 2007, when our group in Tokyo started to collaborate with the NCCD, only a few HIV-1 infected cases had been reported. The reasons for the low epidemic could be the true status of the low epidemic or poor reporting due to lack of any surveillance system during that time period. In the same year, our research group conducted a community survey to evaluate the risk status of HIV-1 infection in Mongolia. A total of 1,415 blood samples from high-risk populations [*e.g.*, female sex workers (FSWs), MSM, mobile men, patients with active tuberculosis and male clients of the sexually transmitted infection (STI) clinic] and 1,050 samples from healthy adults were also collected and tested for HIV. Analysis of those samples showed no HIV-1 infection (*1*). The SGS survey conducted in the same year (2007) showed similar results of no HIV-1 infected cases except one positive in MSM. In the SGS

survey, 600 FSWs, 118 MSM, 750 mobile men and 1,902 male STI clients were tested for HIV (*5*). Therefore, we concluded that the prevalence of HIV-1 infection was really low in 2007. However, another survey in 2009 identified 3 new HIV-1 infection cases among 167 MSM (1.8%) (*6*) and that in 2011 found 21 new HIV-1 infection among 196 MSM (10.7%) (*7*). These results suggested that HIV-1 infection started to increase exponentially among MSM just before 2011, allowing us to conclude that intervention for HIV-1 prevention was urgently needed. Our molecular epidemiological analysis of HIV-1 infection using blood samples obtained between 2005 and 2009 identified the rapidly expanding HIV-1 transmission network among MSM, strongly confirming our conclusion (*8*).

To control the infection, we collaborated with local community-based organizations (CBOs) that provided safer sex education and promoted HIV testing for MSM since 2010. The Mongolian Government has implemented the treat-all strategy irrespective of CD4 count for MSM since early 2013. The objective of this study was to determine the efficacy of these countermeasures. For this purpose, we established an MSM cohort in Ulaanbaatar in order to document the incidence of HIV-1 infection among MSM after the countermeasures and monitored syphilis for reference of sexual activity.

## Materials and Methods

### *Study design*

MSM cohort was established in the capital of Mongolia, Ulaanbaatar, in December 2013 and followed at the end of 2017. Participants were recruited at two HIV testing sites in Ulaanbaatar. The eligibility criteria were MSM aged 20 years and older. A written informed consent was obtained from all participants. HIV-1-positive MSM were able to participate in this cohort because they could also undergo free syphilis testing, and enroll in safer sex education. Registration was conducted anonymously using a deep finger vein authentication system that connected with all study sites both in Mongolia and Japan and formed the network system. A study ID was automatically assigned based on the individual finger vein pattern and registered in the network system. All specimens and test results were treated with the study ID. Participants were able to receive free of charge rapid tests for HIV and syphilis at any time. The testing interval was left to the participants. Participants, who were positive for HIV and/or syphilis and needed confirmation tests, were referred to NCCD, Ulaanbaatar.

### *Recruitment of participants*

Participants were recruited at Together Center and Rainbow Clinic in Ulaanbaatar. Together Center was operated by CBOs and provided voluntary HIV testing services especially targeting MSM. The medical staff of NCCD oversaw the HIV testing service and cooperated with CBOs activities.

Three major CBOs operating in Mongolia; Together Center, Youth for Health Center and Human Rights Youth Health Support, joined effort to form one community organization in 2015. Accordingly, Together Center moved to the center of Ulaanbaatar. At the same time, Rainbow Clinic opened as a free HIV testing site in NCCD adjacent to where Together Center had been located. Rainbow Clinic joined the cohort recruitment site from August 2015. Participants were able to use both sites.

### *Sample collection and HIV and syphilis testing*

Blood samples were collected at Together Center and Rainbow Clinic. HIV and syphilis were diagnosed using the immunochromatography method (DAINA SCREEN HIV-1/2® and DAINA SCREEN TPAb® for the antibody for *Treponema Pallidum*, Alere Medical, Japan). The surplus blood samples after the rapid tests were kept at -4°C at each testing site and transferred to NCCD to confirm the results at the central laboratory of NCCD. The remaining serum samples were frozen at -80°C and periodically transferred to National Center for Global Health and Medicine (NCGM), Japan, to reconfirm the results by ARCHITECT® (Abbott Japan, Tokyo).

### *Data management*

Central monitoring was performed every 3 months through the network system from Japan. The study monitors visited each site periodically (at least once annually throughout the study period) to ensure the study, records and reports adhered to the protocol and ethical guidelines. The monitors reported any protocol violations and other problems to the principal investigator and shared resolving these issues with collaborative researchers. The study progress and results were reported to the cooperative researchers, NCCD and CBOs every year.

### *Data analysis*

Data of participants with HIV-1 or *Treponema Pallidum antibody* (TPAb) positive at study registration were included only in the HIV-1 and syphilis prevalence calculations. After excluding those participants who were HIV-1 antibody-positive at registration and those who received the test only once, the HIV-1 incidence was calculated using the number of seroconversions within the follow-up period. The total number of person-years (PY) represented the accumulated observation period from the registration date to the last test date. The incidence of syphilis was calculated by using the

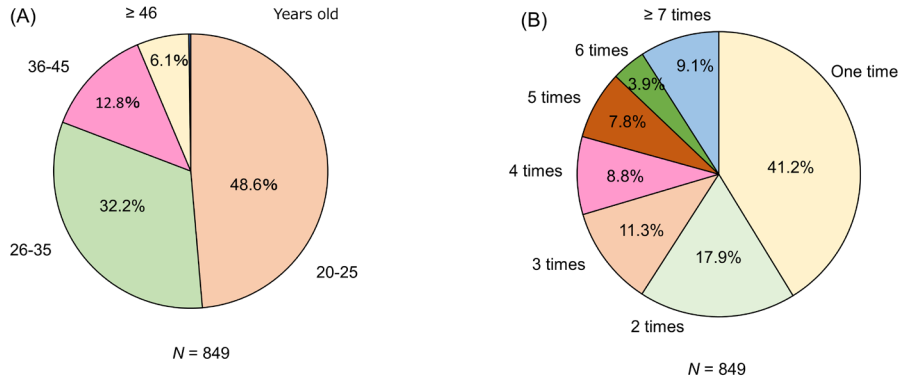


**Figure 1. Background of study participants. (A) Age at registration.** The study included 849 MSM with a median age of 26 years. **(B) Frequency of HIV and syphilis testing during this study.** A total of 2,409 HIV and syphilis tests were conducted in 849 participants. Nearly 60% of the participants received more than one HIV and syphilis test. In other words, 40% of the subjects were regarded as lost-to-follow during the study period.

**Table 1. Prevalence of HIV-1 in our men who have sex with men (MSM) cohort each year**

| Year | Registered MSM (*n*) | Previously diagnosed HIV (*n*) | HIV diagnosis at registration (*n*) | Prevalence of HIV (%) (95% CI) |
|---|---|---|---|---|
| 2014* | 296 | 28 | 9 | 3.4# (1.0-5.7) |
| 2015 | 187 | 7 | 2 | 1.1# (0.0-3.2) |
| 2016 | 212 | 18 | 2 | 1.0# (0.0-3.0) |
| 2017 | 154 | 15 | 2 | 1.4# (0.0-4.1) |
| Total | 849 | 68 | 15 | 1.9 (0.9-2.9) |

*2014 includes data of Dec 2013. #number of HIV diagnosis at registration/(number of registered MSM – number of previously diagnosed HIV) each year.

number of TPAb seroconversions in a manner similar to the calculation used to determine the incidence of HIV-1. The estimated prevalence and incidence were presented with 95% confidence intervals (95% CI).

*Ethics statement*

This study was reviewed and approved by the ethics committees of National Center for Global Health and Medicine (#NCGM-G-001426) on 20 June 2013 and the Ministry of Health, Mongolia (MOH-#3) on 25 October 2013. A written informed consent was obtained from all participants in accordance with the Declaration of Helsinki. This study was registered with the University Hospital Medical Information Network Clinical Trial Registry (Registry number: UMIN000024089).

## Results

*MSM cohort in Ulaanbaatar*

From December 2013 to December 2017, 849 MSM enrolled in this cohort and 2,409 HIV and syphilis tests were performed. At study registration, the majority of participants were relatively young with a median age of 26 years [Interquartile Range (IQR): 21-33] and 413 (48.6%) were 20-25 years old (Figure 1A). Of the 849 enrolled subjects, 499 (58.8%) underwent testing for HIV-1 and syphilis more than once during the study period (Figure 1B). The other 350 (41.2%) enrolled clients were tested only once and did not revisit the testing sites for re-testing, and were thus considered lost-to-follow. At each visit, the CBO staff provided HIV-1 prevention programs that included material on HIV-1 infection, promotion of repeated HIV-1 testing, and safer sex education to the clients. The detailed methods and contents of the HIV prevention strategies offered by the CBOs will be reported in the future.

*HIV-1 prevalence and incidence*

Table 1 shows the prevalence of HIV infection each year and Figure 2 illustrates the study flow and calculations of the prevalence and incidence of HIV-1. Among the 849 MSM participants, 68 had been diagnosed with HIV infection before participation in this study. In addition, 15 new HIV infection cases were confirmed at enrollment. Based on the total number of HIV infected MSM at enrollment of 83, the estimated prevalence of HIV-1 infection in this cohort was 9.8% (95% CI: 7.8-11.8%). The prevalence of each year was relatively low and stable over time (Table 1). Among the 766 cases who were HIV negative on the first test, 446 participants were tested more than once whereas 320 (41.8%) were

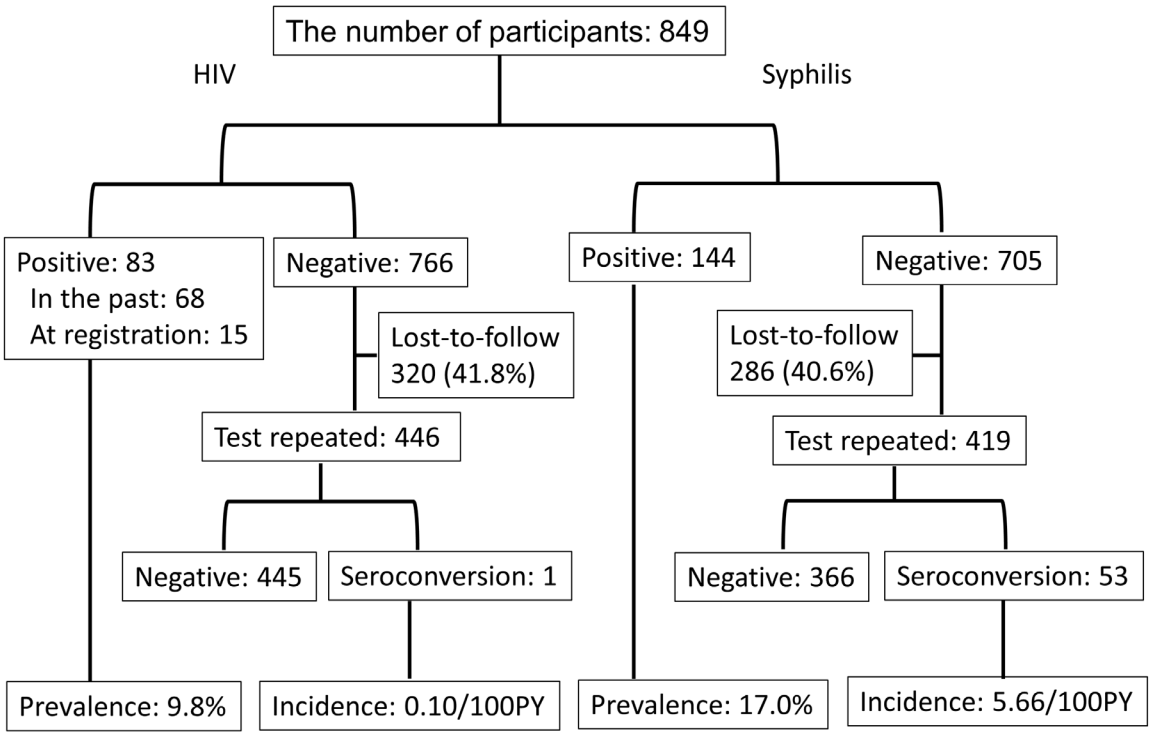


**Figure 2. Prevalence and incidence of HIV and syphilis.** HIV and syphilis tests were conducted in 849 participants. Among these, 83 participants were positive for HIV-1 (68 in the past and 15 at registration) and 766 were negative. Among the 766 participants, 446 were repeatedly tested for HIV and 320 (41.8%) were lost-to-follow. One seroconverted during the study. With regard to syphilis, 144 individuals were positive at registration and 705 were negative. Among 705 participants, 419 were repeatedly tested for syphilis and 286 (40.6%) were lost-to-follow, while 53 seroconverted during the study.

**Table 2. Prevalence and incidence of syphilis in our men who have sex with men (MSM) cohort**

| Year | Registered MSM (*n*) | TPAb-positive at registration (*n*) | Prevalence at registration (*n*) | TPAb negative to positive (*n*) | Cumulative person year (PY) | Incidence (/100PY) (95% CI) |
|---|---|---|---|---|---|---|
| 2014* | 296 | 51 | 17.2 | 2 | 140.6 | 1.42 (0.39-5.19) |
| 2015 | 187 | 30 | 16.0 | 9 | 224.9 | 4.00 (2.11-7.61) |
| 2016 | 212 | 34 | 16.0 | 17 | 299.7 | 5.67 (3.54-9.08) |
| 2017 | 154 | 29 | 18.8 | 25 | 271.9 | 9.20 (6.23-13.58) |
| Total | 849 | 144 | 17.0 | 53 | 937.1 | 5.66 (4.32-7.40) |

*2014 includes data of Dec 2013. TPAb: Antibody for *Treponema Pallidum*.

considered lost-to-follow for HIV testing. Only one HIV seroconversion was noted during the study period. The total observation period was 1,027.3 PY and the median observation period per patient was 2.28 (IQR: 1.30-3.53) years. The overall incidence of HIV was 0.10 (95% CI: 0.02-0.55)/100 PY.

*Syphilis prevalence and incidence*

Table 2 shows the prevalence and incidence of syphilis and Figure 2 illustrates the study flow and calculations of the prevalence and incidence of syphilis. At enrollment, 144 MSM were already TPAb-positive. Accordingly, estimated prevalence of syphilis (history of syphilis infection) was 17.0% (95% CI; 14.5-19.5%). Among the total of 705 syphilis-negative cases, as diagnosed on the first test, 419 were repeatedly tested whereas 286 (40.6%) were regarded as lost-to-follow for the syphilis test. Like HIV, the prevalence each year was relatively stable over the study period. Interestingly, 53 TPAb seroconversions were registered during the study period (937.1 PY). The median observation period per patient was 2.06 (IQR: 1.18-3.40) years. The number of infected individuals increased every year with the calculated incidence for 2014, 2015, 2016, and 2017 of 1.42, 4.00, 5.67, and 9.20/100 PY, respectively. The overall incidence of syphilis was 5.66 (95% CI: 4.32-7.40)/100 PY.

## Discussion

We organized the MSM cohort in Ulaanbaatar from Dec 2013 to Dec 2017 and documented a high prevalence

(9.8%) but low incidence (0.10/100 PY) of HIV-1 infection in this cohort. The nationwide SGS surveillance conducted every two years reported the prevalence of HIV-1 infection in MSM of 0.85%, 1.8%, 10.7%, and 13.7% for 2007, 2009, 2011, and 2014, respectively (5-7,9). These data indicate that HIV-1 infection in MSM increased steeply before 2011. According to the SGS surveillance data and our data of 9.8% (Dec 2013 to Dec 2017), it could be speculated that the prevalence had reached a plateau level. The low incidence data (0.10/100 PY) adds support to our speculation. The HIV and Syphilis Surveillance Survey Report (SSR) 2017 published in 2018 also demonstrated a similar result with regard to HIV-1 prevalence in MSM 9.2% (95% CI: 8.7-9.7) (*10*). These results clearly suggest that our countermeasures for HIV-1 prevention against MSM implemented since 2010 had been effective.

Our countermeasures can be divided into two separate arms. The first was HIV-1 prevention programs for MSM and implemented since 2010 by three CBOs. Before that activity, exposure of Mongolian MSM to HIV prevention programs was limited (*11*) and coverage of HIV testing was suboptimal (*12*). Our previous molecular study documented that HIV-1 infection increased rapidly in MSM before 2011 (*8*). The population of Mongolia is around 3 million and nearly half of them live in Ulaanbaatar. Accordingly, it is assumed that the majority of Mongolian MSM live in the capital Ulaanbaatar and their social and sexual network is rather concentrated in their community. It is therefore not surprising that the spread of HIV-1 infection was rapid before 2011 in the absence of adequate knowledge about HIV-1 prevention. In contrast, the decline in infection rate was thought to be fast also when the MSM community became aware of HIV-prevention programs. The SSR 2017 report indicated that 94.4% of MSM had ever received HIV testing and 89.8% of MSM had received HIV testing in the last 12 months (*10*). It is conceivable that the HIV testing campaign by CBOs was successful. Under these circumstances, HIV-1 infected patients were disproportionally distributed. Therefore, if a cluster of infected patients were included in the cohort, the prevalence in the cohort tended to be high. However, the incidence was low and the number of newly diagnosed cases with HIV-1 infection at registration in each year was also low (Table 1). The other countermeasure was the treat-all strategy for MSM irrespective of CD4 count. The Mongolian Government implemented this strategy since early 2013, well ahead of the WHO treatment guidelines launched in 2015 recommending treat-all HIV-1 patients irrespective of CD4 count (*13*). Most of the developing countries follow WHO guidelines strictly after they were launched. Early implementation of the test and treat strategy could perhaps lead to the successful control of HIV-1 infection in MSM.

On the other hand, the prevalence of syphilis in this cohort was high (17.0%), the incidence was also high (5.66/100PY), and the numbers of newly diagnosed cases at registration over the years were also persistently high (Table 2). Furthermore, the incidence showed a trend for a gradual increase over time. With regard to the sexual behavior among MSM, the SSR reported that condom use during sexual intercourse among men increased from 44.9% in 2014 to 60.2% in 2017 (*10*). These data suggest that while sexual behaviors in Mongolian MSM might be improving, such improvement has not resulted in satisfactory control of syphilis.

This study had certain limitations. First, the number of MSM enrolled in this cohort was limited. Therefore, there was discrepancy between the high prevalence and low incidence of HIV-1 infection. It is possible we missed other expanding transmission networks, like the CRF51_01B cluster (*14*). To obtain more accurate epidemiological data, we need to include a wider range of MSM groups. However, the estimated MSM population in Mongolia is only 3,100 and about one third of those participated in this cohort (*15*). Second, nearly 40% of the MSM were tested only once, indicating a high lost-to-follow rate in this cohort, and suggests possible underestimation of the true incidence of HIV-1 infection. However, judging from the incidence of syphilis, the MSM remaining in the cohort are probably sexually active. Third, this cohort study included only MSM aged ≥ 20 of age due to the restriction imposed by the Japanese ethics regulations. However, male teenagers could be more sexually active and have limited information about HIV-1 infection. In this regard, efforts had been also directed towards the younger Mongolians (*16*). Finally, this cohort only included MSM. However, for better assessment of the epidemiology and to control HIV-1 infection in Mongolia, we need to include FSWs since the prevalence of sexually transmitted infections in this population is reported to be high (*10,17*). In this regard, our second survey documented a shift in the risk groups from MSM to heterosexual males and females (*14*). Thus, we must pay attention to the at-risk population and need more comprehensive HIV-1 prevention strategies in the future.

In conclusion, we found in the present study HIV-1 prevalence of 9.8% and HIV-1 incidence of 0.10/100 PY among MSM living in the capital of Mongolia, based on analysis of tests/data collected between 2014 and 2017. Prevention programs, such as safer sex promotion, testing campaigns, and treat-all strategy for MSM seem to contribute to the obtained data. However, the programs must be maintained from now onward, otherwise new transmission networks could appear, with a potential increase in the incidence of HIV infection.

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