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Kota IWAHASHI
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Kota IWAHASHI, Noriyo KANEKO, Misao TAKANO
Shinichi OKA, Takayuki Homma, Masao Tateyama, Seiichi ICHIKAWA,
Jun ARAKI, Takuya KINAMI, Yuzuru IKUSHIMA, Ikuo SATO, Toshiya FUKUHARA
Tsunefusa HAYASHIDA, Yasuyo NAKAYAMA, Hiroo OBINATA, Akifumi IMAMURA

Japan Health and Labor Sciences Research Grants
Research on the provision of effective HIV testing program for MSM and development of intervention for high risk groups: Expansion of HIV testing opportunities by disseminating HIV self-testing kits and bio-behavior surveys.
Mode of HIV AIDS transmission in Japan 2017

**MSM is the most affected population**

**2017 HIV cases**
- Homosexual (male): 72%
- Heterosexual (male): 15%
- IDUs: 1%
- Others: 2%
- Mother to Infant: 0%
- Unknown: 10%

**2017 AIDS cases**
- Homosexual contact (male): 55%
- Heterosexual contact (male): 24%
- IDUs: 0%
- Others: 16%
- Unknown: 16%

n=976
n=413

*2017 Annual Report National Surveillance Committee, JAPAN MOHLW*
UNAIDS 90-90-90 treatment target
Estimation of the Japanese situation (2017)

The estimated number of Undiagnosed cases: 3,840

- Diagnosed: 85.6%
- On treatment: 82.8%
- Virally suppressed: 99.1%

Testing promotion toward MSM including Regular testing is crucial in Japan

Limited HIV Testing options in Japan

HIV testing experience among MSM in Tokyo (baseline study) N=885

- Ever tested: 84.2%
- Testing every year: 54.5%
- Unable to take test due to limited capacity of testing site: 29.1%

- Only standard point of care testing in a hospital or public health center is admitted as an HIV testing option in Japan
- Limitations of point of care testing for MSM
  - Restrictions on place and timing (ex. daytime only, not available in community venues)
  - Insufficient capacity to provide required number of HIV tests for MSM in Tokyo
  - Cannot reach hidden MSM
Now in JAPAN, the number of tests at point of care faces stagnation, **BUT** the number of self-sampling tests is rising although it is **NOT** officially approved.
Dry-bloodspots-based, self-collection HIV testing kit project as new testing option for MSM living in TOKYO

What is HIVcheck.jp?
1. MSM directly collects the dried blood spots (DBS) self-collection HIV test kit from the community center akta in Shinjuku 2-chome
2. The participants collect their own blood by finger-prick and anonymously post the kit to the laboratory
Dry-bloodspots-based, self-collection HIV testing kit project as new testing option for MSM living in TOKYO

3. DBS is soaked in phosphate-buffered saline overnight and the eluted sample is examined using the fourth-generation HIV Ag/Ab test of LUMIPULSE and followed when the first assay was positive

→ For more details on the methodology of HIV testing, see: M Takano, K Iwahashi et al., BMC Infect Dis. 2018; 18: 627.

4. The result is defined as provisionally positive if both were positive

5. The participants access the study website and check the results of their tests using a unique ID and password
Study design

The “HIVcheck.jp” kit has been distributed since February 2018 and will end in December 2019.

The eligibility criteria are:
1. Men who have sex with men
2. Aged ≥20 years

The target number of kits to be distributed was 1,500 kits/year. This program is provided free of charge and anonymously.
The participating institutions in this cooperative study include:

- The AIDS Clinical Center
- 3 hospitals and clinic Akta
- Community center Akta
- 2 research institutes
- PLACE TOKYO
- The main laboratory for the HIV test
- Peer counseling at the distribution site and telephone counseling
- Collect the questionnaire and enter the responses into the database
- Promote and distribute the test kits to MSM
- Accept HIV positive cases by DBS and conduct confirmatory tests
Recruitment of participants

- Advertisements posted on mobile dating applications for MSM.
  - A click on the banner leads to “HIVcheck.jp.
- Advertisements were distributed to gay bars, gay shops, gay saunas and gay magazines.
Distribution of “HIV check” kit

HIV test kit distribution was conducted every Monday night from 7 to 10 PM at the community center.

- Eligible men were enrolled in the study after they read the informed consent form and checked the agree box about the condition of anonymity.
- Staff members explained how to use the self-collection kit and handed it directly to the participant.
After obtaining informed consent, a self-administered behavior survey was distributed.

Testing results and behavior surveys are linked by a unique ID for each tester (only participants who gave obtained informed consent.)
No. of distributed kits and sample sending rate, profile of sample senders

1,421 Kits

- 90% First time HIVcheck.jp Kit takers
- 10% repeaters

79% Sent dried blood samples

25.2% First HIV testing in lifetime

74.8% Had ever tested

When was your last HIV testing?

- within 6 months 20%
- 1-2 years ago 27%
- over 3 years ago 27%
- 6 months -1 year 26%
• 99% of people checking their test results on the web

• Positive cases and rate: 27 positive cases, 2.4%
  *screening tests

• Confirmation rate of linkage to care among screening positive cases: 12 cases (44.4%)

• 98% of testing kit receivers agreed to link the serological results to their behavior survey
Conclusion

• From February 2018 to July 2019, 1127 DBS samples were collected. 27 positive screening cases were found, for a provisional positive rate of 2.4 %.
• The positive rate of the ‘HIVcheck.jp’ screening test was nearly 8 times higher than that of conventional point of care testing. The effectiveness of this test was demonstrated.
• MSM in their 20s and 30s used the HIV Check most. For 34.1% of those in their 20s, ’HIVcheck.jp’ was the first HIV testing in their lifetime.
• Because ‘HIVcheck.jp’ is available in areas highly frequented by MSM, it provides the opportunity for anonymous testing, counselling, and hospital consultations when needed.
Discussion

• It is necessary to consider whether this new test can be continually provided to MSM in Japan.
• Collaboration with NGOs, communities, clinicians, researchers, administrations is critically important, while budgets for HIV prevention program are shrinking in Japan.
• The community center Akta, located in Japan's largest gay town Shinjuku 2-chome, functions as a key point for such collaboration.
• In preparation for the TOKYO 2020 Olympic and Paralympic Games, additional MSM measures are needed.