



# PrEP in Japan



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# Today's topic

- Epidemiology of HIV and sexually transmitted infection among MSM in Japan
- Demand of PrEP among MSM in Japan
- Perspective of PrEP in Japan

# Pre-exposure prophylaxis (PrEP)

- For HIV-uninfected patients, pre-exposure prophylaxis (PrEP) using antiretroviral medications is an evidence-based way to prevent new infections among those at greatest risk.

TDF/FTC (Truvada) oral prophylaxis

(microbicides/vaginal ring)

(long acting injectable drug for PrEP under studies)

- TDF/FTC (Truvada) daily prophylaxis can reduce HIV infection by more than 90 % if adherence is good enough.

Sci Transl Med. 2012 Sep;4(151):151ra125.

# Efficacy and safety of PrEP is already proven if administered properly

- Issue is to how to implement PrEP based on local situation.
- How to recruit high risk group with good adherence?
- According to IAS-USA, people with HIV incidence of 2%/year is assumed to be candidates for PrEP

# Epidemiology of HIV and sexually transmitted infection among MSM in Japan

# Situation of HIV prevention in Japan

- There had been no constructive discussion about PrEP in Japan, partly due to lack of information on non HIV-infected MSM.
- For instance, the prevalence and the incidence of HIV infection in MSM have been unknown.
- Thus, we evaluated prevalence and incidence of HIV infection among MSM by establishing non HIV infected MSM cohort, [Sexual health clinic study \(SHC\)](#) .

# We started Sexual Health Clinic study in January 2017

The screenshot shows the homepage of the SH Clinic. At the top left is the logo 'SH外来' with 'Sexual Health外来' and 'エスエイチ外来' in smaller text. To the right are navigation links: 'アクセス', 'SH外来について', '参加条件および詳細', 'SH外来の受診方法', and 'オプション検査について'. The main content area has a pink background with the large text 'SH外来、\* はじまる。' and a smaller box containing '\* Sexual Health外来 (通称エスエイチ外来)'. Below this is a yellow banner with the text 'Open 8:30-15:00; Monday and Thursday'. Underneath the banner, it says '国立国際医療研究センターに 「SH外来」オープン'. A pink box contains the text 'この外来は性の健康づくりを応援します。 研究協力者を募集しています。' followed by two lines of smaller text: '※すでに多くのゲイ、バイセクシュアル男性が通院している病院です。' and '※この外来はHIV診療をしている外来とは別のものです。' At the bottom right, there is a search bar with 'NCGM SH' and a blue '検索' button with a mouse cursor.

Home Page address: <http://shclinic.ncgm.go.jp/>

# Purposes of SHC study

## Main objective

- To prepare a future pilot study for PrEP
- To maintain MSM cohort
- To provide package of preventive measures incl. safe sex promotion
- To test and treat STIs
- To investigate incidence of HIV/STI among MSM



## Inclusion criteria of SHC study

- MSM & transgender women who are living in Japan and can understand Japanese
- Age of 16 years and above
- Able to visit SHC every 3 months
- Examine HIV, syphilis, and anorectal STIs regularly
- Give a written informed consent to participate in SHC study

# Enrollment of clients in SHC (~2018/11/1)

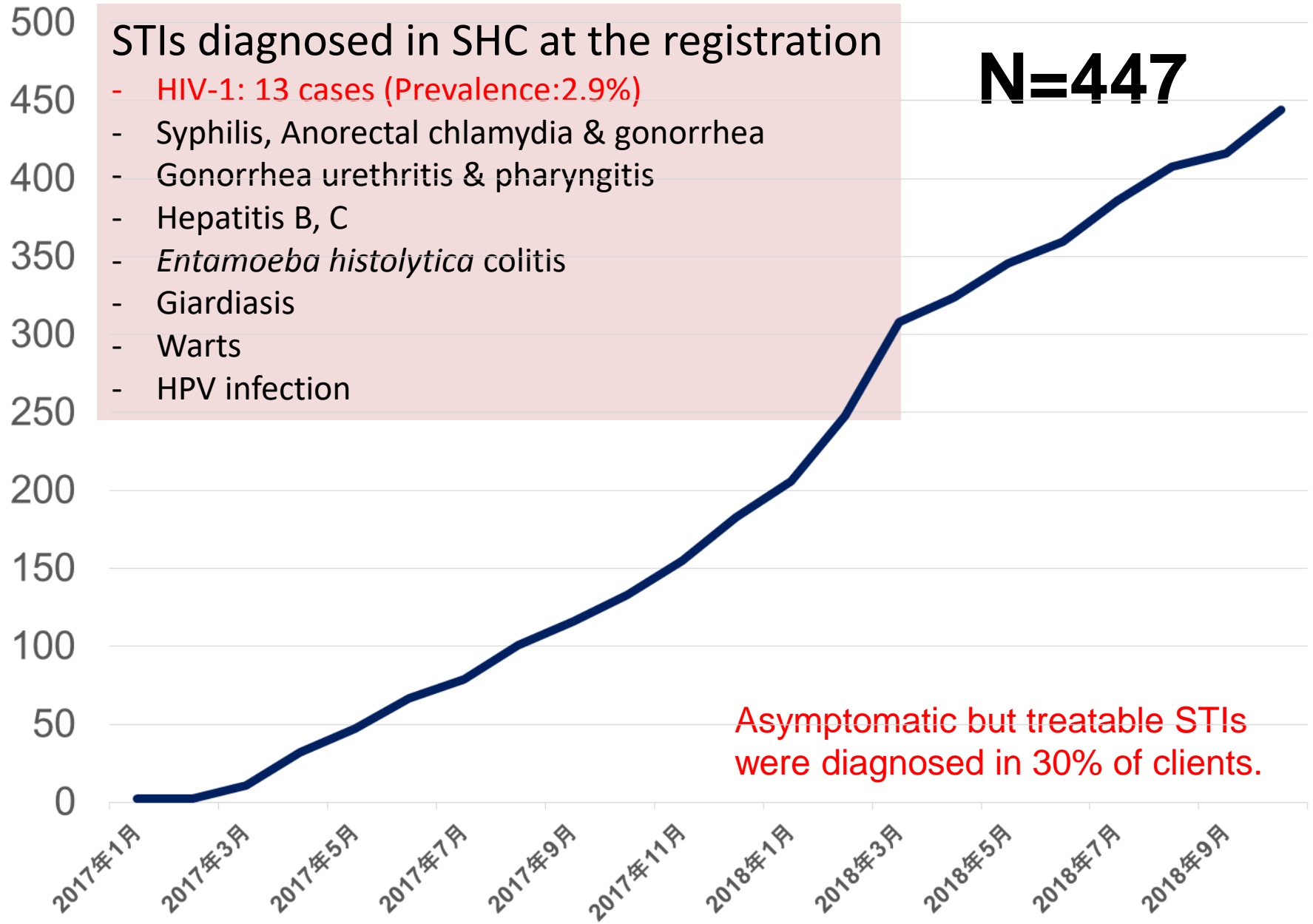


Table 1. Prevalence of rectal STI among MSM w/o HIV infection

		<b>ACC</b>	<b>SHC</b>	<b>p</b>
Number of Participants		561	447	
HIV		+	-	
average age, year		46.4	33.6	<b>&lt;0.001</b>
rectal STIs	n (%)	94 (16.8%)	83 (18.6%)	0.452
<i>Chlamydia trachomatis</i>	n (%)	87 (15.5%)	74 (16.6%)	0.652
<i>Neisseria gonorrhoea</i>	n (%)	13 (2.3%)	18 (4.0%)	0.118
dual infection	n (%)	6 (1.1%)	9 (2.0%)	0.219

Table 2. Incidental HIV, rectal STIs and syphilis among **315 HIV(-) MSM**

Incidental cases	Seroconversion (n)	Incidence* %/year
<b>HIV</b>	<b>7</b>	<b>3.2</b>
Rectal STIs	45	20.3
chlamydia	36	16.2
gonorrhoea	9	4.1

\*average observational period was 257 days (n=315, 222.1 person-year)

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According to IAS-USA, people with HIV incidence of 2%/year is assumed to be candidates for PrEP

**The HIV incidence was 3.2%/year in SHC**

**PrEP should be considered for MSM in Tokyo**

\*average observational period was 257 days (n=315, 222.1 person-year)

# Summary of SHC study

- The risk of HIV acquisition seems to be very high among MSM in Tokyo and is strongly indicative of PrEP.
- Rectal STIs have been neglected, but the prevalence and incidence of rectal STIs among MSM in Tokyo are considerably high.

# We started PrEP demonstration study in February 2018

## Subject

- Sample size: 120
- Duration of the study: at least 2 years

## Design

- Open label, demonstration study of a single arm of Truvada once daily to assess feasibility of PrEP

## Inclusion criteria

- Adult MSM who are at substantial risk for HIV
- Those who have attended SHC continuously for one year and understand the importance and significance of HIV prevention using PrEP
- Those who provide informed consent

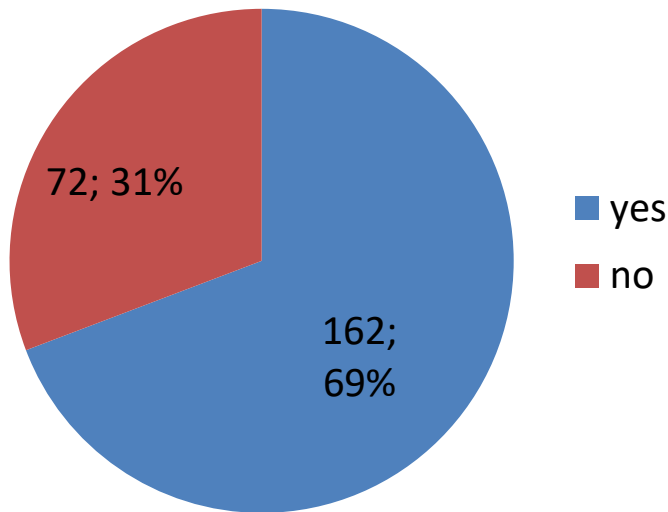
# Demand of PrEP among MSM in Japan



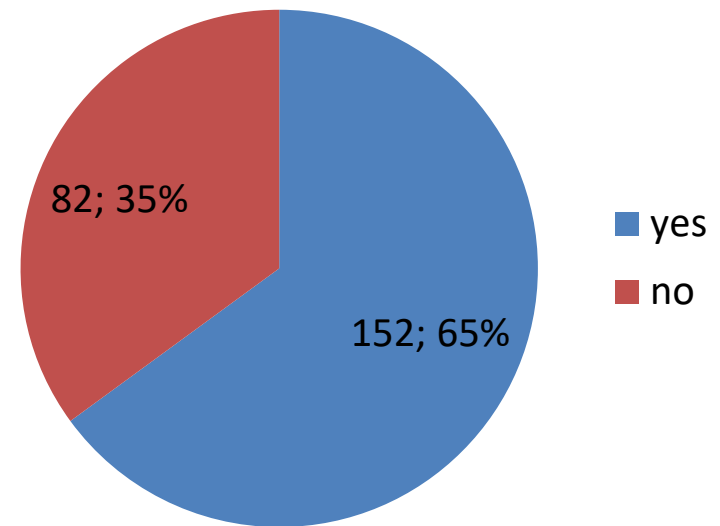
# The results of face-to-face interviews regarding awareness of PrEP in SHC (n=234).

Total of 234 MSM completed the interviews from Nov 2017 through Nov 2018.

Have you ever heard of PrEP?



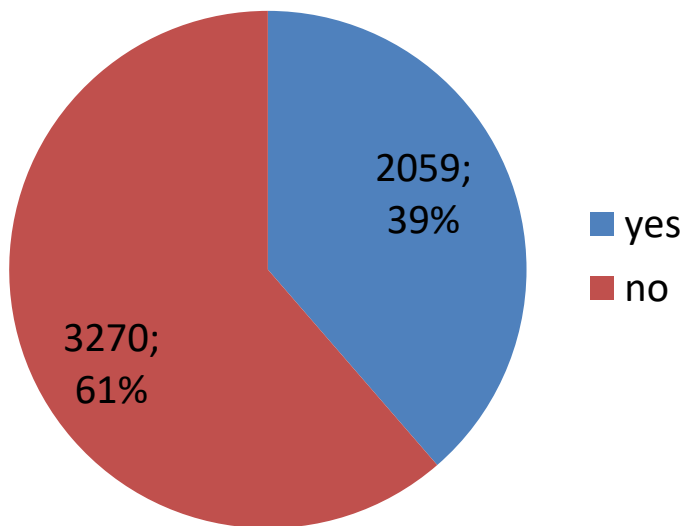
Do you want to use PrEP?



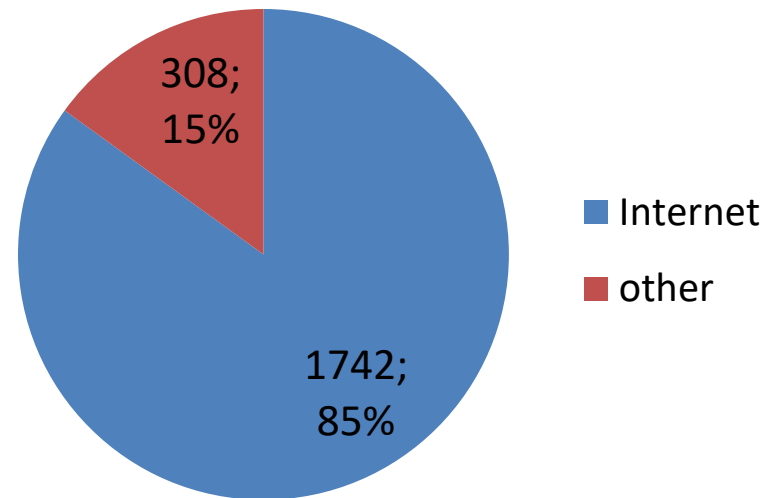
The results of an Internet-based survey for MSM  
via the largest dating app for MSM (n=5329).

Questionnaire survey was done for the users of the  
largest dating app for MSM via internet on Nov 2018.

Do you know what PrEP is?

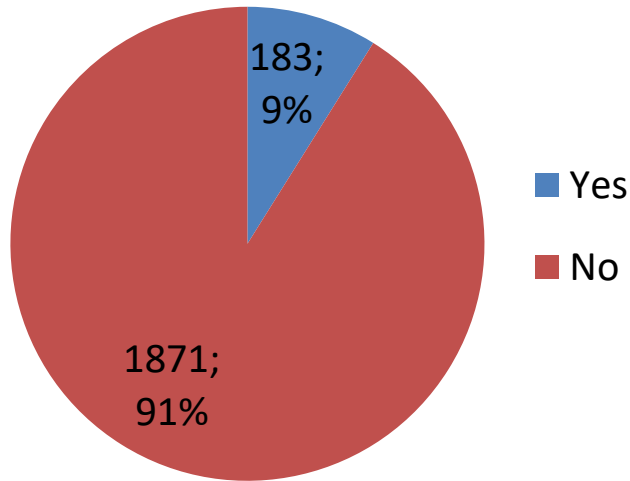


Where did you know about PrEP?

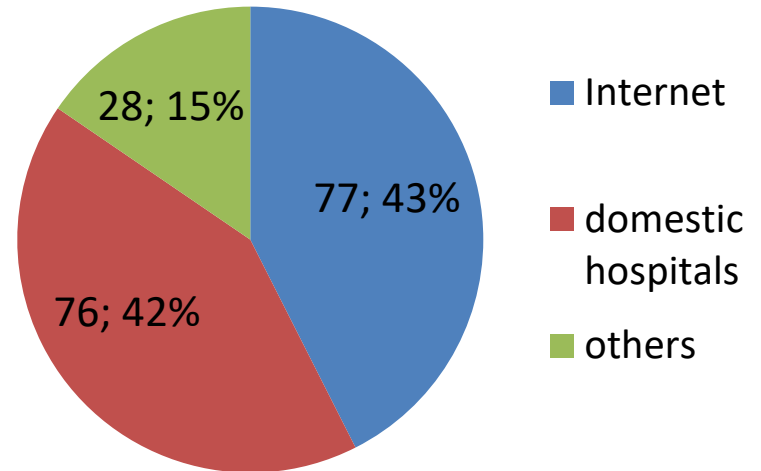


The data from Mr. Ikushima, Place Tokyo

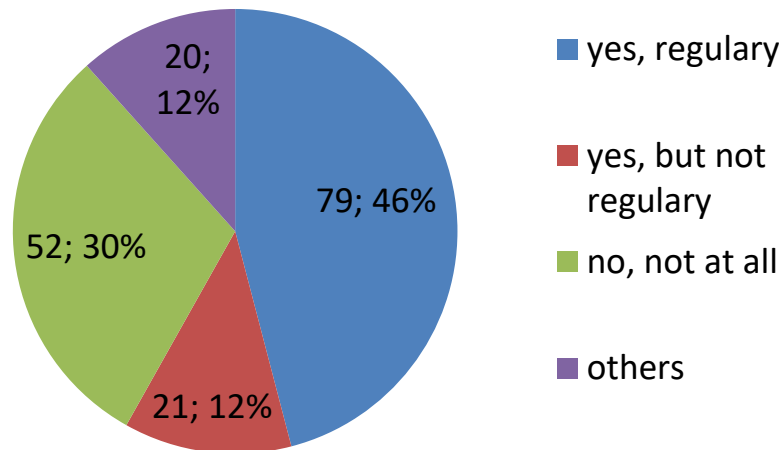
### Have you ever used PrEP?



### Where did you get medicine for PrEP?

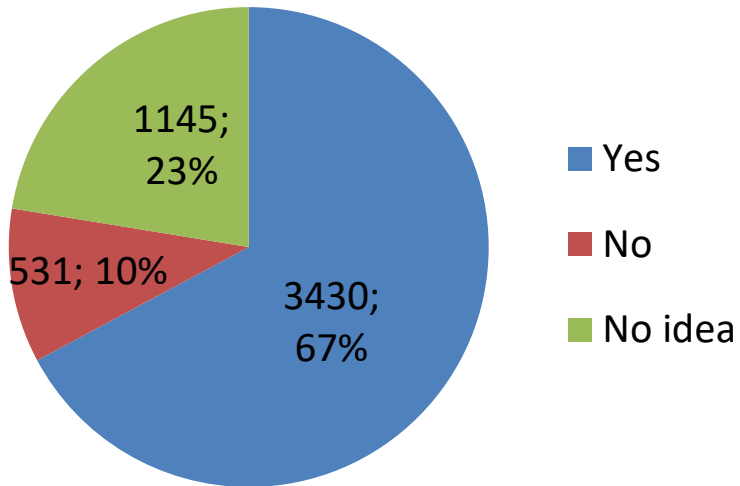


### Do you have medical check ups for PrEP?

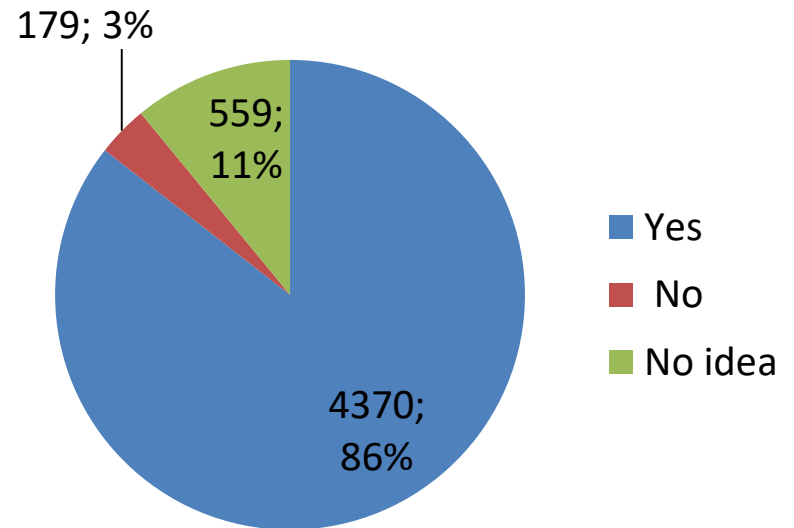


Some PrEP users want to have medical check ups for PrEP, but don't know/have access to PrEP providers.

### Do you want PrEP, if it is available in Japan?



### Do you think PrEP should be approved in Japan?

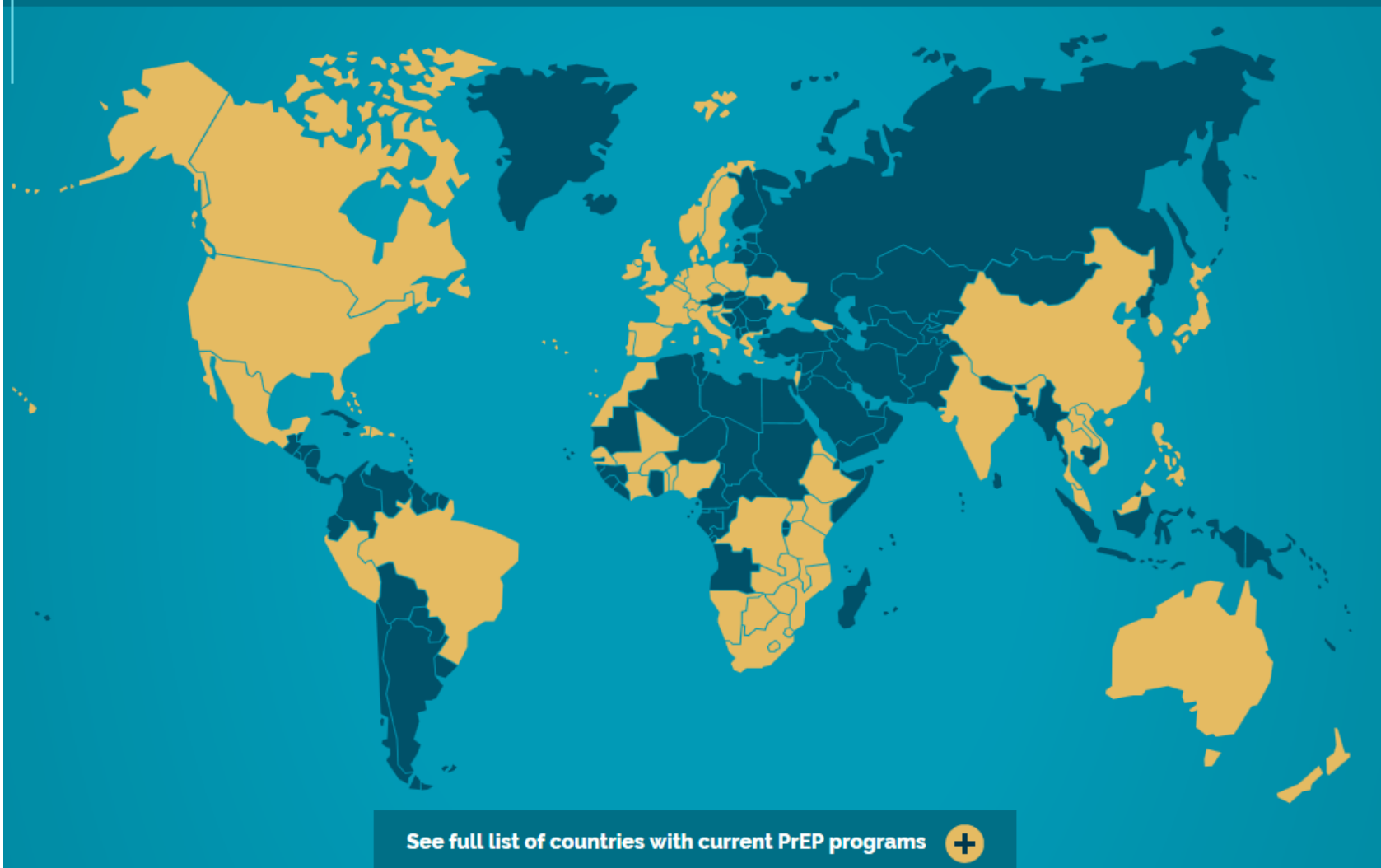


# Summary of demand for PrEP in Japan

- There is an increasing number of MSM who know and want PrEP introduced in Japan.
- 9% of MSM have used PrEP. At least 30% of PrEP users have no medical check ups for PrEP at all.
- Some PrEP users want to have medical check ups for PrEP, but don't know the access to a PrEP provider.

# Perspective of PrEP in Japan

In this regularly updated map, yellow ● countries have some form of PrEP programming; blue ● countries do not. Want to take the next step in expanding access to PrEP? Check out [PrEP Planning A-Z](#).



PrEP Watch: <https://www.prepwatch.org/>

**A feasibility study of PrEP is ongoing in Japan, but sample size is not enough.**

# Regulatory Status of TDF/FTC for PrEP

## Truvada & Generic TDF/FTC approved for prevention

Belgium	Israel	Spain
Canada	Italy	Swaziland*
Czech Republic	Kenya	Sweden
England	Netherlands	Thailand
France	Nigeria	United States
Germany	Portugal	Wales
Greece	Scotland	Zimbabwe
Ireland	Slovenia	
	South Africa	

## Truvada approved for prevention

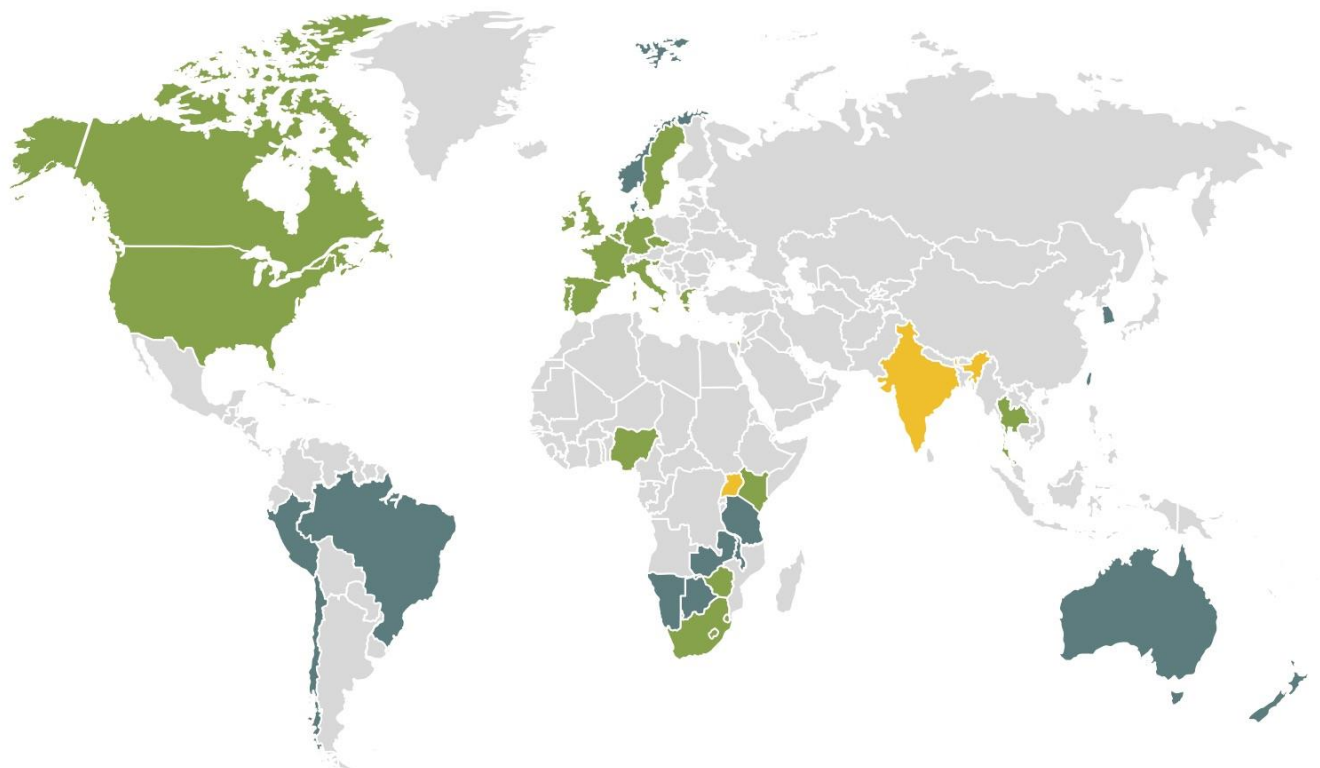
Australia	Denmark	South Korea
Bahamas	Malawi	Taiwan
Barbados	Namibia	Tanzania
Botswana	New Zealand	Zambia
Brazil	Norway	
Chile	Peru	

## Generic TDF/FTC approved for prevention

India	Lesotho*
Uganda	

## Regulatory application submitted for a prevention indication for TDF/FTC

Botswana	Mexico	China
Cote d'Ivoire	Mozambique	
Ecuador	Senegal	
Hong Kong	Ukraine	



\*Approved via import license from South Africa.

AVAC: [https://www.avac.org/sites/default/files/infographics/tdf\\_ftc\\_status\\_april2019.pdf](https://www.avac.org/sites/default/files/infographics/tdf_ftc_status_april2019.pdf)

- **Truvada and generic TDF/FTC were approved for PrEP in more than 40 countries.**
- **In Japan, the Japanese AIDS Society submitted regulatory application for a prevention indication for truvada Aug 2018.**



# Institutional status of PrEP in Japan

- The submission of truvada for PrEP is under review in Japan.
- The feasibility study of PrEP is ongoing in Tokyo, although sample size is small, 120 MSM.

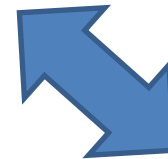
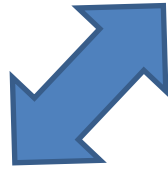
# Gap toward PrEP implementation in Japan

- Approval of truvada for use in PrEP
- Accessibility of generic Truvada
- Providing concise information on PrEP and raising awareness of PrEP
- Promoting study regarding PrEP
- offering PrEP follow-up test for MSM who use internet-based PrEP.

# Collaboration is crucial for success of PrEP in Japan

Community

- providing concise information on PrEP and raise awareness of PrEP



Health care provider

- providing concise information on PrEP and raise awareness of PrEP
- promoting study regarding PrEP
- offering PrEP follow-up test

Government

- approval of truvada for use of PrEP
- accessibility of generic truvada for PrEP
- promoting study regarding PrEP
- offering PrEP follow-up test



# Summary

- PrEP is indicated for MSM in Japan epidemiologically and the demand for PrEP is increasing among MSM in Japan.
- In reality, there is an increasing number of MSM who are already on internet-based PrEP.
- To respond to grass-root PrEP users is an urgent task, in addition to approval of (generic) Truvada for PrEP use.

Thank you for your attention