

Latest developments in biomedical prevention



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Today's topic

- Strategies for prevention of HIV infection
- Situation of HIV prevention in Japan

Strategy for HIV prevention

<Behavioral prevention>
Safe sex (condom use, etc.)

Plus

<Biomedical prevention>
Treatment as prevention (TasP)
PEP (Post-exposure prophylaxis)
PrEP (Pre-exposure prophylaxis)

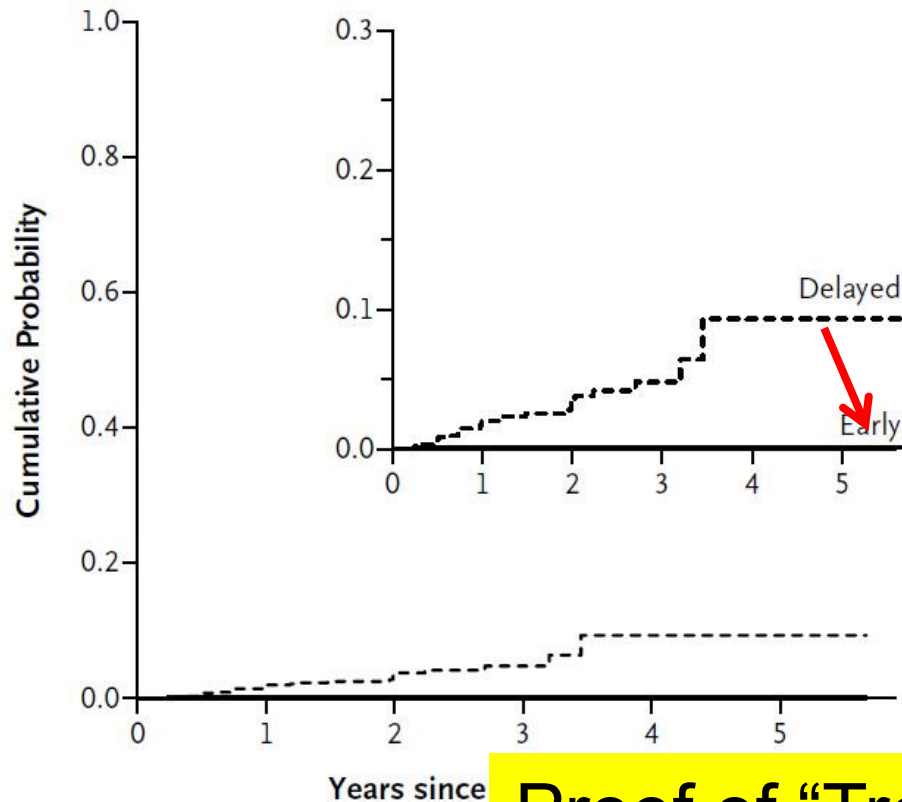
Biomedical prevention: TasP

Treatment as prevention (TasP)

- Successfully treating HIV with antiretroviral therapy (ART) minimizes the risk of transmission by decreasing the HIV plasma viral load, and it assumes the potential of a population level benefit.
- U=U (Undetectable = untransmittable)
- Treat all strategy , 90-90-90

Treatment as prevention (HPTN052)

A Linked HIV Transmission



- 1763 HIV serodiscordant couples with CD4 350-550/ μ L were divided into 2 groups.
 1. Early ART
 2. Delayed ART (CD4 <250)
- HIV infection was decreased by 96% in the early ART group.

No. at Risk

Early	893	658	298	79	31	24
Delayed	882	655	297	80	26	22

Proof of “Treatment as Prevention”

Biomedical prevention: PEP

Post-exposure prophylaxis (PEP)

- Occupational/non-occupational PEP
- To initiate ART within 72 hours of a possible HIV exposure. The duration of PEP is usually 28 days.
- For certain patients who repeatedly require nPEP, the use of pre-exposure prophylaxis (PrEP) will be considered.

Biomedical prevention: PrEP

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.

On-demand pre-exposure prophylaxis (IPERGAY)

● Subject:

Adult MSM who engaged in condomless anal sex

● Methods

on-demand dosing (Two Truvada tablets prior to sexual activity and then one tablet for two more days after sexual activity stops)

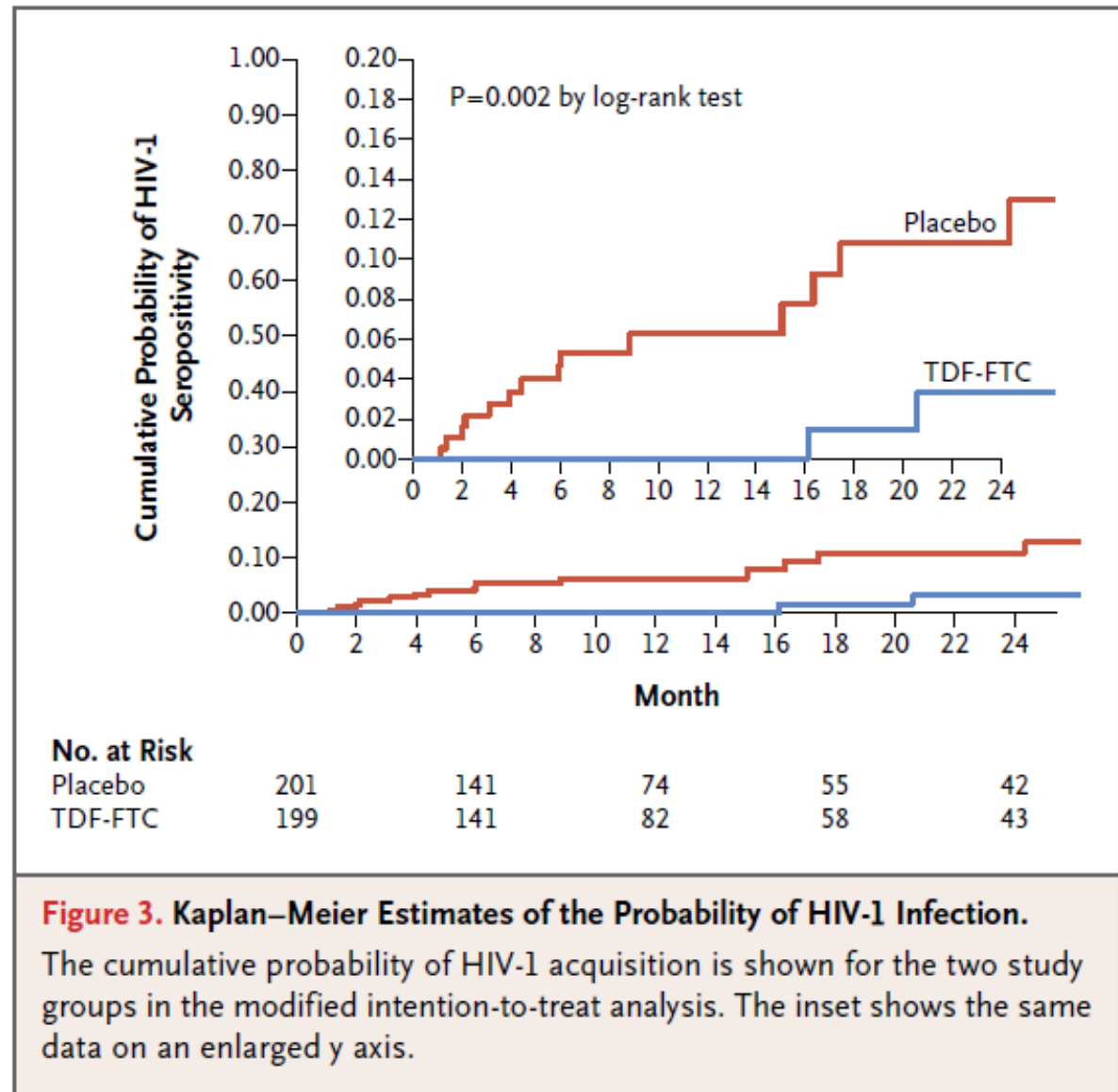
- RCT between Truvada vs placebo.

● Results

- 400 MSM were enrolled.
- Mean follow-up period were 9.3 months.
- 16 cases were infected with HIV. (2 cases in the Truvada arm vs 14 cases in the placebo arm)

86% reduction in HIV transmission ($p=0.002$).

- Severe adverse events were not significantly different between the two groups.



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

Situation of HIV prevention in Japan

- There had been no constructive discussion about PrEP in Japan, partly due to lack of the information on non HIV-infected MSM.
- For example, prevalence and incidence of HIV infection in MSM have been unknown.
- Thus, we evaluated prevalence and incidence of HIV infection among MSM by performing two studies.

1. HIV self-testing study

2. Sexual health clinic study (MSM cohort study)

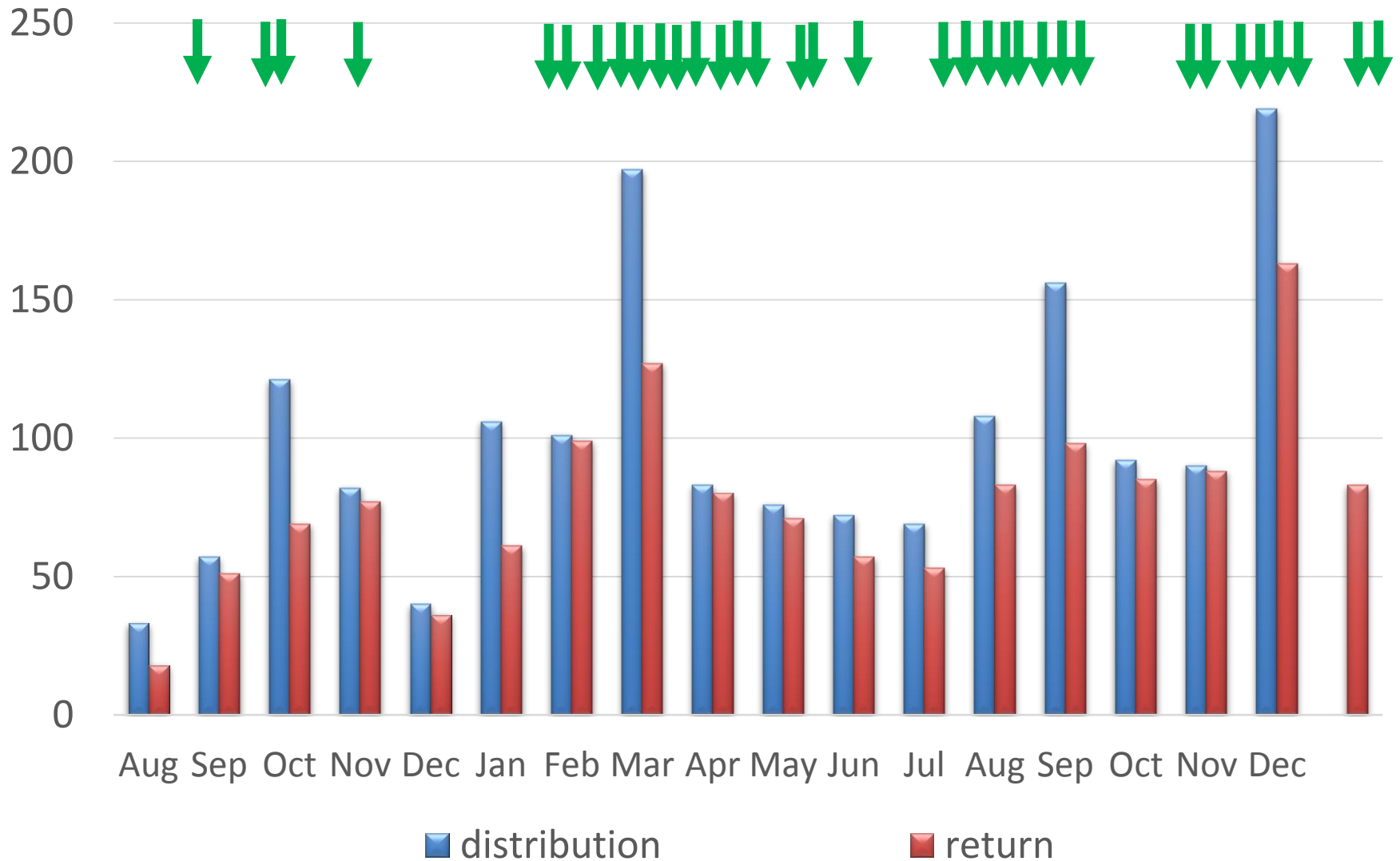
HIV self-testing study

- 1) To investigate HIV prevalence among MSM in Shinjuku 2-chome, which is the biggest gay town in Japan.
- 2) To assess the potency of effective distribution of the home-collection HIV testing kit to MSM by a CBO in the gay town.

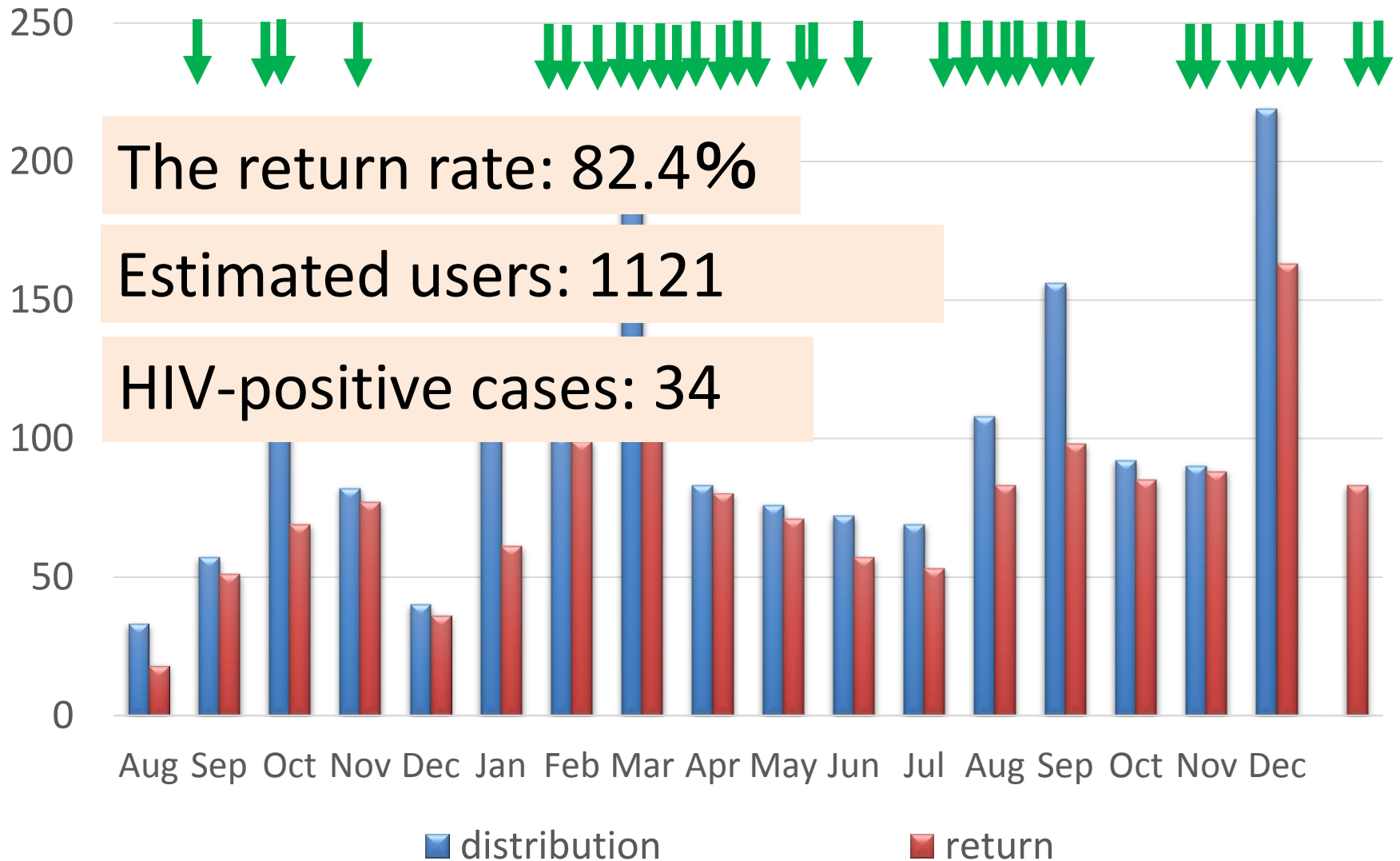
Subject: MSM aged 20 years and older

Study period: August 2015~December 2016

HIV prevalence in the Shinjuku gay town

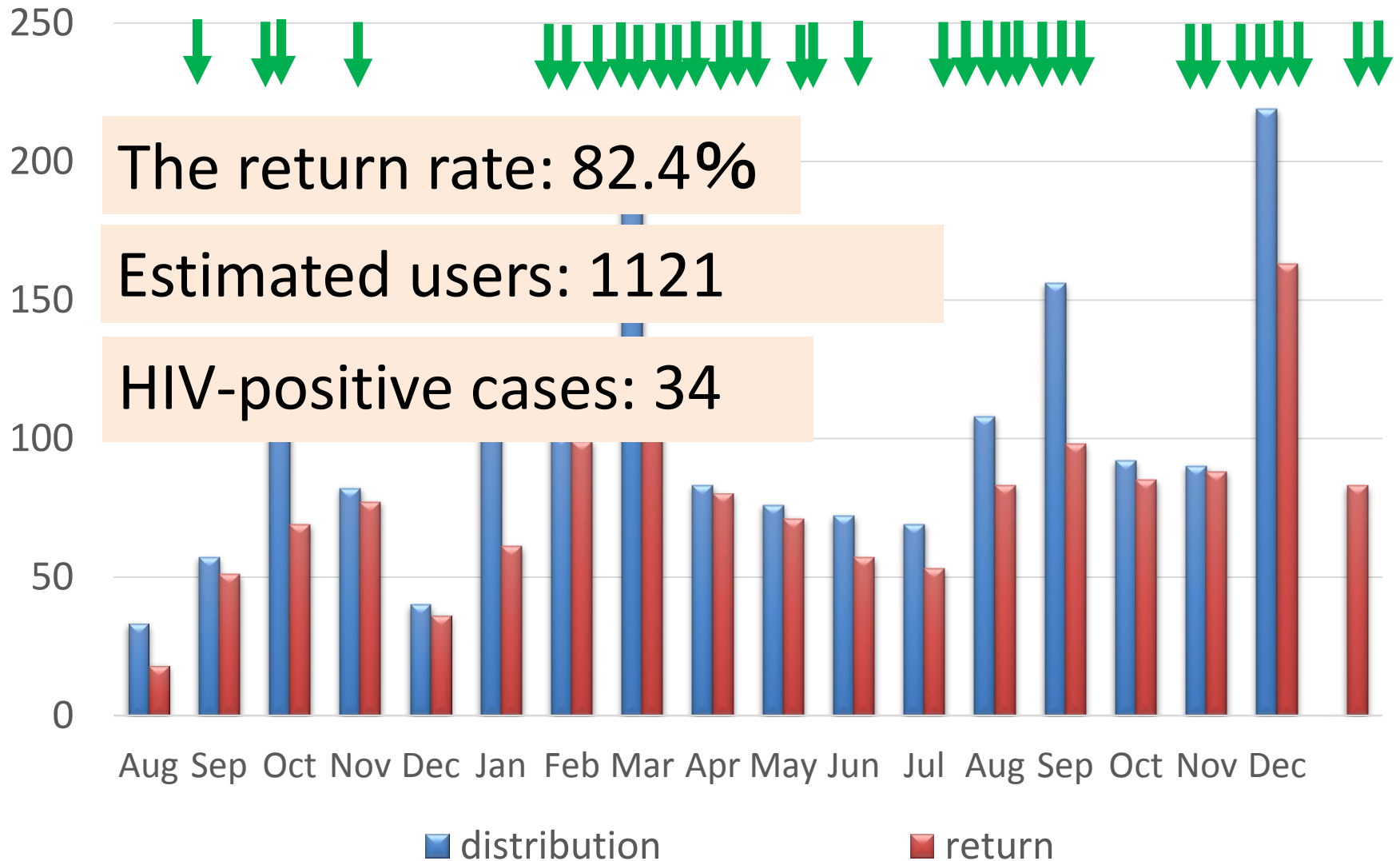


HIV prevalence in the Shinjuku gay town



HIV prevalence in the Shinjuku gay town

3.03%(95%CI:2.03-4.04)



We started Sexual Health Clinic study in January 2017



The screenshot shows the homepage of the SH Clinic. At the top, there is a navigation bar with the logo "SH外来 Sexual Health外来 エスエイチ外来" and links for "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 text "SH外来、* はじまる。" and a small box explaining that "*" refers to Sexual Health外来 (通称エスエイチ外来). Below this, a yellow banner states the clinic's hours: "Open 8:30-15:00; Monday and Thursday". Further down, it mentions the clinic is located at the National International Medical Research Center and is open. 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。" and a note that the clinic is for many gay and bisexual men and is not for HIV treatment.

SH外来 Sexual Health外来
エスエイチ外来

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 オプション検査について

SH外来、* はじまる。

* Sexual Health外来
(通称エスエイチ外来)

Open 8:30-15:00; Monday and Thursday

国立国際医療研究センターに
「SH外来」オープン

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。

※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。
※この外来はHIV診療をしている外来とは別のものです。

NCGM SH

検索

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

Purposes of SHC study

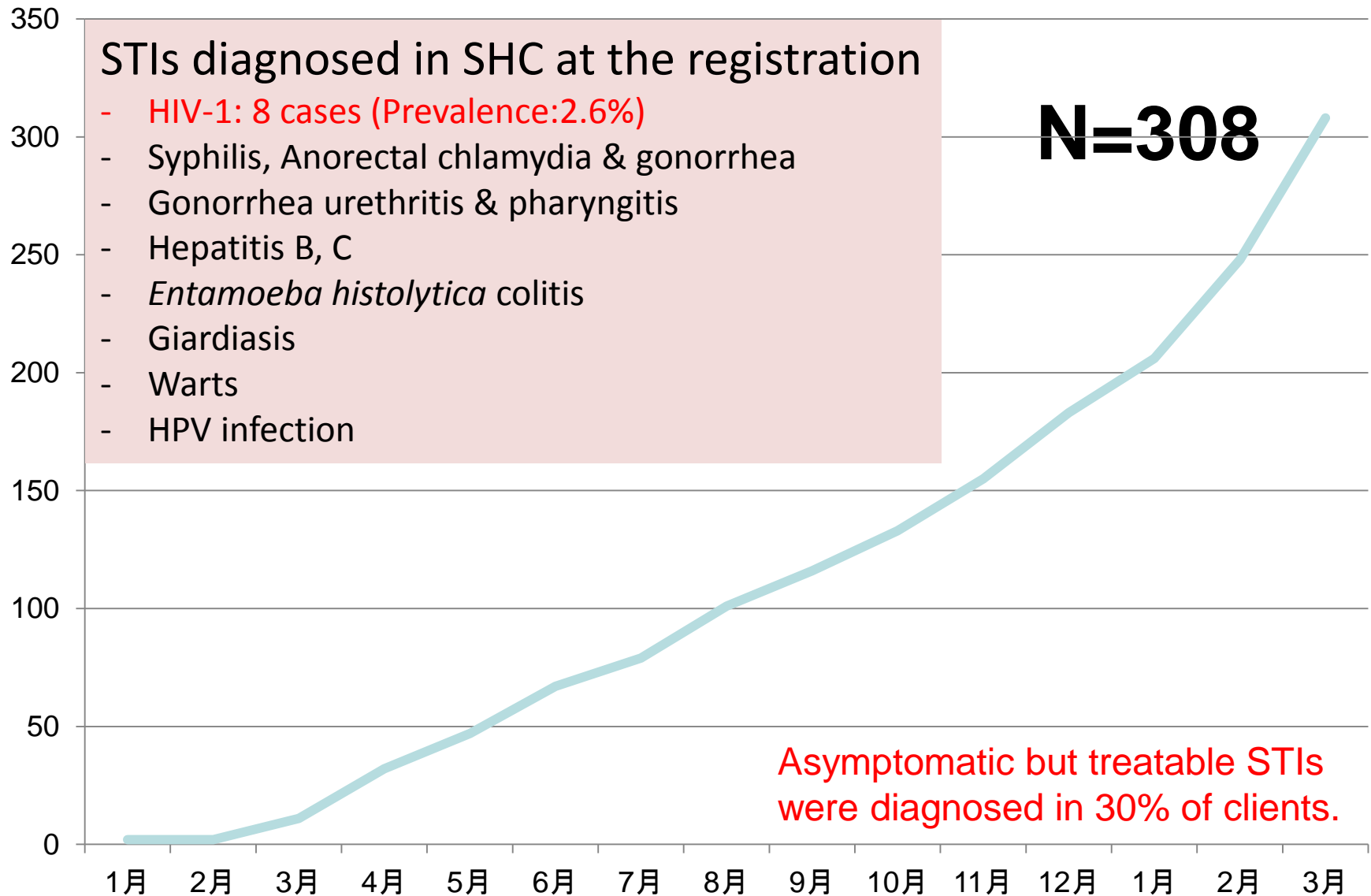
Main objective

- To prepare a future pilot study of 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 or older
- Come to SHC every 3 months
- Examine HIV, syphilis, and anorectal STIs regularly
- Give a written informed consent to participate SHC study

Enrollment of clients in SHC (~2018/3/31)



Incidental HIV, anorectal STIs and syphilis among 152 HIV(-) MSM

Incidental cases	Seroconversion n	Incidence* %/year
HIV	3	4.1
anorectal STIs	10	13.6
chlamydia	8	10.9
gonorrhea	2	2.7
Syphilis	4	5.5

*average observational period was 172 days

* Number of subjects and observational period were not enough for assessment and the data is preliminary. HIV prevalence in SHC was 2.6% (at the registration).

Situation of MSM in Tokyo

The key to success of PrEP is to recruit **high risk group** with **good adherence**.

The risk of HIV acquisition seems to be so high as to be indication for PrEP among MSM in Tokyo.

Good adherence and high retention rate are important for success of PrEP.

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 continue to attend SHC for one year and understand importance and significance of HIV prevention by PrEP
- Those who provide informed consent

Problems to implement PrEP in Japan

- Approval of Truvada (TDF/FTC) for preventive use.
- Costs of Truvada (TDF/FTC).
- Concerns about possible increase in unsafe sex and STIs.
- Accurate Information about PrEP among MSM

Thank you for your attention