



# Implementing PrEP in clinical practice : the Paris experience

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Infectious diseases physician

Clinical Psychopathology - Psychotherapist

Sexologist

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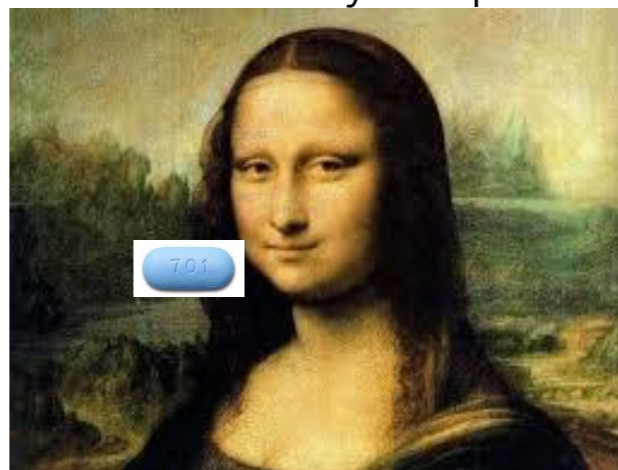
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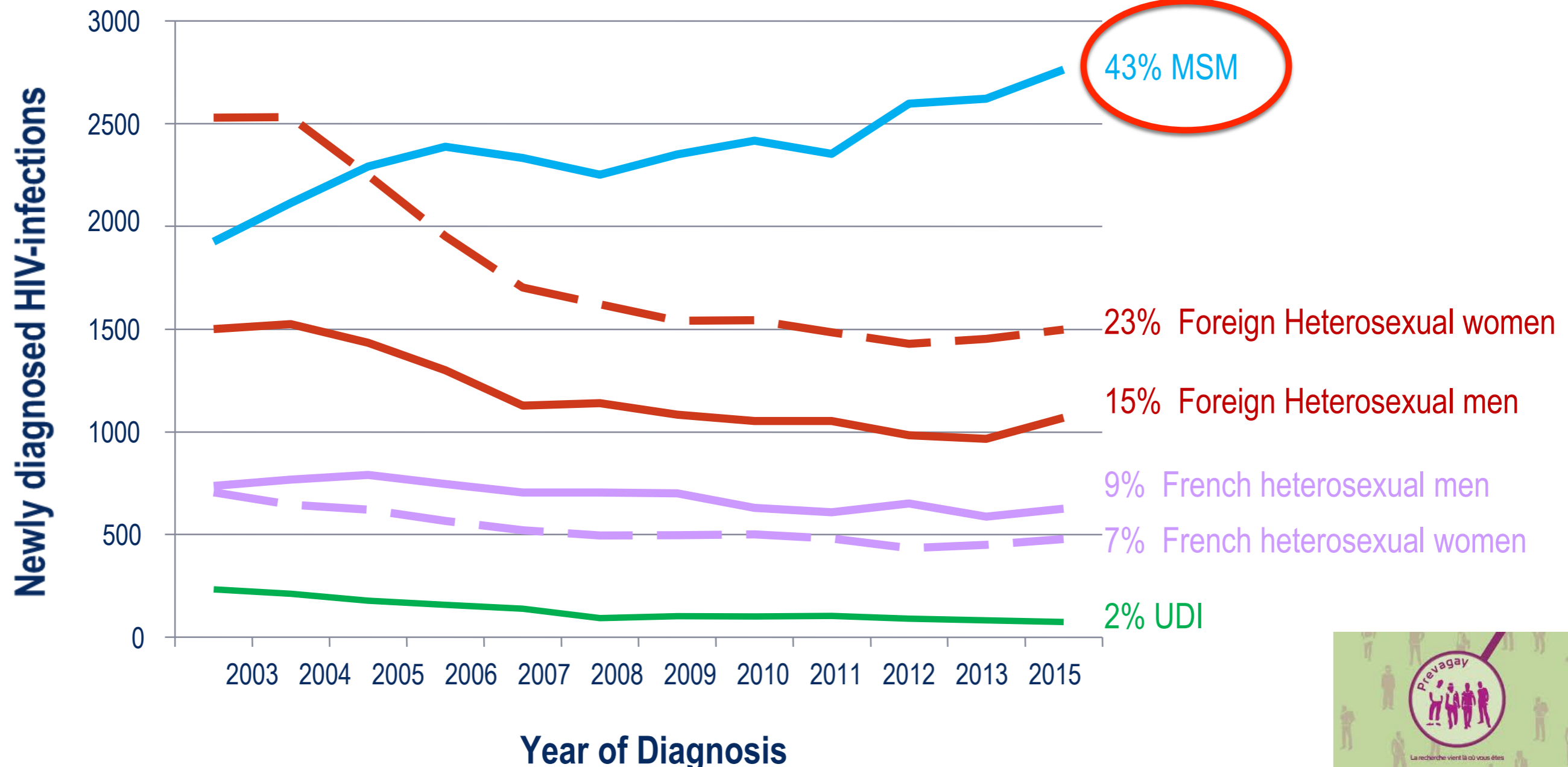
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# Increase in New HIV-infections in MSM

**6000 new HIV-infections in France in 2015**

Public Health France  
December 2016



**Prevagay** is a study held in 2009 (INVS & ANRS), targeting MSM > 18 years old active in gay scene in **Paris** (bars, sauna, sex clubs, backrooms)  
886 men were screened and blood sampled, amongst them 157 (18%) were **HIV+**, of whom 31 (20%) weren't aware of their **HIV + status** at that time.



## HIV Incidence (mITT Analysis)

Treatment	Follow-Up Pts-years	HIV Incidence per 100 Pts-years (95% CI)
Placebo	212	6.60 (3.60-11.1)
TDF/FTC (double-blind)	219	0.91 (0.11-3.30)
TDF/FTC (open-label)	515	0.19 (0.01-1.08)

Incidence: **6.6 /100 PY** overall but **9.17 in Paris** (and 2.45 in other cities)

Median Follow-up in Open-Label Phase 18.4 months (17.5-19.1)

NNT to avert one HIV-infection: 18 (95% CI: 11-50)

**97% relative reduction vs. placebo**



# French Political Decision



- Because NO decrease of HIV infection and still new contaminations
- Need for Combined approach based on 3 pillars :
  - Treat all patients & retain them in care (TASP)
  - relocalized places of testing : Checkpoints
  - PrEP implementation
- Political decision for Truvada reimbursement PrEP & RTU

# Recommendation of Temporary Use (RTU) for Truvada for PrEP (JAN 2016)

- Prescription is limited to hospital specialists experienced in management of HIV patients
- Initial prescription : 1 month, then renewed every 3 months
- Truvada is refunded 100% by social security (but lab exams not necessarily)
- Delivery in hospitals and by private pharmacists
- Initiation of medical file (every first prescription, seroconversion or side effect, daily or on demand)
- On line site for prescribers to fill in for each patient



# High Risk of Sexual HIV Acquisition

PrEP for MSM in the French guidelines :

- For those who declare more than 2 recent rectal intercours without condom during past 6 months
- For those who had more than 1 STI during the previous year
- For those who did more than one PEP during the last year
- For those on psychoactive drugs

- **Adults (18 years or older)**
- **Negative HIV serologic assay (4th generation ELISA)**
- **No sign of primary HIV infection**
- **No recent HIV exposure (< 1 month)**
- **High risk of sexual HIV acquisition**



# Who is Not Eligible for Truvada

- **HIV Serologic assay positive or unknown**
- **Signs or symptoms of primary HIV-infection**
- **Creatinine clearance  $< 50$  ml/mn**
- **Chronic HBV infection if PrEP used On Demand**
- **Breast-feeding**
- **Hypersensitivity to TDF or FTC or excipients**



# Places where PrEP can now be Prescribed and Delivered in France

- **Hospitals (77%) HIV Clinics**
- **STI clinics (23%)**
- **GP able to renew prescriptions as of 03/2017**
- **Drugs are delivered in hospital and private pharmacies.**



# Counseling objectives



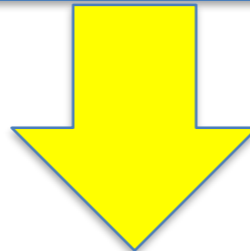
- Community support & counseling by patient association targets :
  - promoting and encouraging the user's **adhesion** to PrEP as a new mode of prevention integrated in a combined approach
  - supporting the PrEP **users' flow** in the health system
  - reinforce, on the long term, the ability of PREP users to take care of their **global sexual health** and **focus on reduced risks behavior** regarding all STIs

# Challenges for PrEP implementation

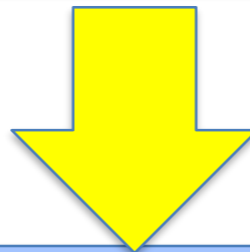
**IDENTIFICATION OF INDIVIDUALS AT RISK FOR HIV (*self id*)**



**LINKAGE TO SITE DELIVERY**

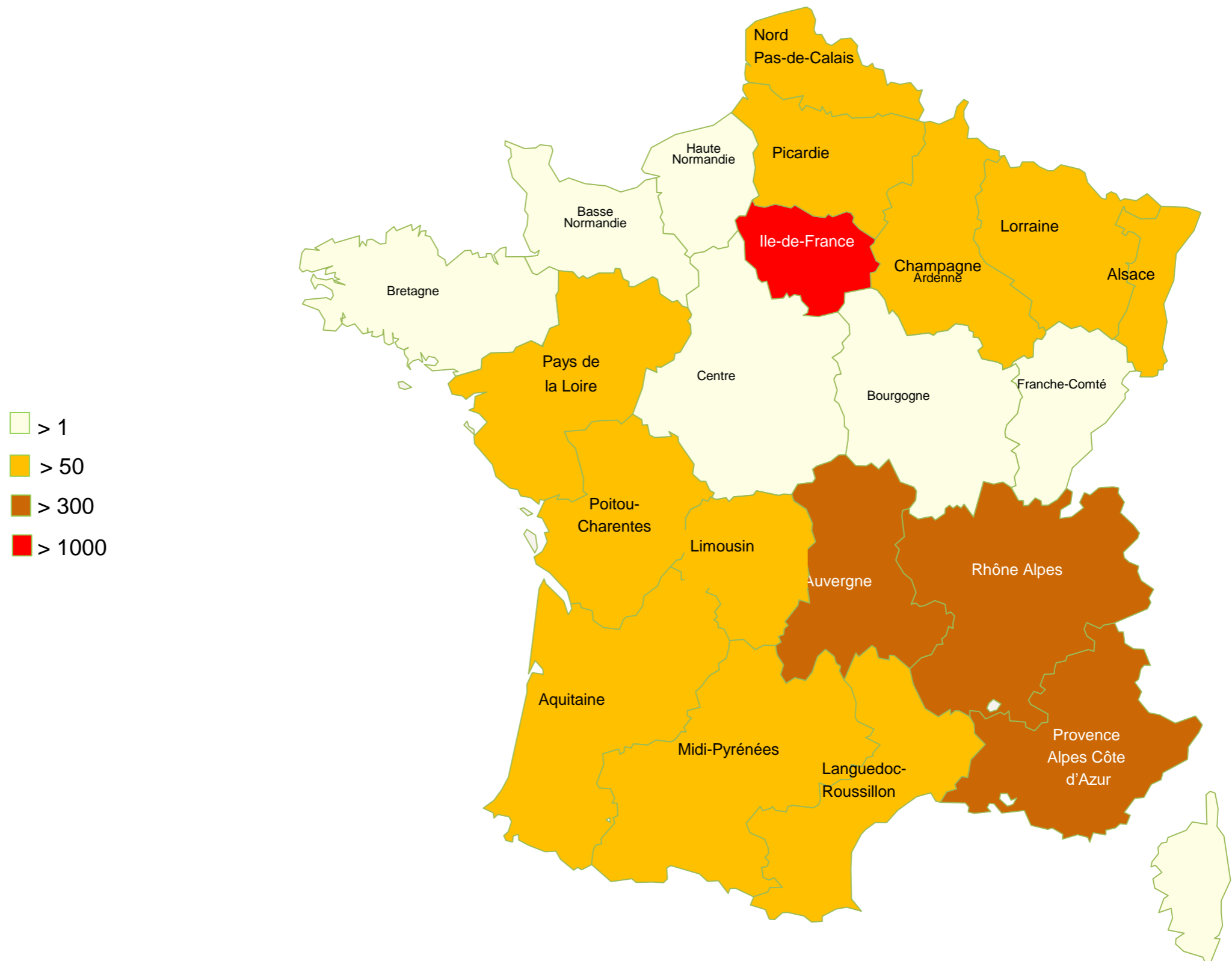


**INITIATION OF PrEP**



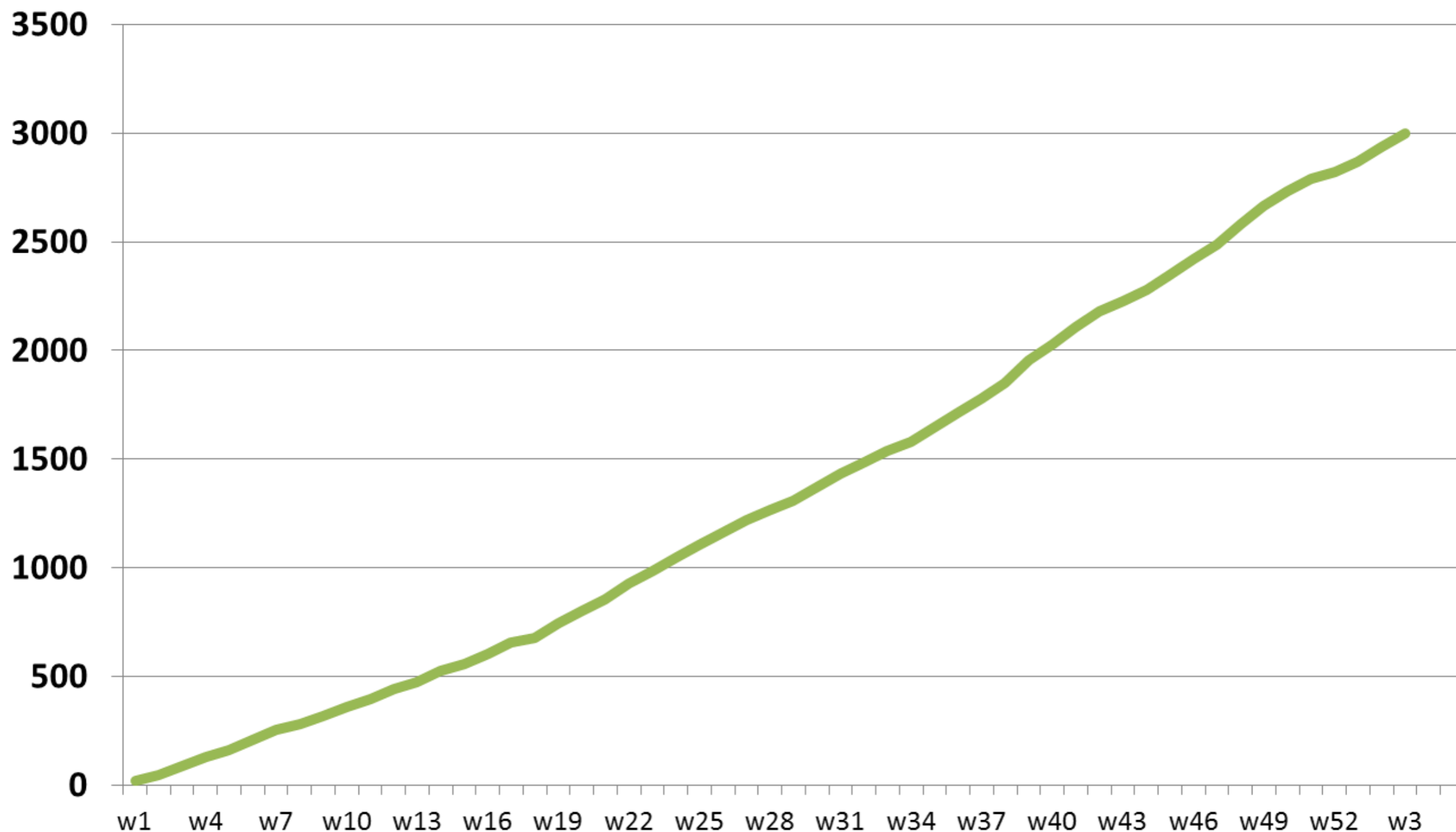
**ENGAGEMENT IN PrEP CARE**

# Number of PreP users registered per Region



# Cumulative Nb of Individuals Enrolled

## Jan 2016 - Jan 2017



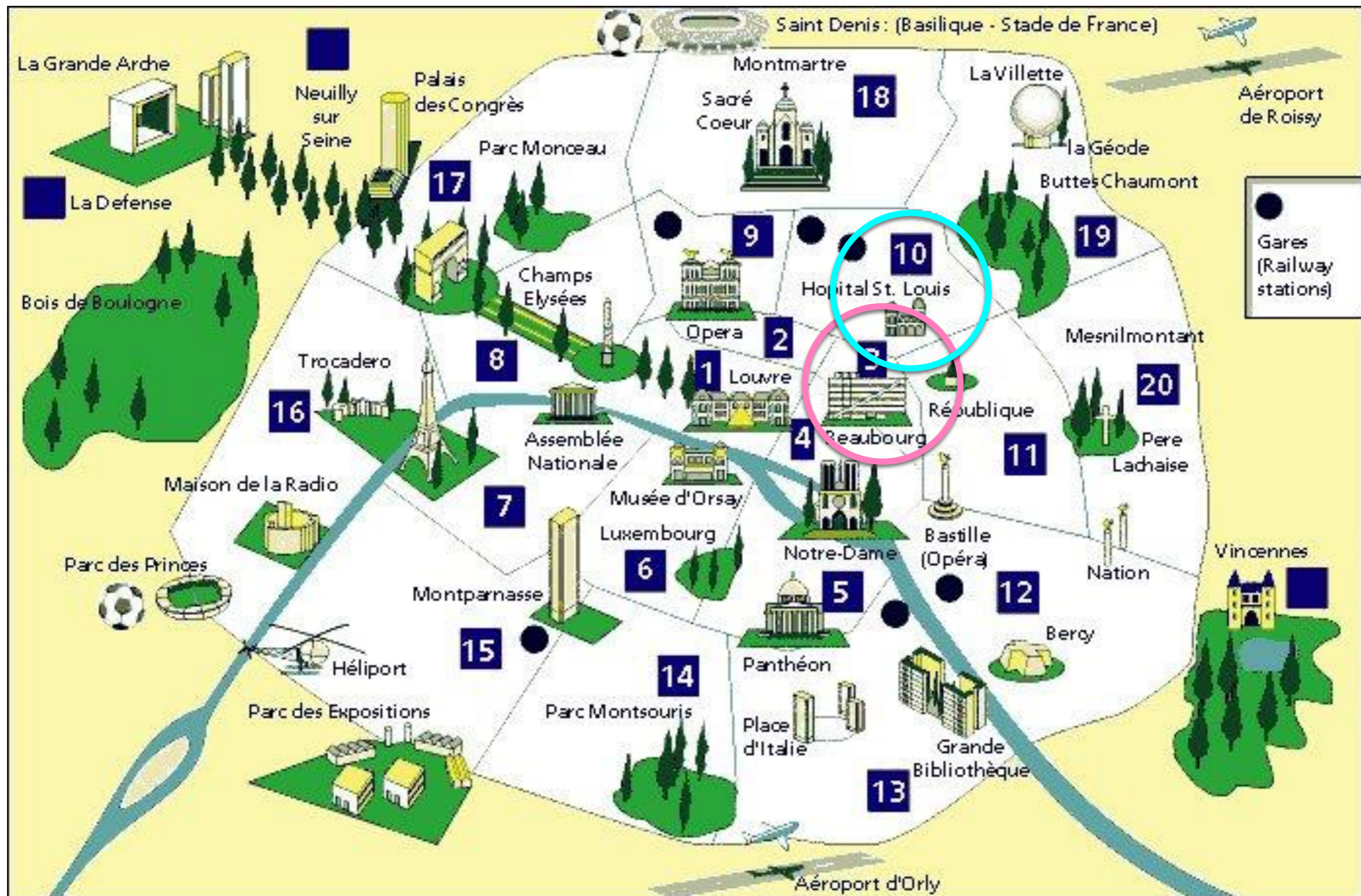
More than 130 PrEP sites in France

# Subjects Registered up to February 2017

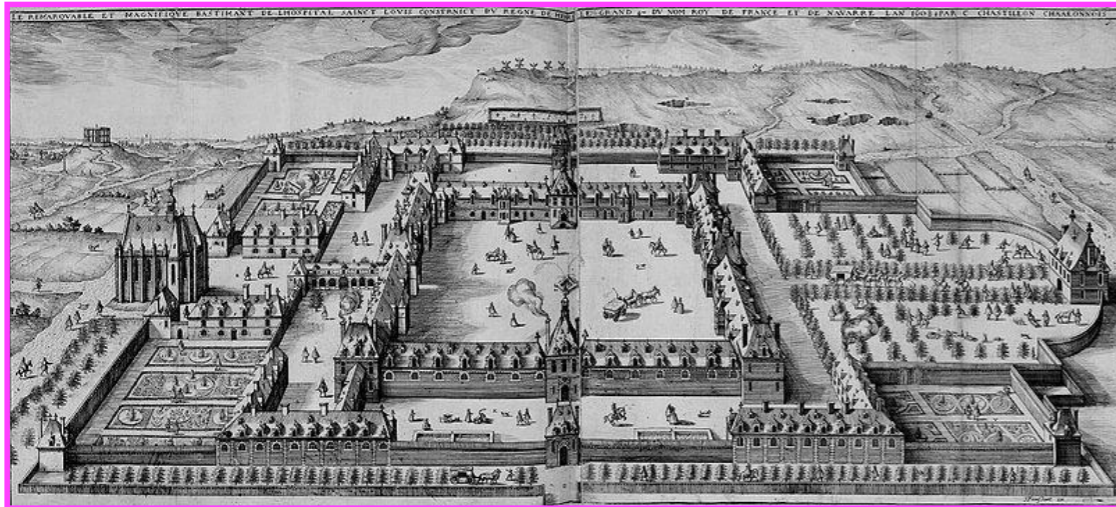
Patients (Median, range) or (%)	N= 3405
Age	37 (18-84)
French	88.9%
Men	97.8%
Women	0.7% (n=21)
Transgender	0.7% (n=20)
MSM	97.4%
Chemsex	19.9%
STIs in prior 12 months	30.6%
PEP in prior 12 months	10.9%
PrEP on demand	58%

3 HIV seroconversion with 1300 person-years of FU  
Overall incidence : 0.23/100 PY

# Location of St Louis University Hospital



# Infectious Diseases in St Louis University Hospital



1607  
-  
2016



- 4000 HIV outpatients followed on site
- PrEP Health care professionals : 10 MD / 6 Nurses / 2 Admins / 4-6 peer Counselors
- Involvement in Ipergay study between FEB 2012 & JULY2016 : 160 patients included
- PrEP consultation started January 2016 : 1069 PrEP users so far...and a daily care / 50-60 new patients per month

# How does our PrEP consultation work?

- The Unit is contacted by a potential user by phone or mail
- The dedicated Study&data manager Nurse (SDMN) handles the first contact to link it with the PrEP clinic in a timely manner according to the recommendations
- SDMN insists on the **importance of having safe sex within the 4 weeks before** having the blood sample taken.
- Prescription for blood sample sent to the patient
- Patient is scheduled for the first appointment with MD & counselor (initiation of PrEP)





# Study and Data Manager Nurse



- Biological screening sent to the patient :
  - HIV 1 and 2 serology (Elisa 4th generation)
  - Creatinemia and clearance MDRD
  - Urine dipstick for glycosuria and proteinuria
  - Hepatitis B and C and A serology
  - Syphilis serology
  - Liver enzymes
  - PCR Chlamydia and gonococcia on 3 sites : throat / anal and urines
  - Pregnancy tested if needed





# First Medical consultation



- First DISCUSS : « *what do you **know** about PrEP and why do you think is good for you ?* »
- **Medical** history
- **Psychological** and **Sexual Health** evaluation
- Medical treatments (**PEPs**?)
- **STI** past history and patient knowledge on HIV
- **Risk** assessment (Sexual & **Drugs** consumption)
- **Vaccine update** (Hepatitis B, A)
- Anoscopic examination for the screening of condyloma or dysplasia post **HPV** with anal smear /other specialists : Proctology/ addiction / psychological
- Search for clinical **signs** of acute infection & STI
- Search for recent exposition (**<1month**)
- Give clear **information** about side effects
- Repeat information about **other methods** of prevention
- Explain the **on-demand or the daily** regimen
- Insist on the importance of **adherence**





# Window period



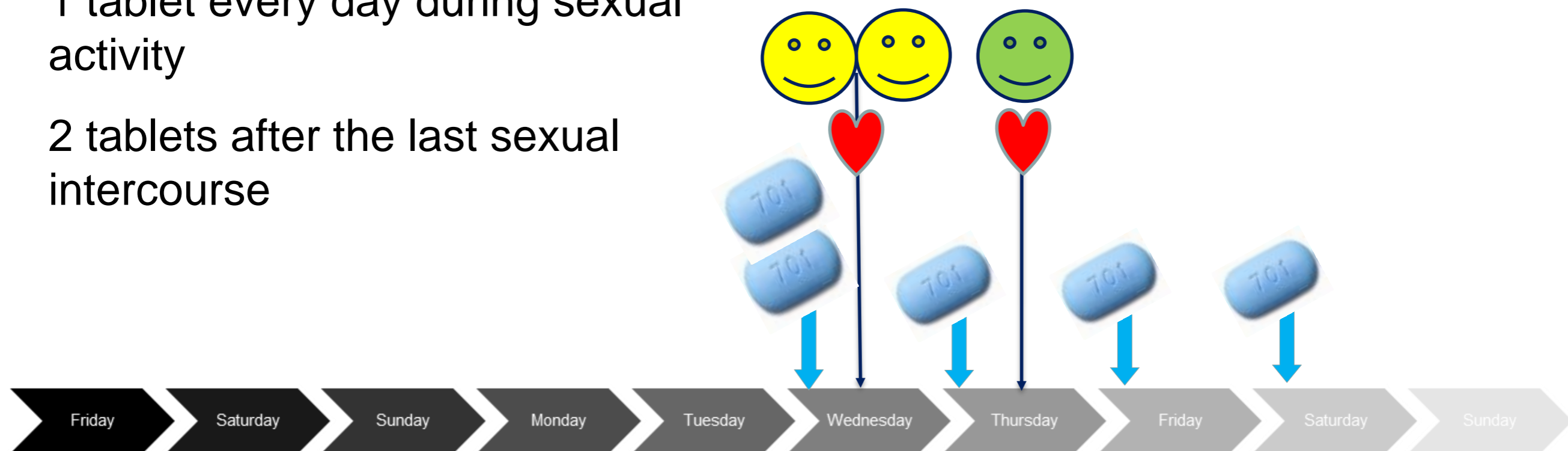
- Clinical evidence of acute infection ?
- When was the last risk-taking ?
- In case of possible window period :
  - **HIV viral load**
  - Test or retest HIV with an antibody/antigen assay
  - Retest antibody in one month
- Ask patient to be safe during the retest period

# IPERGAY : Sex-Driven PrEP

2 tablets 2-24 hours before sex

1 tablet every day during sexual activity

2 tablets after the last sexual intercourse



On demand PrEP tells you **How to Start and How to Stop PrEP**

# Medical follow up

- At each visit (every 3 months) : M 1 / 3 / 6 / 9 / 12
  - Assess/support adherence
  - Risk reduction counseling
  - Provide condoms
  - HIV & STI test
  - Renal function

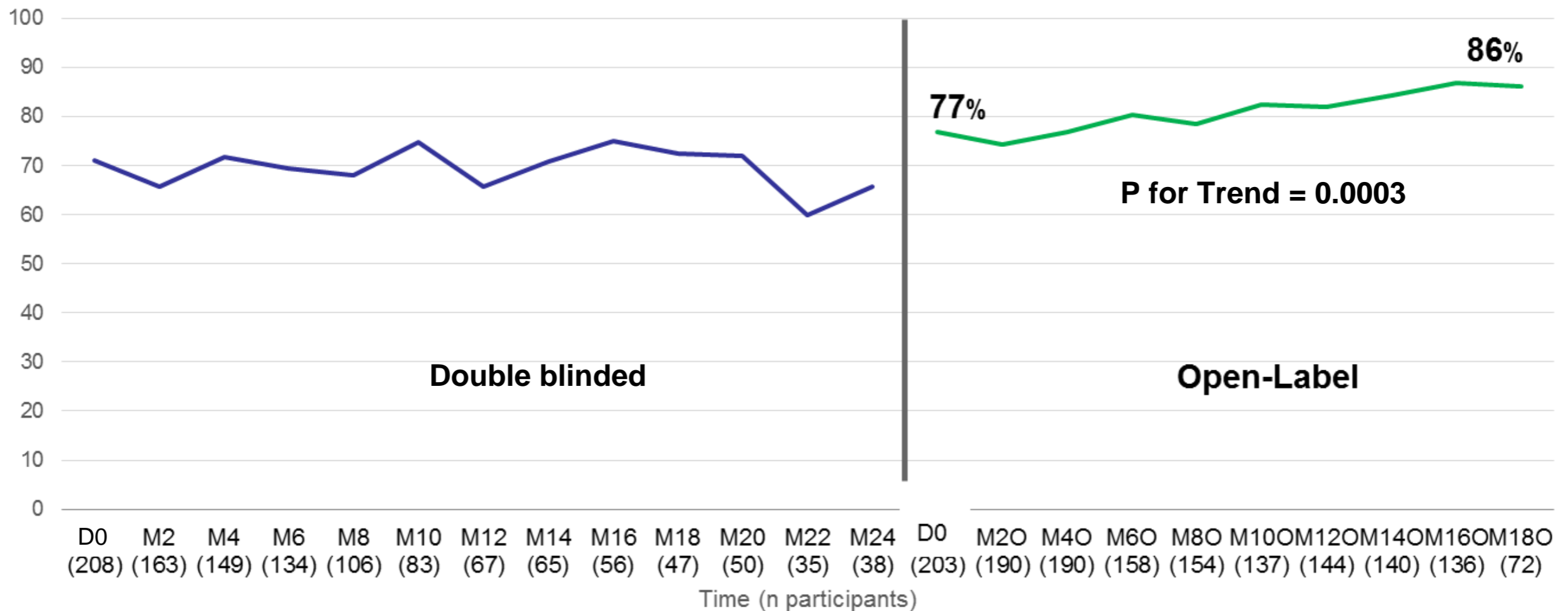


# Our challenges with PrEP implementation

- ★ Dedicated Study nurses to provide information/appointment by email and tel
- ★ HIV and STIs prescription sent by email
- ★ **Organize** outpatient clinic to meet the demand
  - Inform nurses and administrative personnel
  - Identify doctors willing to provide PrEP (> 10 doctors)
  - Increase offer: 16 consultations per week (from **2-10 PM**)
- ★ PrEP to be started at first visit and patients seen at Month 1 and every 3 months
- ★ **Adapt** outpatient clinic for **STI treatment** (injections)
- ★ Monitor and evaluate our practice
- ★ **Peer-counseling by AIDES** (PrEP adherence, risk reduction)

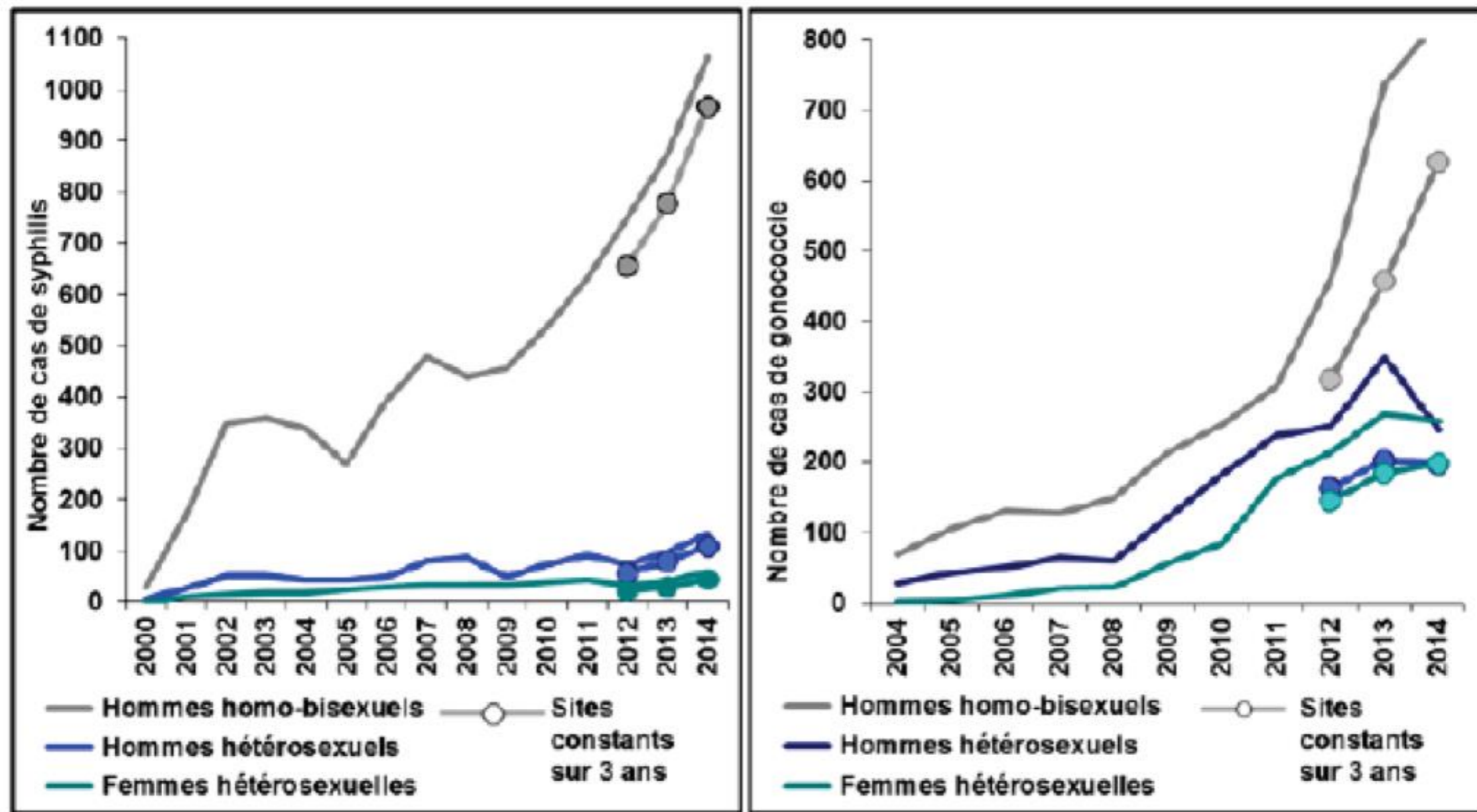
# Sexual Behavior

## Proportion Pts with Condomless Sex for Last Receptive Anal Intercourse



- **No significant change in median Nb of partners or sexual acts during the open-label phase (P= 0.42 and P= 0.12)**

# New syphilis and gonorrhea in France 2000-2014



MME TERREUR



PrEP program **increases STI screening and treatment** for **symptomatic** and **asymptomatic** infection and have implication on STI control via **CONDOM** promotion

MME TERREUR



# How to deal with our own antibodies ?

« *THEY* don't protect themselves,  
and *THEY* put others at risk... »





## So Far So Good...



Managing :

- *HIV patients,*
- *Post Exposure Prophylaxis,*
- *Clinical research activity,*
- *Infectious and tropical diseases activity,*
- ***PrEP is worth-it but time and energy consuming activity...***

Would not have been possible without community and whole team engagement

# Political Support from the City of Paris for HIV Prevention « Paris without AIDS »



# National Prevention Campaign for MSM



/ POUR LA VIE /  
/ POUR UN WEEK-END /  
/ POUR UNE FOIS /

Les situations varient.  
Les modes de protection aussi.

Sexe entre hommes : trouvez vos modes de protection sur [sexosafe.fr](http://sexosafe.fr)

PRÉSERVATIFS / DÉPISTAGES / PREP / TPE / TASP



/ COUP DE FOUDRE /  
/ COUP D'ESSAI /  
/ COUP D'UN SOIR /

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/ S'AIMER /  
/ S'ÉCLATER /  
/ S'OUBLIER /

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PRÉSERVATIFS / DÉPISTAGES / PREP / TPE / TASP



/ AVEC UN AMANT /  
/ AVEC UN AMI /  
/ AVEC UN INCONNU /

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PRÉSERVATIFS / DÉPISTAGES / PREP / TPE / TASP



# National Prevention Campaign for MSM V2

## Still work to do....



# Which Lessons learned



- PrEP consultation is **MUCH more** than just prescribing TRUVADA
- A **multi-disciplinary regular team work** and **follow-up** of risk evaluation and prevention through counseling (patient associations)
- Need for different lighting on the same case, as the information shared by the user can switch from **MD** to **counselor**
- Situate PrEP users in a **sexual health perspective**, with a combined global preventive approach : Infectious, Psychological, Sexual
- PrEP can also be leveraged into a **testing and curative tool for STIs**
- **Know-How** to talk about and evaluate this specific **risk** that patients are taking, what it represents for them and its **meaning**
- Be aware that an evolution of behavior may occur...
- **Monitor and evaluate PrEP implementation** (demonstrate public health benefit : ANRS PREVENIR study) / Educate other physicians



# PrEP is Changing HIV Prevention...



BUT...

# Management by multi-disciplinary team

- Drug consumption (sexual context, IV)
- Social problems and isolation
- Psychological troubles (self-image)
- Psychiatric troubles
- Sexual troubles (erectile dysfunction, sexual hyperactivity)
- Sexual Health (desire, pleasure, changes induced by PrEP)
- Sex workers, transgenders, migrants



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