



MINISTERIO  
DE SANIDAD, SERVICIOS SOCIALES  
E IGUALDAD



***EU Health Programme Projects' Symposium***  
***Malta 31 January-2 February***

# ***HIV Pre-exposure Profilaxis in Spain***



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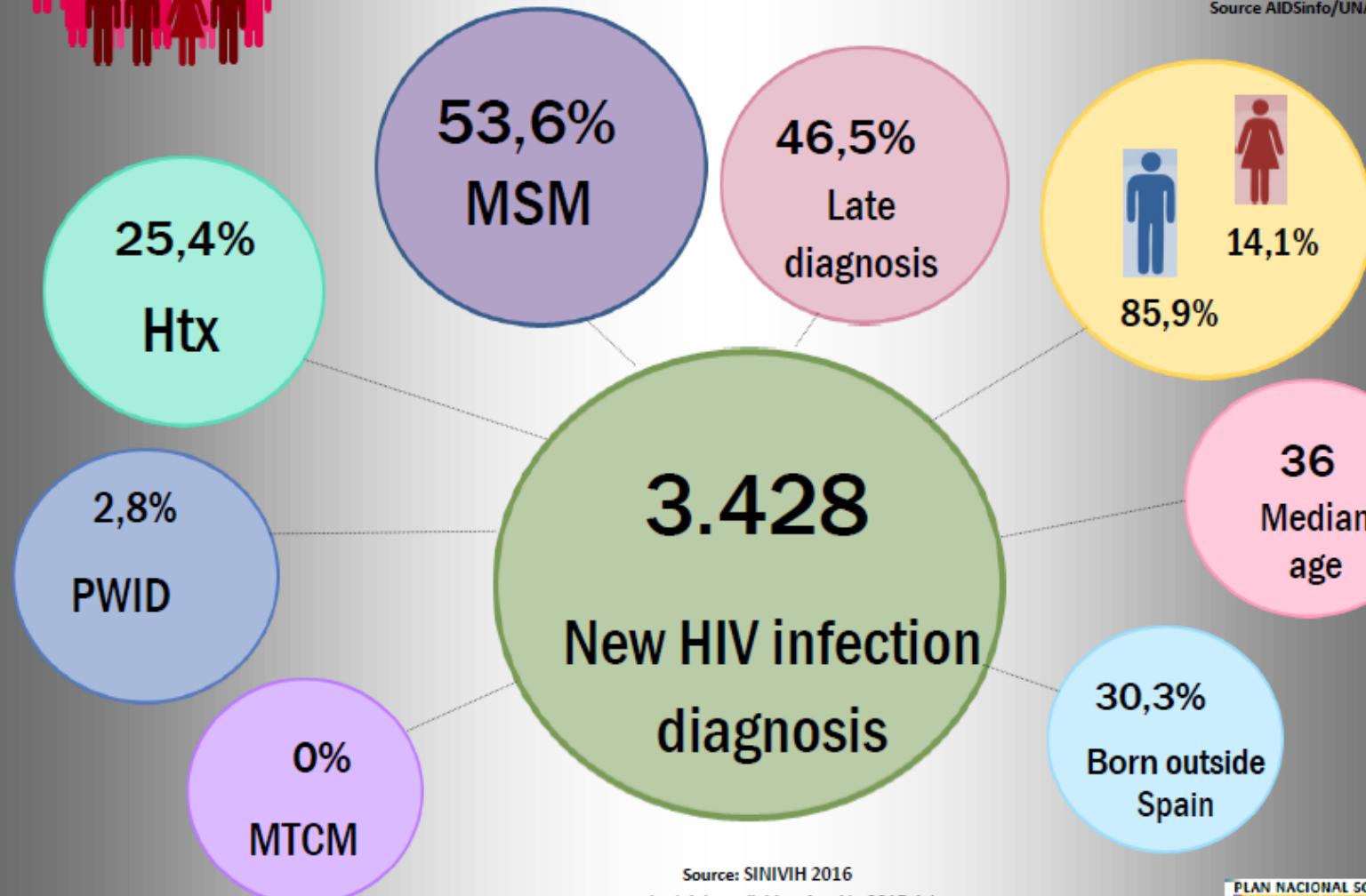
**GENERAL SUBDIRECTORATE OF HEALTH PROMOTION AND EPIDEMIOLOGY**  
**GENERAL DIRECTORATE OF PUBLIC HEALTH, QUALITY AND INNOVATION**

# Epidemiological Situation

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Estimating the prevalence of people with HIV infection in general population 0,4%

Source AIDSinfo/UNAIDS 2015





# PrEP context

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## Regulatory Aspect

- Spanish Medicine and Medical Devices Agency
- Directorate of Portfolio of Health Services and Pharmacy

## Document PrEP

- Drafted by experts: Writing group
- Reviewer group + Consulting group

## Demonstration Project

- Evaluation of the feasibility of the implementation of PrEP as a strategy for the prevention of HIV infection in high-risk population in the National Health System

# Regulatory aspects I

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*Make conditional to the Truvada® (Emtricitabina 200 mg/Tenofovir disoproxil 245 mg) Technical Sheets:*

- Use as PrEp once a day, always in combination with other prevention measures to reduce the risk of HIV-1 infection in adults with high-risk sexual practices
- Subject to **restricted medical prescription** by a doctor with experience in the care of HIV infection and tied to a **hospital**
- Dispensed by the **Hospital Pharmacy Services**

# Regulatory aspects II

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## □ AEMPS

- Review Truvada ® Materials
- Adapt Technical Sheet
- Adapt content of packaging

## MSSSI (Health Ministry)

- Establish The Price of Medicines



## *Price Interministerial Committee*

- Evaluate inclusion requirements



## *National Portfolio Committee*

# PrEP Document

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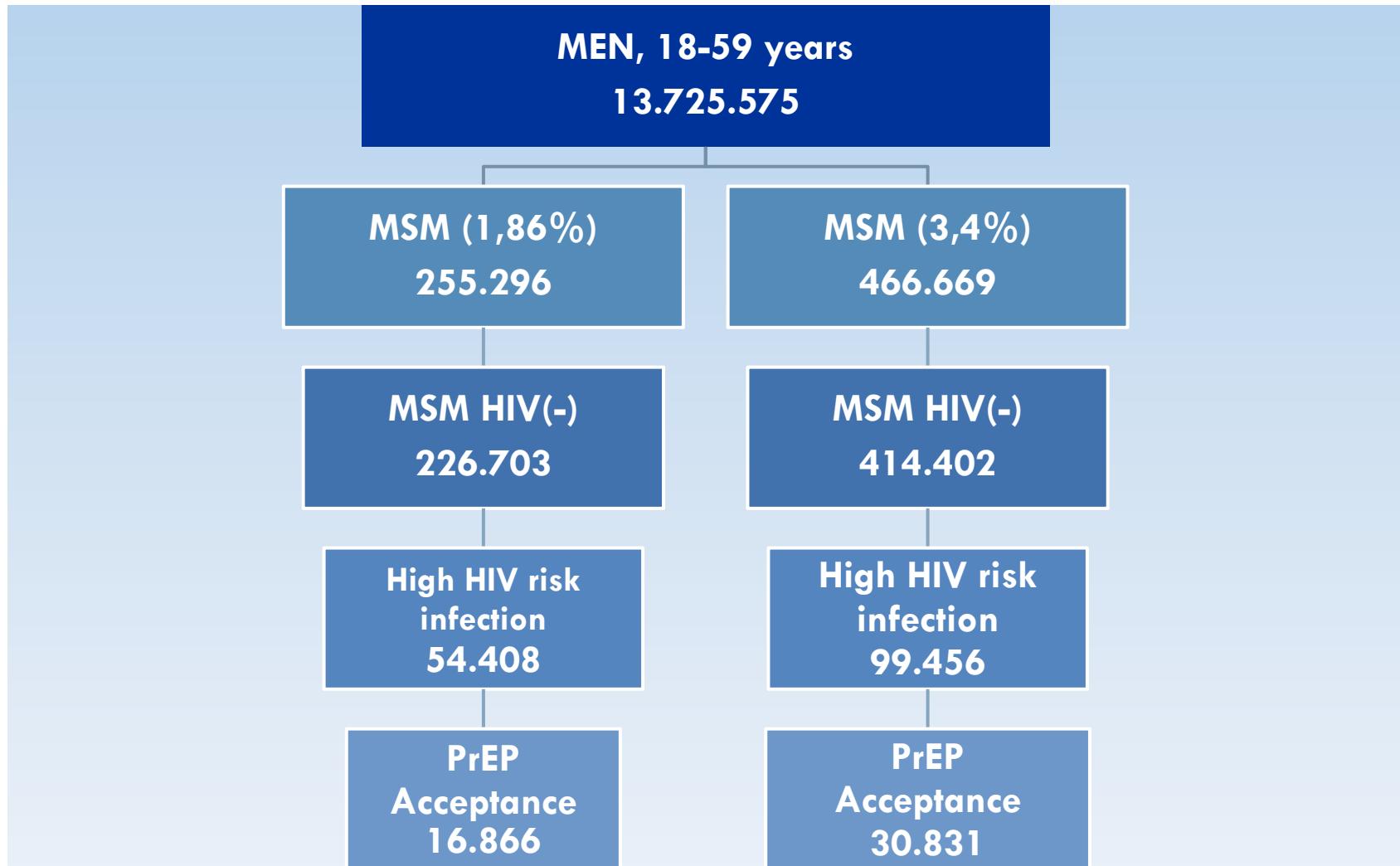
## HIV PRE- EXPOSURE PROFILAXIS IN SPAIN

### Content

- Collects scientific evidence
- Estimation of Key population: MSM
- Eligibility Criteria
  - Exclusion criteria
- Clinical monitoring and control
  - Testing, STI, side effects, adherence, counselling, etc
- Service model
  - Organization in Autonomous Regions
- Evaluation

# MSM Estimations

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# Elegibility Criteria I

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## MSM & TRANSGENDER PEOPLE

1. Older than 18
2. HIV negative
3. At least two of the following criteria:
  - > 10 different sexuals partners
  - Frequent practices of unprotected anal intercourse in the last year
  - Use of recreational drugs in the last years
  - Use of Post-exposure de Profilaxis in the last year
  - Bacterial STI in the last year

# Elegibility Criteria II

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## OTHER AT RISK POPULATION

**PWID:** (included in PIJ and/or OSP) unprotected sex

**SEXUAL WORKERS:** unprotected sex in HIV incidence areas >2%

## HIGHLY VULNERABLE PEOPLE

- Unprotected sex in the previous year with multiple sexual partners or unknown HIV status
- Unprotected sex in the previous year with partners from countries with high prevalence (> 1%), or people who inject drugs

# Delivery model

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**STI/HIV Clinics / Community Settings / Hospitals  
/ Primary Care :**

Identification of susceptible people

**Defined by Autonomalous Regions**

linked to a Hospital

HIV Expert  
Pharmacy

**Monitoring system for people on PrEP**

# Feasibility Study I

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PROTOCOL

Objectives



Evaluate  
the:

- Feasibility of implementation in Spain with current health structures
- Interference with other interventions for key populations
- Feasibility of the current care circuit to follow up and monitoring users
- Healthcare structures and economic (direct costs) Impact

# Feasibility Study II

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PROTOCOL

Methodology

AEMPS  
Qualification

EPA-AS

DIR-TRU-2017-  
01

Research  
Committee  
Authorisation  
(Pending)

- Post-authorisation observational prospective promoted by Public Administration
- 400 users MSM, 3 month recruitment
- 52 weeks following up: 0-4-12-24-36-48-52 weeks
- 3 Autonomous Regions: Models
  - STI Clinic+hospital
  - Hospital
  - Community Center+hospital
- Informed consent



DETEN A SIDA  
BARA EZAZU NIESA.

Detén el Sida. Unidos podemos

STOP  
AIDE.

ATURA LA SIDA.

ОСТАНОВИТЕ СПИД. ... لوقف الإيدز ... 拒绝艾滋

STOP SIDA.

PARA LA SIDA

[www.msc.es/ciudadanos/enfLesiones/enfTransmisibles/sida](http://www.msc.es/ciudadanos/enfLesiones/enfTransmisibles/sida)

i Thank You!