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HIV Pre-exposure Profilaxis in Spain

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Epidemological Situation

Estimating the prevalence of people with HIV infection in general population 0.4%

- 53.6% MSM
- 46.5% Late diagnosis
- 25.4% Htx
- 2.8% PWID
- 0% MTCM
- 14.1% 85.9%
- 36 Median age
- 30.3% Born outside Spain

3.428 New HIV infection diagnosis

Source: SINIVIH 2016
Last data available referred to 2015 data
PrEP context

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
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

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

- **MSSSI (Health Ministry)**
  - Establish The Price of Medicines
  - Evaluate inclusion requirements

  **Price Interministerial Committee**

  **National Portfolio Committee**
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

MEN, 18-59 years
13,725,575

MSM (1.86%) 255,296

MSM HIV(-) 226,703

High HIV risk infection 54,408

PrEP Acceptance 16,866

MSM (3.4%) 466,669

MSM HIV(-) 414,402

High HIV risk infection 99,456

PrEP Acceptance 30,831
# Eligibility Criteria I

**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

### 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

STI/HIV Clinics / Community Settings / Hospitals / Primary Care:
- Identification of susceptible people

Defined by Autonomous Regions
- linked to a Hospital
  - HIV Expert Pharmacy

Monitoring system for people on PrEP
Feasibility Study I

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

- **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**