



MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD



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

HIV Pre-exposure Profilaxis in Spain



Olivia Castillo Soria
Head of Area of Prevention
National Aids Strategy

31 January 2017

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

Epidemiological Situation

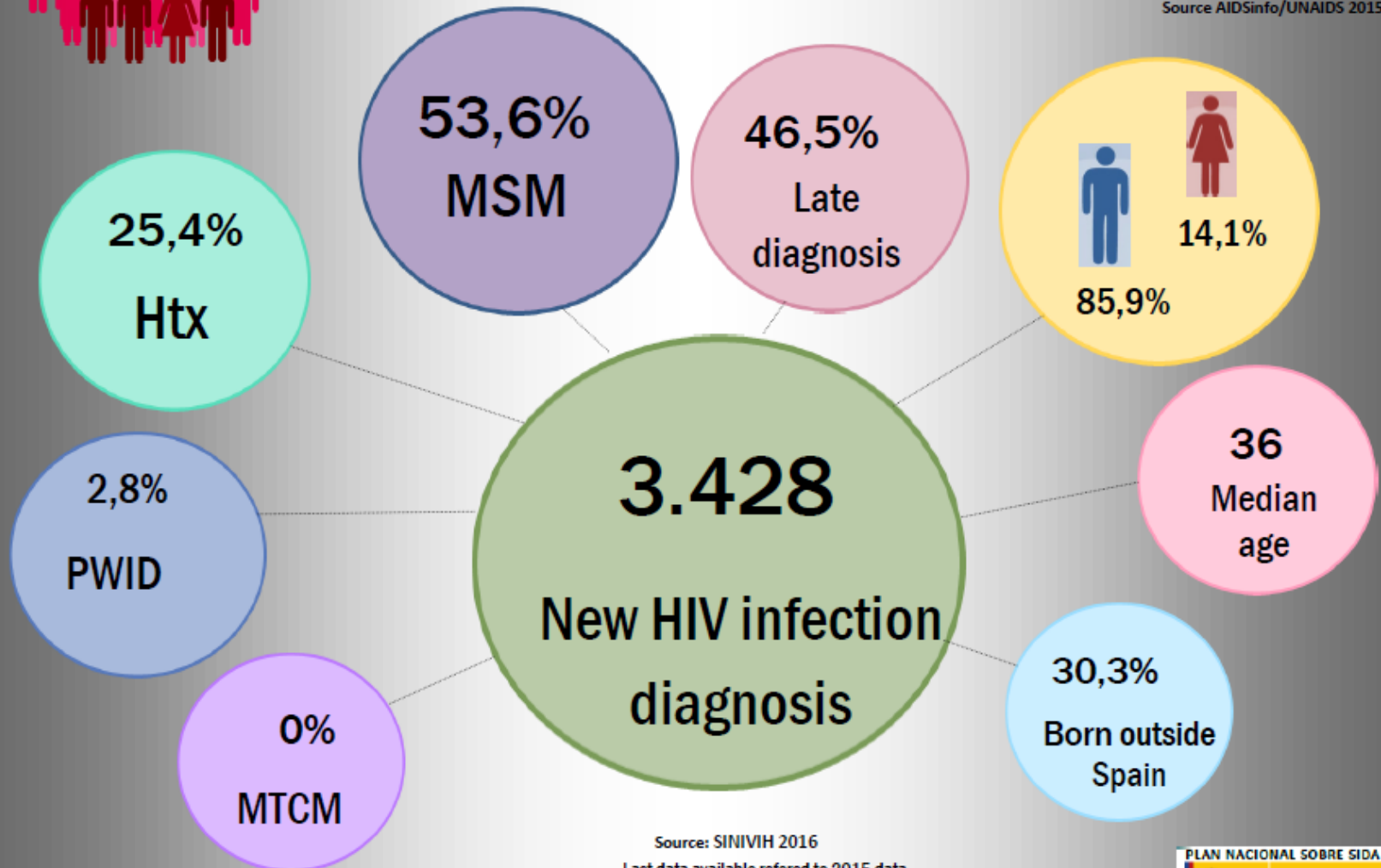


2



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

Source AIDSinfo/UNAIDS 2015





PrEP context

3

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

4

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

5

□ **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

6

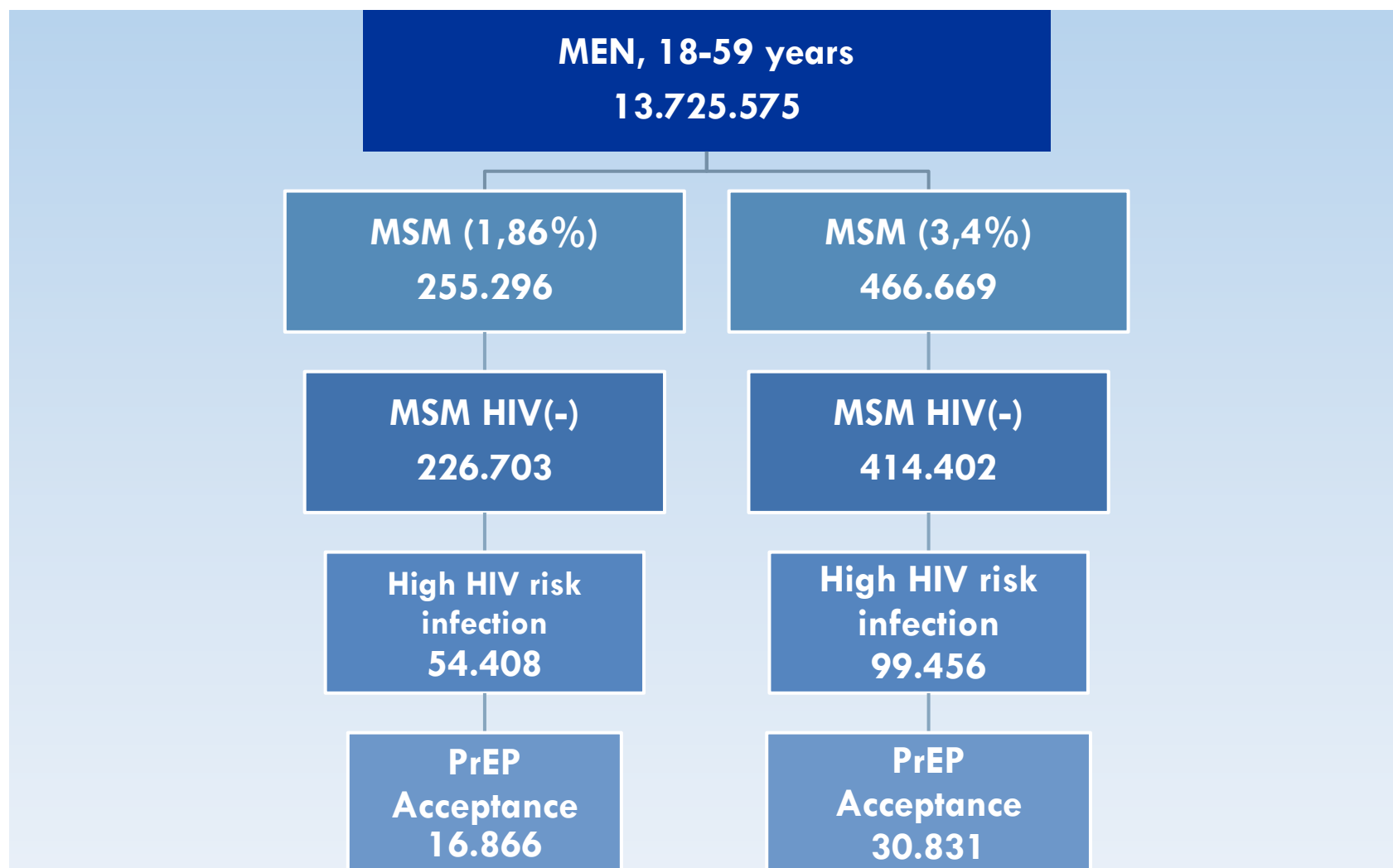
HIV PRE- EXPOSURE PROFILAXIS IN SPAIN

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

7



Elegibility Criteria I

8

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

9

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

10

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

Identification of susceptible people

Defined by Autonompous Regions
linked to a Hospital

HIV Expert
Pharmacy

Monitoring system for people on PrEP

Feasibility Study I

11

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

12

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

BARA EZAZU NIESA.

ATURA LA SIDA.

PARA LA SIDA



iThank You!