



HPV FASTER implementation in Mexico: A pilot study

FASTER - Tlalpan study

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**HPV Prevention
and Control Board**

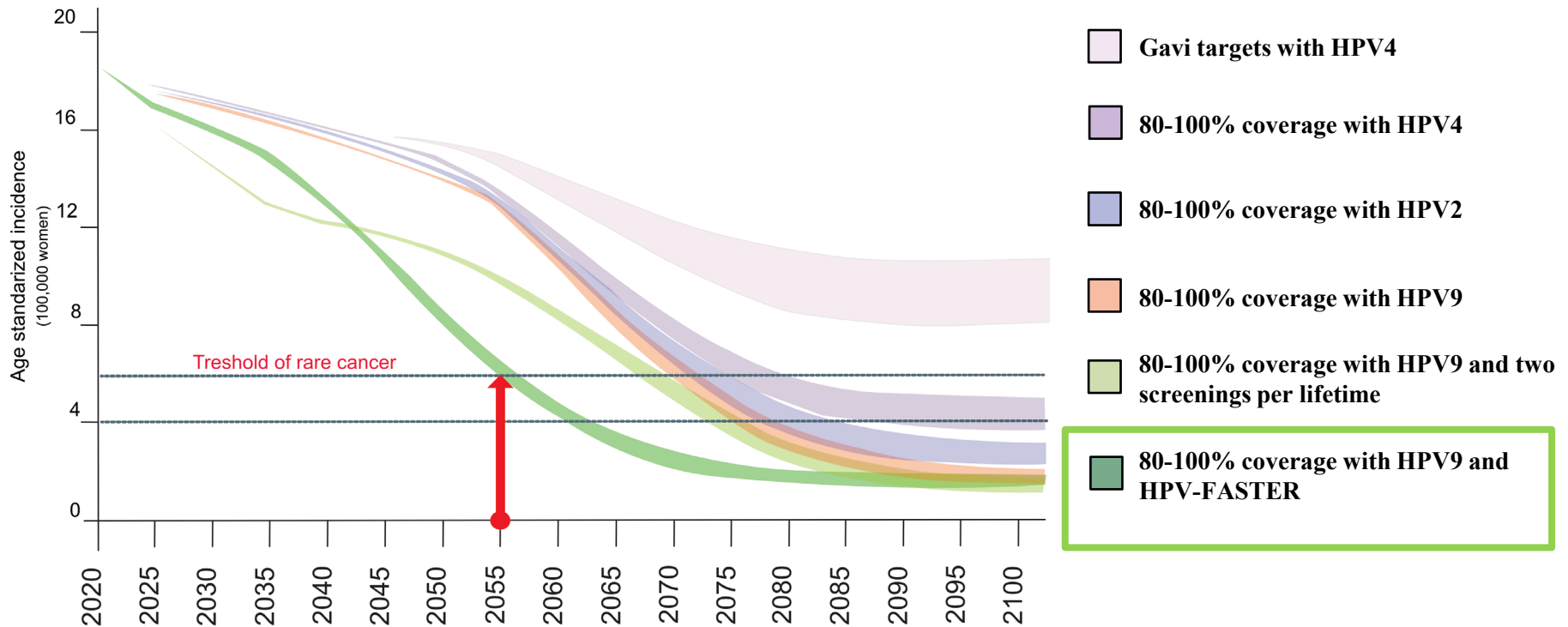
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Background

- We need better ways to reach the goal of cervical cancer elimination.
- Strategies combining screening and vaccination may be a good alternative to improve cancer prevention, and a more efficient path to cervical cancer elimination, in lower and middle-income countries.

Impact of HPV FASTER in cervical cancer elimination

Cervical cancer incidence according to different strategies of vaccination and screening in countries with a medium human development index



HPV FASTER may reduce the time to cervical cancer elimination, in middle income countries

FASTER - Tlalpan study in Mexico

Objetives

To evaluate the feasibility and impact of HPV FASTER in women aged 25 to 45 years, to reduce the number of screenings, in real conditions.

To explore the acceptability of urine self-sample collection as a primary sample for HPV-based screening.

Hypotheses

The combined strategy of HPV vaccination and HPV-based screening can safely extend the interval between screenings from 5 to 10 years.

The HPV FASTER strategy may reduce the occurrence of CIN3+ lesions in subsequent screens.

Methods

Study population.

Women aged 25 to 45 years, living in the borough of Tlalpan, Mexico City, attending healthcare services of Jurisdiction No. 8 in Mexico City.

We enrolled 3,000 women.

Study design.

Randomized, open trial.

Study groups:

- a. HPV-based screening and HPV16/18 vaccine
- b. HPV-based screening and HPV16/18/6/11 vaccine
- c. HPV-based screening

Women aged 25-45 years, Tlalpan, Mexico City

Recruitment – Consent

Randomization

HPV 16/18
vaccination

HPV 6/11/16/18
vaccination

Control

HPV-based screening

HPV-based screening

HPV
negative

HPV
positive

HPV
negative

HPV
positive

Colposcopy
Dx & Tx

Colposcopy
Dx & Tx

Randomization

HPV-based screening

HPV-based screening

HPV
negative

HPV
positive

HPV
negative

HPV
positive

Colposcopy
Dx & Tx

Colposcopy
Dx & Tx

HPV-based screening
5 years later

HPV-based screening

Baseline

M60

M120

Endpoints assessment

M60 evaluation

- CIN2 and CIN3+ incidence.
- Safety evaluation.

M120 evaluation





- CIN 2 and CIN3+ incidence.

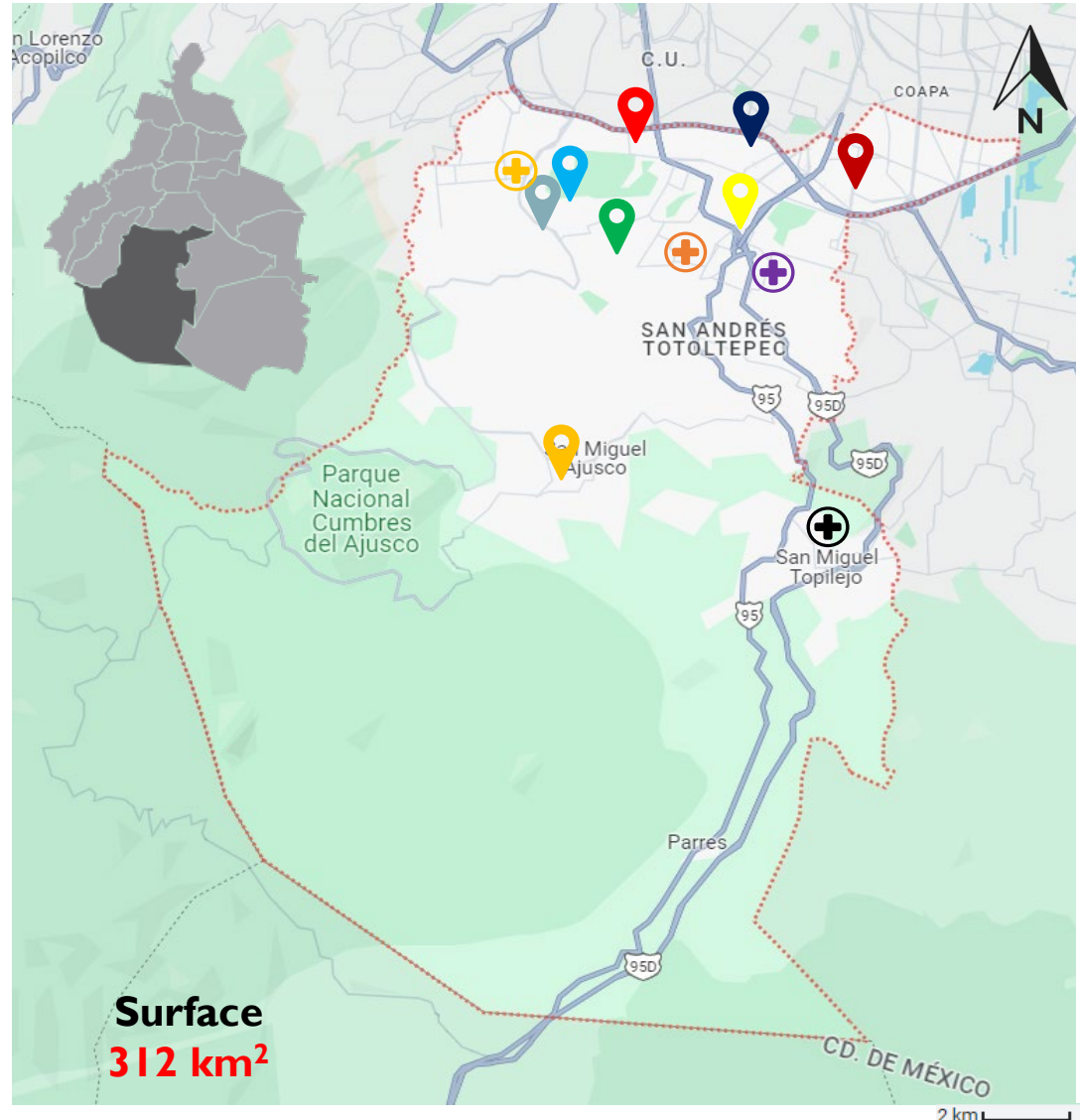
FASTER - Tlalpan study population

Participating healthcare centers

-  Lomas de Padierna
-  Dr. José Castro Villagrana
-  La Salle
-  Cultura Maya
-  Dr. Gerardo Varela Mariscal
-  Ejidos de Huipulco
-  Dirección de Salud, Coscomate
-  Ampliación Miguel Hidalgo

Non participating healthcare centers

-  Dr. David Fragoso Lizalde
-  Pedregal de las Águilas
-  Hortencia
-  Topilejo



Study population distribution by group and study site

Healthcare Centers	HPV16/18 vaccine <i>n = 1,066</i> %	HPV16/18/6/11 vaccine <i>n = 917</i> %	Control <i>n = 990</i> %
José Castro Villagrana	36.9	37.2	37.9
La Salle	11.8	13.4	12.4
Cultura Maya	23.3	20.4	18.9
Gerardo Varela Mariscal	5.7	7.9	7.3
Ejidos de Huipulco	2.1	1.7	2.6
Dirección de Salud, Coscomate	15.2	14.7	15.9
Ampliación Miguel Hidalgo	5.0	4.7	5.1

Participants contact information:

Name, address, phone number and email of participant and a relative or friend.

Preference of contact

Characteristics of study population

Variable	HPV 16/18 vaccine %	HPV 16/18/6/11 vaccine %	Control %
Age	35.9	36.1	36.3
25-34 years	41.3	39.9	37.8
35-45 years	58.7	60.1	62.2
Education			
Primary/Secondary	55.1	54.2	57.2
Highschool/Professional	42.3	43.6	40.1
Occupation			
Housewife	57.2	57.5	57.5
Formal employee	33.7	29.5	30
Civil status			
Married	60.9	69.4	72.8
Single/Widow/Divorced	30.5	30.6	27.2
HPV infection (total)			
Positive for any hrHPV	23.4	25.3	23.7
HPV 16/18 positive	2.3	2.4	2.2

Next steps

The second phase of the study will be conducted during 2024-2025

- **Randomization of vaccinated groups**
- **Re-contact with study participants**
- **Vaccination of control group**
- **Evaluation of CIN2 and CIN3+ detection among screened groups**
- **Evaluation of safety among screened groups – to evaluate continuation of the trial**
- **Evaluation of urine performance as primary HPV-based screening sample**
- **Evaluation of acceptability and feasibility of using urine as a primary screening sample**



Xavier Bosch, Eduardo Lazcano, Leith León, Rubí Hernández, Leticia Torres, Eduardo Franco, Jack Cuzick, Attila Lorincz, Cosette Wheeler, Philip Castle, Patti Gravitt, Berenice Rivera, Aarón Rodríguez, Julia Hernández, Sonia Hernández, Jorge Salmerón

FASTER-Tlalpan study team

Thanks