Costa Rica HPV Vaccine Trials

Carolina Porras and Aimée Kreimer

June 2, 2022

NIH NATIONAL CANCER INSTITUTE

acib
Agencia Costarricense de Investigaciones Biomédicas

HPV vaccine trials in Costa Rica

1. Costa Rica HPV Vaccine Trial (CVT, launched 2004)- conducted prior to licensure, 18 to 25 yr old women

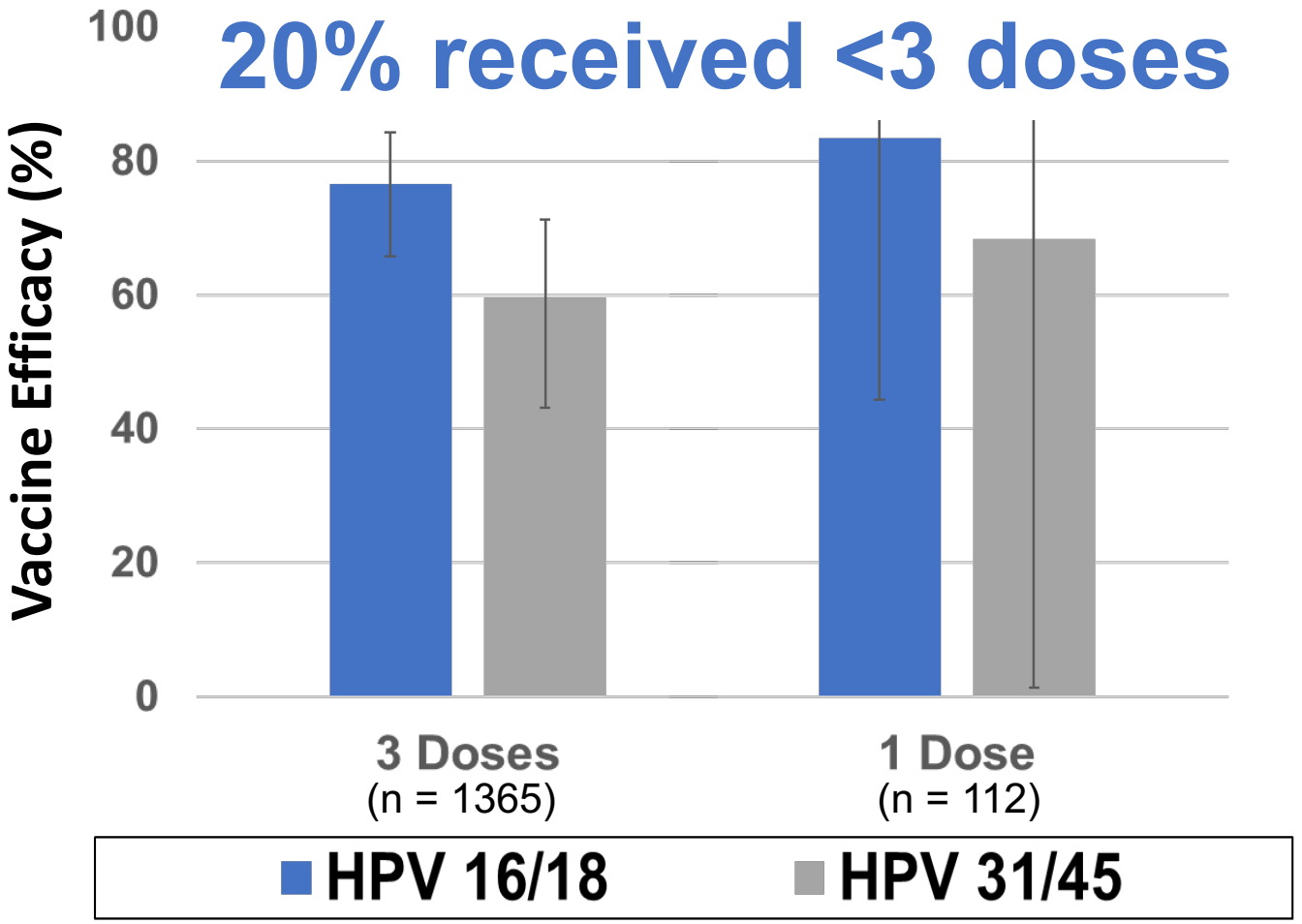
2. ESCUDDO- non-inferiority trial evaluating 1 vs 2 doses of 2v and 9v HPV vaccines among 12- to 16-year-old girls; computed vaccine efficacy (VE) against unvaccinated

3. PRIMAVERA- immunobridging trial comparing antibody levels among girls who received 1 dose of the 2v HPV vaccine compared to levels observed in an efficacy population that received 3 doses of the 4v vaccine

4. NEW: PRISMA- 1 dose HPV vaccination in adult women (18-30 years)

NCI Costa Rica HPV Vaccine Trial: RCT to evaluate safety and efficacy of 3 doses the bivalent HPV vaccine among women aged 18 to 25

Vaccine efficacy >10 years since bivalent HPV vaccine, by dose



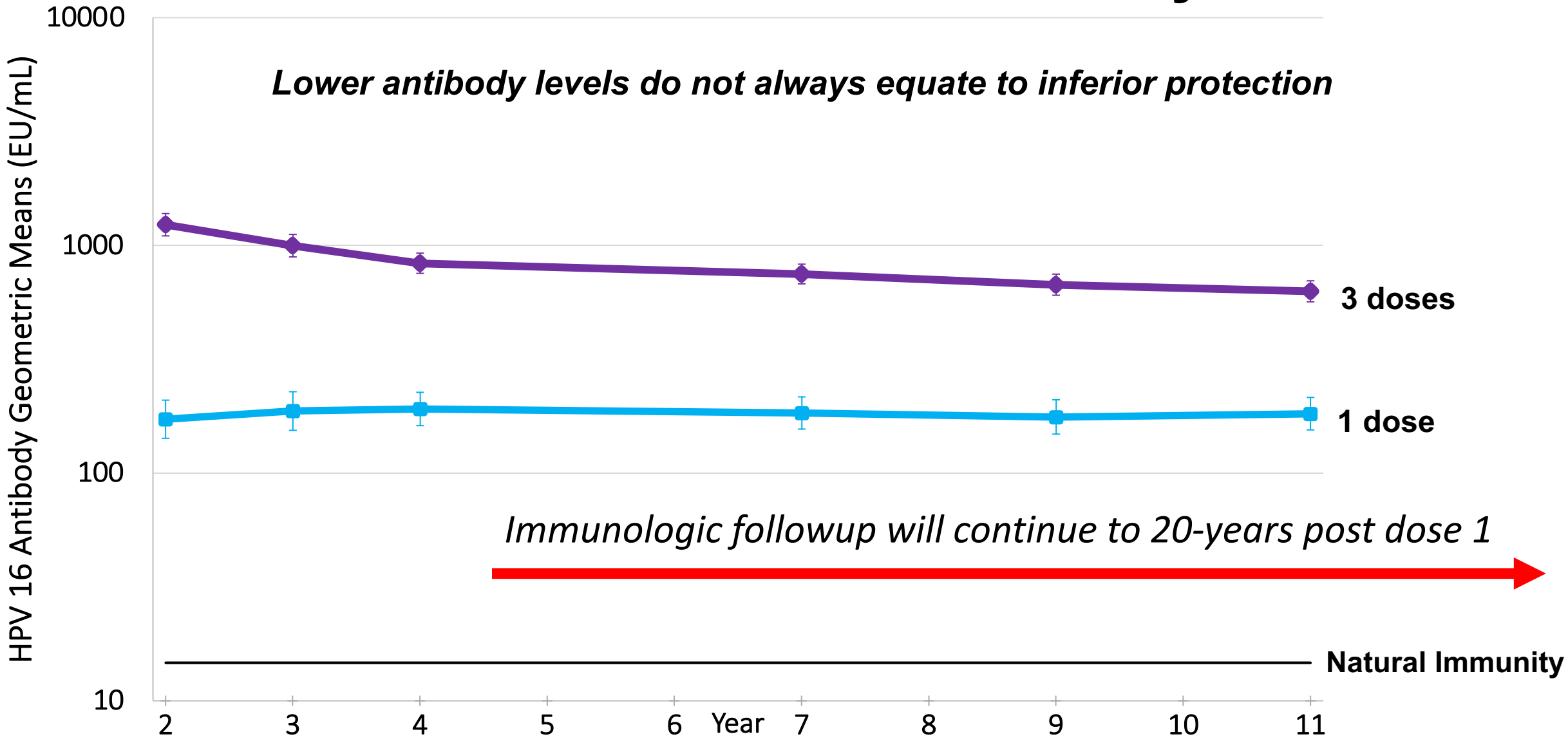
**Lower efficacy with 3 doses because the endpoint was prevalent HPV infection assessed in a total vaccinated cohort*

Kreimer AR et al, JNCI 2020

Tsang SH et al, JNCI 2020

Agencia Costarricense de Investigaciones Biomédicas

One dose of bivalent HPV vaccination induces stable HPV16 serum antibodies for >10 years



Kreimer AR JNCI 2020

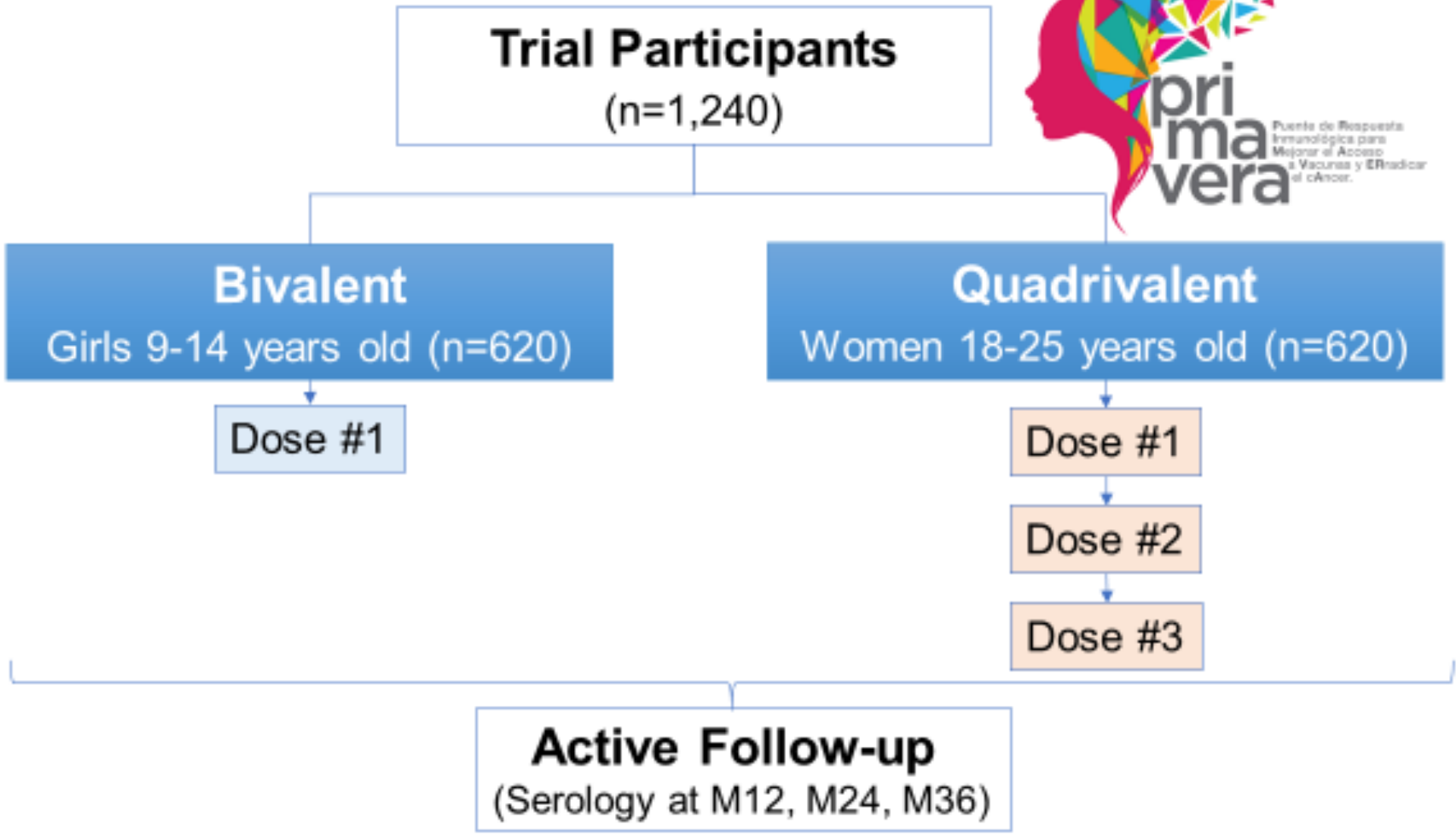
PRIMAVERA: Non-randomized, open-label, clinical trial

Hypothesis based on ratios in the published literature:

- 1-Dose is ⅙ as immunogenic as 3 doses
- Cervarix is 6x as immunogenic as Gardasil
- Girls have a 2x increase in antibody response compared to young adult women

If these effects are multiplicative, we have reason to believe we can demonstrate non-inferiority of the antibody response in girls who receive 1d bivalent vaccine compared to young adult women who receive 3 doses of the quadrivalent HPV vaccine

primavera
Puente de Respuesta Inmunológica para Mejorar el Acceso a Vacunas y ERradicar el cÁncer.

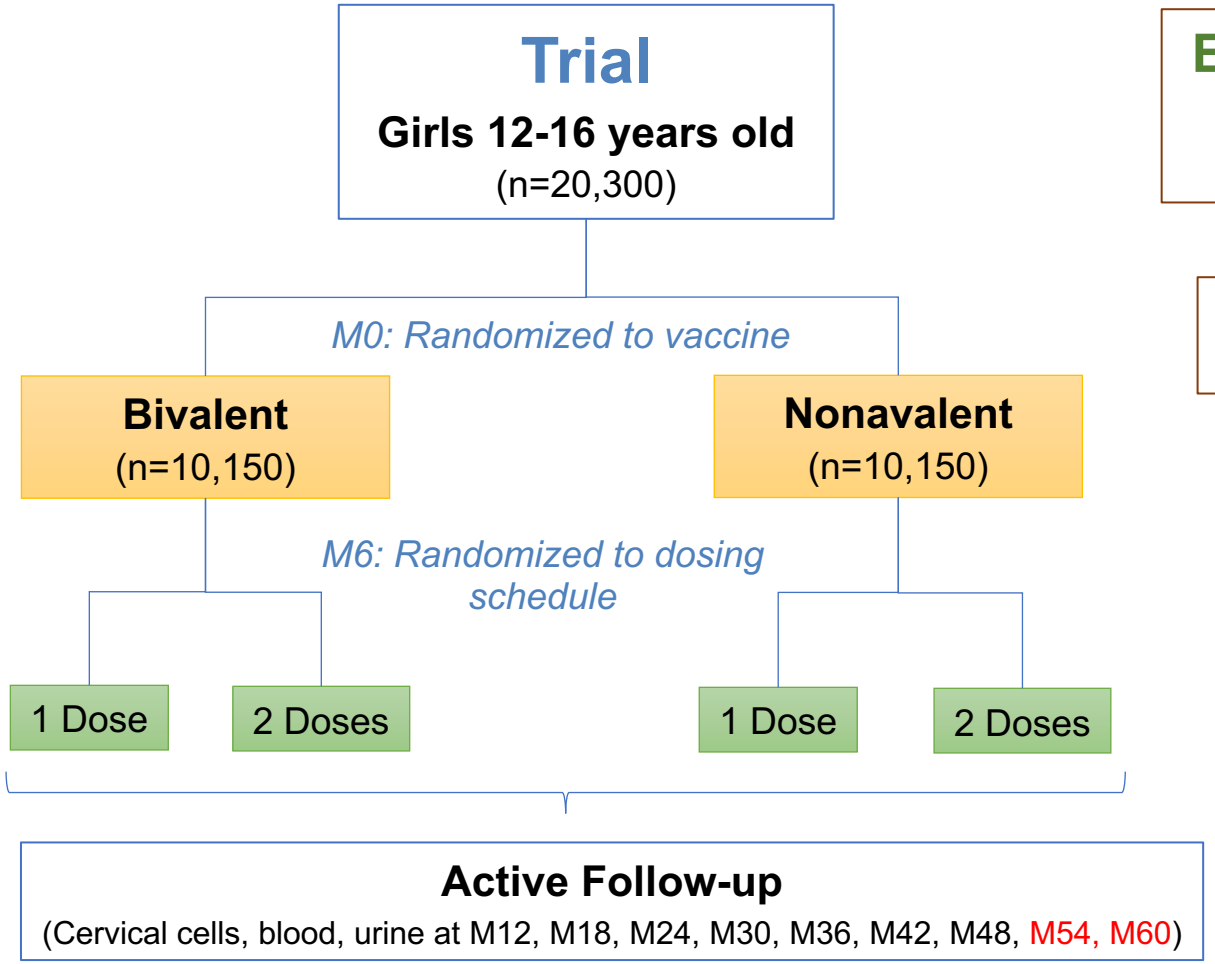


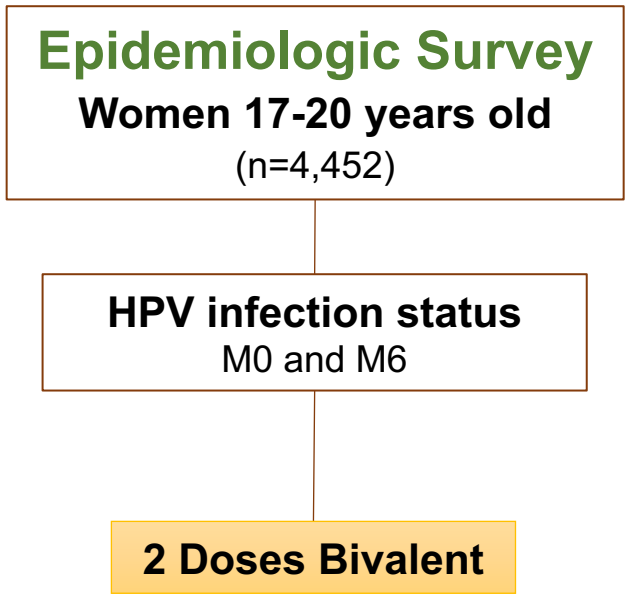
Outcome: HPV16/18 antibodies measured using our well-validated and now qualified ELISA assay, with confirmation using neutralization assays

A scientific evaluation of one or two doses of the HPV vaccine

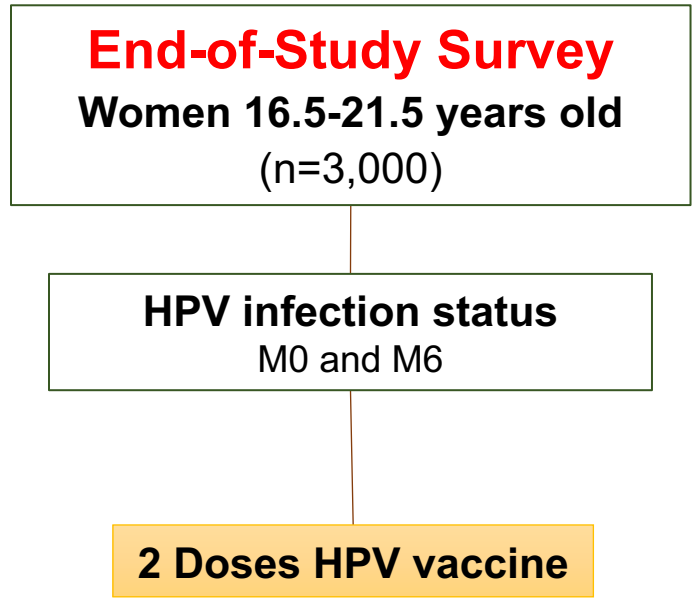
Clinicaltrials.gov identifier: NCT03180034

AIM: Evaluate one dose of HPV vaccination compared to zero doses





Enrollment occurred when trial participants were completing their baseline visit



Enrollment to occur when trial participants are completing their 54 month visit (year 4.5)

Results expected 2024/2025

proyecto esciddo

Single-dose HPV vaccination among young adult women in Costa Rica

How can we accelerate global cervical cancer control with use of single-dose HPV vaccination?

prisma

Prevención del cáncer
de cérvix con **una sola dosis**
de vacuna contra VPH
en mujeres adultas jóvenes.

New study: PRISMA

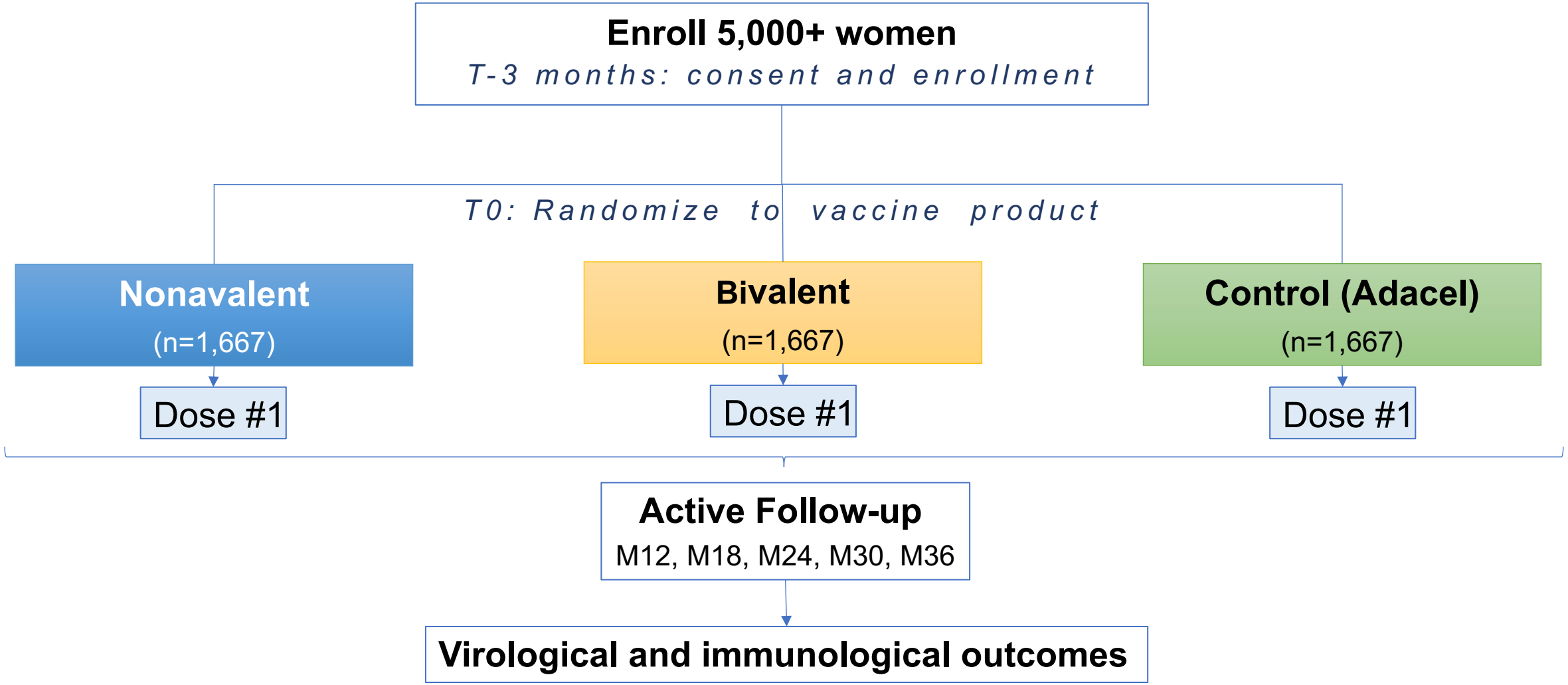
Goal: Expand the recommendation for single-dose HPV vaccination to age 30, if supported by the data

Primary objective

- Evaluate one dose of the HPV vaccines compared to no vaccination in the protection against incident HPV16/18 cervical HPV infections that persist 6-months or more in women aged 18 to 30 years who are HPV16/18 DNA negative prior to and at the time of vaccination (i.e., VE in an ATP cohort).
  - Bivalent (AS04 adjuvanted) and nonavalent HPV vaccines

prisma
Prevención del cáncer de cérvix con una sola dosis de vacuna contra VPH en mujeres adultas jóvenes.

Randomized, blinded, controlled trial



Remarks

- Study launched

- Goal is to have data ready for 2027, when HPV vaccine supply exceeds demand

- The study is an opportunity to save additional women- 1 dose in women may allow for a massive, one-time catchup