# Introduction to policy considerations: Reduced number of HPV vaccine doses

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Advisory Committee on Immunization Practices
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# Outline

- Brief introduction to human papillomavirus (HPV)
- HPV vaccines and vaccination recommendations in the United States
- Overview of data on vaccination with a reduced number of doses
- World Health Organization recommendations and international landscape

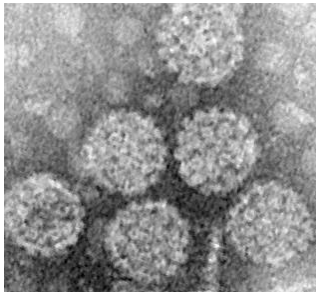
# Introduction

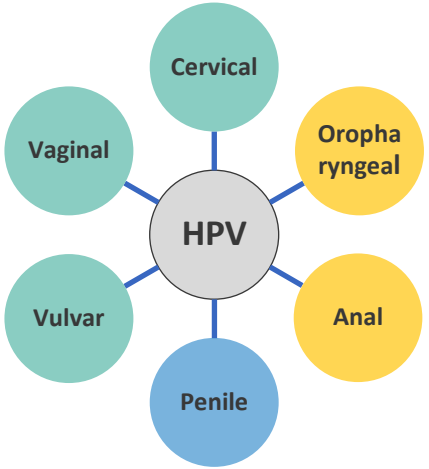
# 18 years since first HPV vaccine licensure

- High vaccine efficacy in clinical trials
- High population impact in real world settings
- Strong herd effects of vaccination programs
- Implementation challenges in many countries
- Lag in vaccine introduction in low- and middle-income counties

# Human papillomaviruses

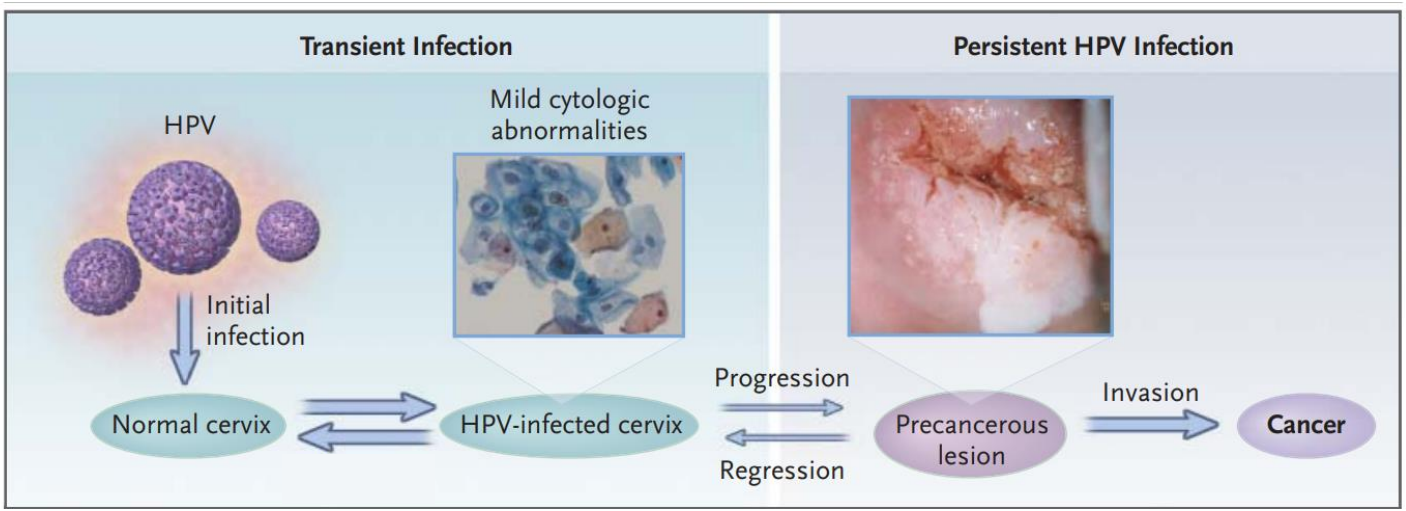
- **Double-stranded DNA virus (8 kb circular genome)**
- **> 200 closely related types**
  - L1 is major capsid protein
    - Sequence of L1 gene determines type
- **12 types classified as high-risk (oncogenic)**
  - HPV 16 and HPV 18 responsible for most HPV-attributable cancer
- **Low-risk HPV types**
  - HPV 6 and HPV 11 cause most anogenital warts and recurrent respiratory papillomatosis
- **Most common sexually transmitted infection**
  - ~ 13 million persons in the United States become infected with a disease-causing HPV type each year
  - Over 90% become undetectable in 2 years






HPV-attributable cancer

# HPV infection causes cervical cancer (and other cancers) after years to decades




Wright and Schiffman. N Engl J Med 2003

# HPV-associated and estimated HPV-attributable cancer cases per year, United States, 2017–2021

| Cancer site | Number of HPV-associated cancers | Percentage probably caused by any HPV type | Estimated number probably caused by any HPV type* | | |
|---|---|---|---|---|---|
| | | | Female | Male | Both sexes |
| **Cervix** | 11,959 | 91% | 10,800 | - | 10,800 |
| **Vagina** | 898 | 75% | 700 | - | 700 |
| **Vulva** | 4,418 | 69% | 2,900 | - | 2,900 |
| **Penis** | 1,381 | 63% | - | 900 | 900 |
| **Anus**** | 7,854 | 91% | 5,000 | 2,200 | 7,200 |
| **Oropharynx** | 21,474 | 70% | 2,300 | 12,900 | 15,200 |
| **TOTAL** | **47,984** | **79%** | **21,800** | **16,000** | **37,800** |

*Estimates were rounded to the nearest 100. Estimated counts might not sum to total because of rounding.

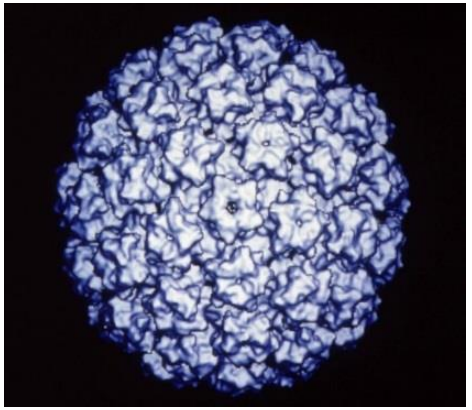
**Includes anal and rectal squamous cell carcinomas

Sources: Cancers Linked With HPV Each Year | Cancer | CDC and http://www.cdc.gov/cancer/dataviz

# HPV vaccines and recommendations

# Available prophylactic HPV vaccines

- Virus-like particle (VLP) vaccines
- L1 major capsid proteins self-assemble into VLPs
- High efficacy with durable protection



HPV VLP

# HPV vaccines licensed in the United States

| Vaccine and brand name | Bivalent (2vHPV) Cervarix | Quadrivalent (4vHPV) Gardasil | 9-valent (9vHPV) Gardasil 9 |
|---|---|---|---|
| **Types** | **16, 18** | **16, 18, 6, 11** | **16, 18, 6, 11 31, 33, 45, 52, 58** |
| **Prevents** | cancer | cancer anogenital warts | cancer anogenital warts |
| **Adjuvant** | AS04 500 $\mu$g aluminum hydroxide 50 $\mu$g 3-O-desacyl-4' monophosphoryl lipid A | AAHS 225 $\mu$g amorphous aluminum hydroxyphosphate sulfate | AAHS 500 $\mu$g amorphous aluminum hydroxyphosphate sulfate |
| **Year licensed** | 2009 | 2006 | 2014 |
| **Manufacturer** | GlaxoSmithKline | Merck & Co. | Merck & Co. |

HPV 16 and 18 are oncogenic types that cause most HPV-attributable cancers; HPV 31,33,45,52,58 are oncogenic types that cause about 12% of HPV-attributable cancers; HPV 6,11 cause most anogenital warts and recurrent respiratory papillomatosis

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**After the end of 2016, only 9vHPV available in the United States**

# Efficacy and immunogenicity trials for initial licensure of HPV vaccines, 3-dose schedules (0, 1-2, 6 months)

**Randomized controlled efficacy trials in ~15–26-year-old women**

**Endpoints:**
- cervical precancers and external genital lesions

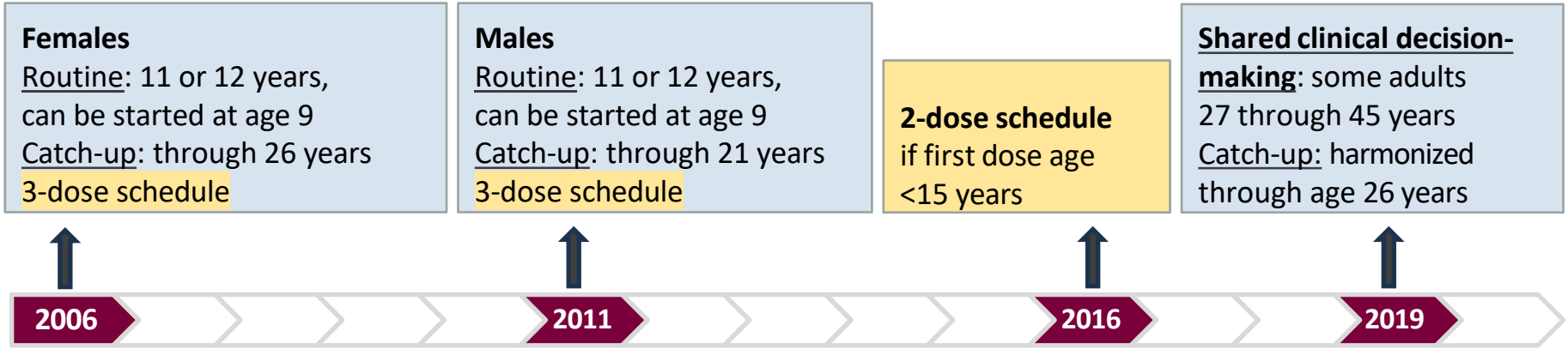
**Per protocol analyses:**
- efficacy >96%
- seroconversion ~ 100%

**Immunobridging trials in 9–15-year-olds**

**Licensure based on non-inferior antibody response compared with women in efficacy trials**

Future II Study Group, NEJM 2007; Garland, et al. NEJM 2007; Paavonen, et al. Lancet 2007
Quadrivalent vaccine trials had other endpoints including, vulvar, vaginal precancers and genital warts

# Evolution of HPV vaccination recommendations – United States



# Current HPV vaccination recommendations, United States

**Routine vaccination**

- Age 11 or 12 years
- Can be started at age 9 years

**Catch-up vaccination**

- Through age 26 years

**Shared clinical decision-making**

- Age 27–45 years

**Number of doses**

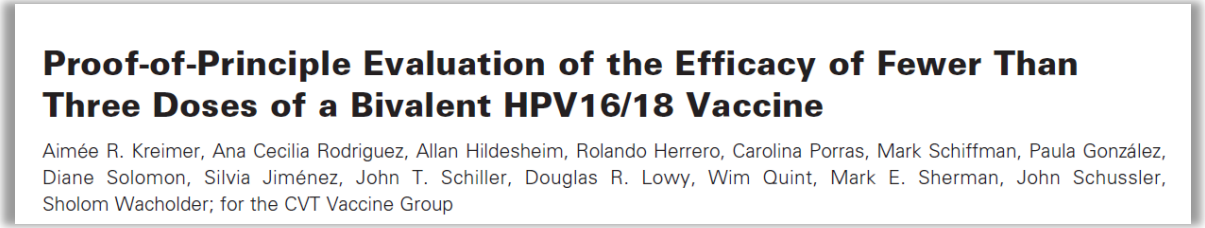
2 doses (0, 6-12 months)
if starting series before 15th birthday

3 doses (0,1-2, 6 months)
if starting series on or after 15th birthday or
if immunocompromising condition

Recommendations of the Centers for Disease Control and Prevention and the Advisory Committee on Immunization Practices
https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hpv.html

# How did we get to 2 doses?

- **Post hoc analyses of a 3-dose randomized trial (2vHPV vs control vaccine)**
  - Not all participants completed 3-dose schedule
  - Efficacy against HPV16/18 infection similar after 3, 2, 1 doses



**Proof-of-Principle Evaluation of the Efficacy of Fewer Than Three Doses of a Bivalent HPV16/18 Vaccine**

Aimée R. Kreimer, Ana Cecilia Rodriguez, Allan Hildesheim, Rolando Herrero, Carolina Porras, Mark Schiffman, Paula González, Diane Solomon, Silvia Jiménez, John T. Schiller, Douglas R. Lowy, Wim Quint, Mark E. Sherman, John Schussler, Sholom Wacholder; for the CVT Vaccine Group

J Natl Cancer Inst 2011

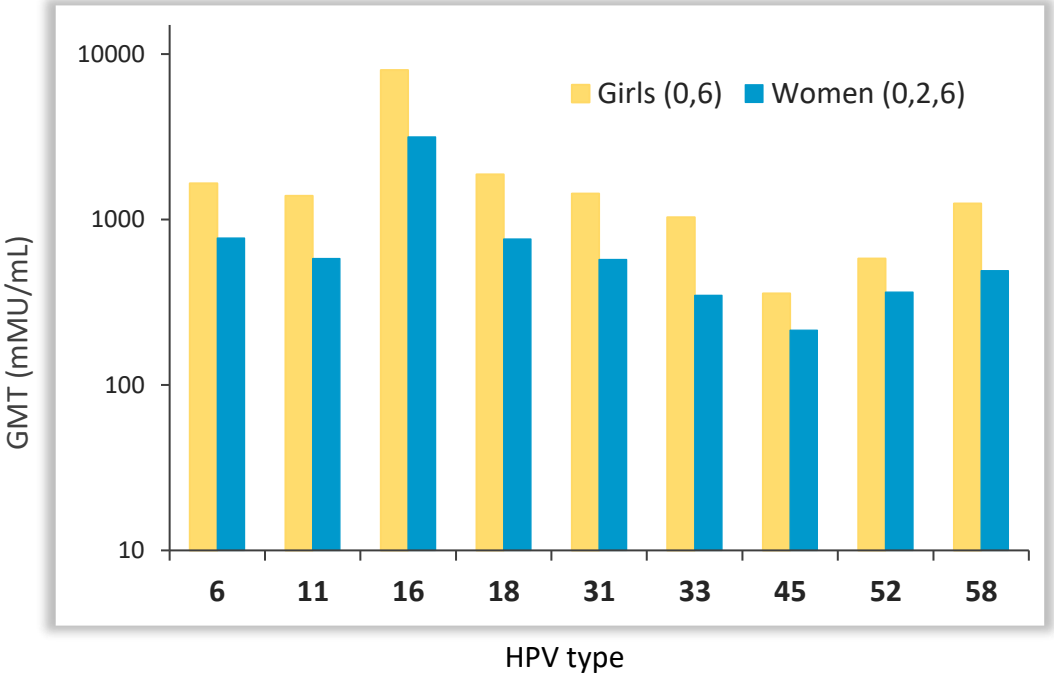
- **Immunobridging trials**
  - **2 doses** in 9–14-year-olds vs **3 doses** in young adult women
  - Seroconversion and GMTs were non-inferior in 2-dose group

# Data from 9vHPV immunobridging trial

**2 doses (0,6 or 0,12 months) in adolescents (9-14 years)**

***compared with***

**3 doses (0,2,6 months) in women (16-26 years)**




Iversen et al. JAMA 2017

Similar findings for 2vHPV and 4vHPV: Romanowski, Hum Vaccin Immunother 2016; Puthanakit, JID 2016; Lazcano-Ponce, Vaccine 2014; Dobson, JAMA 2013; Hernández-Ávila, Hum Vaccin Immunother 2016; Iversen et al. JAMA 2017

# Licensure and recommendations for a 2-dose HPV vaccination schedule

Manufacturers submitted supplemental applications for 2 doses in 9–14-yr-olds

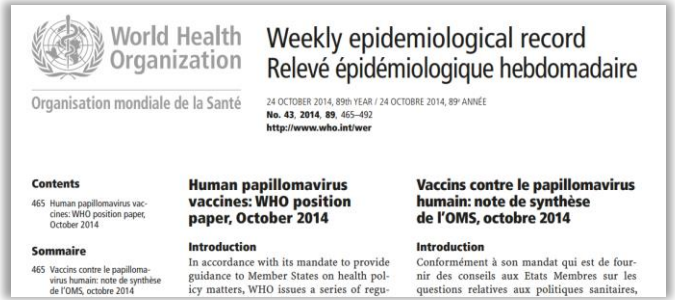
↓

FDA and other regulatory authorities approved

↓

WHO, ACIP, other advisory groups recommended a 2-dose series at 9–14 years

**2014**



World Health Organization

Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

24 OCTOBER 2014, 89th YEAR / 24 OCTOBRE 2014, 89e ANNÉE
No. 43, 2014, 89, 465–492
http://www.who.int/wer

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**Human papillomavirus vaccines: WHO position paper, October 2014**

Introduction

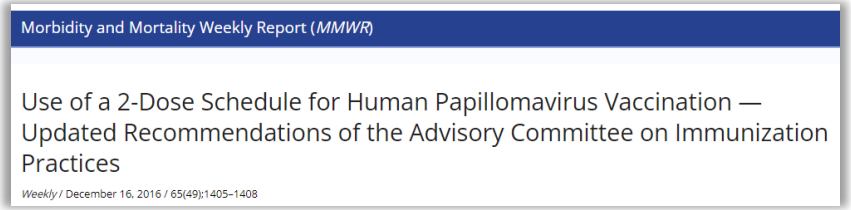
In accordance with its mandate to provide guidance to Member States on health policy matters, WHO issues a series of regu-

**Vaccins contre le papillomavirus humain: note de synthèse de l'OMS, octobre 2014**

Introduction

Conformément à son mandat qui est de fournir des conseils aux Etats Membres sur les questions relatives aux politiques sanitaires,

**2016**



Morbidity and Mortality Weekly Report (*MMWR*)

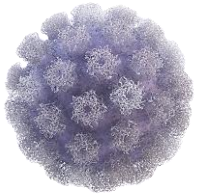
Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices

*Weekly* / December 16, 2016 / 65(49);1405–1408

# Evidence on single-dose vaccination

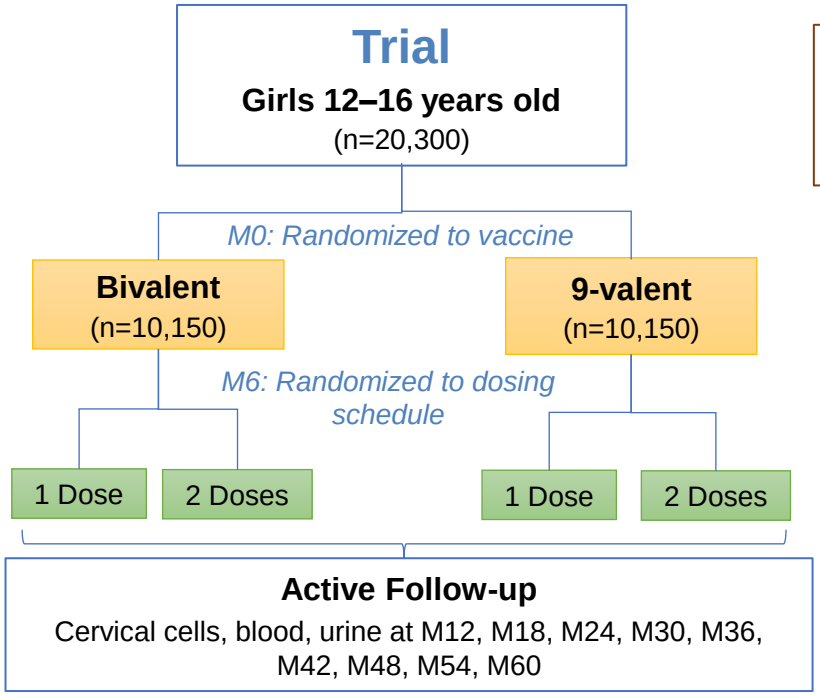
# Single-dose HPV vaccination – initial interest

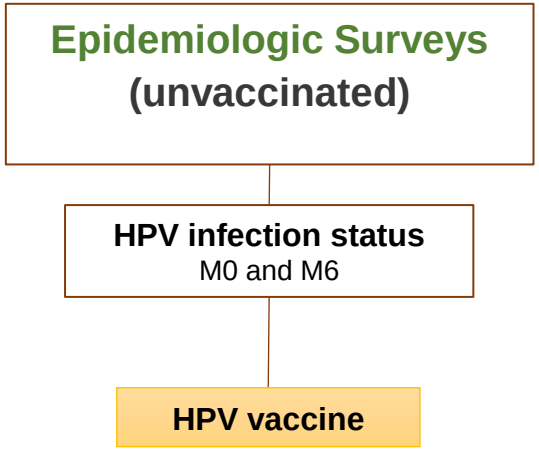
- **Stimulated by same studies that led to 2-dose schedules**
- **Immunobridging trials not possible for single-dose**
  - Single dose results in lower antibody titers than 2 or 3 doses
  - Basis of protection after HPV vaccination thought to be neutralizing antibody
  - No established minimum antibody threshold for protection



# ESCUDDO, Costa Rica (data available 2025)

- Randomized trial to evaluate non-inferiority of one vs two doses of 2vHPV (Cervarix) and 9vHPV (Gardasil 9) for prevention of new cervical HPV16/18 infections that persist at least 6 months
- Evaluate one dose compared to zero doses



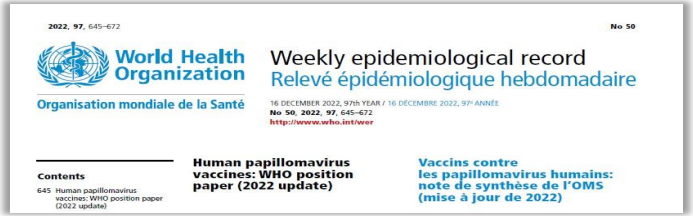




proyecto escuddo

ClinicalTrials.gov: NCT03180034

# Single-dose HPV vaccination – increasing interest

- Studies that initially provided data had further encouraging data
- Recognition of a global HPV vaccine supply/demand imbalance
- Additional studies were planned and conducted
- Review of data led to revised World Health Organization recommendations including, “as an off-label option, a single-dose schedule can be used in girls and boys aged 9–20 years.”


2022, 97, 645–672 No 50

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Weekly epidemiological record
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# Trials with data on single-dose HPV vaccination considered by the World Health Organization in 2022

| Trial/country | Evidence | Vaccine | Age (yrs) at vaccination | Description |
|---|---|---|---|---|
| **CVT**<br>Costa Rica | Efficacy/<br>Immunogenicity | 2vHPV | 18–25 | Post-hoc analyses<br>Original trial: randomized to 3 doses or control, but analyzed as 1-, 2-, 3-dose groups |
| **IARC-India**<br>India | Efficacy/<br>Immunogenicity | 4vHPV | 10–18 | Post-hoc analyses<br>Original trial: randomized to 2 or 3 doses but analyzed as 1-, 2-, 3-dose groups |
| **KEN SHE**<br>Kenya | Efficacy | 2vHPV<br>9vHPV | 15–20 | Randomized trial<br>1 dose 2vHPV, 9vHPV or MCV |
| **DoRIS**<br>Tanzania | Immunogenicity | 2vHPV<br>9vHPV | 9–14 | Randomized trial<br>1-, 2-, 3-dose groups |

2vHPV, Cervarix; 9vHPV, Gardasil 9; CVT, Costa Rica Vaccine Trial; IARC, International Agency for Research on Cancer

# Costa Rica Vaccine Trial (CVT)

## Protection against prevalent HPV after 2vHPV, through 11 years

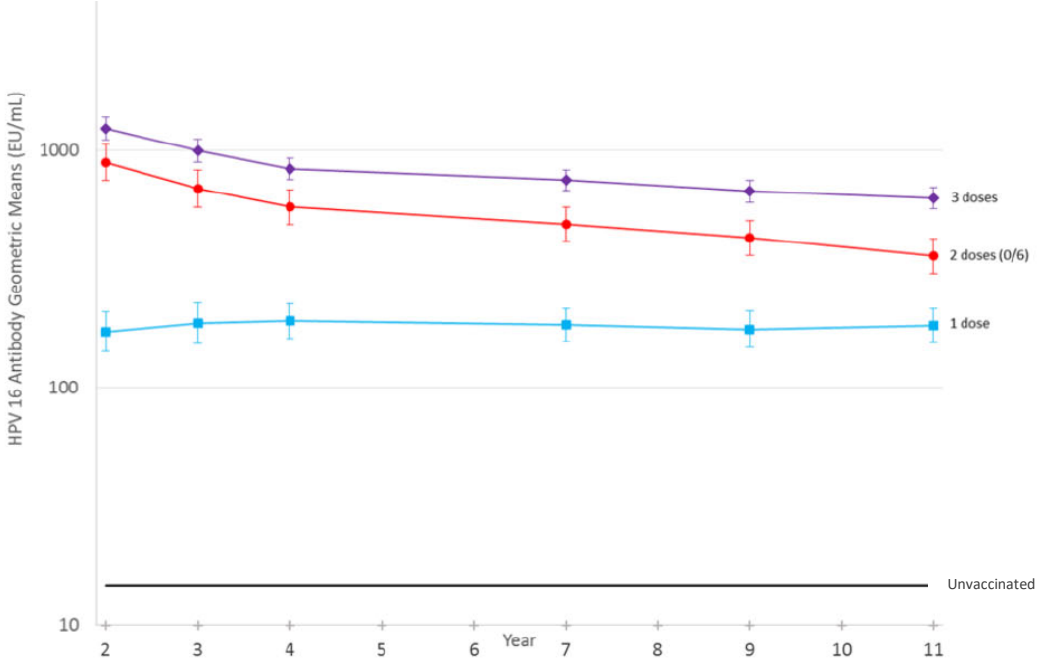
- Post-hoc analysis of RCT: females vaccinated at age 18–25 years
- Randomized to receive 3 doses of 2vHPV or control vaccine

| Doses | Number | Prevalent 16/18 HPV % (95% CI) | Vaccine efficacy % (95% CI) |
|---|---|---|---|
| **3 doses** | 1365 | 2.0 (1.3–2.8) | **80.0%** (70.7–87.0) |
| **2 doses** | 62 | 1.6 (0.1–7.7) | **83.8%** (19.5–99.2) |
| **1 dose** | 112 | 1.8 (0.3–5.8) | **82.1%** (40.2–97.0) |
| **Unvaccinated** | 1783 | 10.0 (8.7–11.4) | Reference |

Kreimer AR, et al. J Natl Cancer Inst 2020

# Costa Rica Vaccine Trial (CVT)

## HPV 16 antibody after 1, 2 or 3 doses of 2vHPV, through 11 years

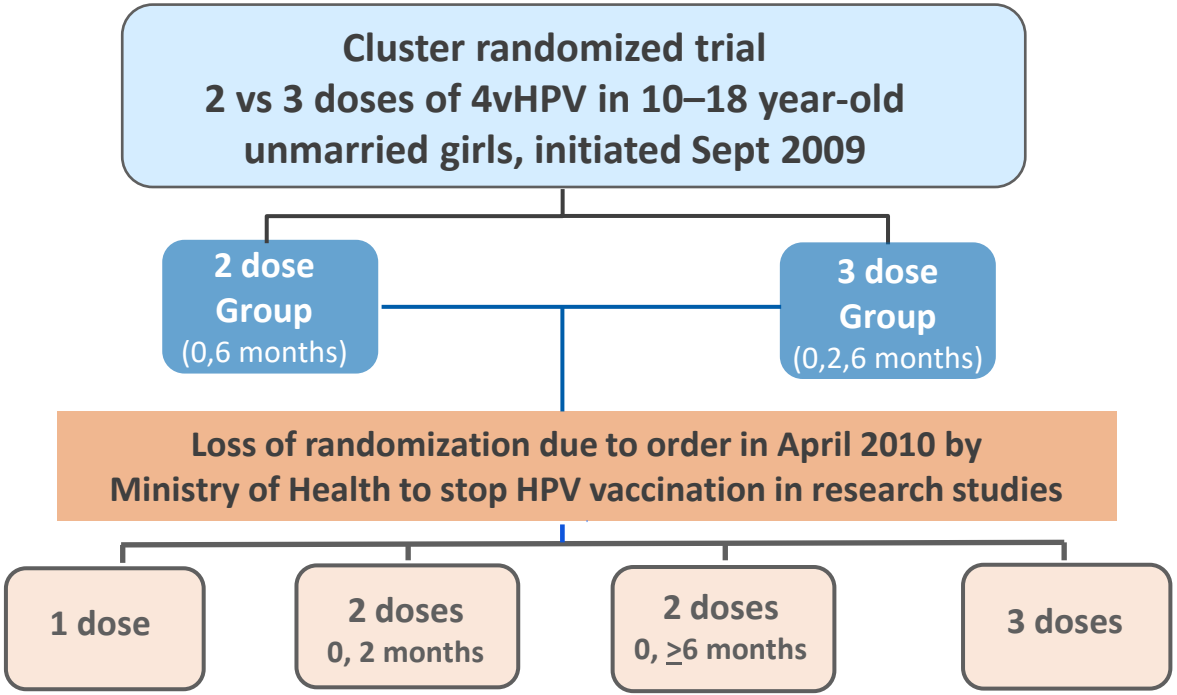



- Stable HPV 16 and 18 antibody levels through 11 years post vaccination with all dosing schedules
- 1 dose levels at least 10-fold above level at enrollment among unvaccinated

Antibody by VLP-based ELISA at the NCI HPV Immunology Laboratory
Kreimer AR, et al. J Natl Cancer Inst 2020

# IARC-India Trial: provides data on immunogenicity and efficacy of 1, 2 and 3 doses of 4vHPV (Gardasil)

Randomized trial design lost and analyzed as observational cohort




IARC, International Agency for Research on Cancer
Sankaranarayanan R, et al. Lancet Oncol 2016

# IARC-India Trial

## Protection after 1, 2 or 3 doses of 4vHPV, through 10 years

- Post hoc analysis of randomized trial: females vaccinated at age 10–18 years
- Randomized to receive 2 or 3 doses 4vHPV

| Doses | Number | Persistent HPV16/18 | | Vaccine efficacy % (95% CI) |
|---|---|---|---|---|
| | | Events | % | |
| **3 doses** | 1460 | 1 | 0.07 | **93.3%** (77.5–99.9) |
| **2 doses** | 1452 | 1 | 0.07 | **93.1%** (77.3–99.8) |
| **1 dose** | 2135 | 1 | 0.05 | **95.4%** (85.0–99.9) |
| **Control** | 1260 | 32 | 2.54 | Reference |

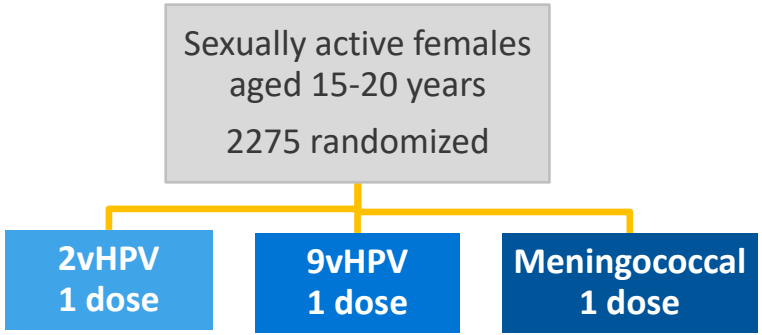
Unvaccinated women age-matched to married vaccinated participants recruited as controls
Persistent infection defined as the same HPV type detected in consecutive samples at least 10 months apart
VE adjusted for background HPV infection frequency, time between date of marriage and first cervical specimen collection, and number of cervical specimens per participant

IARC, International Agency for Research on Cancer

Basu P, et al. Lancet Oncol 2021; published correction in Lancet Oncol. 2022 Jan;23(1):e16. IPVC2023 Abstract O177 / #862.

# KEN SHE Trial - Kenya

- Double-blind, RCT
- Sexually active females aged 15-20 years
- Trial groups
  - 2vHPV (Cervarix)
  - 9vHPV (Gardasil 9)
  - Meningococcal (delayed HPV vaccination)
- Primary objectives
  - Efficacy in preventing incident persistent infection*
    - HPV-16/18
    - HPV-16/18/31/33/45/52/58




*Defined as vaccine-type specific HPV detected at two consecutive time points no less than 4 months apart

Barnabas R, et al. NEJM Evidence 2022

# KEN SHE: RCT of single-dose HPV vaccination

## Incident persistent 16/18 infections and vaccine efficacy

- 1458 evaluated for efficacy in mITT cohort

| Vaccine | N | 18 months | | | 36 months | | |
|---|---|---|---|---|---|---|---|
| | | Incident persistent HPV 16/18 | Incidence/ 100 PY | VE % (95% CI) | Incident persistent HPV 16/18 | Incidence/ 100 PY | VE % (95% CI |
| 9vHPV | 496 | 1 | 0.17 | **97.5%** (81.7–99.7) | 1 | 0.08 | **98.8%** (91.3–99.8) |
| 2vHPV | 489 | 1 | 0.17 | **97.5%** (81.6–99.7 | 2 | 0.16 | **97.5%** (90.0–99.4) |
| Meningococcal | 473 | 36 | 6.83 | Reference | 72 | 6.70 | Reference |

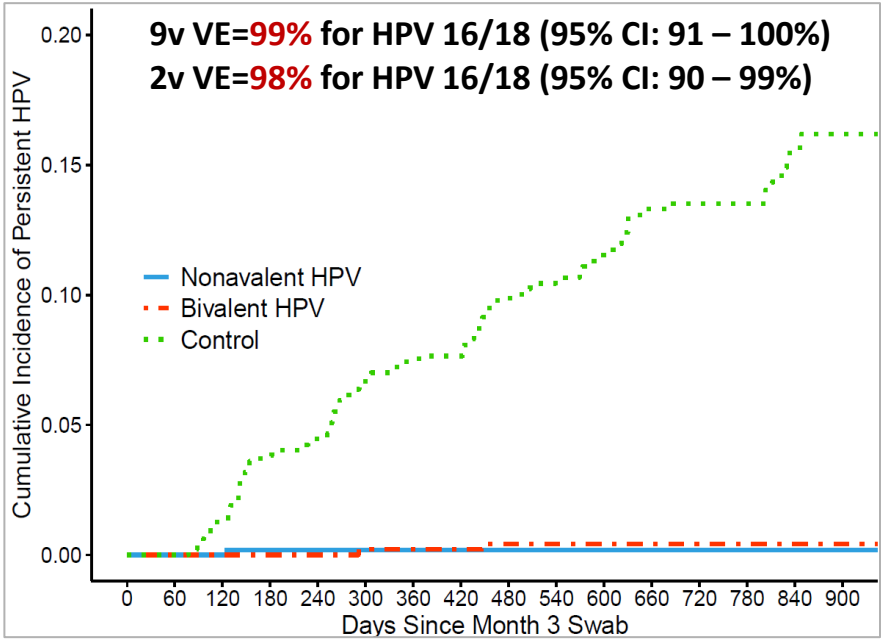
Enrollment criteria: 1-5 lifetime partners; HIV negative; enrollment between December 2018 and June 2021
MCV, meningococcal vaccine; mITT, modified intention to treat: HPV 16/18 HPV DNA negative (external genital and cervical swabs) at enrollment and month 3 (self-collected vaginal swab) and HPV antibody negative at enrollment
PY, person years

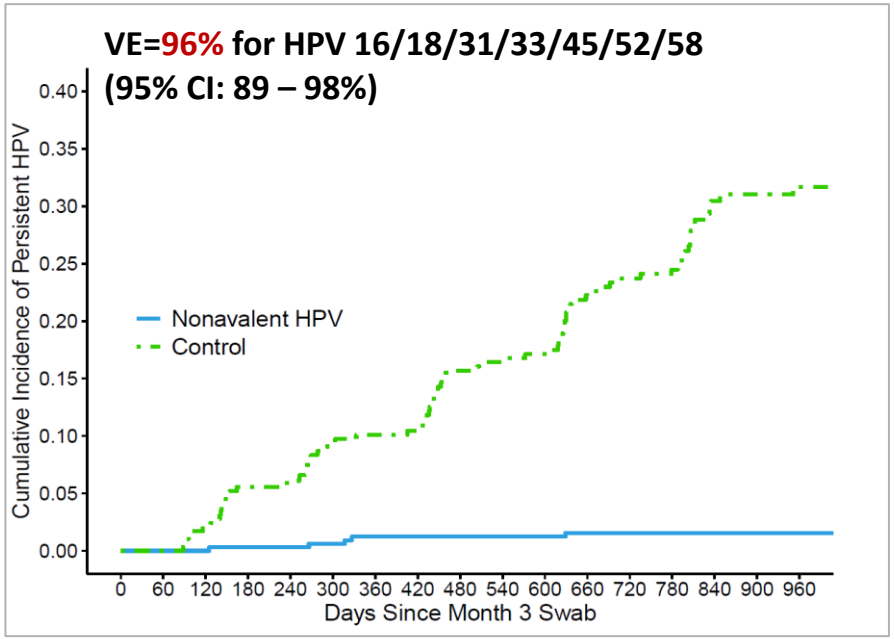
Barnabas R, et al. NEJM Evidence 2022

Barnabas R, et al. Nature Medicine 2023

# KEN SHE: RCT of single-dose HPV vaccination

Through three years after vaccination, 1-dose HPV vaccine efficacy remained high

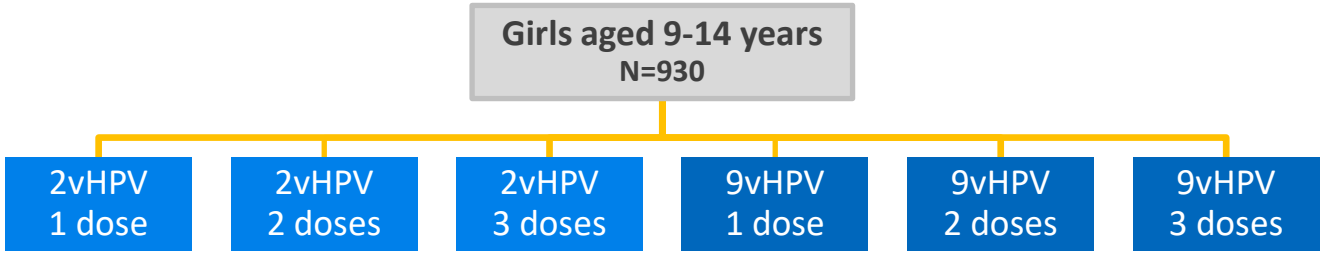



Barnabas R, et al. Nature Medicine 2023

# DoRIS - Tanzania

- **Do**se **R**eduction **I**mmunobridging & **S**afety Study
- Randomized, open label trial in girls aged 9-14 years
- 1, 2, 3 doses of 2vHPV (Cervarix) or 9vHPV (Gardasil 9)
- Objectives – demonstrate noninferiority
  - HPV 16 and 18 antibody response after 1 vs 2 or 3 doses of same vaccine
  - HPV 16 and 18 GMCs: 1 dose in DoRIS vs 1 dose in studies that evaluated efficacy




GMC, geometric mean concentration

# DoRIS conclusions

Immunogenicity and safety of one-dose human papillomavirus vaccine compared with two or three doses in Tanzanian girls (DoRIS): an open-label, randomised, non-inferiority trial

*Deborah Watson-Jones*, John Changalucha*, Hilary Whitworth*, Ligia Pinto, Paul Mutani, Jackton Indangasi, Troy Kemp, Ramadhan Hashim, Beatrice Kamala, Rebecca Wiggins, Twaib Songoro, Nicholas Connor, Gladys Mbwanji, Miquel A Pavon, Brett Lowe, Devis Mmbando, Saidi Kapiga, Philippe Mayaud, Silvia de SanJosé, Joakim Dillner, Richard J Hayes, Charles J Lacey, Kathy Baisley*

Watson-Jones D, et al. Lancet Global Health 2022

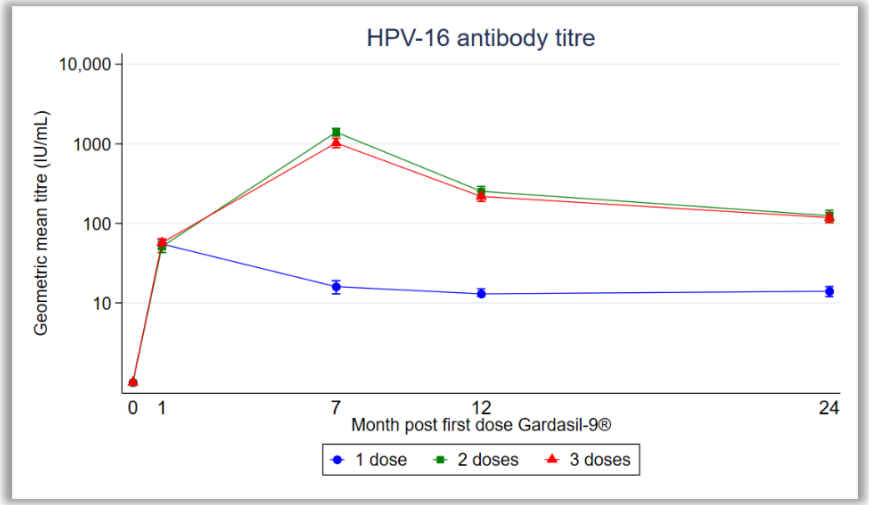
# DoRIS conclusions

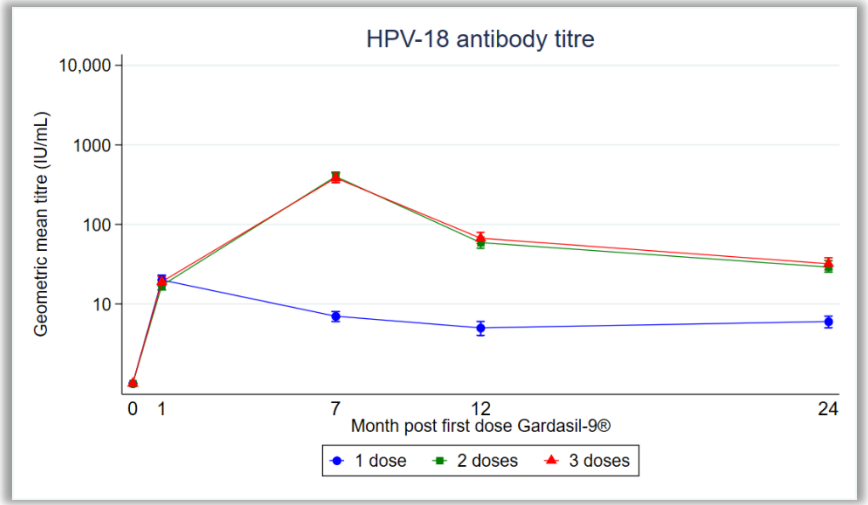
- **Seropositivity >97.8% after vaccination for all vaccine groups**

Watson-Jones D, et al. Lancet Global Health 2022

# DoRIS conclusions

- Seropositivity >97.8% after vaccination for all vaccine groups
- **Antibody levels lower after 1 dose compared with 2 or 3 doses**
  - **Kinetics, with plateau, similar for all doses**



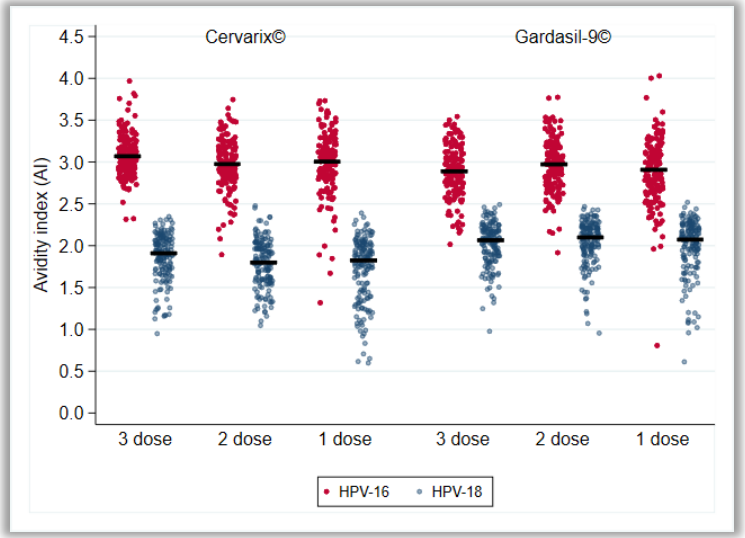




**9vHPV vaccine groups**

Watson-Jones D, et al. Lancet Global Health 2022

# DoRIS conclusions

- Seropositivity >97.8% after vaccination for all vaccine groups
- Antibody levels lower after 1 dose compared with 2 or 3 doses
  - Kinetics, with plateau, similar for all doses
- **Avidity for each HPV type was similar for 3, 2 and 1 doses for both vaccines**




Watson-Jones D, et al. Lancet Global Health 2022

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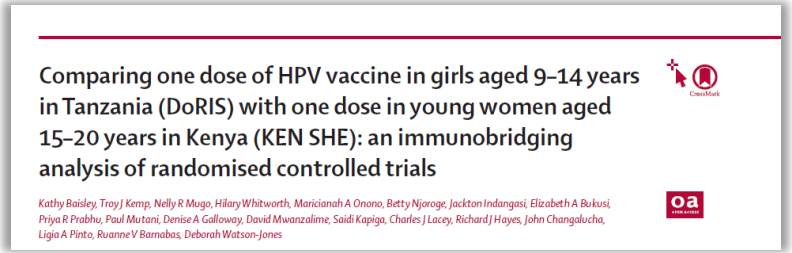
  - Kinetics, with plateau, similar for all doses
- Avidity for each HPV type was similar for 3, 2 and 1 doses for both vaccines.
- **Immunobridging: 1-dose responses were non-inferior in DoRIS (9-14 year-olds) compared with those among women in studies where 1-dose efficacy observed**


Comparing one dose of HPV vaccine in girls aged 9–14 years in Tanzania (DoRIS) with one dose in young women aged 15–20 years in Kenya (KEN SHE): an immunobridging analysis of randomised controlled trials

Kathy Baisley, Troy J Kemp, Nelly R Mugo, Hilary Whitworth, Maricianah A Onono, Betty Njoroge, Jackton Indangasi, Elizabeth A Bukusi, Priya R Prabhu, Paul Mutani, Denise A Galloway, David Mwanzalime, Saidi Kapiga, Charles J Lacey, Richard J Hayes, John Changalucha, Ligia A Pinto, Ruanne V Barnabas, Deborah Watson-Jones

Lancet Global Health 2024

HPV 16 and 18 antibodies measured by ELISA at Frederick National Laboratory for Cancer Research HPV Immunology Laboratory, USA

# Additional studies evaluating single-dose HPV vaccination, data forthcoming

| Study/ country | Evidence | Vaccine | Age (yrs) at vaccination | Description |
|---|---|---|---|---|
| **HOPE** South Africa | Impact/ Effectiveness | 2vHPV | 15–16 | 1 dose as catch-up in grade 10. Baseline and cross sectional prevalence surveys; includes WLWH |
| **Thailand Impact** Thailand | Effectiveness | 2vHPV | Grade 8 age <15 yrs | 1 or 2 doses, by province; Baseline and post-vaccination cross sectional prevalence surveys |
| **HANDS** The Gambia | Immunogenicity | 9vHPV | 4–8, 9–14 15–26 | Randomized trial of 1 or 2 doses vs 3 doses in 15–26-year-olds |
| **Primavera** Costa Rica | Immunogenicity | 2vHPV 9vHPV | 9–14 18–25 | 1 dose 3 doses |
| **PRISMA** Costa Rica | Efficacy | 2vHPV 4vHPV 9vHPV | 18–30 | Randomized trial of 1 dose of three different HPV vaccines vs unvaccinated |
| **ESCUDDO** Costa Rica | Efficacy/ Immunogenicity | 2vHPV 9vHPV | 12–16 | Randomized trial of 1 vs 2 doses |

2vHPV, Cervarix; 9vHPV, Gardasil 9; WLWH, women living with HIV; RCT, randomized controlled trial. All studies conducted among girls/women

# Additional data from studies reviewed today

| Study/ country | Evidence | Vaccine | Age (yrs) at vaccination | Data expected |
|---|---|---|---|---|
| **CVT** Costa Rica | Efficacy/ Immunogenicity | 2vHPV | 12–16 | 14-, 16- and 20-year data |
| **IARC-India** India | Efficacy/ Immunogenicity | 4vHPV | 10-18 | 12-year data and further |
| **DoRIS** Tanzania | Immunogenicity | 2vHPV 9vHPV | 9-14 | 36- and 60-month data |

2vHPV, Cervarix; 9vHPV, Gardasil 9

WLWH, women living with HIV; RCT, randomized controlled trial. All studies conducted among girls/women

# Two HPV vaccine doses for persons aged ≥15 years

- **Studies of single-dose also provide data on a 2-dose schedule**
  - Studies with a 2-dose group (0, 6 months)
    - CVT (2vHPV): 18–25-year-olds
    - IARC-India (4vHPV): 10–18-year-olds

- **Immunogenicity trial of 2 vs 3 doses of 9vHPV***
  - U.S. study in 15–26-year-olds
  - Ongoing - interim data published

*Berenson A, et al. NEJM Evidence 2024

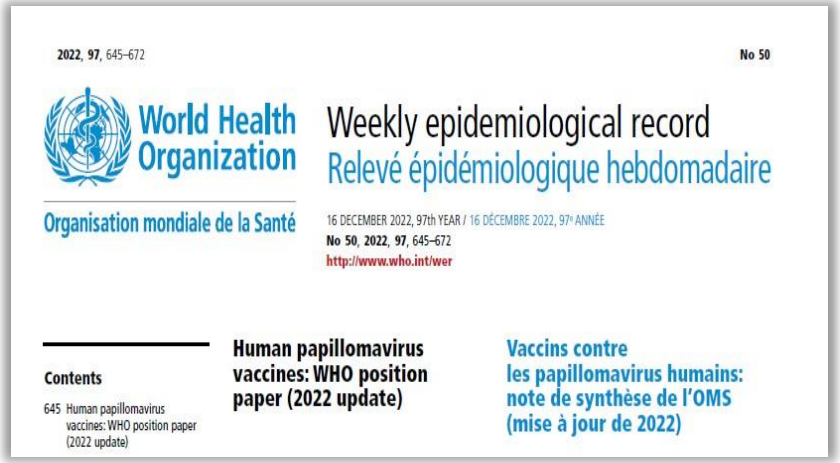
# 2022 World Health Organization recommendations and global landscape

# WHO recommendations for HPV vaccination

**December 2022:**

Evidence supports a 2-dose schedule from age 9 years and for all older age groups for which HPV vaccines are licensed.

As an off-label option, a single-dose schedule can be used in girls and boys aged 9–20 years.



2022, 97, 645–672 No 50

World Health Organization

Organisation mondiale de la Santé

Weekly epidemiological record

Relevé épidémiologique hebdomadaire

16 DECEMBER 2022, 97th YEAR / 16 DÉCEMBRE 2022, 97e ANNÉE

No 50, 2022, 97, 645–672

http://www.who.int/wer

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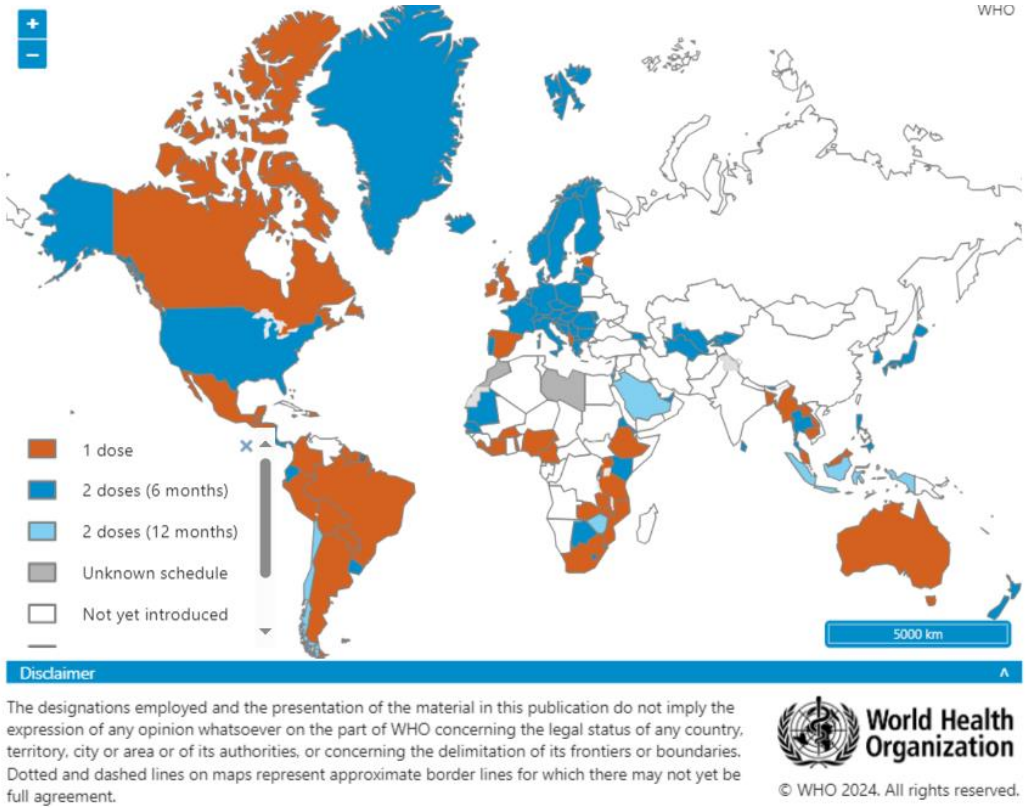
Human papillomavirus vaccines: WHO position paper (2022 update)

Vaccins contre les papillomavirus humains: note de synthèse de l'OMS (mise à jour de 2022)

# Recommended HPV vaccine schedules in 9–14-year-olds, by country

| Doses-interval | No. of countries |
|---|---|
| 1 dose | 58 |
| 2 doses (12 months) | 5 |
| 2 doses (6 months | 76 |
| Not yet introduced | 50 |
| Unknown schedule | 5 |




*Date: October 2024*

# Policy changes since updated WHO HPV vaccination recommendations in 2022

- **Some of the first countries to change to a routine single-dose schedule**
  - England, Ireland, Australia
- **Change from a 3-dose to a 2-dose schedule for persons ages >14 years**
  - Netherlands and Sweden
- **Single-dose recommendations by regional advisory groups**
  - PAHO in 2023 and AFRO in 2024

PAHO Technical Advisory Group recommends countries of the Americas to use single-dose HPV vaccine schedule | OPS/OMS | Organisation panaméricaine de la santé
Africa immunization advisory group urges single-dose HPV vaccine adoption to advance vaccination efforts | WHO | Regional Office for Africa

# Outstanding questions for single-dose vaccination ?

- Longer term efficacy and immunogenicity
- Protection at sites other than the cervix
- Efficacy and immunogenicity in males*
- Efficacy and immunogenicity in immunocompromised persons
- Efficacy and immunogenicity in older age groups

***Additional data expected over the next year will address some of these questions***

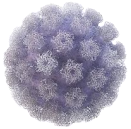
* Data available from a small immunogenicity trial in 11–12-year-old girls and boys: Zeng et al. Pediatrics 2023

# Announcement from Merck, March 2024

- **Plan to conduct two prospective clinical trials, one in females (16-26 years) and one in males (ages 16-26 years).**
- **These randomized, double-blind, multi-year clinical trials will examine the short and long-term efficacy and immunogenicity of a single-dose of Gardasil 9 versus the currently approved three-dose regimen.**
- **Merck is in discussions with FDA about the protocols and the timeline.**

Merck Announces Plans to Conduct Clinical Trials of a Novel Investigational Multi-Valent Human Papillomavirus (HPV) Vaccine and Single-Dose Regimen for GARDASIL®9

# Summary



- HPV vaccines were first studied and licensed in a 3-dose schedule in persons aged 9–26 years and later in a 2-dose schedule in persons aged 9–14 years.
- Data are available on single-dose HPV vaccination, including from a RCT with 3 years of follow-up, showing high efficacy against incident persistent infection.
- Long term follow-up suggests protection for >10 years with a single dose.
- WHO 2022 updated recommendations: 2 doses for persons aged 9 years and older, with option for single-dose HPV vaccination through age 20 years, except those immunocompromised.
- Countries are considering new or updated HPV vaccination policy and an increasing number have recommended single-dose HPV vaccination.
- Further data on 1 and 2 doses will be available over the next year.

# Next steps for ACIP HPV Vaccines Work Group

- **Review further evidence**
  - 1- and 2-dose schedules
  - Modeling data
  - Other relevant data
- **Evaluate evidence using GRADE and evaluate policy questions using the Evidence to Recommendations framework**
  - Should a 1-dose schedule be recommended in some age groups?
  - Should a 2-dose schedule, instead of a 3-dose schedule, be recommended in some age groups older than 9–14 years?

# Questions for ACIP

**What questions does ACIP have regarding the policy questions being addressed?**

# Thank You

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov