

# **HPV vaccination: an update**

**FIGO Committee on Women's Cancer** 

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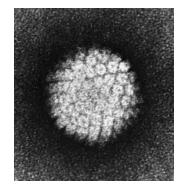
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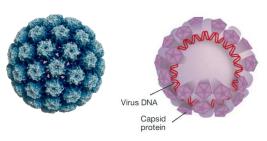
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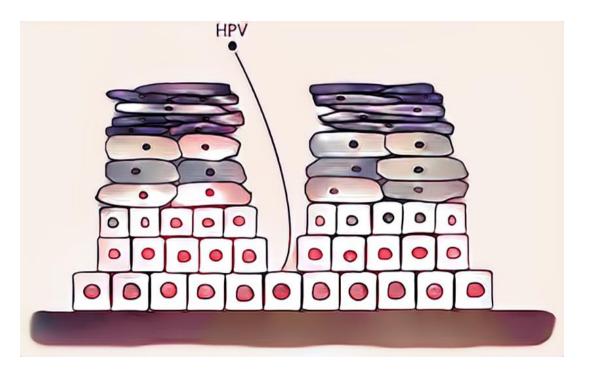
# Human papillomavirus (HPV)



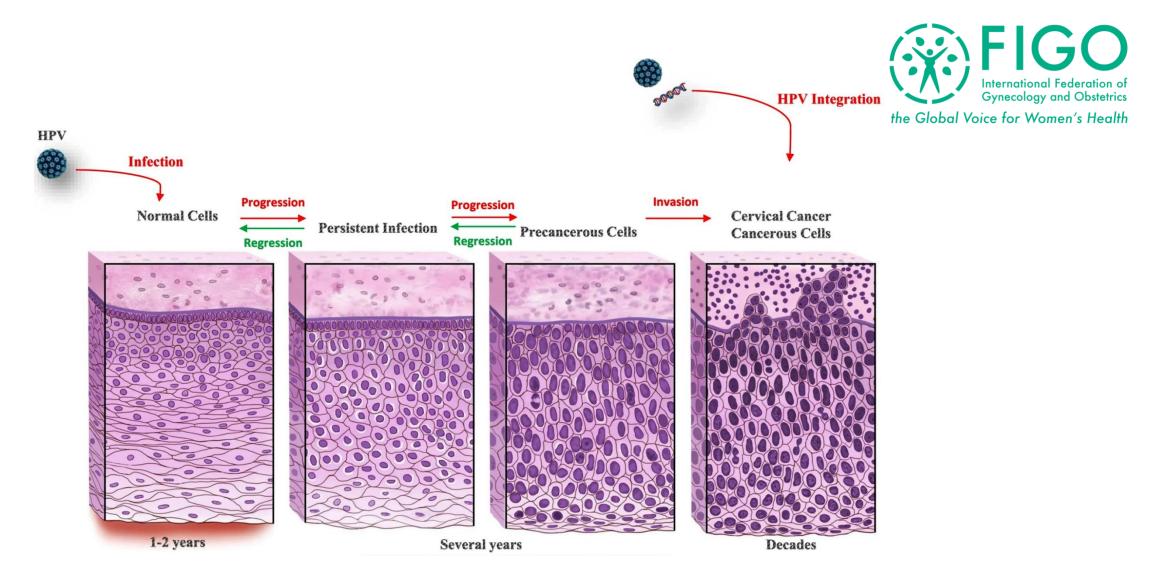




HPV is a DNA virus, about 50-55 nm in diameter, that can easily infect the basal layer of epithelium via microtrauma.



https://commons.wikimedia.org/, https://www.nobelprize.org/

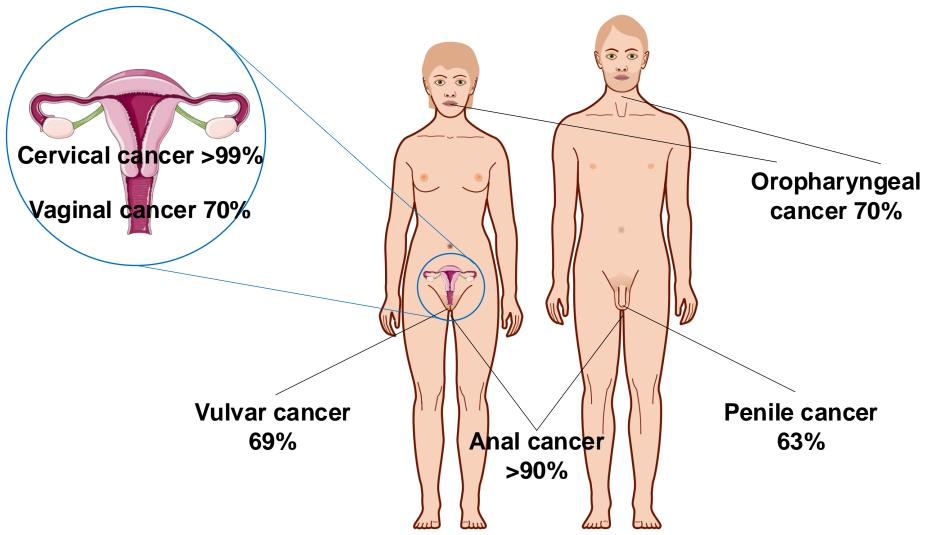


Only 10% of women will have a persistent cervical HPV infection, which may progress to cervical cancer decades later.

Adapted from: Khairkhah N, et al. J Mol Med 2022;100:829-45.

HPV is associated not only with cervical cancer but also with other anogenital cancers and oropharyngeal cancer.

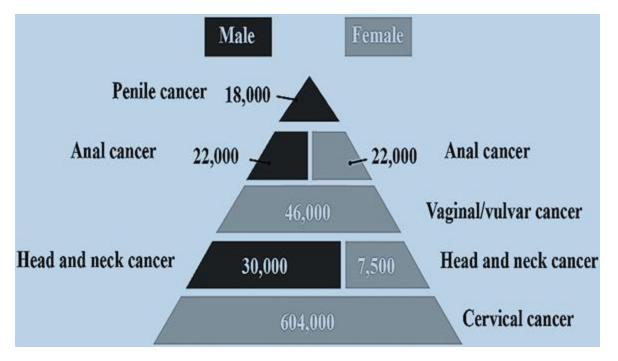




https://commons.wikimedia.org/, https://www.cancer.gov/

# **HPV-associated cancers**





The burden of cancers attributable to HPV infection by site and gender worldwide each year

#### Each year, high risk HPV (HR-HPV) causes

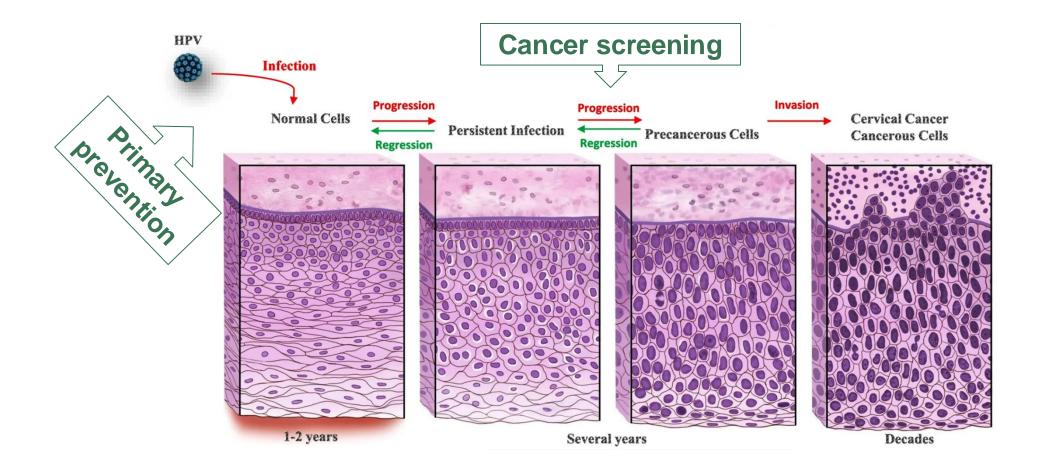
- ~5% of human cancers (>700,000 cases)
- >400,000 deaths

Cervical cancer in 2022

- ~660,000 new cases
- ~350,000 deaths (94% in LMICs)

# **Prevention is better than cure!**





Adapted from: Khairkhah N, et al. J Mol Med 2022;100:829-45.

Condoms are effective in preventing most sexually transmitted infections but not HPV infection.

Therefore, HPV vaccines are essential for primary prevention.

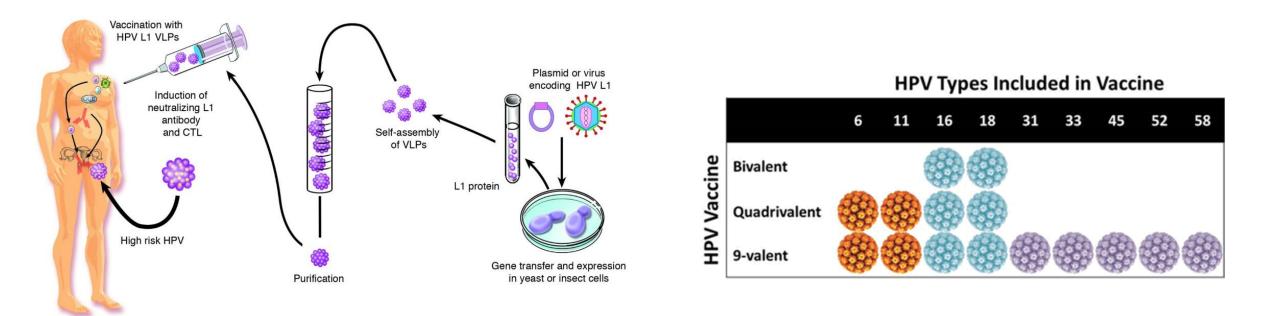




Source: The Naked Gun.



## **HPV vaccines**



HPV vaccines are produced from virus-like particles made from the L1 protein. There are bivalent, quadrivalent, and 9-valent HPV vaccines available.

#### WHO. Wkly Epidemiol Rec 2022;97:645-72., https://www.who.int/

# **HPV** vaccines

- 1<sup>st</sup> HPV vaccine licensed in 2006
- To date (May 2024)
  - 141 countries included in the national immunization programme
    - 66 countries for both sexes



### Licensed HPV vaccines

- Bivalent
  - Cervarix
  - Cecolin
  - Walrinvax
- Quadrivalent
  - Gardasil
  - Cervavax
- Nonavalent
  - Gardasil 9



# **Safety of HPV vaccines**



The Global Advisory Committee on Vaccine Safety (GACVS)

- >270 million doses of HPV vaccines have been distributed
- Anaphylaxis ~1.7 cases per million dose
- Syncope: common stress related reaction to the injection
- No increased risk for Guillain-Barré syndrome, complex regional pain syndrome, postural orthostatic tachycardia syndrome, premature ovarian insufficiency
- Considers HPV vaccines to be extremely safe

## Protection against CIN2+ associated with HPV16/18 Women 15-26 years, who HPV DNA 16/18 negative at baseline

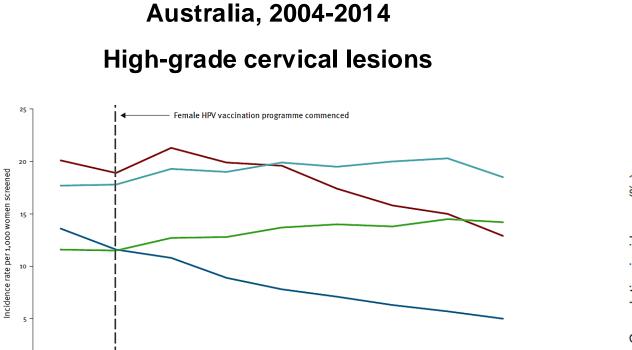


|                                       | Vacci                    | ine      | Place       | ebo                   |                  | Risk Ratio         | Risk Ratio                          |
|---------------------------------------|--------------------------|----------|-------------|-----------------------|------------------|--------------------|-------------------------------------|
| Study or Subgroup                     | Events                   | Total    | Events      | Total                 | Weight           | IV, Random, 95% Cl | IV, Random, 95% Cl                  |
| 9.1.1 3 doses                         |                          |          |             |                       |                  |                    |                                     |
| FUTURE II trial (ph3,4v)              | 1                        | 5305     | 58          | 5260                  | 10.7%            | 0.02 [0.00, 0.12]  |                                     |
| Japanese trial (ph2,2v)               | 0                        | 408      | 1           | 407                   | 4.1%             | 0.33 [0.01, 8.14]  |                                     |
| PATRICIA trial (ph3,2v)               | 4                        | 7344     | 56          | 7312                  | 40.6%            | 0.07 [0.03, 0.20]  |                                     |
| Phase2 trial (v1)                     | 0                        | 114      | 7           | 118                   | 5.1%             | 0.07 [0.00, 1.19]  |                                     |
| Subtotal (95% CI)                     |                          | 13171    |             | 13097                 | 60.6%            | 0.06 [0.03, 0.14]  | ◆                                   |
| Total events                          | 5                        |          | 122         |                       |                  |                    |                                     |
| Heterogeneity: Tau <sup>2</sup> = 0.0 | 10; Chi² = 2             | .77, df= | : 3 (P = 0. | 43); l² =             | 0%               |                    |                                     |
| Fest for overall effect: Z =          | 6.59 (P <                | 0.00001  | )           |                       |                  |                    |                                     |
| ).1.2 1 or 2 doses                    |                          |          |             |                       |                  |                    |                                     |
| UTURE II trial (ph3,4v)               | 2                        | 560      | 29          | 603                   | 20.5%            | 0.07 [0.02, 0.31]  | _ <b></b>                           |
| Japanese trial (ph2,2v)               | 0                        | 14       | 1           | 20                    | 4.3%             | 0.47 [0.02, 10.69] |                                     |
| PATRICIA trial (ph3,2v)               | 1                        | 696      | 35          | 768                   | 10.6%            | 0.03 [0.00, 0.23]  |                                     |
| Phase2 trial (v1)                     | 0                        | 105      | 1           | 94                    | 4.1%             | 0.30 [0.01, 7.25]  |                                     |
| Subtotal (95% Cl)                     |                          | 1375     |             | 1485                  | 39.4%            | 0.08 [0.03, 0.23]  | ◆                                   |
| Fotal events                          | 3                        |          | 66          |                       |                  |                    |                                     |
| Heterogeneity: Tau <sup>2</sup> = 0.0 | i0; Chi² = 2             | .72, df= | : 3 (P = 0. | 44); l <sup>2</sup> = | 0%               |                    |                                     |
| Test for overall effect: Z =          | 4.74 (P ≤                | 0.00001  | )           |                       |                  |                    |                                     |
| Fotal (95% CI)                        |                          | 14546    |             | 14582                 | 100.0%           | 0.07 [0.04, 0.13]  | •                                   |
| Total events                          | 8                        |          | 188         |                       |                  |                    |                                     |
| Heterogeneity: Tau <sup>2</sup> = 0.0 | 10; Chi <sup>2</sup> = 5 | .70, df= | 7 (P = 0.   | 58); l² =             | 0%               |                    | 0.002 0.1 1 10 500                  |
| Test for overall effect: Z =          |                          |          | •           |                       |                  |                    |                                     |
| Test for subgroup differe             |                          |          |             | = 0.65), I            | <sup>2</sup> =0% |                    | Favours (vaccine) Favours (placebo) |

A meta-analysis showed that HPV vaccines could prevent CIN2+ associated with HPV16/18 in initially HPV DNA negative women, with an OR of 0.06 for those completing 3 doses, and

0.08 for those receiving 1 or 2 doses.

# **Real-world effectiveness of HPV vaccination**



201

25–29 years

2012

2004-06

2007

<20 years</p>

2008

2009

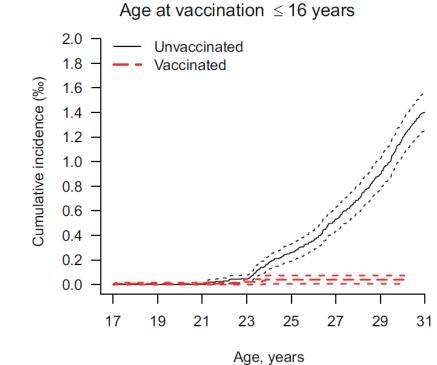
20–24 years

2010

Year

#### Denmark, 2006-2019

#### **Cervical cancer**





Patel C, et al. Euro Surveill 2018;23:1700737., Kjaer SK, et al. J Natl Cancer Inst 2021;113:1329-1335

2013

— 30–34 years

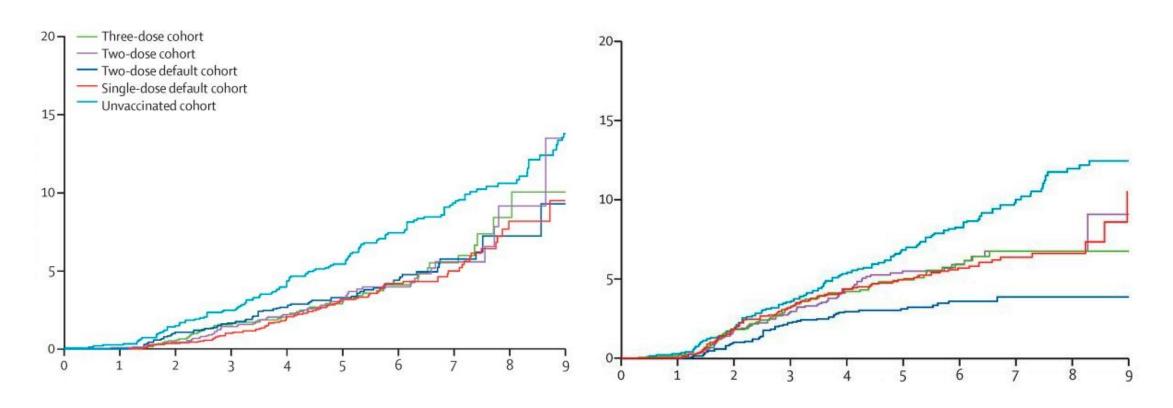
2014

Illah O, et al. Diagnostics (Basel) 2023;13:243., Sankaranarayanan R, et al. Vaccine 2018;36:4783-4791.

Ten-year follow-up data from the Indian HPV vaccine study group showed that the vaccine efficacy against HPV16/18 infection was similar in participants aged 10-18 years receiving one, two or three doses at 95%, 93% and 93%, respectively.

HPV16 & HPV18







# **Cervical Cancer Elimination Initiative**



- May 2018, the World Health Organization (WHO) Director-General announced a global call for action to eliminate cervical cancer, underscoring renewed political will to make elimination a reality and calling for all stakeholders to unite behind this common goal
- Cervical Cancer Elimination Initiative (<u>https://www.who.int/initiatives/cervical-cancer-elimination-initiative</u>) was established to develop a global strategy for the elimination of cervical cancer
- The Global Strategy for cervical cancer elimination has been adopted by the World Health Assembly in August 2020

# WHO Global Strategy to Accelerate the Elimination of Cervical Cancer



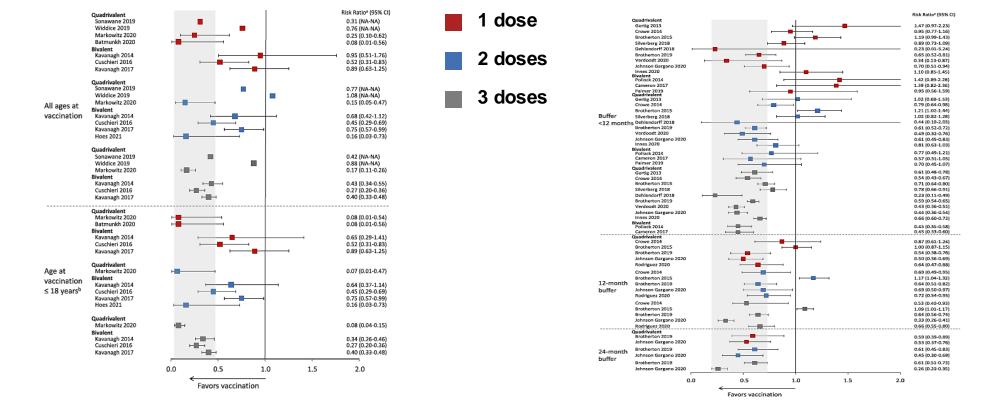
### By 2030

- 90% of girls fully vaccinated with HPV vaccine by 15 years of age
- 70% of women screened using a high performance test by 35 years of age and again by 45 years of age
- 90% of women identified with cervical disease are treated

#### → Prevent 60 million cervical cancer cases and 45 million deaths over the next 100 years

Most observational studies indicate that three doses of HPV vaccines are most effective, with no statistically significant differences observed based on the number of doses, particularly among those vaccinated at younger ages or when longer buffer periods are used.

Against HPV infection



#### Against CIN2+

Markowitz LE, et al. Vaccine 2022;40:5413-5432.



An updated systematic review of evidence from clinical trials showed that the incidence or prevalence of HPV16/18 infection was very low among HPV-vaccinated participants,



regardless of the number of doses received, with no evidence of a difference between dose groups.

Reference / study

Follow-up

| Reference / study                                       | Follow-up                        | Infection                                | RR or PR (95%CI), p-value |                        |                        |  |
|---|----------------------------------|--|---------------------------|------------------------|------------------------|--|
|   | duration                         | outcome                                  | 1 dose/<br>3 doses        | 1 dose/<br>2 doses     | 1 dose/<br>control     |  |
| Incident HPV16/1  | 8 infection                      | 1. |                           |                        |                        |  |
| Kreimer 2015 Mean: 4.0y<br>/ CVT & SD: 0.7y<br>PATRICIA |                                  | One-time<br>incident                     | 0.6 (0.3–1.1)<br>0.12     | 0.8 (0.3–1.7)<br>0.56  | 0.2 (0.1–0.3)<br><0.01 |  |
| Safacian 2018<br>/ CVT LTFU                             | Median: 6.9y<br>IQR: 6.5-7.3y    | One-time<br>incident                     | 0.0 (CI NC)<br>1.0        | UTC                    | ->.                    |  |
| 1. (1. 1998)<br>  | 1. A A 8<br>                     | Cumulative<br>incident                   | 0.3 (0.1-1.4)<br>0.17     | 0.4 (0.1-2.3)<br>0.36  | 70                     |  |
| Kreimer 2020<br>/ CVT LTFU                              | Median: 11.3y<br>IQR: 10.9-11.7y | One-time<br>incident                     | 3.0 (0.7-14.2)<br>0.17    | 1.1 (0.1-12.0)<br>1.00 | 0.5 (0.1–1.9)<br>0.44  |  |
| Tsang 2020<br>/ CVT LTFU                                | 11y <sup>h</sup>                 | One-time<br>incident                     | 3.0 (0.6-14.0)<br>0.18    | 1.1 (0.1-11.9)<br>1.00 | 0.5 (0.1-1.8)<br>0.44  |  |
| Sankaranarayanan<br>2016<br>/ IARC India<br>Study       | Median: 4.7y<br>IQR: 4.2-5.1y    | Cumulative<br>1st incident               | 3.1 (0.7–14.0)<br>0.17    | 1.5 (0.5-4.8)<br>0.06  | •                      |  |
| Sankaranarayanan<br>2018<br>/ IARC India<br>Study       | Up to 7y <sup>r</sup>            | Cumulative<br>incident                   | 1.8 (0.9–3.5)<br>0.11     | 1.8 (0.9-3.5)<br>0.11  | 0.3 (0.2–0.4)<br><0.01 |  |
| Basu 2021<br>/ IARC India<br>Study                      | Median:9.0y<br>IQR: 8.2-9.6y     | One-time incident                        | 1.1 (0.8-1.5)<br>0.62     | 1.2 (0.9-1.6)<br>0.31  | 0.3 (0.3-0.4)<br><0.01 |  |

#### Incident HPV16/18 infection

#### duration outcome 1 dose/ 1 dose/ 1 dose/ **3** doses 2 doses control **Prevalent HPV16/18 infection** Safacian 2018 Median: 6.9y 0.0 (CI NC) 0.0 (CI NC) One-time 0.0 (CINC) / CVT LTFU IQR: 6.5-7.3y prevalent 0.63 0.37 < 0.01 0.9 (0.2-3.7) 1.1 (0.1-12.0) Kreimer 2020 Median: 11.3y Y9 or Y11 0.2 (0.04-0.7) /CVT LTFU IQR: 10.9-11.7y 1.00 < 0.01 prevalent 1.00 Tsang 2020 11v 1.2 (0.3-5.1) 0.9 (0.1-9.3) 0.2 (0.0-0.8) One-time / CVT LTFU 1.00 <0.01 prevalent 0.69 Persistent HPV16/18 infection Kreimer 2011 Median: 4.2y 6m 0.0 (CINC) 0.0 (CINC) 0.0 (CINC) /CVT & 0.17 0.18 < 0.01persistent PATRICIA 12m 0.0 (CINC) 0.0 (CI NC) 0.0 (CI NC) 0.56 <0.01 persistent 0.40 0.3 (0.0-2.4) 0.5 (0.1-4.7) Kreimer 2015 Mean: 4.0y 0.0 (0.0-0.3) 6m persistent /CVT SD: 0.7y 0.37 1.00 < 0.010.5(0.1 - 3.2)0.7 (0.1-6.7) 12m 0.1 (0.0-0.4) persistent 0.72 1.00 < 0.01 0.0 (CINC) Tsang 2020 11y 6m 0.0 (CINC) / CVT LTFU persistent 1.00 UTC 0.26 Barnabas 2022 1.5y 0.0 (0.0-0.2) 6m --/KEN-SHE < 0.01persistent Sankaranarayanan Up to 7y 0.0 (CI NC) 0.0 (CI NC) 12m UTC 2018 persistent 0.39 < 0.01 / IARC India Study Basu 2021 Median:9.0y 10m 0.7 (0.0-10.9) 0.7 (0.0-10.9) 0.0 (0.0-0.1) / IARC India IQR: 8.2-9.6y 0.79 0.78 < 0.01 persistent Study Barnabas 2022 1.5y 0.0 (0.0-0.2) 6m

**Prevalent or persistent HPV16/18 infection** 

Infection

persistent

RR or PR (95%CI), p-value

Adapted from: Whitworth HS, et al. Vaccine X 2024;19:100486.

/ KEN-SHE

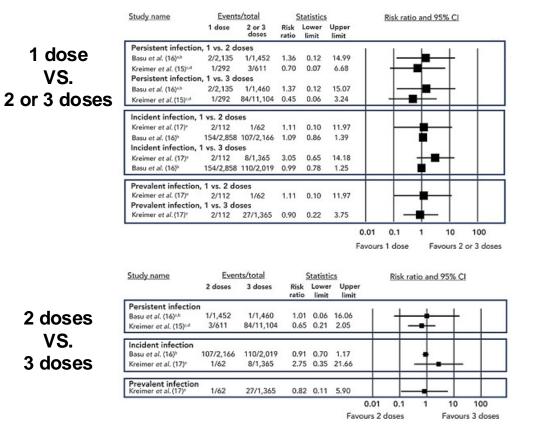
#### www.figo.org | @FIGOHQ

< 0.01

Although antibody levels against HPV vaccine types were statistically significantly lower with <u>International Federation of Gynecology and Obstetrics</u> a single dose schedule compared to 2 or 3 doses, titers were sustained for up to 16 years. <u>the Global Voice for Women's Health</u> Additionally, 1-, 2-, or 3-dose HPV vaccine schedule may offer similar protection from HPV infection.

| Study name                              | Vaccine              | HPV type | Time point |      | Statistics     |                | Ratio of GMTs and 95% CI |  |  |
|---|----------------------|----------|------------|------|----------------|----------------|--------------------------|--|--|
|   |                      |          | (years)*   | RoM  | Lower<br>limit | Upper<br>limit |                          |  |  |
| 1 vs. 2 doses, RCT                      | evidence             | 5        |            |      |                |                |                          |  |  |
| Watson-Jones et al. (22)                | Cervarix             | 16       | 2          | 0.14 | 0.12           | 0.17           |                          |  |  |
| Watson-Jones et al. (22)                | Gardasil9            | 16       | 2          | 0.11 | 0.09           | 0.14           |                          |  |  |
| Watson-Jones et al. (22)                | Cervarix             | 18       | 2          | 0.20 | 0.17           | 0.24           |                          |  |  |
| Watson-Jones et al. (22)                | Gardasil9            | 18       | 2          | 0.21 | 0.16           | 0.26           |                          |  |  |
| 1 vs. 3 doses, RCT                      | evidence             |          |            |      |                |                |                          |  |  |
| Watson-Jones et al. (22)                | Cervarix             | 16       | 2          | 0.06 | 0.05           | 0.07           |                          |  |  |
| Watson-Jones et al. (22)                | Gardasil9            | 16       | 2          | 0.12 | 0.10           | 0.15           |                          |  |  |
| Watson-Jones et al. (22)                | Cervarix             | 18       | 2          | 0.09 | 0.08           | 0.11           | ∎                        |  |  |
| Watson-Jones et al. (22)                | Gardasil9            | 18       | 2          | 0.19 | 0.15           | 0.24           |                          |  |  |
| 1 vs. 2 doses, non-                     |                      |          | 10         | 0.00 | 0.24           | 0.24           |                          |  |  |
| Joshi et al. (20)                       | Gardasil             | 16       | 10         | 0.29 | 0.24           | 0.34           |                          |  |  |
| Joshi et al. (20)                       | Gardasil             | 18       | 10         | 0.39 | 0.31           | 0.48           |                          |  |  |
| Romero et al. (23)                      | Cervarix             | 16       | 16         | 0.54 | 0.42           | 0.71           | •                        |  |  |
| Romero et al. (23)                      | Cervarix             | 18       | 16         | 0.57 | 0.43           | 0.75           |                          |  |  |
| 1 vs. 3 doses, non-                     | RCT evide            | ence     |            |      |                |                |                          |  |  |
| Joshi et al. (20)                       | Gardasil             | 16       | 10         | 0.28 | 0.23           | 0.34           | •                        |  |  |
|   |                      |          | 10         | 0.32 | 0.25           | 0.40           |                          |  |  |
| Joshi et al. (20)                       | Gardasil             | 18       | 10         | 0.06 |                |                |                          |  |  |
| Joshi et al. (20)<br>Romero et al. (23) | Gardasil<br>Cervarix | 18       | 16         | 0.36 | 0.29           | 0.44           |                          |  |  |

#### Ratio of geometric mean titers comparing 1 dose to either 2 or 3 doses



# Risk ratios for persistent, prevalent and incident HPV infections

Montroy J, et al. Can Commun Dis Rep 2024;50:166-178.

# **HPV vaccines: WHO Recommendation**



#### Target groups

- Primary: girls aged 9-14 years before they become sexually active
- Secondary: women aged ≥15 years, boys, older men or men who have sex with men

#### **Vaccination schedule**

- One or two-dose schedule (6-month interval) for girls and young women aged 9-20 years
- Two doses with a 6-month interval for women aged ≥21 years
- Immunocompromised individuals (including people with HIV): 3 doses if feasible, and if not at least 2 doses

The risk of recurrence of CIN2+ after local surgical treatment was reduced in individuals who were vaccinated compared with those who were not vaccinated (RR 0.43). The effect was stronger when CIN2+ related to HPV16 or HPV18 (RR 0.26).

International Federation of **Gynecology and Obstetrics** the Global Voice for Women's Health

(95% CI)

HPV16 or HPV18

#### Any HPV

#### Study Event V Total V Event C Total C Weight (%) Study Event V Total V Event C Total C Weight (%) **Risk ratio Risk ratio Risk ratio Risk ratio** (95% CI) (95% CI) (95% CI) CIN2+ recurrence rates related to HPV16 or HPV18 CIN2+ recurrence rates irrespective of HPV type Design = observational Design = observational 50 0.65 (0.03 to 15.50) Kang 2013 5 360 18 377 39.3 0.29 (0.11 to 0.78) Grzes 2011 0 25 1.2 1 27 377 172 9 172 Kang 2013 9 360 11.7 0.35 (0.17 to 0.75) Ghelardi 2018 0 4.7 0.05 (0.00 to 0.90) 172 103 15 139 25.7 0.27 (0.08 to 0.91) Ghelardi 2018 2 172 11 4.7 0.18 (0.04 to 0.81) Ortega-Quinonero 2018 3 37 Ortega-Quinonero 2018 5 103 22 139 7.9 0.36 (0.13 to 1.03) Vinnytska 2019 2 76 3 12.4 0.32 (0.06 to 1.86) 153 Sand 2019 82 2074 777 15054 21.2 0.86 (0.67 to 1.10) Del Pino 2020 2 4 112 13.4 0.37 (0.07 to 1.96) Vinnytska 2019 7 76 37 8.3 0.57 (0.21 to 1.57) Random effects model 95.5 0.27 (0.16 to 0.47) 6 153 12 112 8.8 0.20 (0.08 to 0.53) Del Pino 2020 5 Prediction interval (0.15 to 0.51) 182 103 0.40 (0.20 to 0.80) Petrillo 2020 6 14 12.7 Heterogeneity: τ<sup>2</sup>=0; P=0.83; I<sup>2</sup>=0% Bogani 2021 2 100 11 200 4.8 0.36 (0.08 to 1.61) Design = randomised controlled trial 81.2 0.43 (0.29 to 0.64) Random effects model Pieralli 2018 0 89 4 89 4.5 0.11 (0.01 to 2.03) (0.14 to 1.27) 4.5 0.11 (0.01 to 2.03) Prediction interval Random effects model Heterogeneity: τ<sup>2</sup>=0.1811; P=0.01; I<sup>2</sup>=60% Prediction interval: not applicable Design = randomised controlled trial Heterogeneity: not applicable Pieralli 2018 0 89 89 1.5 0.11 (0.01 to 2.03) Random effects model 100.0 0.26 (0.16 to 0.43) 23 138 104 17.4 0.42 (0.27 to 0.66) Karimi-Zachri 2020 41 **Prediction interval** (0.16 to 0.45) Random effects model 18.8 0.41 (0.03 to 5.13) Heterogeneity: τ2=0; P=0.87; I2=0% 0.01 0.1 0.5 1 2 10 100 Prediction intervall: not applicable Test for subgroup differences: $\chi^2$ =0.37, df=1, P=0.55 Favours vaccine group Favours non-vaccine group Heterogeneity: τ<sup>2</sup>=0; P=0.37; I<sup>2</sup>=0% Random effects model 100.0 0.43 (0.30 to 0.60) Prediction interval (0.16 to 1.12) Heterogeneity: τ<sup>2</sup>=0.1472; P<0.01; I<sup>2</sup>=58% Test for subgroup differences: x<sup>2</sup>=0.03, df=1, P=0.87 0.01 0.1 0.5 1 2 10 100 Favours vaccine group Favours non-vaccine group

#### Kechagias KS, et al. BMJ 2022;378:e070135.

# **ACOG Practice Advisory, July 2023**



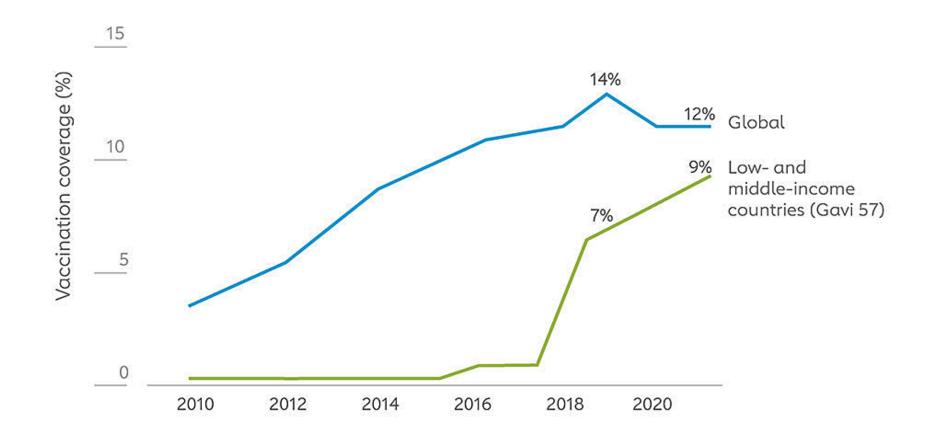
Consider adjuvant HPV vaccination for

immunocompetent previously unvaccinated people aged 27-45 years

who are undergoing treatment for CIN 2+

# HPV vaccination coverage, 2010-2021

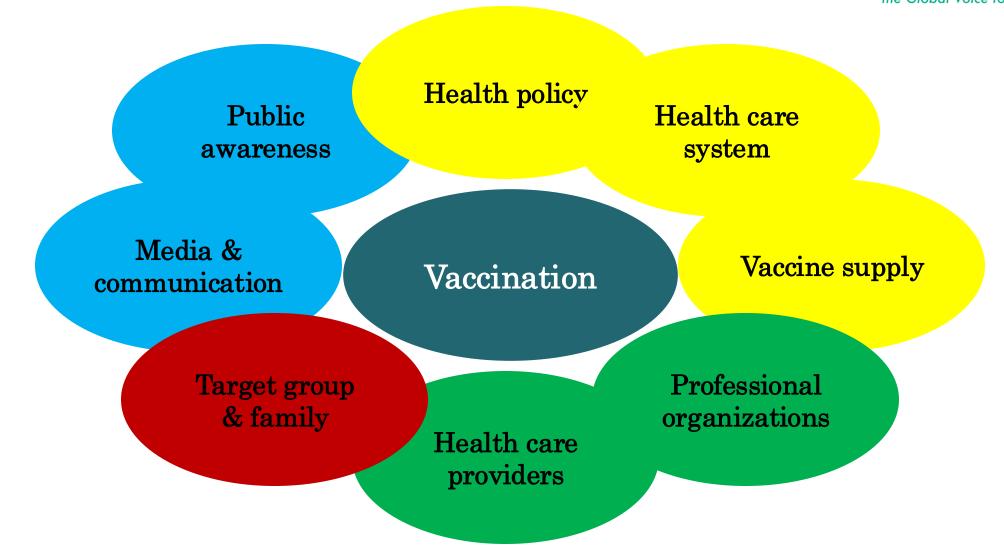




https://www.gavi.org/vaccineswork/five-charts-15-years-hpv-vaccine

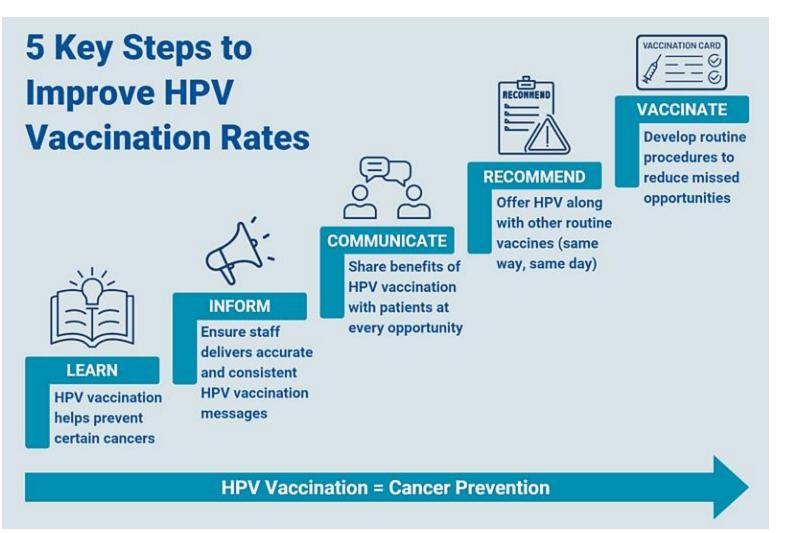
The implementation of vaccination requires the involvement of multiple stakeholders.







the Global Voice for Women's Health



https://www.nfid.org/resource/5-key-steps-to-improve-hpv-vaccination-rates/

# **FIGO Statement**



- FIGO is a partner on the Cervical Cancer Elimination Initiative and endorsed the Statement on Eliminating Cervical Cancer (<u>https://www.figo.org/statement-eliminating-cervical-cancer</u>) in January 2020
- Expert FIGO representatives actively contribute to the WHO's work in accelerating cervical cancer elimination. In addition, FIGO members are embedded on the frontlines of global health, and committed to solving the preventable tragedy of cervical cancer by 2030.

# **FIGO Resources**



- Descamps P, Dixon S, Bosch Jose FX, et al. Turning the tide-Recommendations to increase cervical cancer screening among women who are underscreened. Int J Gynecology and Obstetrics 2024;166 Suppl 1:3-21. (<u>https://obgyn.onlinelibrary.wiley.com/doi/10.1002/ijgo.15600</u>)
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# Take home message



- HPV vaccines provide robust protection against common high risk HPV, reducing the risk of cervical and other HPV-related cancers
- Extensive research and real-world data continue to affirm the safety and effectiveness of HPV vaccines
- Girls <15 years are the primary target group for HPV vaccination to accelerate the elimination of cervical cancer
- One or two-dose schedule (6-month interval) for girls and young women aged 9-20 years and two-dose schedule for women aged ≥21 years are recommended