

# HPV vaccines indicator

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## Benefits of the intervention

### **Serogroup or serotype coverage by vaccines considered (for serogroup- or serotype-specific vaccines)**

As of 2022, authorised HPV vaccines provide protection against HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 (types 6 and 11 are responsible for most anogenital warts).<sup>1</sup>

The older bivalent (Cervarix) and quadrivalent (Gardasil) vaccines show partial protection against HPV types not included in the vaccine (cross-protection), when used in multidose schedules. The bivalent vaccine (targeting HPV-16/18) generally provides stronger and more consistent cross-protection, particularly against HPV31, 33 and 45. Some studies also report partial protection against HPV-35, 52 and 58, though the evidence is less robust and more variable.<sup>2, 3, 4</sup>

No data on cross protection is available for the newer vaccines. Less evidence is available on the extent of cross protection provided by HPV vaccine in single dose schedule.

### **Efficacy and effectiveness estimates (e.g. against infection, disease, hospitalization, death), including in different populations**

Three doses of the bivalent (Cervarix) and quadrivalent (Gardasil) vaccines offered significant protection against cervical adenocarcinoma in situ associated with HPV16 and HPV18 among

young women (15–26 years of age): 88% (95% CI: 30–98%).<sup>5, 6</sup>

Trials among vaccine recipients not already infected with HPV showed high efficacy against high-grade cervical, vulvar and vaginal lesions: 98% (95% CI: 93–100) for CIN2+ and 100% (95% CI 83–100) for vulvar and vaginal intraepithelial neoplasia grade 2+ caused by the HPV types in the quadrivalent vaccine.<sup>6, 7</sup>

Approval of the two-dose schedule in girls 9 to 14-years of age- was based on demonstration of non-inferiority of the immune response when compared with young adult women (16–26 years of age) in whom 3-dose efficacy has been proven (immunobridging).<sup>6</sup>

A one-dose schedule is supported by WHO in the general population based on evidence from post-hoc analyses of efficacy trials, post-licensure observational studies and an RCT (0 vs 1) among African females 15-20 years of age. These studies demonstrate that a single dose of HPV vaccine is sufficient to elicit a lasting, stable immune response, and provides protection against persistent HPV infection similar to that of multidose regimens.<sup>5, 6</sup>

Head-to-head RCTs comparing one and two-dose schedules of Cervarix and Gardasil-9 showed VE was non-inferior with a single-dose schedule within the specified margins.<sup>8, 9</sup>

## **Duration of protection and waning of immunity in general and risk groups**

With a multidose schedule, antibody titres remain high for up to 16 years following the bivalent (Cervarix) vaccine for girls vaccinated at 16-17 years of age, up to 15 years following the quadrivalent (Gardasil) vaccine, and for at least six years following the more recently licensed nonavalent vaccine (Gardasil-9).<sup>10, 11, 12</sup>

Geometric Mean Titers (GMT) following a single dose remain stable for at least 12-16 years.<sup>13, 14, 9</sup>

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