

## Grading of scientific evidence (Males)

**Question:** Is there evidence to support vaccination of males with current HPV vaccines to substantially reduce incidence of cervical cancer in females?

**Settings:** Global

**Conclusion:** Very low quality of scientific evidence in support of vaccination of young males to reduce incidence of female cervical cancer.

| Quality assessment   |           |                      |               |                      |             |                      | Quality          | Importance |
|--|-----------|----------------------|---------------|----------------------|-------------|----------------------|------------------|------------|
| No of studies  | Design    | Limitations          | Inconsistency | Indirectness         | Imprecision | Other considerations |                  |            |
| <b>Evidence that HPV vaccines protect against vaccine-type HPV infection or disease in males</b> |           |                      |               |                      |             |                      |                  |            |
| 5 <sup>1</sup>   | RCTs      | serious <sup>2</sup> | no serious    | no serious           | no serious  | none                 | ⊕⊕⊕O<br>MODERATE | CRITICAL   |
| <b>Impact of male vaccination on incidence of cervical cancer in females</b>                     |           |                      |               |                      |             |                      |                  |            |
| 6 <sup>3</sup>   | Modelling | serious <sup>4</sup> | no serious    | serious <sup>5</sup> | no serious  | none                 | ⊕OOO<br>VERY LOW | CRITICAL   |

<sup>1</sup> Immunogenicity studies by *Block SL et al* and *Reisinger KS et al* (quadrivalent vaccine) as well as by *Lehtinen M et al* (bivalent vaccine) show that both HPV vaccines are as immunogenic and safe in young adolescent males as they are in young adolescent females. Recent reports by *Palefsky J et al* and by *Giuliano A et al* show that the quadrivalent HPV vaccine decreases the incidence of infection and external genital lesions (as a combined outcome of anogenital warts and anogenital intraepithelial neoplasia) due to HPV types 6/11/16/18 in a population of young men aged 16-26 years. Data are not available on the immunogenicity and clinical efficacy of the bivalent vaccine in males.

<sup>2</sup> The only currently available direct evidence that HPV-vaccination can protect males against infection or disease with vaccine-related HPV types is based on two poster presentations. This limits assessment of quality of the underlying study.

<sup>3</sup> *Barnabas RV et al* modelled vaccinating boys with a HPV 16 vaccine at either low or high coverage levels, in addition to vaccinating adolescent girls in Finland and found that vaccination of both genders added little benefit over vaccinating adolescent girls alone. *Taira AV et al* predicted that adding vaccination of adolescent boys with a HPV 16/18 vaccine to a vaccination programme for girls would further reduce cervical cancer cases by 2% in the US. *Ebasha EH et al*, in model studies on the quadrivalent vaccine, predicted that vaccination of males in addition to girls aged < 12 years could further reduce the incidence of cervical cancer from 79% to 91%, compared to vaccinating girls alone at low to moderate coverage levels currently seen in the US. *Insinga RP et al* who examined the potential outcomes of various vaccination strategies using the quadrivalent HPV vaccine in Mexico found that vaccination of 12-year-olds, plus a temporary 12-24-year-old catch-up program covering both sexes was most effective, reducing by 84-98% the HPV 6/11/16/18-related cervical cancer, high-grade cervical precancerous lesions, and genital wart incidence during year 50 following vaccine introduction. *Kim JJ et al*, modelling transmission of HPV types 16 and 18 infection between males and females found that at 90% coverage, vaccinating girls with a HPV 16/18 vaccine reduced cancer risk due to these HPV types by 63%; including boys at this coverage level provided only 4% further cancer reduction. *Kulasingam S et al* found adding HPV 16/18 vaccination of males was not cost-effective for cervical cancer prevention compared with the current policy of vaccinating 12 year old females in Australia.

<sup>4</sup>Information is still insufficient or missing on a number of key issues required for precise modelling of the possible impact of male vaccination on the incidence of female cervical cancer.

<sup>5</sup> Predictions are based on modelling. Although recent studies support the assumption that HPV vaccination also protects against vaccine related HPV type infection and disease in males, there are no studies that currently demonstrate that HPV vaccination of males will result in less sexual transmission of these vaccine related HPV types from males to females and in reduced incidence of cervical cancer.

### Bibliography

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