TITLE: Human Papillomavirus Vaccine: Clinical-Effectiveness

DATE: 16 June 2009

RESEARCH QUESTIONS:

1. What is the clinical-effectiveness of the human papillomavirus vaccine for males?
2. Which strains of human papillomavirus does the vaccine demonstrate clinical-effectiveness?
3. What is the evidence on the longevity of the clinical-effectiveness of the human papillomavirus vaccine?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, the Cochrane Library (Issue 2, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between 2004 and June 2009. Filters were applied to limit the retrieval to health technology assessments (HTAs), systematic reviews, meta-analyses and randomized controlled trials (RCTs). A controlled clinical trials (CCTs) filter was applied to perform a more focused search for CCTs. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS:

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, HTAs, systematic reviews, and meta-analyses are presented first. These are followed by RCTs and CCTs.

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Three HTAs,\textsuperscript{1,2,3} two systematic reviews,\textsuperscript{4,5} five RCTs,\textsuperscript{6-10} and one CCT\textsuperscript{11} were identified on the human papillomavirus (HPV) vaccine.

**OVERALL SUMMARY OF FINDINGS:**

**Clinical-effectiveness of HPV vaccine in males**

Limited information was identified about the clinical-effectiveness of HPV vaccine in males. One RCT reported seropositivity of participants who received the vaccine, regardless of gender.\textsuperscript{7}

**HPV strains affected by the HPV vaccine**

Two HTAs\textsuperscript{1,2} and one systematic review\textsuperscript{5} reported over 90% protection against HPV16 and HPV18 positive cervical neoplasias with the HPV vaccine. An HTA\textsuperscript{2} and systematic review\textsuperscript{4} also reported vaccine effectiveness against any type of HPV. An RCT also reported effectiveness of the HPV vaccine against HPV types 6,11,16,18.\textsuperscript{6} A CCT investigated the effectiveness of HPV vaccine in non-vaccine strains, and found a reduction of HPV infection and neoplasia or adenocarcinoma due to HPV types 31,33,45,52,58,59.\textsuperscript{11}

**Longevity of the HPV vaccine**

The Swedish HTA stated that the average follow-up time for studies was three years, with the longest follow-up being five years.\textsuperscript{1} This study suggested that a longer period of protection against HPV could be achieved in children vaccinated before their sexual debut. The duration of protection was stated as unknown in the other HTA,\textsuperscript{2} and it was stated that the duration of studies was five years. The Danish HTA reported that the seropositivity of the HPV vaccine was five years, which is the longest follow-up period in studies.\textsuperscript{3} Data from one RCT was consistent with information reported in the HTAs, stating that the vaccine was effective up to five years.\textsuperscript{8} Other RCTs reported effectiveness of the vaccine after 12 months,\textsuperscript{7} 1.5 years,\textsuperscript{10} and 3.5 years.\textsuperscript{9}

Overall, no conclusions about the clinical-effectiveness of the HPV vaccine in males can be made due to a lack of information identified. Strains other than HPV 6, 11, 16, and 18 were suggested to be affected by the HPV vaccine in an HTA and systematic review, and a CCT reported activity of the HPV vaccine against additional strains of HPV. No studies have been conducted with a follow-up of longer than five years. Studies report effectiveness of the HPV vaccine up to this time point and suggest a need for longer term studies.
REFERENCES SUMMARIZED:

Health technology assessments


   Note: Full text in Swedish only, but summary available in English. This report contains information regarding the strains the vaccine protects against, as well as the longevity of the vaccination.


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   See section 3.4.3 Duration of protection

Systematic reviews and meta-analyses


Randomized controlled trials


**Controlled clinical trials**


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APPENDIX – FURTHER INFORMATION:

Observational studies


Ongoing studies


Review articles


Additional references
