Doubts raised about effectiveness of HPV vaccines

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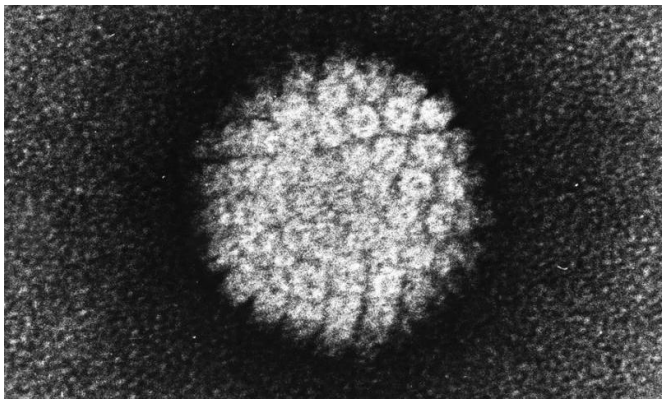

Electron micrograph of a negatively stained human papilloma virus (HPV) which occurs in human warts. Credit: public domain

A new analysis of the clinical trials of HPV vaccines to prevent cervical cancer raises doubts about the vaccines' effectiveness. The analysis, published by the *Journal of the Royal Society of Medicine*, assessed 12 published Phase 2 and 3 randomised controlled efficacy trials of the HPV vaccines Cervarix and Gardasil.

The analysis, carried out by researchers at Newcastle University and Queen Mary University of London, revealed many methodological problems in the design of the Phase 2 and 3 efficacy trials, leading to uncertainty regarding understanding the effectiveness of HPV vaccination.

The researchers found that the trials were not designed to detect cervical cancer, which takes decades to develop. Women in the trials were followed up for six years or less, apart from one trial extension to just under nine years. While the researchers found evidence that vaccination prevents low grade abnormal cell changes, they said this is not clinically important because no treatment is given.

Lead researcher Dr. Claire Rees, of Queen Mary University of London, said: "Trials may have overestimated efficacy by combining high-grade cervical disease with low-grade cervical changes that occur more frequently but often resolve spontaneously without progressing. We found insufficient data to clearly conclude that HPV vaccine prevents the higher-grade abnormal cell changes that can eventually develop into cervical cancer."

Dr. Rees added: "Abnormal cell changes are likely to have been overdiagnosed in the trials because cervical cytology was conducted at 6-12 months rather than at the normal screening interval of 36 months. This, too, means that the trials may have overestimated the efficacy of the vaccine, again because some of the lesions would have regressed spontaneously."

The researchers also found that the trial populations had limited relevance and validity for real world settings. The women in the trials were older than the target population.

Calling for women to still attend regular cervical screening, co-author of the study, Professor Allyson Pollock, of Newcastle University, said: "We have good evidence that cervical screening significantly reduces the risk of cervical cancer in women regardless of whether they have been vaccinated."

More information: Claire P Rees et al, Will HPV vaccination prevent cervical cancer?, *Journal of the Royal Society of Medicine* (2020). DOI: 10.1177/0141076819899308

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