

## Human Papilloma Virus Vaccines and Current Controversy

We wish to comment on importance of HPV vaccination and the recent decision of the Government to suspend two studies on HPV vaccine on account of alleged deaths, sending alarm signals to pediatricians.

HPV vaccination is for primary prevention (serotype-specific, with limited cross-protection) of carcinoma of uterine cervix (CaCx). Both bivalent (Cervarix) and quadrivalent (Gardasil) vaccines are licensed and in clinical use in India. Risk of HPV infection and consequent CaCx is not necessarily predicated by one's sexual promiscuity. Any heterosexual woman has risk because of her partner's private life, past or present. Those who will abstain from sex in adulthood cannot be predicted. Therefore vaccine is proposed for all girls without considering future sex-life. Both vaccines are safe from serious adverse reactions. Secondary CaCx prevention is through periodic screening (for HPV infection or cytological/visual lesion) and appropriate treatment of early stages. Since current vaccines will prevent only 70-80% CaCx, both interventions are essential. India does not have CaCx prevention program; this is perceived by many to indicate lack of need. Had the need existed, they trust that Government would surely have initiated control. Truth is, our Government has no programs for controlling innumerable preventable diseases. Treatment costs of serious illnesses pull many families below poverty line; hence, disease-prevention is also poverty alleviation(1). Unfortunately some health professionals themselves lobby against disease-prevention giving the Government a convenient alibi(2).

Being very expensive (including 10% as taxes), some suspect that HPV vaccination is solely for profit of the vaccine makers/marketers. Had there been a CaCx prevention program and the

Government purchased vaccine in bulk, or if Indian manufacturers are encouraged/enabled to manufacture vaccine, the cost will drop substantially. The gross economic loss on account of CaCx has to be assessed before cost-benefit, and financial benefit to national economy can be understood.

Will vaccination protect against CaCx? Science is predictive. If HPV infection is prevented, CaCx caused by it will be prevented. How long will protection last? The documented attrition rate of antibody indicates that protection will last decades. It is unscientific to wait until after longevity is documented before vaccine is used. We guess that the unlikely worst-case situation may require a booster.

The two HPV vaccination projects were approved by all required agencies. One is for operational feasibility of school-based and community-based vaccination, in Khammam district (Andhra Pradesh, Gardasil) and Vadodara (Gujarat, Cervarix), conducted by the State Governments in collaboration with Indian Council of Medical Research (ICMR) and PATH (a US based not-for-profit non-governmental organization). No biological outcome is measured; hence it is not a clinical trial. The second is a multi-centric clinical trial to investigate immunogenic efficacy of 2 doses (6 months apart) compared to conventional 3 doses (at 0-2-6 months) of Gardasil. If successful, it will lead to 33% cost-reduction. There was allegations in the media of vaccine-caused death of 4 girls in Khammam and the Union Government suspended both studies and initiated enquiry (which is under process as we write this) into the safety of both vaccines. Both vaccines continue in clinical use; suspending clinical trial while allowing clinical use is illogical. The causes of death had been scrutinized by the State Government and reported to ICMR and Drugs Controller General of India; all were satisfied that no death was vaccine-related. We understand that there is an unusually high frequency of death among girls in this community, which is what deserves immediate enquiry and remedial interventions.

The death of a 14-year old British girl shortly after receiving HPV Vaccine, evoked considerable

media attention across the world. The necropsy studies showed that she had malignant tumor affecting her heart and lungs(3). The vaccine was not her cause of death. In summary, we state that HPV vaccines are safe, and, effective against serotype-specific CaCx. We request the Government to take disease-control seriously, and to include CaCx among those targeted for control. The role of immunization in preventing diseases has been time-tested, and it is important that science prevails over misguidance. When vaccine is available against a disease, its non-utilization becomes a risk factor of that disease. Epidemiology, economics and ethics demand that health professions and Government join hands to alleviate the misery caused by innumerable infectious diseases including CaCx.

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