

To: Union Minister for Health and Family Welfare
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Union Minister for Health and Family Welfare,
Ministry of Health and Family Welfare,
Nirman Bhavan,
Maulana Azad Road,
New Delhi 110 011

Date: October 1, 2009

Subject: Concerns around Human Papilloma Virus (HPV) vaccine

Sir,

We, the undersigned, public health organizations, health networks, medical professionals and women's groups, write to express our concern with regard to the introduction of Human Papilloma Virus (HPV) vaccine, Gardasil, to young girls in the country.

On July 9th, 2009 under the demonstration project being implemented by the Union Ministry of Health and Family Welfare in association with Indian Council of Medical Research (ICMR), PATH International and State government, the Andhra Pradesh Minister for Health and Family welfare launched a pilot program for vaccination against cervical cancer. The three doses of HPV vaccine are to be administered to 16,000 girls between 10 and 14 years in the mandals of Bhadrachalam, Kothagudem and Thirumalayapalem in Khammam district in Andhra Pradesh.¹ The vaccine will be administered in 3 doses at the interval of 0, 2 and 6 months.

Similarly, on August 13, 2009, the Gujarat government launched a two-year 'Demonstration Project for Cancer of the Cervix Vaccine' in three blocks of Vadodara District - Dabhoi, Kawant and Shinor - to immunize 16000 girls between 10 and 14 years with three doses of Gardasil. The Gujarat State Minister for Health and Family Welfare claimed that this demonstration project will help the Centre to examine the possibility to introduce the vaccination project across the country²

We are alarmed by this decision by State and Union Governments and we oppose the introduction of the vaccine on the following grounds:

Efficacy of the Vaccine

- Information about the efficacy of Gardasil remains uncertain. The current HPV vaccine prevents infections, resulting from just two of the HPV subtypes (16 and 18) that may cause cervical cancer, and also HPV subtypes 6 and 11 that can lead to genital warts. The subtypes 16 and 18 account for 70% of the cases of invasive cervical cancer globally.³ But there are over 100 HPV subtypes and one of the main concerns is that if the vaccine was to work and indeed 'block'

¹ The Hindu, (July 10, 2009), "Pilot Program for Vaccination against Cervical Cancer launched"

² Press Trust of India (August 13, 2009), "Gujarat Launches Cervical Cancer Vaccine."

³ Schiffman M, Castle PE, Jeronim J, Rodrigue AC, Wacholde S. (2007) "Human Papillomavirus and Cervical Cancer" Lancet; 310

subtypes 16 and 18 then the other carcinogenic subtypes may become dominant.

- There is lack of conclusive data regarding the length of immunologic protection the vaccine confers against HPV subtypes 16 and 18.⁴
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- There is lack of conclusive data regarding the length of immunologic protection the vaccine confers against HPV subtypes 16 and 18.⁴ Studies so far have followed up with the vaccinated 'subjects' for 5 years and have shown that it offers protection only for 5 years. Thus it is not clear whether protection lasts longer than this time period. Since the long term efficacy and protection by the vaccine is unknown we can not claim that even 60-70% protection will be achieved. Moreover, since the highest incidence of cancer of the cervix in India is in women above 35 years of age, it is not clear whether a 3-dose schedule will provide long lasting immunity or if boosters will be required.
- If booster doses are needed, and it is not known how frequently, what will be the impact of the booster doses on the safety of the vaccine? Moreover, booster doses would certainly increase the cost of vaccination per woman as many times as the booster would be given.
- HPV vaccination is not a substitute for cervical cancer screening. All women, including those who are vaccinated, should continue to have regular Pap test screening and also HPV test as the preventive effect of the vaccine on cervical cancer has not yet been demonstrated.
- HPV Infection rarely leads to progression to cancer. Only a minority of infections persist for several years, and only about 10% of low-grade lesions progress to a higher grade. About 5% of high-grade lesions progress to invasive cancer.⁵

Side-effects

1. The Federal Vaccine Adverse Event Reporting System (VAERS) in the US has logged a total of 12,424 of adverse events following HPV vaccination, according to the US Centre for Disease Control and Prevention. Between June 2006 through December 2008, more than 23 million doses were administered in the US alone. Of these, 772 were reports of serious events (6.2 % of the reports) including 32 deaths and the remaining 11652 (93.2%) were classified as non-serious.⁶

The most common events reported were, Syncope, Local reactions at the site of immunization (pain and redness), Dizziness, Nausea and Headache.⁷ Venous thromboembolic events, autoimmune disorders, Guillian Barre Syndrome, motor neuron disease, anaphylaxis, transverse myelitis, pancreatitis and death were amongst the serious adverse events reported. Amongst reports of autoimmune disorders to the VAERS system, 88% were associated with the HPV vaccine alone.⁸

⁴ Lippman A, Melynk R et. al (2007), "Human papillomavirus, vaccines and women's health: questions and cautions" Canadian Medical Association Journal (CMAJ) 177

⁵ Jun 2007 "Human papillomavirus: often harmless but in some cases carcinogenic." Prescrire International, (Vol. 16, Issue 89, Pages 115-119)

⁶ Centre for Disease Control and Prevention, USA, "Summary of HPV adverse events reports published by JAMA" http://www.cdc.gov/vaccinesafety/vaers/HPV_JAMA.htm Accessed on: September 10, 2009.

⁷ Centre for Disease Control and Prevention, USA, "Summary of HPV adverse events reports published by JAMA" http://www.cdc.gov/vaccinesafety/vaers/HPV_JAMA.htm Accessed on: September 10, 2009.

⁸ Slade B., Leidel L., et al (2009) "Post Licensure Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine" JAMA, Vol.302, No.7

Sir, we urge you take action immediately, and await your reply on the steps taken.

We would be grateful for an appointment to discuss the matter with you further.

With thanks,

Sd/-

Subhashini Ali
(President)

Sd/-

Sudha Sundararaman
(General Secretary)