

HPV Vaccine in the Indian Context

Recent months have witnessed considerable focus on HPV vaccines through two channels: (i) academic presentations at national, regional and local scientific events by eminent experts as well as the recent President's Page(1) and (ii) commercial promotion through the mass media by manufacturers of these vaccines. IAP also has recommended the vaccine(2) on the grounds that (i) cervical cancer is the most common cancer, and cancer related cause of death in Indian women, as per the National Cancer Registry; (ii) cervical cancer is responsible for 132,000 cases and 74,000 deaths annually; (iii) compliance with annual Pap smear screening is low; and (iv) the currently available vaccines are safe and efficacious. Therefore the following issues are pertinent.

Data from the Indian National Cancer Registry (**Table I**) record that (i) total number of cervical cancer is 7012 from the population-based survey(3), and 12595 from the hospital-based survey(4); (ii) mortality rate is 18%, unlike 56% suggested; (iii) cervical cancer is the second most frequent malignancy in women after breast cancer; and (iv) incidence is maximal beyond the fifth decade and not in younger age-groups. It could be argued that the National Registry is limited in its reach and extrapolations on limited data could give the oft-quoted figure of 132,000 cases. However, it appears as if the National Registry data is being downplayed in favor of sources suggesting higher burden, a *déjà vu* of the hepatitis B related hepatocellular carcinoma scenario some years back(5).

Assuming that the data quoted in the presidents column(1) are correct, it translates to 56.1% mortality in Indian women compared to 54.6% mortality in the rest of the world; making it difficult to accept that "mortality among Indian women is almost double compared to that for the world."(1)

A very recent large-scale population-based screening study using sophisticated methods to identify HPV in cervical samples of 30-59 year-old ever-married women(6), detected HPV in only 10.3% with almost similar prevalence across different age strata. Even among the "HPV positive" women, only 36.7% had lesions of-cervical intra-epithelial neoplasia (CIN) grade 1 or higher, emphasizing that HPV infection is not synonymous with (pre)cancerous lesions. In addition, the frequency of cervical lesions was similar across various age groups (38% in 30-39 yr, 39% in 40-49yr and 29% in 50-59yr), although detection of cervical cancer was highest in the oldest age bracket.

Based on the above data, if HPV vaccination still merits consideration in India, the vaccine must guarantee protection (against cervical cancer, not merely HPV infection) for at least 3-4 decades after primary immunization. Such information is not available at present from anywhere in the world.

Additional considerations must take into account (i) the limited practical experience from HPV vaccination programmes worldwide; (ii) questionable acceptance of a vaccine to prevent a sexually acquired infection that sometimes (but not always) causes cancer, and that too only if vaccination is completed before exposure; (iii) vaccination does not protect against all causes of cervical cancer, hence HPV vaccine is not synonymous with cervical cancer vaccine; and (iv) some developed countries have rejected a vaccination program for these reasons(7).

The question of recommending a vaccine to those who can afford it as against those who need it(1,2), and that too with the aim of increasing awareness among physicians and people(1) raises ethical issues over and above the epidemiological and economic aspects.

Screening programs are designed to identify the cohort that needs to undergo diagnostic investigations, and not to treat those who test

TABLE I CERVICAL CANCER IN INDIA: NATIONAL CANCER REGISTRY 2001-2003

Age in years	0-19	20-29	30-39	40-49	50-59	60-69	>70	Total	Breast	All cancers	Cervical cancer mortality	Cervical cancer mortality (%)
Bangalore	0	21	147	296	284	265	136	1151	1781	7247	158	13.7
Barshi	0	1	10	29	28	50	13	131	60	356	2	1.5
Bhopal	0	7	26	81	71	60	33	278	351	1409	50	18.0
Chennai	0	17	130	364	422	340	146	1419	1744	6689	422	29.7
Delhi	2	48	312	614	584	489	177	2241	3777	15044	103	4.6
Mumbai	1	13	219	534	449	374	199	1792	3789	13792	531	29.6
Total	3	107	844	1918	1838	1578	704	7012	11502	44537	1266	18.1
Cumulative percentage	0.04	1.57	13.6	41.0	67.2	89.7	99.7*					

*The age of 0.3% of cervical cancer patients is not known.

positive, hence “screening in the absence of a treatment program” would not be automatically unethical, as suggested(1). HPV vaccination does not replace annual screening programs for cervical intra-epithelial neoplasia; hence its low level of coverage(1) argues against a vaccination program rather than in favor.

Therefore, there are several considerations that need to be resolved before recommending/prescribing/using HPV vaccines in India.

Joseph L Mathew

*Advanced Pediatrics Centre,
PGIMER, Chandigarh 160012, India.
jmathew@rediffmail.com*

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