

# CERVICAL CANCER - IS VACCINATION THE ANSWER

## CERVICAL CANCER: IS VACCINATION REALLY THE ANSWER?

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From print media to television, the country has recently been flooded with high profile advertising of a vaccine to prevent cervical cancer, supposedly put out in public interest by GlaxoSmithKline. The Drugs Controller asked the company to desist from advertising in violation of laws of the land. In the wake of this disinformation campaign, we, along with Sama, organised a public meeting in Delhi to raise awareness about the problems and limitations of these vaccines in end December 2009.

Gardasil, marketed by MSD Pharmaceuticals (Merck in India) and Cervarix marketed by GlaxoSmithKline (GSK) are the controversial vaccines which are claiming to protect women against two of the many high risk Human Papilloma Virus (HPV) strains associated with cervical cancer. But are they really the answer for the prevention of cervical cancer?

But first, some basic information: HPV is mainly transferred through genital sexual contact and persistent infection with it could lead to cervical cancer among women at around the age of fifty. Most men and women get this infection at some point of their sexual lives and it normally clears up on its own in about 90% cases. It is important to understand that HPV infection is a necessary, but not sufficient, cause for cervical cancer. The vaccines currently being promoted protect against only 70% of infection due to HPV, so all women, vaccinated or not, still need to be screened for cervical cancer in their 30s-40s. Medical evidence also points to the fact that smoking, long term use of the contraceptive pill and having multiple sex partners are some other risk factors.

Since these vaccines do not work as well on those who already have the infection, the strategy being used is to vaccinate young girls before they become sexually active. The attempts to introduce these vaccines in India came to light when in mid 2009 the media reported on a study involving 32,000 girls, 10-14 years old, being carried out in Khammam District in Andhra Pradesh and Vadodara District in Gujarat, mainly in rural tribal areas.

### **Women's groups respond.**

After studying the vaccine, and the laws concerning introduction of new drugs and vaccines, 39 women and health groups had submitted a memorandum to Ghulam Nabi Azad, the Union Health Minister, opposing the study and proposed introduction of the vaccine, Gardasil. For two months there was no response. Then came the media blitz designed to generate a widespread scare about cervical cancer, and urging all parents to 'protect their young girls' via vaccination. Hence, in an

attempt to raise awareness on a range of related issues, and get answers from key players involved in the studies and the marketing of Cervarix and Gardasil, a public meeting was called. The invitees included governmental and non-governmental actors currently involved in the HPV story, namely, MSD, GSK, the Drugs Controller General of India, the Health Ministry, National Commission for Protection of Child Rights, the Indian Council for Medical Research and PATH. However, none of them attended, and the PATH representative who did, declined from making any comment.

### **How real is the cervical cancer scare?**

There is no doubt that cervical cancer is a significant problem for Indian women, and that its incidence (along with that of all other cancers) is expected to rise sharply in the coming years. However, it is equally true that cervical cancer is not a new problem that has suddenly surfaced. The world over, it has been dealt with by methods of prevention, screening, detection and treatment. For instance, access to clean water, and better hygiene can reduce the risk of HPV infection; better nutrition can enable the body to get rid of the infection quickly. Widespread screening and treatment available in developed countries has brought down the incidence of cervical cancer by 80% in the last few decades.

In India, not only is a large part of the population at risk due to living in conditions of poverty, but there is no population-based screening facility. Pap smears are available only in tertiary health facilities, and then too the quality of smears is poor. These very conditions are what make international agencies believe that the vaccine will be a boon for countries like India. Which brings us to the next crucial question: where will the money for cervical cancer vaccines come from? The three shots required of these vaccines cost nearly Rs 10,000 per young woman, as compared to less than Rs 20/- that the government spends on reproductive health per capita. If every girl 10-14 years old were to be vaccinated, the expense would amount to two and a half times the current union budget on health. Not to mention that the vaccine is not sufficient as a standalone, but has to be given in a full context of regular screening and treatment which are an urgent requirement of the day, but for which there is no plan. The picture that then emerges is that substantial numbers of young girls will suffer side effects of the vaccines through their youth without guarantee of being protected against the cancer.

Undue haste in pushing the vaccine.

The United States Food and Drug Administration (USFDA) approved the vaccine on a fast track in six months as compared to the normal three years. ICMR did not even wait for the USFDA, but signed a MoU with Merck in 2005. The Drugs Controller approved Gardasil for use after only a small 7 month study on 110 girls aged 9-15 had been conducted in India. Close on the heels of this, PATH-ICMR began the study in Andhra Pradesh and Gujarat (funded by the Bill & Melinda Gates Foundation) aimed at designing appropriate vaccine delivery strategies and a communications and advocacy strategy. Thus, even before the safety and effectiveness has been established among the Indian population, thousands of girls are being given the vaccine in India, so that Merck can create a market. It is evident that this is because countries like India constitute a huge market, and if India introduces the vaccine, then many other third world countries will probably do so.

The ongoing PATH-ICMR study and the earlier trial done by Merck violate several existing measures to protect the rights of the child in matters of medical research. Firstly, the trials can be carried out only in respect of diseases that the children can acquire during childhood; secondly poor and disadvantaged people cannot be used as subjects of trials for therapeutics aimed at the well off; trials on children can be conducted only after the drug has been tried out on adults; and lastly, the consent of children able to express themselves and their guardians has to be taken before they are enrolled for research. Yet, Merck did a trial on girls, with Gardasil in India, even before their trial with adults. Also, the study in Khammam on 16,000 girls is tantamount to both 'neglect' and 'physical abuse' by the

agencies, as defined under the WHO guidelines on child abuse. Many child rights organizations are unanimous about the unethical nature of the ICMR-PATH study and the need to put an end to it. They object to a two year study being done on 10 year olds which would be over before they really needed protection against HPV.

### **Information package full of lies.**

The PATH-ICMR literature from the study area states that Gardasil is harmless and will give life long protection, and will not prevent the girl from having healthy babies later. Each one of these statements is false, according to the package insert of the products, even in India - which also states that pregnant women enrolled by accident in the trials had higher instances of spontaneous abortions, of producing congenitally malformed babies, and infants of breast feeding trial subjects had higher incidence of acute respiratory infections.

The information being given to private consumers in India is no better. While the package insert from U.S. clearly mentions death as a reported reaction; the Indian package insert omits it. The ads, being purportedly issued in public interest hype the risk of cancer, fail to state even the age at which this vaccination ought to be given. They make cervical cancer out to be an epidemic for which they urge parents to approach their doctors "today", rather than a problem which could develop in the coming three decades.

### **Discussions at the meeting.**

After Sama and Saheli members made presentations on various aspects ranging from the Public Health implications of the HPV vaccine programme, the ethical violations in the study projects, the technical aspects of the vaccines and their impact on the health of young girls and women, to the violations inherent in the media campaign by MSD and GSK, a vibrant discussion followed. Dr Mohan Rao from Centre for Health and Social Medicine, JNU commented on the sad state of affairs where public health priorities were being determined by GAVI (Global Alliance for Vaccines and Immunization) and other international agencies and not by Indian government. He also felt that the Federation of Obstetricians and Gynaecologists Society of India (FOGSI) should take a responsible position on the matter. Dr Rukmini Rao from Gramya, a women's organization active in Khammam, reported that the study was being done on girls staying in hostels. She was outraged that the study be conducted with those who can be coerced and misguided. She also reported that in the entire district of Khammam there is no facility for screening. Ms Enakshi Ganguly from Haq, a child rights organization, said that all options including legal and protest must be explored to put an end to the study, urgently. A doctor present at our meeting also drew attention to the fact the fast tracking to push the current HPV vaccines in the market (even before dose determinations, side effects and efficacy vis-à-vis newer vaccines have been proven) was not surprising as it was the only way for the company to cash in before the patent expires.

It is evident that the campaign against HPV vaccines must be fought on many fronts: against unethical studies, against illegal promotion, against experimental use of Indian girls for the purpose of corporate profit, and above all, against the callousness of the government in allowing it all to happen.

**Taken from Saheli (women's resource group) website:**

<https://sites.google.com/site/saheliorgsite/health/hpv-vaccines/cervical-cancer-is-vaccination-the-answer>