

Trial and Error: Ethical Violations of HPV Vaccination Trials in India

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On July 9, 2009, the Andhra Pradesh Minister for Health and Family Welfare in association with the Indian Council of Medical Research (ICMR) and PATH (Programme for Appropriate Technology in Health) International a non-profit organization based in USA launched what it described as a ‘demonstration project’ for vaccination against cervical cancer. The vaccine, against the Human Papillomavirus (HPV), which is one of the most common families of viruses and the source of a common sexually transmitted infection, was administered to 14,000 girls between the ages of 10 and 14 in three *mandals* – Bhadrachalam, Kothagudem and Thirumalayapalem – of Khammam district in Andhra Pradesh. In Andhra Pradesh, the vaccine used was Gardasil, manufactured by Merck Sharpe and Dohme, the Indian subsidiary of Merck and Co. Inc., a US-based pharmaceutical company.

In a similar project, 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 administer three doses of the HPV vaccine to 16,000 girls between 10 and 14 years. There were reports of deaths of four girls from Andhra Pradesh and two girls from Gujarat following the administration of the vaccine.

During March 27-30, 2010, a team of women’s and health activists visited Bhadrachalam *mandal*, one of the three *mandals* of Khammam district where the ‘demonstration project’ was undertaken to understand the ground reality; in particular, to look at the nature and procedures of taking consent and providing information to the girls and their parents, and the availability of the health infrastructure required to support cancer screening and prevention.

The children selected to participate in this project were from four social groups with poor economic background – scheduled tribes, scheduled castes, Muslims and other backward communities. Majority were tribal children, whose parents were agricultural labourers. Some girls were from families that have been displaced by the ongoing conflict in the neighbouring state of Chhattisgarh; circumstances that serve only to compound their vulnerability.

Majority of the vaccinated girls in Bhadrachalam were residents of *ashram paathshalas* (boarding schools). The selection of these girls for the project is striking, given that their parents, living separately, cannot monitor and respond to any adverse developments in their children’s health. Moreover, this has allowed providers to conveniently side-step the provision of parental consent.

The vaccine was administered through a camp approach in the hostels and school campuses. In many instances, the wardens of the residential schools and hostels were asked to provide consent or permission for vaccination, while parents were not informed. The very nature of this project appears to be in violation of all ethical norms as a warden, whether a legal guardian or not, be allowed to provide consent for hundreds of children without consulting their parents, who are their natural guardians;

The 'consent form' was used primarily in the case of non-residential schools, and children were asked to get signatures from their parents. This violates the designated protocol for obtaining informed consent, whereby the 'researcher' is required to directly provide information mandatory for consent to the person(s), in this case the parents.

Selected girls were given HPV Immunization Cards, which were in English – a language that neither the girls, nor their parents, were familiar with. Further, all involved (the wardens, teachers and students) believed the project to be part of the public immunization program, and had no idea that they were in fact, part of a research study. They were not even aware that they had a *choice* regarding participation in the study.

Many stated that they were given to understand that the government was providing free of cost an expensive vaccine that would prevent 'uterine' or 'cervical cancer'. This would otherwise be unaffordable for them. Several parents brought their daughters to the vaccination camps themselves when they heard about the project. One mother said, *"Since it was a vaccine being given by the government, we all trusted it blindly and considered it reliable, like any other vaccine that is given in the immunization programme"*. Participants were verbally informed that the vaccine would provide life-long protection, with no side-effects or impact on fertility. The fact that the vaccine protects against only two types of the HPV virus and that regular pap screening is required even after vaccination was mentioned at all- neither verbally, nor in the written material given to some girls. Since the long term efficacy and protection by the vaccine is unknown, it cannot be claimed that even 60-70% protection will be achieved. Currently is also unclear if, when and how booster shots will be required.

Many of the vaccinated girls continue to suffer from stomachaches, headaches, giddiness and exhaustion. There have been reports of early onset of menstruation, heavy bleeding and severe menstrual cramps, extreme mood swings, irritability, and uneasiness following the vaccination. No systematic follow up or monitoring has been carried out by the vaccine providers.

While the project was being carried out under the banner of the National Rural Health Mission (NRHM) shockingly enough the Mission's mandate does not extend to or mention any such research project. Further, the existing health infrastructure in the region is woefully inadequate. Pap smear facilities are conspicuous by their absence in all government facilities in the area. The entire tribal mandal of Bhadrachalam does not have a single gynaecologist.

The vulnerability of these communities are thus further compounded by of the lack of access to health care, lack of access to information and absence of mechanisms for reporting adverse effects.

The state government has claimed that the deaths of the four girls post-vaccination were unrelated to the 'project'. However, parents of Kudumula Sarita, who died in January 2010, believe that their daughter died due to the vaccination, and not by consuming pesticide, as has been officially declared by the authorities.

The trial has been suspended temporarily by the government after a strong campaign by health networks, women's groups and by parliamentarians. A committee has been set up by the government to conduct an inquiry, the composition of the committee leaves much to be desired and is far from representative.

The Ministry of Health and Family Welfare, on 22nd April 2010, finally conceded that the HPV vaccination project was in fact, a "post-licensure operational research study", which on further clarification, was confirmed to be a Phase IV, post marketing, clinical trial.

On 29th April, the ICMR admitted that their ethical guidelines had been flouted in the course of this trial.