At What Price? Gardasil Research Targets Girls from Vulnerable Communities

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Editors’ Note: In this issue of DifferenTakes two activists with the Indian women’s health group Sama document serious breaches in medical ethics in a trial of the Gardasil vaccine on young girls in a poor area of Andhra Pradesh state. Their findings raise important questions about the current international drive to promote Gardasil and other HPV vaccines as a strategy to curtail cervical cancer, and about medical experimentation directed at the bodies, families, and reproduction of vulnerable communities. The article reveals a pressing need for international women’s health activists to closely monitor such trials.

— Co-editors Katie McKay Bryson and Betsy Hartmann

During July and August 2009, the Andhra Pradesh and Gujarat governments, in association with the Indian Council of Medical Research (ICMR) and the Program for Appropriate Technology in Health (PATH), launched what they described as a ‘demonstration project’ for vaccination against cervical cancer. Vaccines against the Human Papillomavirus (HPV) were administered to 13,791 girls in Khammam district in Andhra Pradesh, and to 9,637 girls in Vadodara district in Gujarat. The girls were between the ages of 10 and 14.

In Andhra Pradesh, the vaccine administered was Gardasil, manufactured by Merck Sharp & Dohme (India) Pharmaceuticals Private Limited (MSD), the Indian subsidiary of US-based pharmaceutical company Merck & Co. Inc. In Gujarat, Cervarix, manufactured by Glaxo SmithKline Biologicals (GSK) of Rixensart, Belgium, was administered. Both vaccines were approved for marketing in India in 2008.

As part of a four-nation initiative against cervical cancer beginning in 2006, PATH has launched ‘demonstration projects’ for the HPV vaccination in Peru, Uganda, Vietnam and India, using a grant of $27.8 million from the Bill and Melinda Gates Foundation.
Women's groups, health networks, human rights groups and child rights groups in India have been voicing concerns about the safety, efficacy and public health value of the two HPV vaccines since they were first announced. Many joint memoranda enumerating these concerns have been submitted to the Union Minister for Health and Family Welfare, demanding an immediate halt to the ‘demonstration projects’.

On April 22, 2010, the Ministry of Health and Family Welfare (MOHFW) finally conceded that the HPV vaccination project was in fact a “post-licensure operational research study.” Further investigation confirmed it as a Phase IV, post-marketing clinical trial. On April 29, the ICMR admitted that their ethical guidelines had been flouted in the course of this trial.

The trial has been temporarily suspended by the government, and a committee has been formed to conduct an inquiry. According to V. M. Katoch, ICMR Director-General:

“This is not a phase-3 clinical trial but a post-licensure observational study as the vaccine — Gardasil by MSD Pharmaceuticals — is approved for use in India. ICMR just evaluated the study’s protocol and methodology. The state has to monitor ethical compliance but following the objection we have asked Andhra to suspend the program till a review is done.”

This paper reflects observations made by a fact-finding team of women’s rights and health activists from Sama, Jan Swasthya Abhiyan and Anthra, who visited the Bhadrachalam project site in Andhra Pradesh. Their investigation revealed the so-called ‘demonstration project’ to be a calculated, multi-level violation of all existing protocol on clinical trials, as well as a glaring breach of child rights.

Vulnerable Communities

The children selected to participate in this project were from impoverished social groups — scheduled tribes, scheduled castes, Muslims and other marginalized communities. The majority were tribal children whose parents were agricultural labourers. Some girls were from families displaced by the ongoing violent conflict between Maoist groups and the government in the neighbouring state of Chhattisgarh — circumstances that served only to compound their vulnerability.

Many of the vaccinated girls in Bhadrachalam were residents of ashram paathshalas (boarding schools for tribal children). The selection of these girls for the project is striking, given that their parents, living away from them, couldn’t monitor and respond to any adverse development in their children’s health. Moreover, this allowed providers to side-step the provision of parental consent. It is clear that the ‘target group’ could not question the motive or the procedure of the ‘project’.

Informed 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. It is extremely questionable how and why a warden, whether a legal guardian or not, was allowed to provide consent for hundreds of children to be vaccinated without consulting parents or other guardians. Moreover, no consent form was filled out or signed, even by the wardens. Any consent given was verbal.

Consent forms were apparently used mainly in the case of non-residential schools. The children were asked to get the form signed, another violation of the designated protocol for obtaining consent. Informed consent requires researchers to provide information mandatory for consent directly to the person(s) giving it — in this case the parents — which was not done.

The informed consent form did not include any information on compensation, procedures to be followed, specific appropriate alternative procedures or therapies available, or risk management, all of which are mandatory for informed consent.

Misleading Information

At the Bhadrachalam project sites, selected girls were given HPV Immunization Cards written in English, which neither the girls nor their parents were able to read. Further, the interactions with the wardens, teachers and students did not at all imply that they understood the vaccination initiative to be a study; rather, they believed it to be a public immunization program. They had no idea that they were part of an ongoing research study. To them it appeared that the government was providing an expensive and otherwise unaffordable vaccine free of cost, which would prevent
‘uterine’ or ‘cervical cancer’. In fact, they were not even aware that they had a choice regarding participation in the study, or that the administration of the vaccine was contingent on their consent.

Many 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.”

Throughout the project period, the girls and their parents were misinformed that the vaccination would prevent uterine or cervical cancer. The HPV immunization card states that the “HPV vaccine prevents HPV infection.” However, the HPV vaccine in its current form prevents infections resulting from just two HPV subtypes (16 and 18) and is not a substitute for cervical cancer screening. All women, including those who are vaccinated, need to undergo regular pap test screening. These facts are clearly acknowledged on the official Gardasil website but were not communicated to girls or families selected for the study.

Participants were verbally informed that the vaccine would provide life-long protection and had no side effects or effects on fertility. Factually, however, there is lack of conclusive data regarding the length of immunologic protection the vaccine confers against HPV subtypes 16 and 18. Since the long term efficacy and protection by the vaccine is unknown, it cannot be claimed that even 60-70% protection will be achieved. It is also unclear if, when and how booster shots will be required.

Many of the vaccinated girls suffered from stomachaches, headaches, giddiness and exhaustion. There were also reports of early onset of menstruation, heavy bleeding and severe menstrual cramps, extreme mood swings, irritability, and uneasiness following the vaccination. Many of the girls sought treatment — in the private sector and with local healers — for the adverse events they were suffering.

There have been reports of four girls’ deaths in Andhra Pradesh and two in Gujarat followed the vaccinations, but no systematic follow-up or monitoring has been carried out by the providers. In fact, local authorities as well as PATH have written these deaths off as occurring due to causes other than the vaccine, including suspected malaria, snakebite, anaemia and suicides.

For months there was no further investigation, until health activists raised an alarm and demanded that the projects be halted.

Public Health in Bhadrachalam

Bhadrachalam division has a 28% tribal population, comprising the Koyas, Kondareddi and Lambada tribes. The area is grappling with a range of problems, including the loss of livelihoods resulting from large-scale deforestation. Most of the tribal communities are solely dependent on agriculture and non-timber forest produce for the livelihoods. Floods are also a regular occurrence along the river Godavari and its tributaries, and the situation is likely to worsen as a consequence of a proposed Polavaram dam on the river.

Bordering Chhattisgarh, the area has a huge inflow of displaced (mostly) tribal families and children as a result of the ongoing conflict, resulting in constant surveillance and increased vulnerability of communities in the surrounding villages. Children suffer from a range of health problems related to poverty, lack of access to nutrition and the absence of health services. Several studies have shown that iron deficiency anaemia is widespread, and malnutrition in the tribal communities is higher than both their urban and rural counterparts. The entire area is susceptible to malaria, dengue, diarrhea and other health problems.

Currently, in the entire area of Bhadrachalam, there is no gynecologist, and none of the public health facilities have the capacity to perform pap smears. This public health context raises grave concerns for the girls selected to participate in the vaccination study, including the problem of competing budgets, and the wisdom of focusing on an expensive vaccine to the exclusion of other cancer control measures, such as screening.

The Social Context of Research

Although the trials have currently been suspended by the government pending the findings of an inquiry committee, the composition of the committee is problematic and far from representative. These ‘projects’ have highlighted the question of transparency, wherein the scientific purpose of certain trials may be unclear and sponsors are able to circumvent ethics through regulatory loopholes. Companies’ promotional practices, the pressure applied by international organisations, and the co-option of the support
of medical associations in influencing public health priorities are areas of major concern.

In settings where populations are oppressed, the conduct of research requires considerations that address and prevent human rights abuse. Drug companies’ apparent ease of access to such populations raises serious questions about the unequal social contexts in which research is being performed and about how conditions of inequality are at present facilitating a global proliferation of pharmaceutical drug trials. The regulatory authorities have a responsibility to ensure that new drugs and vaccines go through proper scientific evaluation before they are considered for approval. This also underscores a need for national vaccine policies that address the interests of public health, rather than those of the market.

Perhaps it is time to heed the call of the parents of thirteen-year-old Sarita, one of four girls in Andhra Pradesh who died following the administration of the vaccine:

“We lost our child, and we know the pain and the agony of that loss. We don’t want any other child to die. We don’t want any other parent to suffer.”

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**About the Authors**

**N.B. Sarojini** has been working on women’s health and rights for many years and is the Director of Sama — Resource Group for Women and Health. She is involved in the coordination of national level research on reproductive technologies and their implications for women. She has co-authored “Women’s Right to Health,” published by the National Human Rights Commission, contributed to the Political Science Textbook for Class 7 by the National Council of Educational Research and Training, and co-authored a book, *Touch me, Touch me not: Women, Plants and Healing* (1997). She is also the Joint Convenor of Jan Swasthya Abhiyan (People’s Health Movement — India), and the ex-convenor of Medico Friend’s Circle. She co-coordinated the MFC fact finding committee that studied the impact of health after the Gujarat riots of 2002 and contributed significantly to the report, “Carnage in Gujarat: A Public Health Crisis.”

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**Notes**

1. The Indian council of Medical Research is the apex body in India for the formulation, coordination and promotion of biomedical research.
2. PATH is a Seattle based healthcare organization.