

Tribal Girls are not Guinea Pigs: The HPV Vaccine Issue

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It required a huge public outcry, strong intervention by women's organizations including AIDWA, and efforts by parliamentarians like Brinda Karat before the Government finally suspended the HPV (Human Papilloma Virus) vaccination programme being conducted in Andhra Pradesh (AP) and Gujarat on April 6th 2010. The immediate trigger was the death of 4 young tribal girls in Khammam district of AP, due to side effects linked to the administration of the drug. A number of girls who had been vaccinated were also complaining of adverse reactions like epileptic seizures, severe stomach aches, vomiting, headaches, and mood swings, and there were reports of early onset of menstruation, heavy bleeding, and severe menstrual cramps following the vaccination. The local authorities initially refused to accept that the vaccine could be at fault. Two of the deaths were written off as suicides, despite evidence to the contrary. However, after widespread protests at many levels, the government was finally forced to accede to the demand, and call off the programme, pending an investigation into the whole issue.

What was the issue at stake? The tragedy of young tribal girls dying for no fault of theirs highlighted once again the degree to which ethical norms and human rights are violated with impunity in our country by drug companies, with able assistance provided by the Indian Government. In this case of the HPV vaccine, the cervical cancer prevention drugs Gardasil and Cervarix, produced by MNCs Merck (MSD) and Glaxo Smith Klein (GSK) respectively, were administered to young, mainly tribal girls in the age group 10-14 years in some backward districts of our country, under the aegis of PATH, (one of the world's largest health care NGOs) from July 2009 onwards. Despite the fact that the

efficacy of these drugs in the prevention of cervical cancer, as claimed by the producers, has yet to be proven, the so called demonstration project was launched in collaboration with ICMR and the State governments of AP and Gujarat, with even the NRHM logo being used in some districts of these two states.

Though the programme ostensibly claimed to be an observational study, the secrecy regarding the non-transparent selection criteria of the area, the girls and the aim of the project raised undeniable fears

that this was a Phase IV clinical trial being carried out under the guise of a 'demonstration project'. Moreover, the inexcusable lack of clarity with regards to the role and accountability of international agencies such as PATH (in turn linked to the Bill and Melinda Gates Foundation)

and the supply of these expensive vaccines by the drug companies free of cost all raise questions about the underlying profit motives fuelling this experiment. In fact, the AP Commissioner of Family Welfare claimed that the objective of the two operational research studies was to "generate critical data and experience for evidence based decision making about public sector immunization programs as part of a broader cancer of the cervix prevention and control strategy." When asked how ICMR guidelines for bio-medical research which state that children cannot be tested upon until they stand to gain directly were violated, the response was that the study was NOT a clinical trial, and in any case, the vaccine had already been licensed by the Indian government, and was available in the private market! It is such obfuscation of the objectives that caused concerns and pointed to a possible cover up of what the real intentions of the programme were.

Organizations like the US based Judicial Watch and the Vaccine Adverse Events Reporting System - a US Government body - list a range of potential side effects associated with the Gardasil Vaccine. Among them are blood clots, autoimmune disorders, seizures, epileptic fits, and severe allergies. It is imputed to have caused 61 deaths in the US from June 2006, prompting a big media backlash against Merck.

fighting for carbon space for development that will not only ensure the material well-being of their populations but also assist in building adequate infrastructure to ensure protection from the impacts of climate change. Demands for global equity are intrinsically connected with action for equity within the nation and political intervention is necessary at both levels. Women's movements have an important role here as women have a stake in ensuring an industrial future for the country.

Impacts of Climate Change and Vulnerability

If the governments of the developed world (and to some extent the developing world) do not take the necessary action to limit total carbon emissions, the likely result is temperature increases of greater than 2 deg. C. As we have already mentioned earlier, there is now scientific consensus on the fact that a temperature increase of more than 2 deg. C will lead to disastrous impacts on human life and human society. Around 46 million people around the world, living in coastal regions are at risk due to flooding from storm surges⁵. Global warming is also likely to have serious impacts on human health ranging from an increase in respiratory diseases to a wider geographical spread of vector borne diseases like malaria, dengue etc. affecting more than 60% of the world's population.

Increasing variation of rainfall patterns, such as heavy or very heavy rainfall in short time periods as well as increased periods of drought will have a greater impact on developing countries with their large dependence on agriculture. Indian agriculture for example is highly sensitive to climate change, due to its heavy reliance on the monsoon. Any climate impact on agriculture will naturally have an impact on food security in the country. With child malnutrition rates as high as they are in India (46% of all children under the age of 5 are malnourished⁶), a further reduction in food security will be disastrous.

Another severe impact of climate change will be on water availability. While India has 17% of the world's population, it only has 4% of the world's fresh water resources⁶. Per capita water availability is very low (1900 m³) and expected to reduce further by 2050, taking the Indian population from a status of "water stressed" to "water scarce"⁶. In addition to this is the lack of public distribution of

drinking water in many parts of the country. It then puts the responsibility of fetching water on women. It is estimated that women spend an average of 1 hour per day fetching water in most parts of the country⁷. Thus, while impacts on water resources will affect everyone, a lack of infrastructure (reservoirs, pipelines, public taps etc.) will put a larger burden on women. The provision of drinking water to all, irrespective of their capacity to pay, is a basic public service which should be provided by the Government. Current trends of privatization or public-private partnerships in the water sector (with a view to improve the so-called efficiencies of water supply) will only lead to the exclusion of the poor from this service, further exacerbating their vulnerability to climate change.

It is evident that climate change mitigation is one of the most important and urgent issues before the world as well as India today. While the developed countries will need to reduce their emissions (politically, developing countries such as India will need to make sure that they meet their developmental goals while staying within the constraints placed on global emissions. Building the capacity to adapt to the changes in climate that will take place with the expected level of temperature rise (even if adequate action is taken immediately to keep global warming is kept below 2 degrees Centigrade) should also be firmly on the agenda of third world governments. This requires political empowerment of the poor towards addressing the gross social and economic inequities that plague our country as well as our world today. The only way forward in a climate constrained world is to pursue equity both globally and nationally while taking measures to drastically reduce emissions as well as protecting people from the impacts of the temperature increase that appear inevitable.

⁵ *Climate Crises: Challenges and Options*, All India Peoples Science Network and Center for Science Technology and Society (TISS), December 2008

⁶ International Food Policy Research Institute, 2003 Report

⁷ ESMAP Energy Survey 1996

The implementation of the project was also very revealing because it showed up the shocking laxity with which the term "informed consent" was interpreted. A verbal consent to vaccinate girls staying in Ashram schools had been taken from the Hostel Warden/ teacher in-charge, while parents were not even informed about it. In cases of day scholars, where consent was obtained from the parents, the form given held the nomenclature of an approval information with no provisions for addressing in detail the need for follow up. In fact, when a lady warden of a hostel took objection to the vaccine being administered to the hostel girls, she was told that this vaccine is mandatory!

Consent and information were a farce, since it was limited to a few, and was based on provision of wrong information. Many of the girls were told that the vaccine would prevent uterine cancer and would provide life-long protection. This information was factually incorrect and provided the recipient with a false sense of security against the "dreaded" disease. As per the claims by the pharmaceutical companies themselves, the vaccine only protects against infections caused by 2 types of HPV (of the 13 high risk strains of HPV) that are associated with a higher risk of cancer of the cervix. Moreover, once again as claimed by the companies themselves, the protection by the vaccines is understood to last for only 4.5 years with Gardasil and 7 years with Cervarix, while the need for a booster dose has not yet been established. There are reports in developed countries that this number too is an over-estimation and that the protection, in fact, may not last for more than 3-5 years.

Thus, the whole programme is indicative of the shocking criminal negligence on the part of the au-

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thorities, who provided permission and support to this study for the benefit of the drug companies within the public health system, by allowing them access to the tribal girls in backward regions of our country.

The incident brings to the fore the need for strict regulation by the Government to prevent such exploitation. It was in this context that AIDWA and other organizations demanded from the health minister for clinical trials/ demonstration projects, regardless of which vaccine or drug is being administered. Financial support from the industry or from an international organization should not be the criteria to introduce any vaccine, whether in a pilot project or in the universal immunization programme.

Most important is the provision of medical facilities for testing women, since cervical cancer diagnosed in time is treatable. However, the existing facilities in the backward regions are extremely inadequate. For instance, while Pap smear facilities are not available as a part of Government health services in the area (a must for even those who have been vaccinated against HPV), the absence of a gynaecologist in the entire tribal Mandal (block) district of Bhadrachalam is absolutely appalling.

The entire incident underscores the need for women's organizations to be vigilant and ensure that the MNCs in collusion with the government do not use our poor citizens, especially women from deprived sections as guinea pigs for unethical drug trials.

AIDWA MEMORANDUM TO THE HEALTH MINISTER ON HPV VACCINE ISSUE

29 February 2010

Dear Shri Ghulam Nabi Azad,

AIDWA would like to bring to your attention the deeply disturbing reports as regards the HPV vaccination programme that has been launched with young tribal girls in certain districts of AP, and Gujarat, with the approval of the State government, and the ICMR. Though the vaccination's efficacy in

preventing cervical cancer amongst pre puberty girls, as claimed by its producers, Merck, Sharpe, and Dohme is still unproven, the drug Gardasil has been allowed to be administered in some backward districts of our country under the aegis of PATH, (one of the world's largest health care NGOs) as a demonstration project from July 2009.

Reports show that in Khammam district of AP alone, 14,000 girls were identified - a large percentage of them from poor, tribal families - for vaccination with three doses of Gardasil. The three

so serious developments, the authorities have been engaged in finding alternate reasons for the deaths, to escape from the consequences of their callousness.

AIDWA would like to register its strong objection to the entire programme, making guinea pigs of our poor tribal girls, the lack of precautionary measures, and the subsequent attempts being made to cover up the real situation. We would like to raise some pertinent questions that the Health Ministry must address such as

- What is the criterion on which the target population for the vaccine was selected? We would particularly like a clarification on the choice of young tribal girls from rural areas for this programme.
- Was there a proper procedure to obtain "informed consent?" We would like some details about the discussions with parents of minors, and whether they knew about the possible range of adverse side-effects.
- What was the screening mechanism put in place to monitor those who had been administered the vaccine?
- We are also keen to know about the booster requirements, and the payment for the same. What would be the cost of these booster doses?
- Has there been any cost/ benefit study made to assess the suitability of introducing an expensive vaccine like Gardasil in India?

who died). They also visited the Bhadrachalam S.C. Hostel, Gurukula hostel, St. Paul School, Nallakunta residential school and met the girls to enquire about the after effects of the vaccine. They also visited Nelakondapalli School where 250 of the 370 girls who were vaccinated got severe diarrhoea.

Thereafter an AIDWA delegation met the District Collector and gave memorandum demanding an immediate health check-up for all the girls who had been vaccinated, and an *ex gratia* payment to the families whose daughters had died due to the vaccine.

On 2nd April, AIDWA leader and CPI(M) Rajya Sabha MP Brinda Karat visited seven villages and interacted with the families of affected girls. State and District leaders of AIDWA accompanied her.

Sir, AIDWA believes that tribal children cannot be the means for MNCs to promote their vaccines. This constitutes shocking criminal negligence on the part of the authorities to permit such a large programme outside the public health service system. We need immediate government intervention to prevent such shocking occurrences from getting repeated.

In this context, AIDWA demands that

- The government should set up an inquiry into the deaths of the tribal girls and also

zones selected in the district were Thirumalayapalem (urban), Kothagudem (rural) and Bhadrachalam (tribal). There was virtually no dissemination of information before the actual vaccination about the nature of the drug or its side effects. Unfortunately, the District Collector also does not appear to have recognized the importance of educating the target group before they were vaccinated, or to assess the implications of adverse side effects amongst them.

The Andhra state unit of AIDWA brought the issue to the attention of the authorities, after the deaths of two young tribal girls - Sode Sayamma and Kudumula Saritha - were registered as suicides due to poison by the local police, when in fact these deaths were related to the administration of the HPV vaccine. As per present reports, four tribal girls have lost their lives as a result of the side effects linked to the drug. Many more girls have been, and are still suffering from severe headache, stomach ache, and vomiting. Far from responding to these serious developments, the authorities have been engaged in finding alternate reasons for the deaths, to escape from the consequences of their callousness.

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INTERVENTION BY AIDWA ANDHRA PRADESH UNIT HPV VACCINE ISSUE

A Press Conference was organised on 20th March 2010 at Hyderabad after Memorandum was submitted to the Governor and the Chief Minister of the state.

A "Round Table Discussion" was organized on the 24th of March 2010 along with youth, students and other organizations, including Doctors participated. It was also attended by Member of Parliament Comrade P. Madhu.

AIDWA leader Hymavathi along with the District AIDWA leadership of Khammam visited the families of the young girls who had died of the side effects of the vaccination. They spoke to villagers of Erragattu, Aangipaka and the people of Kottagudem town. They also met the parents of Sayamma, Saritha, and Swathi (three of the girls who died). They also visited the Bhadrachalam S.C. Hostel, Gurukula hostel, St. Paul School, Nallakunta residential school and met the girls to enquire about the after effects of the vaccine. They also visited Nelakondapalli School where 250 of the 370 girls who were vaccinated got severe diarrhoea.

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- The government should set up an inquiry into the deaths of the tribal girls and also

o Into the side effects of the vaccine on other girls

o A national policy must be put in place to regulate any such medical interventions and unless

the implementation of the project was also very revealing because it showed up the shocking laxity with which the term "informed consent" was interpreted. A verbal consent to vaccinate girls staying in Ashram schools had been taken from the Hostel Warden/ teacher in-charge, while parents were not even informed about it. In cases of day scholars, where consent was obtained from the parents, the form given held the nomenclature of an approval form ("Angikaara Patram"). It provided minimal information with no provisions for addressing in detail the need for follow up. In fact, when a lady warden of a hostel took objection to the vaccine being administered on the hostel girls, she was told that this vaccine is mandatory!

Consent and information were a farce, since it was limited to a few, and was based on provision of wrong information. Many of the girls were told that the vaccine would prevent uterine cancer and would provide life-long protection. This information was factually incorrect and provided the recipient with a false sense of security against the "dreaded" disease. As per the claims by the pharmaceutical companies themselves, the vaccine only protects against infections caused by 2 types of HPV (of the 13 high risk strains of HPV) that are associated with a higher risk of cancer of the cervix. Moreover, once again as claimed by the companies themselves, the protection by the vaccines is understood to last for only 4.5 years with Gardasil and 7 years with Cervarix, while the need for a booster dose has not yet been established. There are reports in developed countries that this number too is an over-estimation and that the protection, in fact, may not last for more than 3-5 years.

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Most important is the provision of medical facilities for testing women, since cervical cancer diagnosed in time is treatable. However, the existing facilities in the backward regions are extremely inadequate. For instance, while Pap smear facilities are not available as a part of Government health services in the area (a must for even those who have been vaccinated against HPV), the absence of a Gynaecologist in the entire tribal Mandal (block) district of Badrachalam is absolutely appalling.

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- Into the side effects of the vaccine on other girls so that responsibility can be fixed and suitable action taken.
- The state government should take appropriate action including providing compensation to the families who have lost their children and to the children suffering side-effects. All those suffering from side effects should be identified and provided proper medical treatment free of cost.
- A national policy must be put in place to regulate any such medical interventions and unless proved totally safe, no such drugs should be administered.
- The Government should put a stop to any similar programmes in other areas also.
- Sir, we urge you take action immediately, and await your reply on the steps taken.

THE JOINT PRESS RELEASE GIVEN ON WORLD HEALTH DAY BY SEVERAL ORGANISATIONS TO PROTEST THE HPV TRIALS

7 April 2010

Protests, representations and extensive coverage in the media against PATH-ICMR project being carried out in AP and Gujarat seem to have fallen on deaf ears and the government has gone ahead with a vaccination programme with Gardasil (HPV vaccine manufactured by Merck) leading to four deaths and 120 girls suffering from debilitating new illnesses like epilepsy, headaches, stomach disorders and early menarche.

The girls, 10-14 years old, belonging to poor families, were enrolled in a study being carried out jointly by PATH (an International NGO), Indian Council of Medical Research and the respective state governments funded by Bill and Melinda Gates Foundation. The objective of this two year study is to look into acceptability and service delivery issues of Gardasil, marketed in India by MSD Pharmaceuticals Pvt. Ltd, being misleadingly promoted as a preventive for cervical cancer.

The literature circulated in the project makes outright false statements about its safety, efficacy and duration of effectiveness. The girls and their parents have been told through the project documents that the vaccine will give lifelong immunity, has no side effects other than minor ones like fever and rash and will not affect future fertility of the young girls.

When deaths started getting reported local groups in Andhra Pradesh were alarmed by and carried out a fact finding to discover that no consent was taken from parents and the girls and their families have been left uncared for. Post mortem reports

were also not easily accessible, and in cases of death cover up was the general dictum.

We question:

1. Why are poor girls and their families being actively misled? Who is liable for the debilitating effects of the vaccine and who will medically look after these girls and pay compensation for the damages suffered by these people?
2. How has the government embarked on this study of giving three injections to the girls when it is also planning a massive multi-centric dose termination study to see if two doses will suffice?
3. How has the Drugs Controller General granted approval to the vaccine without proper research in India? For a drug to be administered to children, it has to go through stages of clinical trial, including Phase 3 adult clinical trials. So far with Gardasil only one trial has been carried out with just a small sample of 10 girls which has followed them up for just one month after the completion of vaccination and that too only to look at the immune response post vaccination. The vaccine has also been approved for adult women till 27 years of age without doing any trials with them at all.
4. Why are these studies being carried out when at various times the concerned government officials have gone on record to say that it is not feasible for the vaccine to be introduced in the Indian Public Health system given its costs? Is it not then using these poor girls as guinea pigs for a vaccine which can be used only in the private market by well to do families? Why is a two year study being carried out with no future guarantee even for the subjects of this study to keep them protected with boosters when they actually get married by when the effect of this vaccination will wear off? The effect of the vaccine seems to wear off after 4-5 years, and will require periodic booster injections to retain claimed effectiveness.

The path of licensing of the vaccine in India raises many serious questions as time and again scientific logic and the ethical guidelines have been violated at each step. Our law clearly states that no trials of drugs can be conducted among children before trials are conducted on adults. While the other HPV vaccine, Cervarix, made by GlaxoSmithKline has also been licensed in India it has been approved for use for children without any trials among them at all. It should be remembered that last year the two drug companies had engaged in massive advertisement of these vaccines in the media and are continuing with giving incentives to doctors and holding promotional camps in schools among the paying segment of the market.

All this is being done for products which have no proven value. Even the license given by US FDA has asked Merck to actually study whether there is a reduction in the incidence of cervical cancer due to vaccination.

Even as their effectiveness and usefulness remains unproven information on the adverse effects of these vaccines are pouring in from all quarters. The tally in US alone crossed the mark of 17000 adverse effects (as reported under the voluntary adverse effects reporting system); and even the US FDA gave a hearing to health advocates to present the case against the vaccines on March 12, 2010. The adverse effects include heart, immune, blood clotting, respiratory, nervous, digestive and musculoskeletal systems and occur with far greater frequency than those observed with any other vaccines. Many experts and established medical journals have already termed it the biggest public health experiment.

In the public health system of India this vaccination will prove to be an expensive and hazardous exercise. These vaccines at best protect against two sub types among 15 which are associated with cervical cancer and hence ideally women will have to un-

dergo pap smear tests for an effective cancer control strategy along with various hygiene and nutrition related strategies. Unfortunately, there is no investment in screening which can help the adult population today.

We demand:

- Complete suspension of all studies and trials with Gardasil and Cervarix and suspension of their licence for marketing in India till such time that a public enquiry is held on their licensing in violation to the India law.
- Proper enquiry in the deaths in Khammam that have been dubbed as suicides. Unless it becomes clear that the vaccine has no impact on the mental health of girls the project authorities cannot be absolved of the blame.
- Each vaccinated girl be examined by independent authority to assess the range and incidence of side effects. While this will provide the much needed information about vaccine safety it will also detail the care that these girls require and the compensation they and their families deserve for having been actively misled.
- Proper long-term follow-up of the vaccinated girls till they get married and have children and booster doses at the right time free of cost, with full informed consent for those girls who wish to continue vaccine protection.

Unless the government details a plan for cervical cancer control, with full complement of boosters, screening and treatment this project is sheer experimentation with innocent, vulnerable and poor people of the society who cannot afford this expensive vaccine. According to us the government is constitutionally bound to take care of the life of all citizens and not subject them to new medical problems at the behest of foreign NGOs.

SAMA, ALL INDIA DEMOCRATIC WOMEN'S ASSOCIATION, SAHELI, ALL INDIA PEOPLE'S SCIENCE NETWORK, JAN SWASTHYA ABHIYAN