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Business & Human Rights Resource Centre

PATH appreciates the opportunity to respond to statements made by Sama Resource Group for Women and Health and Saheli Women's Resource Centre in a press release distributed on 28 December 2009. The two groups express concern about immunization demonstration projects in Gujarat and Andhra Pradesh, India, against human papillomavirus (HPV), the virus that causes cancer of the cervix. The vaccine manufacturers have already replied regarding the safety and effectiveness of their respective vaccines. We would like to respond to other issues raised in the press release.

First, some background on the operational research study in question. The Indian Council of Medical Research (ICMR) and the State Governments of Gujarat and Andhra Pradesh, in collaboration with the international nonprofit organization PATH, are implementing a cervical cancer prevention project in India. The project's objective is to generate critical data and experience for decision making about whether and how—some day in the future—to introduce HPV vaccines into public sector immunization programs as part of a broader cancer of the cervix prevention and control strategy. The operational research is designed to help regional and local health program managers better understand how best to protect adolescent girls from this disease through vaccination. The research can do this by answering questions such as the following: 1) how many eligible girls can be reached by different strategies; 2) is the vaccine acceptable in the community; 3) is it feasible to vaccinate young adolescent girls, who are not the usual target for the well-established infant immunization program; and 4) what will it cost to implement a vaccination program. For example, in terms of reaching girls, is it better to ask immunization teams to visit schools to vaccinate, or to ask the girls to come to health centers for that purpose? Adolescents are a group that is typically difficult to reach, so the evidence generated by these studies will prove extremely useful if and when the Indian states or the central government are able to procure an affordable HPV vaccine and decide to use it.

Similar HPV vaccine operational studies are being conducted in Peru, Uganda, and Vietnam, but none of those countries has yet made any commitment to nationwide vaccination after the research is completed. We at PATH, and they, are preparing for the day when these vaccines become affordable—as they surely will—so we will then know how to design an effective and efficient HPV vaccination program. For effective cervical cancer prevention and control in the coming decades, countries must work now to develop and maintain screening programs with treatment for adult women, as well as vaccination programs for adolescent girls.

Understanding the seriousness of cervical cancer in India

According to World Health Organization (WHO) data, about 132,082 cases of cervical cancer are diagnosed every year and about 74,000 women die each year. This high burden of cervical cancer affects not only the women, but also their families and communities.

The importance of a comprehensive prevention strategy: vaccination plus cervical cancer screening

As noted earlier, we agree wholeheartedly that it is imperative to make cervical cancer screening available to more adult women in India. HPV vaccination should be considered, once vaccine prices drop, a part of the comprehensive cervical cancer prevention strategy along with screening. This comprehensive approach is endorsed by the WHO, the Alliance for Cervical Cancer Prevention, the Cervical Cancer Action coalition, and many other agencies. PATH has supported efforts to improve screening along with its work on vaccination.

HPV vaccine safety

The HPV vaccines currently used in this project are licensed in India and in at least 100 other countries, and are available in the private market in India and many other countries. Moreover, the vaccines have been approved by the DCGI, FDA, EMEA, and other national regulatory bodies and have been pre-qualified by WHO for purchase by UNICEF. As of 2008, these vaccines have been recommended by advisory committees and MOH officials to be used in national vaccination programs in more than 22 countries. The Indian Academy of Pediatrics also recommends this vaccine for adolescent girls.

HPV vaccine protection

As with all new vaccines, definitive information on how long protection will last will not be available for some years. However, recently published data show no waning of protective effect up to five to seven years after vaccination—and it is possible the protection may last much longer. Studies are under way in several Nordic countries that will give an early signal if a booster dose is needed. Current data are encouraging, and it shows that HPV vaccines induce strong and sustained serologic antibody titer responses, much higher than those observed after natural infection.

HPV vaccine and cervical cancer risks

One study reported that among women who were already infected with HPV-16/18 before vaccination, a minor increase in pre-cancer was seen (15.9 percent versus 14.3 percent among non-vaccinated). This difference of nine women could have happened by chance alone; the study also reported that before vaccination, more cytological abnormalities were observed among the women who were in the vaccine group than in the placebo group. Finally, HPV vaccine is not recommended for women who are already infected, which is precisely why the focus has been on vaccinating adolescent girls who are not yet sexually active.

Safeguarding Children's Health and Rights

This project is not bio-medical research looking into the effectiveness or safety of the vaccines. It is not a clinical trial. No bio-medical outcomes are being researched, no blood or other samples are being drawn, and no therapies are being tested. Clinical trials of these vaccines were completed long ago and both of the vaccines were licensed for use in India prior to inception of the ICMR-PATH project. These are not experimental products; they have been approved by the Drug Controller General of India (DCGI) for general use.

The girls in the study received, at no cost, a vaccine that is proven effective and safe, and is licensed by Indian regulatory authorities. If these girls had not participated in the study, only a small percentage of their families would have been able to afford the vaccine. We feel that these girls have benefitted in a way that their peers will not until routine HPV vaccination is offered to all girls throughout India.

The deaths that have occurred in the vaccination areas in India have been carefully investigated and no association was found between the vaccinations and any deaths (the deaths were caused by one snake bite, two suicides, and one well drowning). It is expected that some deaths will occur by chance in the vaccination areas, as well as in areas not receiving the vaccine. In 2008, there were 104 deaths in the 10-14 year age group reported in the district where we are vaccinating this year, and there were 21 deaths that occurred before we started vaccination.

ICMR-PATH project teams conducted extensive community outreach and education prior to HPV vaccination to ensure that authorities, parents, and girls understood the purpose, uses, and potential minor side effects of the vaccine and the purpose of the operational research project. Written consent was obtained for all vaccinations. Vaccine uptake has been very high, indicating high acceptance of the vaccine among parents.

Public health resources for HPV vaccine

A main concern of the authors seems to be that health care resources in India will soon be spent on an expensive vaccine. As far as we know, no such plans have been made.

For those readers who would like to examine other documents and scientific papers about cervical cancer, HPV vaccines, and cervical screening, we recommend visiting the RHO Cervical Cancer Library at www.rho.org. There, users will find science-based evidence from many renowned sources such as the WHO, the International Union Against Cancer, the American Cancer Society, the US Centers for Disease Control, PATH, and many others.

It is our hope that there will be opportunities for future dialogue with interested groups so that accurate information is shared and we can work together to achieve our shared goal of preventing and controlling cervical cancer among women in India.