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NEWS

Indian MPs criticise HPV vaccination project for ethical violations

Ganapati Mudur

New Delhi

A parliamentary panel has criticised the Indian Council of Medical Research and the international non-profit Program for Appropriate Technology in Health (PATH) for their human papillomavirus (HPV) vaccine project in India, which drew controversy three years ago.[1]

The panel that oversees India's health ministry has said that the project, which administered the HPV vaccine to about 20 000 girls aged 10 to 14 years in Andhra Pradesh and Gujarat during 2009-10, had breached medical ethics and violated Indian regulations on clinical trials.

Health activists and women's rights groups had asked the government to look into the project in early 2010 after they had documented irregularities in the project's informed consent papers and after adverse effects were reported among vaccinated girls in Andhra Pradesh.[1]

The parliamentary panel, which submitted its report last week, investigated the affair after a committee set up by the health ministry had confirmed that the project had violated ethical guidelines but did not hold anyone or any agency responsible for the lapses.

PATH, which is based in Seattle, Washington, has challenged the panel's assertions. "We strongly disagree with the findings, conclusions, and tone of the report and its disregard of the evidence and facts," the agency said in a statement issued this week.

PATH said that the project was part of a four country initiative in India, Peru, Uganda, and Vietnam to generate evidence to help national health authorities pick suitable vaccine delivery strategies if they chose to introduce the HPV vaccine into universal immunisation programmes. The HPV vaccine is intended to be a key tool to prevent cervical cancer, as a complement to periodic screening in older women.

But the parliamentary panel said that the project seemed to have been designed to help promote the vaccines as safe all over the world.

It said that the Indian Council of Medical Research had "completely failed" to perform its role as the country's key agency for overseeing medical research and instead had acted with "over-enthusiasm" to work with PATH, transgressing the domains of other government agencies.

The council had opposed suggestions by India's drug regulators to treat the project as a post-marketing surveillance exercise and had argued that the project did not need to report serious adverse events within a specific time frame or to follow other rules for the conduct of clinical trials.

The panel has questioned the council's interest in the project when another agency, the National Technical Advisory Group of Immunization, is supposed to assess vaccines for introduction into India's vaccination programme.

Merck and GlaxoSmithKline donated the vaccines for the project, which was funded by the Bill and Melinda Gates Foundation. The project, executed through state authorities, had also been approved by two ethical committees.

The panel also criticised the project's protocol and execution, saying that it did not provide adequate information about the vaccine to parents of the girls, failed to establish mechanisms to track possible adverse effects, and piggybacked on the government's rural health programme. The information material distributed at the study sites "implied that the government had started a vaccination programme," the panel observed.

Sarojini Nadimpally, the director of Sama, a non-profit resource group for women and health in New Delhi, which had alerted the government about the irregularities in 2010, told the *BMJ*, "We don't want this to be a 'report and forget' affair. We want the government to identity the officials who facilitated the project and give them exemplary punishment."

Senior PATH officials have said it would be wrong to view the project as a clinical trial.

Vivien Tsu, an epidemiologist and director of the HPV vaccines project with PATH in Seattle, told the *BMJ*, "I'm bewildered by the [suggestion] that the project was intended to assess the safety of the vaccine."

PATH said in its statement that the safety of HPV vaccines had already been established through clinical trials in India and other countries and that Indian regulators had approved the vaccine in India in 2008, months before the project started. The project's arms in Peru and Uganda had generated useful information that had allowed both countries to launch national HPV immunisation programmes, PATH said.

Tsu said, "It [the project] has guided governments towards decisions on how best to deliver this vaccine. In Peru, for example, the project has shown that delivering the vaccine through schools is efficient in urban regions but not in remote rural locations, where community health centres have been shown as a more efficient option."

PATH's statement said, "We believe poor and low income girls in India should not be denied the right or access to this proven and safe vaccine that wealthy and middle class girls in India have access to through the private market."

The parliamentary panel also questioned the marketing approvals granted by India's drug regulators to the HPV vaccines, saying that the clinical trials carried out for approval had violated rules governing clinical trials.

Amit Sengupta, a physician and a coordinator in India for the People's Health Movement, told the *BMJ*, "I think this episode exposes the huge regulatory gaps in India that allowed such a large study to take place without adequate checks."

1 Mudur G. Human papillomavirus vaccine project stirs controversy in India. *BMJ* 2010;340:c1775.

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