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PATH rejects standing commitee's report on cervical cancer project

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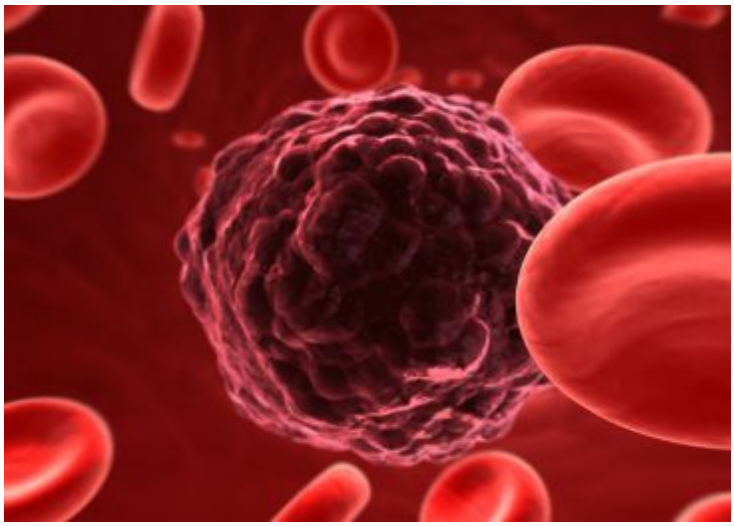

The Indian Parliament's Standing Committee on Health and Family Welfare on August 30, 2013, released a report critical of a cervical cancer vaccine demonstration project conducted in India from 2009 to 2010 through a collaboration among PATH (an international nonprofit organization), the Indian Council of Medical Research (ICMR), and the state governments of Andhra Pradesh and Gujarat.

The demonstration project in India was part of a four-country project to explore suitable vaccine delivery strategies and help provide evidence for national health authorities to make informed decisions about the potential benefits and challenges of introducing vaccines against human papillomavirus (HPV), the primary cause of cervical cancer. These projects in India, Peru, Uganda, and Vietnam generated important new evidence on the best ways to introduce HPV vaccines and are informing the work of governments across Africa, Asia, and Latin America to help prevent cervical cancer deaths. The results paved the way for Peru and Uganda to launch national immunization programs against HPV and contributed to the GAVI Alliance's decision to subsidize HPV vaccines for the world's poorest countries.

Responding to the report, PATH issued a statement that welcomeed public discussion about the role of vaccines in preventing life-threatening diseases such as cervical cancer but also rejected the unneccessary crticism of the vaccine project. It mentioned, "We thank the committee members for their time and effort in reviewing this matter. We support the adoption of reasonable measures to further strengthen and clarify protections for individuals participating in research projects. However, we are troubled by the report's inaccurate characterization of this important work."

Cervical cancer is a preventable disease, yet it kills 275,000 women every year, nearly all of them in low-resource countries. India bears one-quarter of the world's burden of cervical cancer, which kills an estimated 72,825 Indian women annually.

The ICMR, India's highest medical research authority, reviewed and approved the protocol for this project, including its design and methodology. At the time of its review, the ICMR determined the project was a post-licensure observational study and not

a clinical trial. The project did not seek to evaluate the efficacy or long-term safety of the vaccines, which had already undergone clinical evaluation in India and had been licensed and approved by the Drugs Controller General of India.

The ICMR's view was crucial, as it established the approval processes and protocols for the work that followed. PATH designed the project protocols in compliance with the ICMR's instructions and fully complied with the ICMR's requirements regarding the necessary approval processes and the requirements of state governments regarding consent processes.

"We believe that by following the guidance provided by the ICMR, as well as two state governments and three ethical review committees, we designed a project that met or exceeded the country's existing regulatory standards for demonstration projects while providing the greatest health benefit to Indian women," said the report, "It is important to note that the safety of HPV vaccines had already been scientifically established through clinical trials in India and other countries before any use of the vaccines in this demonstration project. Scientific evidence continues to show that the vaccines have excellent safety profiles, with more than 100 million vaccine doses delivered and not a single death causally associated with the vaccine anywhere in the world.

HPV vaccines are currently licensed and available in India and more than 120 other countries. At least 40 countries include them in their national immunization programs. The HPV vaccines used in the project had been licensed and approved by the Drugs Controller General of India before any vaccines were administered, and HPV vaccination had been recommended by the Federation of Obstetric and Gynaecological Societies of India, the World Health Organization, and the US Centers for Disease Control and Prevention, among others. HPV vaccines remain available in India today from private medical providers serving primarily wealthy families but not from the Indian public health system.

An essential goal of the project was to understand the challenges of equitable introduction of HPV vaccines in routine public-sector immunization services. In support of that goal, state authorities and PATH worked together to ensure an economically diverse group of project participants, including urban, rural, and tribal populations. Specific districts and blocks within those districts were selected in consultation with state officials, the ICMR, and state-level project advisory groups, to ensure that project participants were representative of all segments of society. HPV vaccines were then made available to 10- to 14-year-old girls in the project sites, regardless of their social, economic, ethnic, or religious status, if their parents or guardians provided written, informed consent and if the girls provided verbal assent.

India bears a disproportionate share of the burden of cervical cancer deaths, and girls in low-income areas are least likely to have access to the vaccines that could save their lives. It is both scientifically sound and morally imperative to include underserved populations in our work to improve health in India and around the globe. For adult women, who would not benefit from the vaccine, PATH also worked to strengthen screening programs in the project areas.